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The Effect of Male Partner Involvement in ANC and IPTp-SP Uptake in Urban and Rural Areas of Benue State, Nigeria

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Abstract

Globally, malaria infection is a serious communicable infectious disease that is a threat to the lives of half of world population. In regions where malaria is widespread, the World Health Organization (WHO) advises that every pregnant woman should receive a minimum of three doses of intermittent preventive treatment with Sulfadoxine-pyrimethamine (IPTp-SP) to reduce the risk of malaria during pregnancy. This study examined how male partner involvement like accompaniment to ANC, IPTp-SP awareness, and encouragement/reminders affects optimal IPTp-SP uptake among pregnant women in urban and rural of Benue State, Nigeria, comparing settings to inform targeted interventions. A community-based comparative cross-sectional study was conducted among women of reproductive age (15–49 years) in selected urban and rural communities in Benue State using a multistage sampling technique. Data analysis involved chi-square tests, logistic regression, and Spearman's correlation ($p \leq 0.05$ significance). Male involvement was higher in urban areas (65.2% partner accompaniment to ANC) than rural (49.4%). Urban women whose partners accompanied them to ANC (OR = 3.882, 95% CI: 2.561–5.885), were aware of IPTp-SP (OR = 3.600, 95% CI: 2.374–5.458), or encouraged/reminded them (OR = 4.778, 95% CI: 1.718–13.298) had significantly higher odds of optimal uptake. In rural areas, male partner awareness of IPTp-SP was significantly associated with optimal uptake (OR = 1.534, 95% CI: 1.074–2.193). Targeted strategies in rural communities, including community education, male partner engagement, and improved access to antenatal care services, are essential to reduce disparities and enhance maternal and neonatal health outcomes.

Keywords: Involvement, Male, Optimal, Sulfadoxine-Pyrimethamine, Uptake.

Introduction

Globally, malaria infection is a serious communicable infectious disease that is a threat to the lives of half of world population. It affects about 515 million people in Asia, Latin America, and Sub-Saharan Africa region and causes yearly one to three million deaths [1]. It is a critical public health issue, particularly in tropical and subtropical regions where malaria is endemic. Pregnant women

are more susceptible to malaria which is because of the changes in their immune system during pregnancy, which can have severe consequences for both the mother and the unborn child [2, 3]. The effects of malaria in pregnancy includes maternal and newborn anemia, low birth weight, stunting, and reduced cognitive ability in children born to such mothers [4]. In regions where malaria is widespread, the World Health Organization [WHO] advises that every pregnant woman

should receive a minimum of three doses of intermittent preventive treatment with Sulfadoxine-pyrimethamine [IPTp-SP] to reduce the risk of malaria during pregnancy [5]. Using SP for intermittent preventive treatment in pregnancy [IPTp] continues to be a reliable approach to protect against malaria. This strategy requires that pregnant women receive the full recommended dose of SP during antenatal care visits, regardless of whether they are currently infected with malaria [6].

Despite the great progress made over the past twenty years to increase IPTp-SP uptake worldwide, a recent report by the WHO shows a decline in progress in many African countries, including Nigeria [7, 8]. About 125.2 million pregnant women worldwide are at risk of contracting malaria each year, including 30.3 million and 1.5 million in sub-Saharan Africa, where the burden is highest. Malaria in pregnancy is a major public health issue that leads to severe maternal and newborn outcomes, accounting for roughly 20% of stillbirths and 11% of neonatal deaths in the region [9, 10].

Partner support, particularly from husbands, plays a pivotal role in enhancing pregnant women's engagement with ANC and adherence to IPTp-SP. A study in Nigeria revealed that husband's encouragement, remind women to take medication, and accompanying to ANC visits, facilitated access to care and preventive interventions [11]. Several barriers linked to partner dynamics persist as women often require spousal consent before ANC attendance or SP administration, and lack of such consent or financial backing contributes directly to low IPTp coverage [12, 13]. The purpose of this study was to examine the effect of male partner involvement on the uptake of intermittent preventive treatment with sulfadoxine-pyrimethamine (IPTp-SP) among pregnant women attending antenatal care (ANC) services in urban and rural communities of Benue State, Nigeria.

Specifically, the study sought to determine how different dimensions of male partner involvement—such as accompanying women to ANC visits, awareness of IPTp-SP, and encouragement or reminders to take the medication influence the likelihood of pregnant women achieving optimal IPTp-SP uptake. Additionally, the study aimed to compare the level and impact of male involvement between urban and rural settings to identify contextual differences and inform targeted interventions that could improve malaria prevention during pregnancy and ultimately enhance maternal and neonatal health outcomes.

Materials and Methods

Study Site

The study was carried out in urban and rural areas of Benue State in the North-Central region of Nigeria. The study population were women of reproductive age (15 – 49 years) who have given birth a year before the study. The calculated minimum sample size was 488 for each of urban and rural areas after adjusting for 10% non-response rate. A multistage sampling technique was used to select the study participants. The Local government Areas (LGAs) were stratified in urban and rural LGAs and Makurdi and Otukpo were selected among the urban LGAs while Obi and Konshisha were selected among the rural LGAs using simple random sampling technique by balloting without replacement. From the four chosen LGAs, two wards (communities) were randomly selected in each using a balloting method without replacement. Within these wards, household lists obtained from the respective primary healthcare centres served as the sampling frame. A proportionate allocation approach was applied to determine the number of households to be included in each ward. Subsequently, households were selected through systematic sampling, with the sampling interval (k) calculated by dividing the total number of households in a ward by

the required sample size for that ward. Finally, in every selected household, one eligible woman was identified and enrolled in the study.

Data Collection Technique and Instrument

Open Data Kit (ODK) interviewer administered questionnaire was used for data collection to obtain information. A semi-structured interviewer-administered questionnaire adapted from previous studies [14, 15].

Measuring and Scoring Variables

A 4-item tool was used to assess male partner involvement. Favourable answers were awarded a score of 1 while unfavourable answers were awarded a score of 0. A 4-point Likert scale with “Rarely, Sometimes, often and Always” scoring 1, 2, 3 and 4 respectively. A score of 50% and above was termed good husband/Partner’s involvement in IPTp-SP uptake while a score below 50% was termed poor husband/Partner’s involvement in IPTp uptake. A 5-item tool was used to assess the uptake of IPTp-SP among the study participants. Respondents who have taken 3 to 5 doses of SP in their previous pregnancy was term to have good (optimal) uptake of IPTp while those who have taken below 3 doses in their previous pregnancy was termed to have poor (Suboptimal) uptake of IPTp-SP.

Data Analysis

The Statistical Product and Service Solutions (SPSS) version 26.0 was used for analysis which was based on the objectives of the study. Chi-square, logistic regression and

spearman’s correlation were used to assess and compare male partner involvement in ANC with IPTp-SP uptake among women of reproductive age in urban and rural areas of Benue State. A p-value of ≤ 0.05 was considered statistically significant.

Ethical Approval and Consent to Participate

Ethical approval for this study was obtained from the Health Research and Ethics Committee (HREC) of the Ministry of Health and Human Services, Benue State. Written informed consent was obtained from all participants before enrolment. Participation was voluntary, and confidentiality of information was strictly maintained throughout the study.

Results

In urban areas, those whose male partners were 20-29 years, 30-39 years, 40-49 years and ≥ 50 years made up 2.0%, 50.6%, 33.6% and 13.7% respectively while in rural areas, those whose male partners were 20-29 years, 30-39 years, 40-49 years and ≥ 50 years made up 19.5%, 52.7%, 25.8% and 2.0% respectively. In urban areas, those whose male partners had completed tertiary education had the highest proportion of completed formal education with 54.5% and while in rural areas whose male partners had completed secondary education had the highest proportion of completed formal education with 46.5%. In urban and rural areas, those whose male partners were employed were 90.8% (433) and 69.7% (340) respectively (Table 1).

Table 1. Sociodemographic Characteristics of Male Partner of the Respondents in Urban and Rural Areas of Benue State

Characteristics	Location	
	Urban (n = 488) Frequency	Rural (n = 488) Frequency
Male partner’s age (Years)		
20-29	10 (2.0)	95 (19.5)

30-39	247 (50.6)	257 (52.7)
40-49	164 (33.6)	126 (25.8)
≥ 50	67 (13.7)	10 (2.0)
Male partner's highest level of education attained		
None	10 (2.0)	17 (3.5)
Some primary	7 (1.4)	11 (2.3)
Completed primary	15 (3.1)	19 (3.9)
Some secondary	17 (3.5)	60 (12.3)
Completed secondary	47 (9.6)	227 (46.5)
Some tertiary	126 (25.8)	60 (12.3)
Completed tertiary	266 (54.5)	95 (19.3)
Male partner's employment status		
Employed	433 (90.8)	340 (69.7)
Unemployed	45 (9.2)	148 (30.3)

In the urban areas, majority of respondents (65.2%) reported that their male partners accompanied them to antenatal care (ANC), and among them, majority (60.1%) indicated their male partners did so sometimes. Additionally, 67.2% of urban male partners were aware of IPTp-SP, among which 95.0% encouraged or reminded their partners to take

it. Among rural respondents, 49.4% reported that their male partners accompanied them to ANC, out of which majority (62.7%) indicated that they did so sometimes. With respect to awareness of IPTp-SP, 49.6% indicated that their male partners were aware out of which 98.0% encouraged or reminded their wives to take it (Table 2).

Table 2. Husband/Partner's Involvement in ANC and Uptake of IPTp-SP

Characteristics	Location	
	Urban (n = 488) Frequency (%)	Rural (n = 488) Frequency (%)
Husband/partner accompany for ANC		
Yes	318 (65.2)	241 (49.4)
No	170 (34.8)	247 (50.6)
Frequency of accompanying to ANC	(n = 318)	(n = 241)
Always	65 (20.1)	42 (17.4)
Often	40 (12.6)	30 (12.4)
Rarely	23 (7.2)	18 (7.5)
Sometimes	191 (60.1)	151 (62.7)
Husband/partner aware of IPTp-SP		
Yes	328 (67.2)	242 (49.6)
No	160 (32.8)	246 (50.4)
Husband/partner encourage/remind to take IPTp-SP	(n = 328)	(n = 242)
Yes	312 (95.0)	237 (98.0)
No	16 (5.0)	5 (2.0)

Good male partner's involvement in ANC and IPTp-SP in urban and rural areas was 61.1% and 47.1% respectively. Respondents in

urban and rural areas differed with respect to male partner's involvement ($\chi^2 = 19.079$, $p < 0.001$). Those who had good male partner's

involvement in ANC and IPTp-SP had 1.8 odds (COR = 1.757, 95% CI: 1.364 – 2.269, p

<0.001) of being in urban areas than in rural areas (Table 3).

Table 3. Comparison of Husband/Partner's Involvement in ANC and Uptake of IPTp-SP Between Urban and Rural Areas in Benue State

Variable	Location		χ^2	OR (95% CI)	p-value
	Urban (n = 488) Frequency (%)	Rural (n = 488) Frequency (%)			
Husband/partner involvement					
Good	298 (61.1)	230 (47.1)	19.079	1.759 (1.364 – 2.269)	<0.001*
Poor	190 (38.9)	258 (52.9)		1	

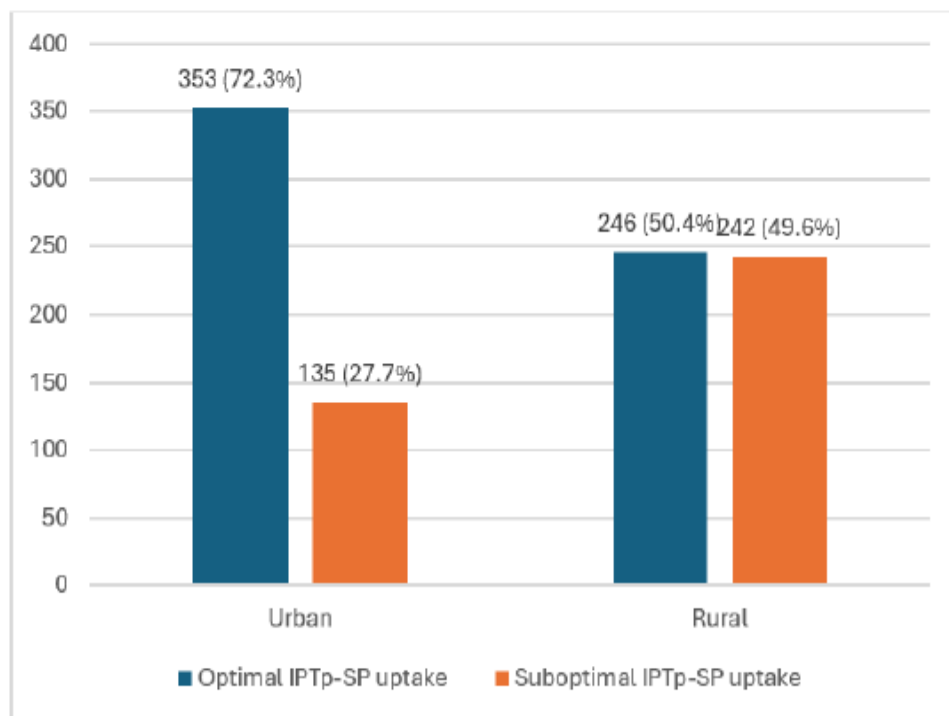


Figure 1. Showing Optimal and Suboptimal Uptake of IPTp-SP in Urban and Rural Areas of Benue State

In Benue State, optimal uptake of IPTp-SP in urban and rural areas was 72.3% and 50.4% respectively (Figure 1).

In urban areas, uptake of IPTp-SP was not associated with male partners accompanying for ANC ($\chi^2 = 43.271$, $p < 0.001$) aware of IPTp-SP ($\chi^2 = 38.376$, $p < 0.001$) and encouraging/reminding women to take IPTp-SP ($\chi^2 = 10.611$, $p = 0.001$). They did not differ in terms of frequency of accompanying for ANC ($\chi^2 = 1.525$, $p = 0.677$). Those whose male partners accompanied for ANC, were

aware of IPTp-SP and encouraging/reminding women to take IPTp-SP had 3.9 odds (OR = 3.882, 95% CI: 2.561 – 5.885, $p < 0.001$), 3.6 odds (OR = 3.600, 95% CI: 2.374 – 5.458, $p < 0.001$) and 4.8 odds (OR = 4.778, 95% CI: 1.718 – 13.298, $p = 0.001$) respectively of having optimal uptake of IPTp-SP compared to those whose male partners did not accompany them for ANC, were not aware of IPTp-SP and did not encourage/remind women to take IPTp-SP respectively (Table 4).

Table 4. Relationship Between Husband/Partner Involvement in ANC and Uptake of IPTp-SP and, Uptake of IPTp-SP in Urban Areas of Benue State, Nigeria

Variable	Uptake of IPTp-SP		χ^2	p-value	OR (95% CI)	p-value
	Optimal (n = 353) Frequency (%)	Suboptimal (n = 135) Frequency (%)				
Male partner accompanies for ANC						
Yes	261 (82.1)	57 (17.9)	43.271	<0.001*	3.882 (2.561 – 5.885)	<0.001*
No	92 (54.1)	78 (45.9)			1	
Frequency of accompanying to ANC	(n = 126)	(n = 57)				
Always	17 (73.9)	6 (26.1)	1.525	0.677		
Often	156 (81.7)	35 (18.3)				
Rarely	34 (85.0)	6 (15.0)				
Sometimes	54 (84.4)	10 (15.6)				
Male partner aware of IPTp-SP						
Yes	266 (81.1)	62 (18.9)	8.376	<0.001*	3.600 (2.374 – 5.458)	<0.001*
No	87 (54.4)	73 (45.6)			1	
Male partner encourage/remind to take IPTp-SP	(n = 266)	(n = 62)				
Yes	258 (82.7)	54 (17.3)	10.611	0.001*	4.778 (1.718 – 13.298)	0.001*
No	8 (50.0)	8 (50.0)			1	

*=Statistically significant

In urban areas, uptake of IPTp-SP was not associated with male partners being aware of IPTp-SP ($\chi^2 = 5.549$, $p = 0.018$). They did not differ in terms of accompanying for ANC ($\chi^2 = 2.967$, $p = 0.085$), frequency of accompanying for ANC visits ($\chi^2 = 5.791$, $p = 0.122$), and encouraging/reminding women to take IPTp-

SP ($\chi^2 = 1.271$, $p = 0.271$). Those whose male partners were aware of IPTp-SP 1.5 odds (OR = 1.534, 95% CI: 1.074 – 2.193, $p = 0.018$) of having optimal uptake of IPTp-SP compared to those whose male partners were not aware of IPTp-SP (Table 5).

Table 5. Relationship between Husband/Partner Involvement in ANC and Uptake of IPTp-SP and, Uptake of IPTp-SP in Rural Areas of Benue State, Nigeria

Variable	Uptake of IPTp-SP		χ^2	p-value	OR (95% CI)	p-value
	Optimal (n = 246) Frequency (%)	Suboptimal (n = 242) Frequency (%)				
Male partner accompanies for ANC						
Yes	131 (54.4)	110 (45.6%)	2.967	0.085		
No	115 (46.6)	132 (53.4%)				

Frequency of accompanying to ANC	(n = 131)	(n = 110)				
Always	10 (55.6)	8 (44.4)	5.791	0.122		
Often	74 (49.0)	77 (51.0)				
Rarely	18 (60.0)	12 (40.0)				
Sometimes	29 (69.0)	13 (31.0)				
Male partner aware of IPTp-SP						
Yes	135 (55.8)	107 (44.2)	5.549	0.018*	1.534 (1.074 – 2.193)	0.019*
No	111 (45.1)	135 (54.9)			1	
Male partner encourage/remind to take IPTp-SP						
Yes	131 (55.3)	106 (44.7)	1.214	0.271		
No	4 (80.0)	1 (20.0)				

*=Statistically significant

On Spearman's correlation, there is a positive and statistically significant relationship between male partner involvement and uptake of IPTp-SP ($r = 0.295$, $p < 0.001$) in urban areas of Benue State (Table 6).

Table 6. Spearman's Rank Correlation between Husband/Partner Involvement and Uptake of IPTp-SP in Urban Areas of Benue State

Variables	Male partner involvement	Uptake of IPTp-SP
Male partner involvement	1.000	0.295** ($p < 0.001$)
N	488	488

On Spearman's correlation, there was a weak association between Husband/partner involvement and uptake of IPTp-SP ($r = 0.066$, $p = 0.144$) in rural areas of Benue State which was not statistically significant (Table 7).

Table 7. Spearman's Rank Correlation Between Husband/Partner Involvement and Uptake of IPTp-SP in Rural Areas of Benue State

Variables	Male partner involvement	Uptake of IPTp-SP
Male partner involvement	1.000	0.066 ($p = 0.144$)
N	488	488

Discussion

This study was carried to assess how male partner involvement in ANC and IPTp-SP uptake affect the optimal uptake of IPTp-SP among women of reproductive age in Benue State. Good husband's/partner's involvement in ANC and IPTp-SP in urban and rural areas was 61.1% and 47.1% respectively. Those who had good husband's/partner's involvement in

ANC and IPTp-SP to be in urban areas than in rural areas. This suggests that women in urban settings are more likely to receive partner support in maternal health services than those in rural settings, possibly due to greater health awareness, better access to information, and improved availability of health services in urban areas. A study in Nigeria have shown that spousal support improves access and adherence to IPTp-SP [11]. Another reason for

this finding may be due to financial stability in which may be higher in urban compared to rural areas. It is barriers such as cost of transportation and clinic fees, thereby improving access to and uptake of IPTp-SP. Evidence from studies in Nigeria and Tanzania shows that women from households with higher socioeconomic status or employed partners are more likely to complete optimal IPTp-SP doses compared to those from poorer households [16, 17].

In urban areas, male partner accompanying to ANC visits, awareness of IPTp-SP and encouraging/reminding women to take IPTp-SP facilitated optimal uptake of IPTp-SP while in rural areas only male partner awareness of IPTp-SP facilitated optimal uptake of IPTp-SP. This indicates that in urban settings, broader social support and active male participation play a stronger role in shaping women's health-seeking behavior, likely due to better exposure to health information, higher literacy, and improved access to health services. Conversely, in rural areas, limited male participation beyond basic awareness may reflect structural barriers such as distance to facilities, cultural norms, or lower health literacy. Also, in urban areas as husband's/partner's involvement in ANC and IPTp-SP uptake increased, uptake of IPTp-SP also increased among the women which emphasizes the importance of male engagement in maternal health.

These findings in this study show the value of male involvement as both a social support mechanism and a motivator for women to comply with ANC recommendations. In contrast, the absence of a similar effect in rural areas points to gaps in male engagement which could be attributed to potential systemic or cultural barriers that limit its impact. A study in Ghana using negative binomial and time-series models found that male involvement in antenatal clinics significantly increased IPTp-SP uptake [18]. Another study in Ghana revealed that spousal support led better IPTp-

SP adherence, attributing this to emotional encouragement and support from male partners during pregnancy [19]. A recent scoping review emphasized that gender-sensitive, community-based strategies are essential to improving IPTp-SP uptake suggesting that males should be intentionally included in health interventions to support maternal access and adherence [20]. The urban advantage in male involvement in this study emphasizes the need for targeted interventions especially in rural areas such as community-based education, male engagement initiatives, and improved access to ANC services which will aid in reducing disparities and improve maternal and neonatal health outcomes.

Conflict of Interest

There was no conflict of interest.

Authors' Contributions

JA conceived and designed the study, led data collection and analysis, and drafted the manuscript. OA and TA contributed to study design, data collection, and manuscript review. EO provided methodological input, contributed to data interpretation, and reviewed the manuscript. All authors read and approved of the final manuscript.

Availability of Data and Materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Data-Linked Community-Health Facility Strategy to Identify and Reach Zero-Dose Children in Urban Informal Settlements: An Implementation Study in Wakiso District, Uganda

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Abstract

Despite substantial global progress in routine childhood immunisation, inequities persist, particularly among children living in urban informal settlements. Globally, an estimated 13 million children remain zero-dose each year—defined as children who have not received the first dose of a diphtheria–tetanus–pertussis (DTP)–containing vaccine. These children represent the most systematically excluded populations within immunisation systems and face the highest risk of vaccine-preventable diseases. In Uganda, rapid urbanisation has contributed to the concentration of zero-dose children in peri-urban districts such as Wakiso, where informal settlements are characterised by high population mobility, weak community–health facility linkages, and fragmented immunisation data systems. This study evaluates the effectiveness and implementation performance of a data-linked community–health facility strategy to improve identification, referral completion, and vaccination uptake among zero-dose and under-immunised children aged 0–23 months in urban informal settlements of Wakiso District, Uganda. A mixed-methods implementation research design will be used. Quantitative data will be obtained from routine immunisation records, household verification surveys, and integrated community registers, while qualitative data will be collected through focus group discussions and key informant interviews with caregivers, Village Health Teams, and health workers. Primary outcomes include changes in the identification and vaccination initiation of zero-dose children, measured through DTP1 uptake. Secondary outcomes include the acceptability, feasibility, and scalability of the intervention using the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework. By strengthening integration between community-generated data and health facility immunisation records, the study aims to generate practical implementation evidence for improving immunisation equity in urban informal settlements. Findings will inform district immunisation microplanning and outreach strategies. The study will also generate implementation-relevant evidence to support national immunisation policy and scalable approaches for identifying and reaching zero-dose children in rapidly urbanising settings.

Keywords: *Immunization Equity, Implementation Research, Routine Immunization, Uganda, Urban Informal Settlements, Zero-Dose Children.*

Introduction

Routine childhood immunisation remains one of the most effective public health interventions for reducing morbidity and mortality from vaccine-preventable diseases. Over the past two decades, global immunisation programmes have significantly expanded coverage, contributing to major declines in childhood mortality [1]. However, these gains have not been equitably distributed. An estimated 13 million children globally remain zero-dose each year, meaning they have not received the first dose of a diphtheria–tetanus–pertussis containing vaccine (DTP1), which serves as a key tracer indicator for immunisation system reach [2].

Zero-dose children represent populations that are systematically excluded from routine health services and are often concentrated among the poorest and most marginalised communities [3]. Recent global evidence indicates that the epidemiology of zero-dose children is shifting from predominantly rural settings to rapidly growing urban areas, particularly informal settlements in low- and middle-income countries [4]. These communities often experience overcrowding, insecure housing, high population mobility, and limited access to basic services, which collectively undermine routine immunisation delivery [5].

The phenomenon known as the “urban proximity paradox” highlights that children living near health facilities in informal settlements are sometimes less likely to receive vaccines than those living in rural areas [6]. Structural barriers, fragmented data systems, and weak community–facility linkages contribute to missed opportunities for vaccination despite geographic proximity to health services.

Uganda reflects similar trends. Although national routine immunisation coverage has improved over time, inequities persist, particularly in rapidly urbanising districts surrounding Kampala [7]. Wakiso District—the

most populous district in Uganda—reports some of the highest absolute numbers of zero-dose children nationally. The district contains numerous urban informal settlements characterised by high population turnover and complex health service delivery challenges.

Routine immunisation data systems in Uganda include the District Health Information System 2 (DHIS2), the electronic Community Health Information System (eCHIS), health facility immunisation registers, and Village Health Team (VHT) household registers. However, these systems frequently operate in parallel rather than as an integrated ecosystem, limiting the ability of health workers to accurately identify and follow up missed children [8].

Evidence from other urban African settings suggests that integrating community-level data with health facility immunisation records, combined with community health worker follow-up and flexible service delivery models, can substantially reduce the burden of zero-dose children [9]. Nevertheless, empirical evidence on how such data-linked community–facility strategies can be operationalised within Uganda’s routine health system remains limited.

Structural barriers, vaccine hesitancy, and social determinants of health have also been identified as important contributors to missed vaccinations in urban and low-resource settings [11–16].

The conceptual framework guiding this study integrates Andersen’s Behavioural Model of Health Service Use, the Socio-Ecological Model (SEM), and the RE-AIM implementation framework to explain the determinants of zero-dose status and the mechanisms through which the intervention is expected to improve immunisation outcomes [17–19].

At the input level, predisposing and enabling factors—including caregiver knowledge, beliefs, past experiences with health services, access to vaccination services, and associated

costs—interact with broader socio-ecological influences operating at individual, interpersonal, community, and health system levels. These interacting factors contribute to the persistence of zero-dose and under-immunised children in urban informal settlements.

The intervention focuses on strengthening a data-linked community–health facility strategy, whereby immunisation data from DHIS2, health facility registers, and Village Health Team (VHT) household records are systematically triangulated to improve identification, referral, and follow-up of zero-dose and under-immunised children. Key implementation mechanisms include DHIS2-guided targeting, VHT-led household mapping and follow-up, mobile and flexible outreach services, and participatory co-design with communities to improve service accessibility and responsiveness to the realities of urban informal settlements.

Implementation performance and outcomes are evaluated using the RE-AIM framework, which assesses the intervention’s reach, effectiveness, adoption, implementation fidelity, and maintenance within routine district health systems [19]. Through these mechanisms, the intervention is expected to contribute to increased vaccination coverage, reduced prevalence of zero-dose children, and strengthened immunisation planning capacity at the district level.

Ultimately, the framework illustrates how addressing behavioural, structural, and health system determinants through data-linked community–facility collaboration can improve identification and vaccination of missed children, thereby contributing to improved immunisation equity in urban informal settlements. The relationships between these determinants and the intervention mechanisms are illustrated in Figure 1.

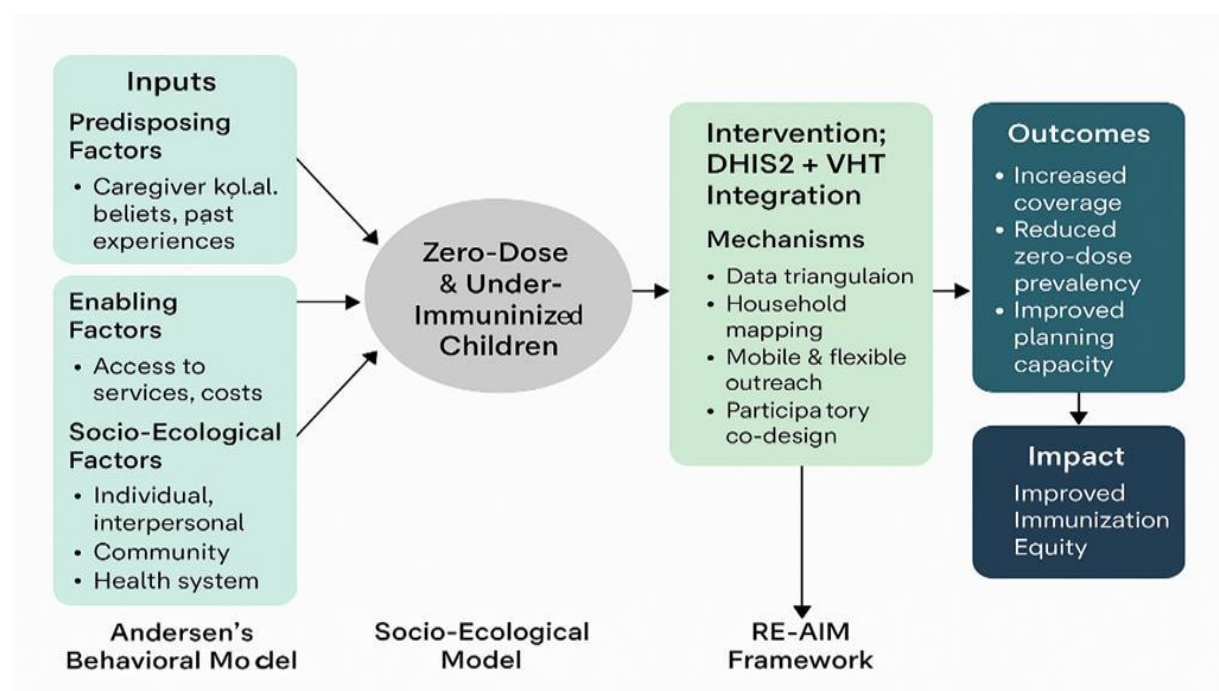


Figure 1. Conceptual Framework Illustrating the Determinants of Zero-Dose Children and the Data-Linked Community–Health Facility Intervention Integrating Andersen’s Behavioral Model, the Socio-Ecological Model, and the RE-AIM Implementation Framework. Developed by the Author based on Established Theoretical Models [17–19]

This study therefore aims to assess the effectiveness and implementation performance of a data-linked community–health facility strategy to improve identification, referral completion, and vaccination uptake among zero-dose children living in urban informal settlements of Wakiso District.

Materials and Methods

Study Design

This study employs a mixed-methods implementation research design to evaluate the effectiveness and operational feasibility of a data-linked community–health facility strategy for identifying, referring, and vaccinating zero-dose children in urban informal settlements of Wakiso District, Uganda.

The study integrates quantitative and qualitative approaches to assess both intervention outcomes and implementation processes under real-world service delivery conditions. Quantitatively, the study measures changes in the identification, referral completion, and vaccination uptake of zero-dose children, while qualitatively exploring behavioural, contextual, and health system factors that influence implementation of the strategy.

The methodological approach combines cross-sectional prevalence assessment, analytical household survey, and prospective implementation evaluation within a single integrated study framework. Routine immunisation data sources—including DHIS2 reports, health facility immunisation registers, the electronic Community Health Information System (eCHIS), and Village Health Team (VHT) household registers—will be triangulated with household verification and geospatial mapping to identify and track zero-dose and under-immunised children.

In addition, focus group discussions (FGDs) with caregivers and key informant interviews (KIIs) with health workers, VHTs, and district immunisation managers will be conducted to explore perceptions of feasibility, acceptability,

and scalability of the intervention. The implementation process and outcomes will be evaluated using the RE-AIM framework, which assesses reach, effectiveness, adoption, implementation fidelity, and maintenance within routine health system settings.

This mixed-methods design enables a comprehensive assessment of both the effectiveness of the intervention and the contextual factors influencing its implementation, thereby generating implementation-relevant evidence to inform strategies for reducing immunisation inequities in urban informal settlements.

Study Setting

The study will be conducted in selected urban informal settlements in Wakiso District, Uganda, which forms part of the Greater Kampala Metropolitan Area (GKMA). Wakiso District is the most populous district in Uganda and has experienced rapid urbanisation characterised by expanding informal settlements, high population density, and significant population mobility [20, 21]. These structural and demographic dynamics contribute to persistent inequities in access to routine childhood immunisation services.

The selected study sites include urban informal settlements served by lower-level public health facilities providing routine immunisation services under the Uganda National Expanded Programme on Immunization (UNEPI). These facilities include Health Centre II, Health Centre III, and Health Centre IV levels, which provide both facility-based and outreach vaccination services to densely populated communities [22].

Routine immunisation programme reports indicate that urban informal settlements in Wakiso District represent high-burden areas for zero-dose and under-immunised children, partly due to fragmented immunisation data systems, high population mobility, and weak community–health facility linkage mechanisms [23, 24]. These characteristics make Wakiso

District an appropriate setting for evaluating a data-linked community–health facility strategy aimed at improving identification, referral, and vaccination uptake among missed children.

To ensure that the study will be implemented in high-burden settings, four urban informal settlements were purposively identified based on analysis of routine immunisation data from the District Health Information System 2 (DHIS2). In collaboration with district immunisation programme managers and following Ministry of Health guidance for identification of priority areas for zero-dose interventions, DHIS2 indicators including DTP1 coverage, dropout rates, and reported numbers of zero-dose children were reviewed. Settlements consistently reporting high numbers of missed or under-immunised children were identified and selected as the primary implementation sites for the study.

Study Population

The study population will comprise children aged 0–23 months living in selected urban informal settlements of Wakiso District, Uganda, and the individuals involved in their immunisation care and service delivery. Specifically, the study will include caregivers of children aged 0–23 months, who are responsible for making decisions regarding child health and vaccination.

In addition, the study will involve Village Health Team (VHT) members, who serve as community-based health volunteers responsible for household registration, health education, and referral of children for immunisation services. Health workers involved in routine immunisation service delivery at selected health facilities will also participate, including those responsible for vaccination services, child registers, and outreach activities.

Furthermore, district and sub-district immunisation programme managers, including Expanded Programme on Immunization (EPI) focal persons, will be included as key informants to provide insights on programme

implementation, supervision, and health system factors influencing the identification and follow-up of zero-dose children.

Sample Size

The sample size for the household survey was estimated using the single population proportion formula:

$$n = \frac{Z^2 p(1-p)}{d^2}$$

- n = required sample size.
- Z = Z-score for 95% confidence level (1.96).
- p = estimated prevalence of zero-dose children.
- d = margin of error (0.05).

Assuming a zero-dose prevalence of 12%, a 95% confidence level, and 5% margin of error, the minimum sample size was estimated at approximately 162 children.

To account for non-response and population mobility, a 10% adjustment will be applied:

$$n_{adj} = \frac{n}{1 - \% non-response}$$

$$n_{adj} = 162 / 0.9 = 180.$$

Given that sampling will occur within clustered settlement environments, a design effect (DEFF) of 1.5 will be applied to adjust for potential intra-cluster correlation:

$$n_{final} = n_{adj} \times DEFF.$$

$$n_{final} = 180 \times 1.5 = 270.$$

Therefore, the statistically derived minimum sample size for the quantitative component of the study is 270 caregiver–child pairs.

However, to enhance statistical power, allow for subgroup analyses across different informal settlements, and mitigate operational challenges such as high population mobility and incomplete household records, the study will target approximately 500 caregiver–child pairs.

Data Collection

Quantitative Data

Quantitative data will be collected using multiple complementary sources to support identification and verification of zero-dose and

under-immunised children. These will include structured household caregiver surveys, review of health facility immunisation registers, and Village Health Team (VHT) household child registers. Additional data will be obtained from routine health information systems, including the electronic Community Health Information System (eCHIS) and the District Health Information System 2 (DHIS2). Household visits will also involve GPS-enabled verification of households to confirm residence and support geospatial mapping of zero-dose and under-immunised children within the study settlements.

In order to identify zero-dose and under-immunised children who may not appear in routine health facility or community registers, the study will incorporate active household verification within the selected settlements. Village Health Teams (VHTs) will support household mapping and listing of children aged 0–23 months within their catchment areas. Trained research assistants will then conduct structured household caregiver surveys to verify vaccination status using child health cards where available, or caregiver recall when documentation is not available. Children identified during household visits who have not received any routine vaccines, including the first dose of a diphtheria–tetanus–pertussis containing vaccine (DTP1), will be classified as zero-dose children, while those who have initiated but not completed the recommended schedule will be classified as under-immunised. Information obtained from household verification will be cross-checked with health facility immunisation registers, Village Health Team household registers, and electronic health information systems such as eCHIS to validate vaccination status and support referral and follow-up of missed children. This approach enables the study to identify both registered and previously unregistered children, thereby improving the completeness and accuracy of zero-dose identification in urban informal settlements.

Qualitative Data

Qualitative data will be collected through Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) to explore behavioural, community, and health system factors influencing identification and vaccination of zero-dose children. A total of four FGDs will be conducted with caregivers of children aged 0–23 months, with each group comprising 6–10 participants. In addition, approximately 10–12 KIIs will be conducted with Village Health Team (VHT) members, health workers, EPI focal persons, local leaders, and district immunisation programme managers. Participants will be purposively selected based on their roles and experience in routine immunisation service delivery. All discussions and interviews will be guided by semi-structured interview guides and audio-recorded with participant consent.

Data Analysis

Data analysis will integrate both quantitative and qualitative approaches to comprehensively assess the effectiveness and implementation performance of the data-linked community–health facility strategy.

Quantitative Data Analysis

Quantitative data obtained from household surveys, health facility immunisation registers, Village Health Team (VHT) household registers, and electronic systems (DHIS2 and eCHIS) will be cleaned, coded, and analysed using Stata version 18 (or SPSS version 26). Data quality checks including range checks, missing value assessment, and logical consistency verification will be conducted prior to analysis.

Descriptive Statistics

Descriptive statistics will be used to summarize the characteristics of the study population and immunization status of children. Continuous variables such as caregiver age will be summarized using means and standard

deviations, while categorical variables such as child sex, caregiver education level, and immunization status will be summarized using frequencies and percentages.

The prevalence of zero-dose children will be calculated as:

$$\text{Prevalence (\%)} = \frac{\text{Number of children who have not received DTP1}}{\text{Total number of children aged 0–23 months surveyed}} \times 100$$

Spatial distribution of zero-dose children across the study settlements will be visualized using Geographic Information System (GIS) mapping based on GPS coordinates collected during household verification.

Bivariate Analysis

Bivariate analysis will be conducted to examine associations between zero-dose status and potential explanatory variables including demographic, socioeconomic, behavioural, and health system factors.

Statistical tests to be used include:

- Chi-square tests for associations between categorical variables.
- Student's t-tests for comparison of continuous variables between groups.

Associations between categorical variables will be assessed using the Chi-square (χ^2) test, calculated as $\chi^2 = \sum \frac{(O-E)^2}{E}$ where O represents observed frequencies and E represents expected frequencies. Differences in continuous variables between groups will be evaluated using the independent samples Student's t-test, calculated as $t = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$, where t denotes the

test statistic used to assess differences between group means $\bar{x}_1$ and $\bar{x}_2$ represent the mean values of groups 1 and 2 respectively, s_1^2 and s_2^2 denote the variances of the two groups, and n_1 and n_2 represent the respective sample sizes. Statistical significance will be considered at $p < 0.05$.

Multivariable Analysis

Multivariable logistic regression will be performed to identify independent predictors of

zero-dose status among children aged 0–23 months.

The regression model will be expressed as:
 $\text{logit}(P) = \beta_0 + \beta_1 X_1 + \dots + \beta_k X_k$

Where:

- P represents the probability of a child being zero-dose.
- $X_1, X_2 \dots X_k$ represent explanatory variables such as caregiver education, household mobility, distance to health facility, and awareness of immunization services.

Adjusted Odds Ratios (AOR) with 95% confidence intervals will be reported. Statistical significance will be considered at $p < 0.05$.

Intervention Effectiveness Analysis

To assess the effectiveness of the data-linked community–health facility strategy, changes in key indicators before and after implementation will be evaluated, including:

- Number of zero-dose children identified.
- Proportion of identified children referred to health facilities.
- Proportion initiating routine immunisation (DTP1 uptake).

Differences between baseline and follow-up measurements will be analysed using paired proportion tests and difference-in-differences analysis where appropriate.

Implementation Outcome Analysis

Implementation outcomes will be assessed using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework, focusing on:

- **Reach:** proportion of zero-dose children successfully identified and followed up:
$$\text{Reach (\%)} = \frac{\text{Total number of zero-dose children in the target population}}{\text{Number of zero-dose children identified and followed up}} \times 100$$
- **Effectiveness:** change in vaccination initiation and completion.
- **Adoption:** proportion of health facilities and VHTs using the data-linkage tools.

- **Implementation:** fidelity of intervention processes including referral tracking and outreach services.
- **Maintenance:** extent to which the strategy is integrated into routine district immunisation systems.

Qualitative Data Analysis

Qualitative data from Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) will be audio-recorded, transcribed verbatim, and analysed using thematic analysis.

The analysis will follow six steps:

1. Familiarization with the data
2. Coding of transcripts
3. Development of themes
4. Review of emerging themes
5. Definition and naming of themes
6. Interpretation and synthesis of findings

Coding will be conducted using NVivo software. Themes will focus on barriers and facilitators to immunization uptake, community perceptions of the intervention, and feasibility of scaling the strategy within routine district health systems.

Data Triangulation

Findings from quantitative and qualitative analyses will be triangulated to provide a comprehensive understanding of both the effectiveness and implementation dynamics of the intervention.

This mixed-method integration will strengthen the interpretation of results and enhance the validity of the study conclusions.

Ethical Approval

Ethical approval for this study was obtained from the Hospice Africa Uganda Research Ethics Committee (HAUREC) (Ref No: HAU-2026-214). The study was further registered and cleared by the Uganda National Council for Science and Technology (UNCST) (Permit No: HS7295ES), in accordance with national research regulations governing studies involving human participants in Uganda.

Administrative authorization to conduct the study was obtained from the Wakiso District Health Office and Kira municipality, where the research will be implemented in selected urban informal settlements served by lower-level health facilities providing routine immunisation services.

Written informed consent will be obtained from all adult participants prior to data collection. For caregivers participating on behalf of children aged 0–23 months, consent will be obtained from the primary caregiver responsible for the child. Participation in the study will be entirely voluntary, and participants will be informed of their right to decline participation or withdraw from the study at any time without any consequences.

Confidentiality of participant information will be strictly maintained. Personal identifiers will not be recorded in analytical datasets, and all collected data will be securely stored in password-protected databases accessible only to the research team. Results will be reported in aggregated form to ensure that no individual participant can be identified.

The study will adhere to internationally accepted ethical standards for research involving human participants, including the principles outlined in the Declaration of Helsinki.

Results (Expected Outcomes)

As this study represents an implementation research protocol, the results will evaluate the effectiveness and implementation performance of a data-linked community–health facility strategy designed to improve identification and vaccination uptake among zero-dose children in urban informal settlements.

Specifically, the study will generate evidence on:

1. Baseline prevalence and spatial distribution of zero-dose and under-immunised children in selected urban informal settlements of Wakiso District.

2. Determinants of zero-dose status, including demographic, socioeconomic, behavioural, and health system factors influencing vaccination initiation among children aged 0–23 months.
3. Effectiveness of the data-linked community–health facility strategy, measured through changes in:
 - Identification of zero-dose children.
 - Referral completion rates.
 - Initiation of routine immunisation (DTP1 uptake).
4. Implementation outcomes, including reach, adoption, implementation fidelity, and maintenance of the intervention within routine district immunisation systems, assessed using the RE-AIM implementation framework.

The findings are expected to generate practical implementation evidence to support district-level immunisation microplanning, targeted outreach strategies, and policy decisions aimed at reducing immunisation inequities among children living in urban informal settlements.

Discussion

The study addresses a critical implementation gap in urban immunisation programmes. By integrating community and facility data systems, the intervention aims to improve the visibility and follow-up of missed children.

Previous studies have demonstrated that community health worker-led tracking systems can significantly improve immunisation coverage in complex urban environments [9]. Similar approaches implemented in Tanzania achieved reintegration of more than half of identified zero-dose children within a short period [10].

If effective, the strategy evaluated in this study could inform district-level microplanning

and strengthen Uganda's efforts to reduce immunisation inequities.

Conclusion

Urban informal settlements represent a growing challenge for routine immunisation programmes in many low- and middle-income countries. Fragmented data systems and weak community–facility linkages limit the identification and follow-up of zero-dose children.

This study evaluates a practical strategy for integrating community and health facility immunisation data to improve identification, referral, and vaccination uptake among missed children.

Findings from this research will contribute implementation evidence to guide immunisation programme strengthening in urban settings.

Conflict of Interest

The authors declare no conflict of interest.

Data Availability

The datasets that will be generated and analysed during the course of this study will include household survey data, qualitative interview transcripts, and routine immunisation programme data obtained from health facility records and national health information systems (DHIS2 and eCHIS). Due to ethical and regulatory restrictions related to participant confidentiality and health system data governance, these datasets will not be publicly available. However, de-identified datasets may be made available from the corresponding author upon reasonable request and subject to approval by the relevant ethical and regulatory authorities, including the Hospice Africa Uganda Research Ethics Committee (HAUREC) and the Uganda National Council for Science and Technology (UNCST).

Author Contributions

Dominic Savio Kakeeto (PhD student in Public Health at Texila American University)

conceptualized the study, developed the research design, conducted the literature review, and prepared the original manuscript draft. Savio also designed the data collection tools and will lead data collection, analysis, and interpretation of the study findings. Prof. Edgar Mulogo Mugema and Prof. Ibrahim Farahat Mohamed El Bayoumy provided academic supervision, methodological guidance, and critical review of the manuscript. All authors reviewed and approved the final version of the manuscript.

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Intergenerational Transmission of Menstrual Shame: A Qualitative Investigation of Parental Influence on Adolescent Menstrual Health Attitudes in Urban Ghana

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Abstract

This qualitative study examined how parents transmit menstrual health attitudes and knowledge to their adolescent daughters in urban Ghana through focus group discussions with 15 parents representing diverse socio-economic backgrounds and educational levels. Thematic analysis revealed four major themes: intergenerational transmission of menstrual shame despite improved hygiene practices, persistent influence of cultural and religious beliefs on menstrual attitudes, notable generational shifts in comfort levels with menstrual discussions, and evolving perspectives on male involvement in menstrual health education. Parents acknowledged transmitting the same shame and discomfort they experienced in their own adolescence, despite possessing better factual knowledge than previous generations. Cultural restrictions preventing menstruating girls from cooking, touching food, or participating in ceremonies remained firmly embedded across socio-economic levels, while religious beliefs imposed additional constraints on worship and spiritual activities. Parents expressed internal conflicts between maintaining traditional practices and adapting to modern health perspectives, using ancestral teachings to legitimize restrictive attitudes. However, parents also recognized that their daughters' generation demonstrates greater openness and comfort with menstrual topics compared to their own upbringing, though many admitted their personal discomfort continues despite intellectual acceptance of menstruation as normal. Educated urban parents increasingly supported teaching boys about menstruation to create supportive environments, while traditional attitudes maintaining menstruation as exclusively female knowledge persisted particularly in less educated populations. These findings illuminate the complex mechanisms through which cultural beliefs persist across generations even as health knowledge improves, highlighting the critical need for family-centered interventions addressing both parents' and daughters' attitudes simultaneously rather than focusing on adolescent education alone.

Keywords: *Adolescent Menstrual Health, Cultural Beliefs, Intergenerational Transmission, Parental Attitudes, Qualitative Research, Urban Ghana.*

Introduction

Menstrual hygiene management (MHM) represents a critical aspect of adolescent reproductive health that extends beyond individual hygiene practices to encompass complex social, cultural, and psychological

dimensions [1-3]. While substantial research has examined knowledge and practice patterns among adolescent girls [4-7], limited investigation has explored the mechanisms through which parents transmit attitudes, beliefs, and behavioral patterns regarding

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menstruation to their daughters [15, 29]. The family environment serves as the primary context for initial menstrual health socialization, with parents playing critical roles in shaping how adolescent girls perceive and manage menstruation throughout their reproductive years [1, 15, 29].

In Ghana and across sub-Saharan Africa, menstruation remains subject to cultural taboos, religious restrictions, and social stigma that significantly influence adolescent girls' experiences and management practices [3, 9, 14, 25]. Traditional beliefs about menstrual impurity, contamination, and spiritual effects persist alongside modern health knowledge, creating complex environments where multiple belief systems coexist and compete [9, 14, 25]. Parents navigate these tensions as they guide their daughters through menarche and ongoing menstrual experiences, often transmitting contradictory messages that combine factual health information with culturally embedded attitudes and restrictions [3, 15].

Social Cognitive Theory emphasizes that health behaviors and attitudes develop through observational learning, modeling, and social reinforcement within family and community contexts [1, 15]. Parents serve as primary role models whose own attitudes, behaviors, and communication patterns profoundly influence how adolescent girls conceptualize menstruation and develop management strategies [1, 15]. The intergenerational transmission of menstrual attitudes occurs through both explicit instruction and implicit modeling, with daughters internalizing not only what parents say about menstruation but also how parents behave, what they avoid discussing, and which aspects they treat with shame or discomfort [10, 15, 16, 19].

Despite the recognized importance of parental influence in adolescent health behavior development [15, 29, 30], qualitative research examining parents' perspectives on menstrual health guidance remains limited in sub-Saharan African contexts [3, 9, 25]. Existing studies

have primarily focused on adolescent girls' experiences and perceptions [4-7, 13], with minimal exploration of how parents understand their roles, navigate cultural expectations, experience intergenerational change, and transmit attitudes to the next generation. This gap limits understanding of family-level dynamics that shape menstrual health outcomes and constrains development of effective family-centered interventions [29, 30].

This study addresses this critical gap through in-depth qualitative exploration of parental perspectives on menstrual health guidance in urban Ghana. The research examines how parents perceive their roles in menstrual health education, how they navigate tensions between traditional beliefs and modern health knowledge [14, 17, 25], how they transmit attitudes despite changing generational contexts, and how their own experiences shape the guidance they provide. Understanding these parental perspectives and transmission mechanisms provides essential insights for developing comprehensive interventions that address family-level attitudes and communication patterns rather than focusing exclusively on adolescent education [29, 30].

Materials and Methods

Study Design and Setting

This qualitative study employed focus group discussion methodology to explore parental perspectives on menstrual health guidance in the Greater Accra Region of Ghana [14]. The study was conducted as the qualitative component of a larger sequential explanatory mixed-methods investigation examining knowledge, attitudes, and practices in adolescent menstrual hygiene management. The Greater Accra Region was selected due to its demographic diversity encompassing urban, peri-urban, and semi-urban communities, providing opportunities to examine variations in parental perspectives across different socio-economic and geographic contexts [10, 13, 22].

Participant Selection and Recruitment

Participants were selected using purposive maximum variation sampling strategies designed to ensure representation of diverse parental characteristics, experiences, and perspectives [14]. Selection criteria included having at least one adolescent daughter aged 10-19 years who had experienced menarche, willingness to discuss menstrual health topics openly in group settings, and demographic diversity across educational levels, socio-economic status, residential locations, and family structures. Recruitment occurred through multiple channels including school administrators, community health centers, religious organizations, and community leaders

who identified potential participants meeting the selection criteria.

The final sample comprised 15 parents including 14 mothers and 1 father, reflecting the predominant pattern of mothers serving as primary providers of menstrual health guidance [3, 15]. Participant ages ranged from 38 to 52 years, with educational backgrounds spanning no formal education (n equals 3), primary education (n equals 3), junior high school (n equals 3), senior high school (n equals 4), and tertiary education (n equals 2). Residential locations included urban (n equals 7), peri-urban (n equals 5), and rural areas (n equals 3) (Table 1). All participants provided informed consent and were assured of confidentiality and anonymity in reporting.

Table 1. Participant Demographic Characteristics

Characteristic	Frequency (n=15)
Gender	
Mothers	14
Fathers	1
Education Level	
No Formal Education	3
Primary Education	3
Junior High School	3
Senior High School	4
Tertiary Education	2
Residential Location	
Urban	7
Peri-urban	5
Rural	3

Source: Field Survey (2025)

Data Collection Procedures

Data were collected through three focus group discussions with 4-6 participants each, organized to facilitate comfortable discussion among parents with similar socio-demographic characteristics [14]. Focus groups were conducted in community centers and school facilities providing private, quiet spaces conducive to open discussion. Each focus group discussion lasted 90-120 minutes and was conducted in English with occasional use of local languages when participants preferred

expressing certain concepts in their native tongue.

A semi-structured discussion guide developed based on theoretical frameworks [1, 2] and literature review [3, 9, 14] facilitated exploration of key topics while allowing flexibility to pursue emerging themes. The guide addressed five main areas: parental experiences and attitudes regarding their own menstrual health education and management, current approaches to discussing menstruation with daughters, cultural and religious beliefs

influencing guidance provision [9, 14, 19, 25], challenges and barriers encountered in providing menstrual health education, and perceptions of generational changes in menstrual health attitudes and practices. The research team included trained qualitative researchers experienced in facilitating sensitive health discussions.

All focus group discussions were audio recorded with participant permission and supplemented by detailed field notes documenting nonverbal communication, group dynamics, and contextual observations [14]. Recordings were transcribed verbatim by professional transcriptionists, with transcript accuracy verified through comparison with audio recordings and field notes. Non-English segments were professionally translated to English with back-translation procedures ensuring accuracy and cultural authenticity.

Data Analysis

Qualitative data analysis followed Braun and Clarke's six-phase thematic analysis approach [12] utilizing NVivo 14.0 software to manage and organize data systematically. The analysis process began with data familiarization through repeated reading of transcripts and review of field notes to develop comprehensive understanding of content, patterns, and meanings. Initial coding involved systematic line-by-line analysis identifying meaningful units of data and assigning descriptive codes capturing content and meaning. This process incorporated both deductive codes derived from theoretical frameworks [1, 2] and inductive codes emerging organically from data content [12].

Theme development involved organizing codes into broader conceptual categories capturing patterns of meaning across the dataset [12]. This process included examining relationships between codes, identifying higher-order themes encompassing multiple related codes, and developing thematic maps illustrating connections between themes and

subthemes. Theme review and refinement involved systematic checking of themes against coded data and the entire dataset ensuring themes accurately represented data content and provided coherent distinct analytical categories [12]. Final theme definition involved developing clear names and descriptions capturing essence and scope of each theme while ensuring themes worked together to provide comprehensive understanding of research questions.

Quality assurance followed established criteria for trustworthy qualitative research [13] including prolonged engagement, persistent observation, member checking, audit trails, reflexivity practices, and triangulation across multiple data sources and analytical perspectives. Two researchers independently coded selected transcripts with comparison and discussion of coding decisions ensuring consistency and comprehensiveness in analytical interpretations [13, 14].

Ethical Considerations

Ethical approval was obtained from the Institutional Review Board prior to data collection. All participants provided informed consent after receiving detailed information about study purposes, procedures, potential risks and benefits, confidentiality protections, and rights to withdraw participation at any time without consequences. Participants' identities were protected through use of pseudonyms and demographic descriptors rather than identifying information in reporting findings. Audio recordings and transcripts were stored securely with access limited to the research team.

Results

Thematic analysis of focus group discussions with parents revealed four major themes illuminating the complex mechanisms through which menstrual health attitudes, beliefs, and practices are transmitted across generations in urban Ghana [12]. These themes demonstrate persistent tensions between

traditional cultural beliefs and modern health knowledge [9, 14, 25], revealing how parents simultaneously transmit shame and improved hygiene practices, navigate religious and cultural restrictions, recognize generational shifts while maintaining personal discomfort, and grapple with evolving perspectives on gender inclusivity in menstrual health education [27].

Intergenerational Transmission of Menstrual Shame

The first and most pervasive theme revealed how parents explicitly recognize that they transmit the same feelings of shame and embarrassment about menstruation to their daughters that they experienced in their own adolescence, despite simultaneously teaching improved hygiene practices and factual biological knowledge [1, 15]. This intergenerational transmission occurs through both conscious instruction and unconscious modeling [1, 15, 16], creating contradictions where daughters receive messages that menstruation is natural while simultaneously learning to hide, conceal, and feel embarrassed about their menstrual status.

Parents demonstrated awareness of this transmission pattern through reflective acknowledgment of how their own upbringing shaped current guidance approaches. A 38-year-old mother with no formal education from a rural area articulated this pattern clearly:

"Menstruation is something private and a bit shameful. I was taught this by my mother, and now I see my daughter has learned the same attitude from me. When she started menstruating, I told her this is something women go through but we don't talk about it openly. She has absorbed this lesson. She is very secretive about her period now, just like I am." (38 years, No formal education, Rural)

This transmission manifested through specific behavioral modeling around menstrual

product management and discussion patterns [5, 18]. Parents acknowledged teaching daughters to hide menstrual products, speak in whispers when mentioning menstruation, and maintain secrecy about their menstrual status even within family contexts. A 40-year-old mother with primary education from a rural area explained:

"My daughter feels ashamed when she goes to buy pads at the store. She says she feels like everyone is looking at her and judging her. I understand this feeling because I still feel that way too when I buy pads for myself. Sometimes I send her father to buy them so we don't have to face the shopkeeper. It's just uncomfortable." (40 years, Primary, Rural)

Parents provided detailed descriptions of how they model concealment behaviors that daughters subsequently adopt [1, 15]. A 42-year-old mother with junior high school education from a semi-urban area elaborated:

"Even though pads are just a hygiene product like soap or toothpaste, buying them feels different. When I go to the pharmacy with my daughter, she whispers to me to buy pads instead of speaking out loud. She wraps them quickly and hides them in her bag. I don't correct her because I do the same thing. We both feel embarrassed about it, and I think this is normal for women." (42 years, JHS, Semi-urban)

This transmission pattern persisted even among educated parents who intellectually understood menstruation as a normal biological process [5, 18, 28]. Parents acknowledged contradiction between the facts they taught and the attitudes they modeled, revealing how deeply embedded shame operates independently of biological knowledge. The pattern demonstrated how effective hygiene practices can coexist with persistent shame-based attitudes, with parents successfully

teaching daughters proper hygiene procedures while simultaneously transmitting emotional discomfort and social embarrassment about menstruation.

Cultural and Religious Influences on Menstrual Attitudes

The second major theme highlighted the persistent and powerful influence of cultural and religious beliefs on menstrual attitudes across generations [9, 14, 25], shaping both parents' guidance approaches and daughters' experiences. Parents articulated specific traditional restrictions limiting menstruating girls' activities based on beliefs about menstrual contamination, spiritual impurity, and cultural propriety. These restrictions operated across diverse socio-economic levels and educational backgrounds, though their specific manifestations varied by family context [14, 25].

Cultural restrictions centered primarily on food preparation and consumption practices [9, 14]. A 46-year-old mother with no formal education from a semi-urban area explained traditional prohibitions firmly embedded in family practice:

"In our culture, when my daughter is menstruating, she cannot enter the kitchen or touch food that others will eat. This is our tradition passed down from our ancestors. She knows this rule and follows it without question. During those days, she stays away from the cooking area and eats separately. This is how we respect our culture and maintain purity in our home." (46 years, No formal education, Semi-urban)

Additional cultural restrictions extended to social participation and family ceremonies [9, 14, 25]. A 50-year-old mother with primary education from a rural area described comprehensive activity limitations:

"There are many things my daughter cannot do during her period according

to our customs. She cannot touch newborn babies because the menstrual blood is considered unclean. She cannot participate in family ceremonies or important events. She cannot even sit on certain furniture in the house. These rules may seem strict, but they are our cultural beliefs that have existed for generations." (50 years, Primary, Rural)

Religious beliefs imposed parallel restrictions on worship and spiritual activities, particularly within Islamic and some Christian denominations [9, 25]. A 42-year-old mother with junior high school education from an urban area explained religious teachings about menstrual impurity:

"Our religion teaches that when my daughter is on her period, she cannot pray or enter the mosque. She is considered temporarily impure and cannot participate in religious activities until her menstruation ends and she performs the cleansing ritual. This is not punishment but part of our faith. My daughter understands and accepts these religious rules even though she wishes she could pray with us." (42 years, JHS, Urban)

A 45-year-old mother with secondary education from a peri-urban area elaborated on religious restrictions affecting spiritual participation [9, 25]:

"During menstruation, my daughter cannot touch the Quran or participate in religious studies at the mosque. She must stay home during prayer times on those days. At first, she was confused about why menstruation affects her relationship with God, but I explained this is what our religion teaches. She has accepted it now, though sometimes I see she feels excluded from our spiritual life during those days." (45 years, Secondary, Peri-urban)

Parents expressed internal tensions between maintaining traditional practices and adapting to modern health perspectives [5, 14, 25]. Many acknowledged awareness of alternative viewpoints but felt compelled to preserve ancestral teachings despite potential conflicts with health information. A 48-year-old mother with primary education from a rural area articulated this tension:

"I know times are changing and young people have different ideas about menstruation now. At the health center, they tell us menstruation is natural and girls should not be restricted. But I still follow what my grandmother taught me about keeping girls separate during their period. It's difficult to abandon these teachings even when I hear modern information. Our traditions are important to us." (48 years, Primary, Rural)

Even highly educated parents acknowledged struggling with competing belief systems [15, 25]. A 43-year-old mother with senior high school education from an urban area expressed similar internal conflict:

"I am educated and I understand the scientific facts about menstruation. I know the blood is not really dirty or impure. But at the same time, I was raised with certain beliefs and practices that are hard to let go. So with my daughter, I try to teach her both the modern understanding and the traditional rules. Sometimes these two approaches contradict each other, and I'm not sure which one is right." (43 years, SHS, Urban)

Parents used ancestral teachings and cultural continuity as justification for maintaining restrictive practices despite awareness of alternative perspectives [14, 15]. A 52-year-old mother with no formal education from a rural area emphasized the importance of preserving intergenerational tradition:

"These restrictions on menstruating girls have been practiced in our family for many, many generations. My great-grandmother taught my grandmother, who taught my mother, who taught me. Who am I to break this chain? These traditions exist for a reason, and we must respect them. If we abandon our cultural practices, we lose our identity and connection to our ancestors." (52 years, No formal education, Rural)

Generational Shifts in Comfort and Openness

The third theme revealed notable generational shifts in comfort levels and communication openness regarding menstrual health [5, 18, 21], with parents recognizing that their daughters' generation demonstrates substantially greater ease discussing menstruation compared to their own upbringing. This recognition occurred across educational and socio-economic levels, suggesting widespread awareness of changing social norms around menstrual health discourse. However, parents simultaneously acknowledged that their personal discomfort persists despite intellectual acceptance of these positive changes [15, 16].

Parents observed and often appreciated the increased openness among contemporary adolescents [18, 21]. A 39-year-old mother with senior high school education from an urban area described this generational difference:

"My daughter and her friends talk freely about their periods. They discuss which pads are best, when they started, how they feel during menstruation. They even joke about it sometimes. We could never do that in my time. Menstruation was whispered about in secret, and we were too ashamed to mention it even among ourselves. I see this openness in the young generation and I think it's actually healthy." (39 years, SHS, Urban)

Educational institutions contributed significantly to this generational shift through formal health education curriculum [5,26]. A 40-year-old mother with tertiary education from an urban area noted:

"In school, my daughter learns about menstruation in biology class. Her teachers explain it openly, and the students ask questions freely. This is very different from my experience where no teacher ever mentioned menstruation. The girls learn together with boys about the menstrual cycle. I think this openness helps remove shame and makes menstruation feel more normal for this generation." (40 years, Tertiary, Urban)

Despite recognizing and sometimes appreciating increased openness among youth, many parents admitted their own discomfort continues [15, 16]. A 41-year-old mother with junior high school education from a semi-urban area confessed:

"I try to be open with my daughter about menstruation. I want her to feel comfortable asking me questions. But honestly, I still feel uncomfortable talking about some things. When she asks detailed questions about menstrual blood or her body changes, I feel awkward and don't know how to answer properly. My own upbringing makes it hard for me to discuss these topics naturally." (41 years, JHS, Semi-urban)

A 44-year-old mother with secondary education from a peri-urban area expressed similar struggles between intentions and behaviors [15]:

"Even though I tell my daughter that menstruation is natural and nothing to be ashamed of, I realize my behavior doesn't always match my words. I still hide my own pads, I whisper when talking about periods, and I become uncomfortable when the topic comes up

in public. My daughter notices this contradiction. She sees that I'm not as comfortable as I claim to be." (44 years, Secondary, Peri-urban)

Parents identified a critical gap between cognitive understanding and emotional comfort [15, 16]. A 47-year-old mother with tertiary education from an urban area reflected on this knowledge-attitude disconnect:

"I have read books and attended health talks about menstruation. Intellectually, I understand it's a normal biological process that should not carry shame. But emotionally, I still carry the shame I learned as a girl. So when I teach my daughter, I can give her the right information, but I cannot fully give her the attitude of confidence and openness I want her to have. There is a disconnect between my knowledge and my feelings." (47 years, Tertiary, Urban)

This theme demonstrated that generational change in menstrual attitudes occurs gradually, with knowledge and behavioral patterns shifting more rapidly than deeply embedded emotional responses and comfort levels [15, 18]. Parents recognized their daughters' generation as transitional, experiencing less shame than previous generations while not yet achieving complete comfort and openness. Parents acknowledged their own limitations as role models, understanding that their persistent discomfort constrains their ability to fully support their daughters' development of shame-free menstrual attitudes despite possessing improved knowledge [15, 16].

Changing Gender Perspectives on Menstrual Health

The fourth theme highlighted evolving perspectives on male involvement in menstrual health education [27], revealing substantial variation in attitudes ranging from progressive gender-inclusive approaches to traditional gender-segregated frameworks. These

divergent perspectives correlated strongly with parental education levels and geographic locations, with educated urban parents more likely to support male education while less educated rural parents maintained traditional exclusionary approaches [14, 27].

Progressive parents, particularly those with higher education and urban residence, articulated strong support for educating boys about menstruation [27]. A 45-year-old mother with tertiary education from an urban area explained the rationale for male inclusion:

"I think boys should learn about menstruation in school so they can support their sisters, friends, and future wives. When boys understand what girls go through during menstruation, they become more sympathetic and helpful. My husband knows about menstrual health, and he buys pads for our daughter without embarrassment. I want my sons to be the same way. Menstruation affects half the population, so everyone should understand it." (45 years, Tertiary, Urban)

Another urban mother with senior high school education supported gender-inclusive education based on school experiences [26, 27]:

"In my daughter's school, boys and girls learn about menstruation together in their health education class. I support this approach. Boys need to know that menstruation is natural, not shameful or dirty. When boys are educated, they don't tease girls about periods or make them feel bad. They understand it's just a normal part of life. This creates a more supportive environment for everyone." (42 years, SHS, Urban)

In contrast, traditional attitudes maintaining menstruation as exclusively female knowledge persisted strongly among less educated parents, particularly in rural areas [14, 27]. A 43-year-

old mother with primary education from a rural area firmly stated:

"Menstruation is women's business. Men don't need to know about it. It's not for them to understand or discuss. In our culture, these things stay among women. My husband doesn't know when I am menstruating, and he doesn't need to know when our daughter is menstruating either. This is private female matters that should remain private." (43 years, Primary, Rural)

Another rural mother with no formal education expressed similar exclusionary views [14]:

"Why should boys learn about menstruation? It doesn't concern them. When my daughter started menstruating, I taught her, and my mother helped. Men have no role in this. If we start teaching boys about periods, it will make girls embarrassed and uncomfortable. Some things should stay separate between males and females. This has always been our way, and it should continue." (48 years, No formal education, Rural)

The contrast between progressive and traditional gender perspectives revealed clear patterns related to education and location [14, 26, 27]. A 46-year-old mother with tertiary education from an urban area observed:

"I notice that educated families in urban areas are more open to teaching boys about menstruation, while traditional families in rural areas keep it strictly among women. Education makes a difference in how we think about these things. When you understand the biology and health aspects, you see menstruation differently and you want everyone, including boys, to have accurate information." (46 years, Tertiary, Urban)

This theme demonstrated ongoing transitions in gender norms regarding menstrual health knowledge and support [27]. While traditional gender-segregated approaches remain dominant in many contexts, educated urban populations increasingly embrace gender-inclusive frameworks recognizing male education as beneficial for creating supportive environments and challenging stigma. The persistence of exclusionary attitudes in less educated populations suggests that changing gender norms around menstrual health requires not only health education but broader educational advancement and urbanization processes that shift cultural frameworks [14, 26, 27].

Discussion

This qualitative investigation provides critical insights into the complex mechanisms through which parents transmit menstrual health attitudes, beliefs, and practices to their adolescent daughters in urban Ghana. The findings reveal that intergenerational transmission operates through multiple simultaneous pathways including explicit instruction, behavioral modeling, cultural practice maintenance, and emotional communication, often conveying contradictory messages that combine improved factual knowledge with persistent shame-based attitudes [1, 15, 16, 24].

The intergenerational transmission of menstrual shame despite improved hygiene knowledge represents the most striking and problematic finding. Parents demonstrated remarkable self-awareness about transmitting the same emotional discomfort they experienced yet felt unable to break this pattern despite intellectual understanding of menstruation as normal [15, 16]. This phenomenon aligns with Social Cognitive Theory's emphasis on observational learning and modeling [1], whereby daughters internalize not only explicit teachings but also implicit attitudes conveyed through parents'

behaviors, emotional reactions, and communication patterns. The persistence of shame across generations despite knowledge improvement suggests that attitudinal change requires more than factual education; it necessitates addressing deeply embedded emotional and social conditioning that operates independently of cognitive understanding [2, 15].

The finding that parents successfully teach proper hygiene practices while simultaneously transmitting shame challenges simplistic assumptions about attitude-behavior relationships [2]. This pattern demonstrates that behavioral competence and emotional comfort represent distinct dimensions that do not necessarily develop in parallel. Parents can effectively teach daughters what to do during menstruation while failing to convey that menstruation is nothing to be ashamed of [5, 18]. This disconnect has important implications for intervention design, suggesting that programs must explicitly address attitudinal dimensions rather than assuming that teaching proper practices automatically builds positive attitudes [2, 5].

The persistent influence of cultural and religious beliefs across generations illuminates the power of traditional frameworks in shaping menstrual attitudes despite modernization and health education [9, 14, 25]. The finding that restrictions on food preparation, ceremony participation, and religious activities remain firmly embedded across socio-economic levels challenges assumptions that education automatically displaces traditional beliefs. Instead, the data suggest that traditional and modern belief systems coexist in complex configurations, with educated parents often attempting to honor both frameworks simultaneously despite their contradictions [14, 25].

Parents' use of ancestral teachings to legitimize maintaining restrictive practices reveals how cultural continuity and intergenerational identity operate as powerful

motivators for preserving traditional beliefs even when alternative perspectives become available [14, 15]. The statement that abandoning traditional practices would break intergenerational chains and disconnect families from ancestral heritage demonstrates how menstrual restrictions function not merely as isolated beliefs but as integral components of cultural identity and family continuity. This finding suggests that interventions challenging traditional menstrual restrictions must carefully navigate cultural sensitivity and identity concerns rather than simply dismissing traditional beliefs as superstition [9, 14, 25].

The recognition of generational shifts in comfort and openness provides some optimism about gradual attitudinal change over time [18, 21]. Parents' observations that their daughters' generation demonstrates substantially greater ease discussing menstruation suggests that social norms are evolving, likely driven by formal education [26], peer communication, and broader social changes reducing gendered shame. However, the persistence of parental discomfort despite recognizing these positive changes demonstrates that generational shifts occur slowly and unevenly, with knowledge and behavioral patterns changing more rapidly than deeply embedded emotional responses [15, 16].

The knowledge-attitude disconnect articulated by educated parents particularly highlights the challenge of translating intellectual understanding into emotional comfort [15, 16]. Parents acknowledged possessing scientific knowledge about menstruation as normal biology while simultaneously experiencing persistent shame rooted in childhood socialization. This pattern validates psychological research demonstrating that emotional conditioning established during childhood often persists despite later cognitive learning, requiring specific interventions targeting emotional reconditioning rather than merely providing factual information [2, 15].

The divergent perspectives on male involvement in menstrual health education reveal ongoing negotiations between traditional gender frameworks and emerging inclusive approaches [8, 24, 27]. The strong correlation between education level, geographic location, and support for male education suggests that changing gender norms around menstruation requires not only targeted interventions but broader social transformations including educational advancement and urbanization [14, 26, 27]. The finding that educated urban parents increasingly support male education based on practical benefits including reduced teasing, increased support, and normalized discourse provides compelling rationales for gender-inclusive approaches [27].

However, the persistent exclusionary attitudes among less educated populations demonstrate that traditional gender segregation around menstruation remains deeply embedded in many contexts [14, 27]. The framing of menstruation as women's business that men should not understand reflects broader gender frameworks where certain knowledge domains remain gender-restricted. Challenging these frameworks requires sensitivity to how menstrual education intersects with larger questions of gender roles, family privacy, and cultural authenticity [9, 14].

These findings have critical implications for intervention design [29, 30]. The demonstration that parents transmit shame despite improved knowledge suggests that family-centered interventions must address parents' own attitudes alongside daughters' education. Programs targeting only adolescent girls while ignoring parental attitudes may have limited effectiveness because parents continue modeling shame-based behaviors regardless of what daughters learn in educational settings [15, 29]. Effective interventions should engage both generations simultaneously, helping parents recognize and address their own internalized shame while supporting daughters' development of shame-free attitudes [29, 30].

The persistence of cultural and religious restrictions suggests that interventions must engage with traditional belief systems rather than dismissing them [9, 14, 25]. Culturally sensitive approaches might involve dialogue with religious leaders about interpretations of religious teachings, exploration of cultural practices that honor tradition while promoting health, and respectful discussion of how traditional beliefs can coexist with modern health knowledge. Interventions adopting confrontational approaches that directly challenge cultural identity and ancestral teachings risk backlash and rejection [14, 23, 25].

The generational shift toward greater openness suggests that supporting institutional changes in schools, religious organizations, and community structures can accelerate attitudinal change at population levels [18, 26]. Formal education systems incorporating comprehensive menstrual health education with gender-inclusive approaches appear to contribute substantially to reducing shame and normalizing menstrual discourse [26, 27]. Supporting and expanding such programs while simultaneously engaging parents can create synergistic effects where institutional and family-level changes reinforce each other [29, 30].

Study limitations include the focus on urban and peri-urban contexts limiting generalizability to rural populations where traditional beliefs may be even more firmly embedded [11, 13, 14]. The predominance of mothers in the sample reflects typical family patterns but limits understanding of paternal perspectives on menstrual health guidance [27]. The qualitative design provides rich insights into mechanisms and meanings but cannot quantify the prevalence of different perspectives across broader populations [12, 14]. Future research should examine paternal perspectives [20, 27], include substantial rural samples [13], and employ mixed-methods

approaches combining qualitative depth with quantitative prevalence estimation.

Conclusion

This qualitative investigation reveals that parents transmit complex and often contradictory messages about menstruation to their daughters, combining improved factual knowledge with persistent shame-based attitudes, cultural restrictions, and emotional discomfort [1, 9, 14, 15]. The intergenerational transmission of menstrual shame operates through both explicit instruction and implicit behavioral modeling [1, 15, 16], with parents demonstrating remarkable awareness of perpetuating patterns they experienced while feeling unable to break these cycles despite intellectual understanding. Cultural and religious beliefs continue exerting powerful influence across generations and socio-economic levels [9, 14, 25], with parents using ancestral teachings to legitimize maintaining restrictive practices even as they acknowledge tensions with modern health perspectives. Generational shifts toward greater openness provide optimism about gradual attitudinal change [18, 21], though parental discomfort persists despite recognition of positive changes among youth. Divergent perspectives on male involvement reflect ongoing negotiations between traditional gender frameworks and emerging inclusive approaches [27, 11], with education and urbanization correlating with progressive attitudes. These findings demonstrate that effective interventions must address family-level dynamics and parental attitudes rather than focusing exclusively on adolescent education [29, 30]. Family-centered approaches engaging both parents and daughters simultaneously, addressing internalized shame and cultural beliefs while respecting identity concerns, and supporting institutional changes in schools and communities offer the greatest potential for transforming menstrual health attitudes across

generations in urban Ghana and similar contexts.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Ethical Approval

Ethical approval was obtained from the Institutional Review Board prior to data collection. All participants provided informed consent after receiving detailed information about study purposes, procedures, potential risks and benefits, confidentiality protections, and rights to withdraw participation at any time without consequences. Participants' identities were protected through use of pseudonyms and demographic descriptors rather than identifying information in reporting findings. Audio recordings and transcripts were stored securely with access limited to the research team.

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Data Availability

The datasets generated and analysed during the current study are not publicly available due to confidentiality and privacy obligations to the study participants. However, the data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions

All authors contributed equally to this work. All authors have read and approved the final version of the manuscript.

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Navigating Institutional Gaps: Lived Experiences of Family Caregivers Managing Chronic Psychosis in Zambia

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Abstract

Family caregivers bear the burdens of managing chronic psychosis as critical yet unrecognised partners in clinical decision making particularly in low resource settings where institutional support is inadequate. Their support exceeds beyond relational responsibility to include clinical decision making, medication management and crisis management. The objective of the study was to explore the experiences of caregivers on the roles, challenges and interactions with the formal mental health services. The study recruited 30 participants through purposive sampling and collected data using in-depth interviews. Data were analysed using the interpretive phenomenological design by Smith et.al (2009) criteria to identify superordinate and subordinate themes. Three overarching themes were identified: 1) primary managers of treatment decisions, 2) integrating biomedical and spiritual decision making, and 3) bearing clinical responsibility without adequate support. The experiences highlight the central role of caregivers in the management of psychosis within the limited mental health services. In conclusion, caregivers should be recognised as core stakeholders in clinical decision making rather than health seekers, as failure to integrate them may endanger their wellbeing. This risk of mismanagement could result from emotionally based decisions due to poor education on the illness. There is need to continuously engage caregivers in care planning, knowledge on adverse effects, provision of coping strategies and management of psychosis. These findings provide a basis for mental health policy to structure caregivers' frameworks that include mandatory crisis guidance and to nursing practice by incorporating routine assessments of caregiver wellbeing and support as standard psychiatric care.

Keywords: Chronic Psychosis, Decision Making, Family Caregivers, Informal Caregivers, Institutional Gaps.

Introduction

Psychosis is defined as a mental disorder characterised by sensory perceptual intrusions such as delusions and hallucinations which may involve periods of crisis or relapses [1]. Globally, Schizophrenia has been found to be a major contributor to the high burden of mental disorders, in which over 65 % of psychosis management is undertaken by family caregivers

illustrating an over reliance on family support [2]. Family caregivers experience poor quality of life associated with age, psychiatric symptoms and caregiving burden hence the need to improve community based mental health care [3]. Similarly, increasing caregivers' awareness through education on psychosis management and peer support has shown to improve quality of care and their ability to

navigate shared decision making on therapy goals [4, 5].

Caregivers take on the responsibility of managing medication in the community to ensure continuity of care hence require specific medication management skills to enhance their role [6]. However, caregivers perceive limited collaboration with health professionals as they receive inadequate information on Antipsychotics [7]. Undoubtedly, ambivalence on reduction or continuation among caregivers has been observed due to the medication adverse effects that patients undergo hence the need to support families to promote adherence [8]. In the same vein, caregivers' continue to express their unmet needs of lack of involvement in the management of adverse effects as they feel they are better at observing than health professionals [9].

Caring for patients with psychosis carries a risk of violence exposure, which ranges from verbal (35.5%) to physical (25.5%) associated to symptoms of illness at 57.3% and refusal to take medication at 49.1% [10]. Furthermore, significant levels of fear and anxieties about relapses have been observed and have been associated to unmet needs for relapse-focused education which could impact relapse prevention negatively [11]. In this vein, caregivers need to be trained with stress coping skills in order to cope with daily struggles of the caring process [12].

In Africa, Moral commitment compounded by cultural expectations have significantly contributed to the caregivers' resilience and loyalty in the management of chronic psychosis [13]. Likewise, traditional beliefs contribute to poor help-seeking behaviours acting as a source of understanding accounting for poor perception on the causes of illness and increased stigma in the community [14]. Further, stigma associated with mental illness has impaired the need for help seeking behaviors leading to people choosing traditional and spiritual healing methods over hospital

based care [15]. Some of the challenges faced by caregivers in Zambia are disturbances in family function, financial difficulties, stigma and poor social support in which acceptance of the illness and faith-based beliefs used as a means of coping [16]. It is worth noting that financial constraints have highly contributed to the preference of traditional healing methods compared to medical care due to accompanied expenses like transport, hospital fees and purchase of medication [17].

Reduction of caregiver burdens have been associated with high levels of hope enhancing ability to continue caring and improving care recipient outcomes [18]. Additionally, family centered collaborative care is acceptable intervention that has suggested to have potential to improve caregiver and patient well being [19]. In the same way, psychoeducation improves confidence and autonomy by empowering caregivers' with adequate knowledge to manage psychosis [20]. However, integrating psychoeducation into mental health services and policies pose a challenge as implementation requires sustained support [21]. Although several interventions are being implemented, they fall short of caregiver inclusion into the mental health system to reduce the gap between in-patient and community services for continuity of care [22]. They require support and guidance as they navigate the uncertainties of caring by ensuring that they are engaged in shared decision making to promote participation in management [23].

The main objective of the study was to explore experiences of how family caregivers function as unrecognised and informal clinical decision makers in the management of individuals with psychosis, as well as how they navigate the challenges of inadequate institutional infrastructure. The novelty of the study is based on the reframing of caregivers as core stakeholders in the management of psychosis and not merely patient helpers. Furthermore, the study introduces decision

making as a lived and contextual process experienced throughout the caring process. The application of interpretive phenomenological design reveals the interpretive and meaning making process rather than challenging task. Also, the use of interpretive phenomenological analysis adds depth to the experiences making a significant methodological contribution to the body of knowledge to Zambia and globally.

Materials and Methods

Research Design

A qualitative research design rooted in interpretive phenomenology was adopted to explore and gain insights into how family caregivers experience and make sense of managing chronic psychosis within institutional gaps in Zambia. Interpretive phenomenology analysis (IPA) enabled the researcher to co-construct meaning with the participant while in-depth exploration of the phenomena highlighted both unique personal experiences and shared patterns [24, 25].

Study Setting and Sampling Procedures

Chainama Hills Hospital was the study site because it's a national referral facility that admits individuals from diverse geographical, social and cultural backgrounds providing diversity in the manner institutional gaps are navigated. Participants were selected using purposive sampling to include family caregivers who were directly involved in caring for the patient for a minimum period of 12 months. Through the application of the IPA principles on sample size determination, the study used 30 participants as there is no strict rule on the exact number [26, 27]. The choice was based on the context that the study needed to engage more participants considering that the phenomena required wider exploration for better insights [28, 29].

Data Collection Methods and Techniques

Interview guides were used to collect data from family caregivers who met the inclusion criteria. Through semi-structured, in-depth interviews, caregivers were enabled to share their experiences guided by open ended questions to facilitate free expression into rich contextual insights. The core research question was "*Can you describe your experience of caring for a family member with chronic psychosis at Chainama Hills Hospital?*". Also probes were used to elicit further clarifications and depth. English language was used for the interview guide and translated into Chichewa (Nyanja) one of the primary local languages for inclusivity and authenticity. Health professionals assisted in the recruitment process; all sessions were audio recorded while researcher took notes on nonverbal cues. Participants who presented with distress were emotionally supported through empathetic listening techniques, and where necessary additional support was sought from mental health professionals.

Data Management

Audio recordings from interviews were stored in password protected files and backed up for preservation. Researcher's notes were locked up in cabinets while identifying information was replaced with participant codes (e.g. P002) prior to transcription. Data access was restricted to researcher and academic supervisors and used only for academic purposes.

Rigour and trustworthiness were ensured using Lincoln and Guba's criteria (1985) [30]. Credibility was achieved through prolonged engagement with participants, in-depth interviews and verbatim transcription to accurately represent caregivers' experiences of navigating institutional gaps. Dependability was maintained through a clear audit trail documenting methodological decisions, coding

processes and adherent to analytic steps with the IPA framework. While Conformability was ensured through reflexive journaling and grounding the interpretations in participants' direct quotes to minimise researcher bias. Researcher positionality as a mental health nurse was informed through prior knowledge and contextual familiarity enhancing interpretive depth while maintaining reflexive awareness. And transferability was supported by providing rich contextual descriptions of the caregivers' at Chainama Hills Hospital allowing readers to determine applicability to similar mental health settings.

Data Analysis

Data were analysed using IPA framework as guided by Smith et.al, 2009 [31]; grounded in phenomenology to explore caregivers' lived experiences, guided by the double hermeneutic in which the researcher co-constructed meaning with the participants on navigating institutional gaps, and informed by idiographic commitment to detailed case by case analysis before identifying shared patterns which were framed as superordinate and subordinate themes. The process was supported by the utilisation of NVivo version 11 to facilitate efficient organisation, coding and retrieval of data. Its visualization tools enabled the researcher to present patterns and provide baseline for interpretation of caregivers' experiences.

Participants

This section describes the methods followed and responds to the question of how the problem was studied. The order is as follows:

The study included 30 participants who were family caregivers comprising parents, siblings, children and spouses. To ensure rich and insightful accounts of the phenomenon, participants were required to have been first line caregivers for a minimum period of 12 months. Table 1 presents the participants' sociodemographic characteristics. The age ranged from 30 to 85 years showing representation across key life stages and rich diverse experiences. Females constituted the majority with 23 participants (76.7%) including mothers, sister, daughters and wives, while males had 7 participants (23.3%) comprising fathers, brothers, sons and husbands. The study achieved 90% national representation with participants drawn from nine provinces: Lusaka 10 (33.3%), Eastern 5 (16.7%), Central 4 (13.3%), Copperbelt and Western 3 each (10%), Southern 2 (6.6%), and Muchinga, Luapula and Northern 1 each (3.3%).

Most participants were married (16;53.3%), widowed (6;20%), single (5;16.7%), and divorced (3;10%). Educational attainment varied with 13 participants (43.3%), having completed secondary education, with primary education 8 (26.7%), with tertiary education (26.6%), no formal education 1(3.3%). Majority of caregivers were engaged in some form of employment, including formal employment 14 (46.7%), self employed 12 (40%) and retired 4 (13.3%).

Table 1. Sociodemographic Characteristics of Participants

Participant	Relationship to Patient	Age	Residence	Marital status	Education Level	Employment
P001	Wife	44	Mansa	Married	Secondary	Self employed
P002	Mother	60	Kabwe	Married	Secondary	Formal
P003	Sister	35	Lusaka	Married	Primary	Formal
P004	Sister	66	Lusaka	Single	Tertiary	Retired

P005	Brother	33	Ndola	Married	Tertiary	Formal
P006	Sister	64	Kitwe	Married	Secondary	Formal
P007	Mother	54	Kasama	Single	Secondary	Formal
P008	Sister	40	Chongwe	Widow	Secondary	Formal
P009	Mother	57	Kaoma	Divorced	Primary	Self-employed
P010	Husband	48	Monze	Married	Primary	Self-employed
P011	Mother	70	Mpika	Widow	No formal	Self-employed
P012	Sister	50	Kalomo	Divorced	Primary	Formal
P013	Mother	44	Lusaka	Married	Primary	Self-employed
P014	Sister	30	Kafue	Married	Secondary	Self-employed
P015	Sister	41	Lusaka	Married	Secondary	Self-employed
P016	Sister	38	Lusaka	Single	Secondary	Self-employed
P017	Mother	67	Chipata	Widow	Primary	Self-employed
P018	Sister	43	Luangwa	Divorced	Primary	Formal
P019	Mother	50	Chipata	Married	Secondary	Formal
P020	Father	74	Katete	Married	Tertiary	Formal
P021	Husband	49	Kabwe	Married	Tertiary	Self-employed
P022	Mother	59	Lusaka	Married	Secondary	Self-employed
P023	Daughter	34	Liteta	Single	Secondary	Self-employed
P024	Sister	39	Mumbwa	Single	Tertiary	Formal
P025	Mother	78	Mongu	Widow	Secondary	Retired
P026	Brother	51	Ndola	Married	Tertiary	Formal
P027	Mother	69	Mongu	Married	Primary	Formal
P028	Wife	44	Lusaka	Married	Tertiary	Formal
P029	Father	85	Chongwe	Widower	Tertiary	Retired
P030	Father	81	Lusaka	Widower	Secondary	Retired

Results

This section presents results from in-depth face to face interviews with family caregivers, demonstrating the existing gaps in the mental health care system and community mental health support placing them as unrecognised decision-makers in the care of patients with psychosis. The findings obtained were organised into themes across the participants and included three themes: 1) primary

managers of treatment, 2) integrating biomedical and spiritual decision-making, and 3) bearing clinical responsibility without adequate support. Verbatims were included to show the caregivers' deep understanding of the phenomenon and aid to consolidate the interpretation of findings. Table 2 below illustrates both the superordinate and subordinate themes of the study.

Table 2. Superordinate and Subordinate Themes

Superordinate themes	Subordinate themes
Primary managers of treatment decisions	Control medication administration
	Decide the necessitate of hospital care
	Manage adverse effects without professional guidance
Integrating biomedical and	Assessing if medication works

spiritual decision-making	Balancing hospital care and prayer-based care
Bearing clinical responsibility without adequate support	Managing crises without training
	Carrying responsibility for every decision

Theme 1: Primary Managers of Treatment Decisions

Caregivers are attributed to practice as untrained clinicians as they manage their patients throughout the caring process. They have demonstrated that by the many acts and experiences that are encountered largely meant for professional clinicians. The impact of caregivers' commitment to care determines the health outcomes of the patient suffering from psychosis as they are decision makers outside the health institutions.

Control Medication Administration

"Administering medication can be difficult at times.....i buy a drink then put the tablets.....that's how he agrees to drink" (P002).

The caregiver must formulate ways of negotiating the when and how the medication is administered to the patient. The form of the drugs to be given is also determined by the caregiver based on the condition that is presenting at that point. Determining whether the drug should be melted or smashed even hidden in food just so the patient can drink it and its efficacy changed is unknown because the caregivers have no education on such aspects of information even from the professionals.

"Certain times I have to go to the hospital without her to collect the medication just so I could give from home" (P020).

The narration articulated that the commitment of the caregiver determines the patient's adherence to medication. The caregiver illustrates the importance of drug collection from the hospital even when they must defy professional instruction to present the patient for every visit. This was further demonstrated by P016 who highlights the

struggles of engaging the patient to a hospital visit.

"You see.....even when he refuses I still must give the same haloperidol" (016).

This suggests that caregivers' have the sole responsibility to decide to acquire medication even amidst the need for financial stability to sustain the patient on treatment. This interpreted that the professionals do not have to give such options as purchasing medication because of patient refusal, instead the caregiver oversees everything including the availability of medication against all odds.

Deciding the Necessity of Hospital Care

"I manage him from home.....but when he is very bad, that is when I bring him to the hospital for medication or to be seen by the doctor" (009).

The caregiver illustrates that it is within their ability to choose when the patient requires to be taken to the health facility for management. Their decision is based on their ability to recognise the difference between what is manageable and what is dangerous. This unrecognised empowerment indicates that the caregivers should have adequate information and education on the disease process for them to appropriately manage the patient's wellbeing.

"Sometimes I sign against medical advice and take him home..... I don't like the way they are kept.... how can my patient who's doing much better be harassed by other patients" (P019).

Caregivers are faced with the choice of home management over hospital-based care considering the displeasures they observe at health facilities. They decide when it fits for

the patients to be in a hospital environment, and how safe it is for them. When the safety of their patients is threatened, they withdraw them regardless of medical orders.

"If he feels better..... He refuses reviews, so I just come to get the drugs. These patients can be stressful..... but my duty is to help him get better" (P016).

It is also observed that caregivers feel obligated to solely take care of the patients' desires. They interpret this obligation as part of patient's care than forcing them to be confined to the schedules of the hospitals. They act as mediators between the patient and health facilities especially when the feel better and regain their autonomy leading to the intervention by the caregivers.

Manage Adverse Effects Without Professional Guidance

"Despite him being difficult I still buy the same haloperidol and Artane I don't give him Artane daily but only when I see a change in his behaviour..... the way he is doing now, I see drooling" (007).

The caregiver expresses the emotional toll of caring, in which they are expected to navigate difficult medication regimens, often requiring alterations to doses without regular expert guide. The mention of managing medications based on observed behavioural changes indicates a trial-and-error method, which could be risky if not managed overtime.

"Now look at the tongue, he is stiff and drooling..... I can't be happy and they are saying it's not the drugs no! I told them that me I give the drugs at home and leave him..... and I give him every day, but he doesn't behave this way..... he doesn't look like that " (P013).

This illustrates the distress the caregiver undergoes at the sight of the child seeming to be mismanaged by the professionals. There is

a deeper cry insinuating that 'I know this behaviour; something is not right'. It demonstrates the importance of professionals paying attention to caregivers' observations as their insights about the patient could provide basis for better treatment plans. This level of concern for the significant other is further observed by P28 who says.

"The other problem is that some of these drugs like the other injection..... that they give him, it makes his leg to be numb so you find that we will be walking very slowly back home.....until I chance a bus then that becomes easy" (P028).

This shows how the caregiver deals with the practicality of managing side effects of medication which affects daily activities. This seems like they are experts in navigating the best care despite the varied challenges they are exposed to, while needing the health professionals to listen and adapt treatment plans accordingly.

Theme 2: Integrating Biomedical and Spiritual Decision-Making

This is a reflection on how caregivers combine hospital-based care with spiritual explanation of causes of psychosis especially when in the face of challenges and a sought for understanding of the disease process. They place themselves as key decision makers across intersecting belief systems as they avoid relying on one system of knowledge especially in the face of limited professional care. It is observed that they manage a complementary decision-making system that combines clinical judgement with faith-based interpretation.

Assessing If Medication Works

"You pray for one thing another thing comes up.....so the problems continued and continued for some time and the hospital were not really helping because the drugs they were giving us were not working" (P030).

This illustrates the frustration the caregiver feels between the expectation of the prayers being answered and the help the hospital should render, compared to the reality of the patient not responding to treatment. They express a feeling of helplessness and a disconnection that reality holds on the disease process and hoped for care. They suggest a sense of stagnation which keeps them cycling around a reality of suffering, breaking down the trust that the hospital has answers to their need.

"So, after I stopped going to the hospital, I kept the child home and we were just praying and praying for a long time and when he felt better again.... it started this time it was total confusion very aggressive, very restless and this time you could see that wasn't losing memory or looking very mad, but you can see that is a problem" (P022).

Consistent with participant 030, the caregiver tuned to prayer after they felt let down at the hospital's inability to offer the expected treatment. This narration carries a sense of escalating distress to the realisation that even amid prayer they were losing control of the child's wellbeing, while also harbouring empathy and pain for the child's experience. They use prayer as a complementary path of coping with the illness, suggesting the complex ways people use to navigate between healthcare and spirituality in their search for answers.

"When he comes here (hospital), he looks pale he looks hydrated and when I look at him, I feel bad and that's why I sometimes sign against medical advice. Sometimes I prefer I... I just go home because if I live him I feel like he's neglected sometimes beaten. And when I come back, I find this ...this is very bad" (P018).

The participant's narrative highlights the emotional turmoil they are facing at the reality

of seeing their loved one entrusted into institutional care, leaving them to grapple with feelings of guilt and powerlessness. The decision to sign against medical advice can be seen as a sign desperation to regain their agency and therefore protect their child from the perceived harmful environment.

Balancing Hospital Care and Prayer-Based Care

"Continuing hospital with also prayers it helps ... that's why some children get mismanaged because other parents just rely on drugs from the hospital, but something again is missing because some children need also to go for prayers" (P25).

This experience implies that prayer can be a complement to hospital care, as it is regarded cardinal in addressing both the emotional and spiritual aspects of healing. It therefore acknowledges that hospital care isn't only about physical care but also nurturing the mind and spirit. It further shows that relying on one aspect either drugs or prayer may likely leave gaps in care. Therefore, it seems to suggest that the use of more integrated approaches is better in weaving together different threads of support through which the caregiver benefits too. This is in line with P17's belief as shown below.

"And I can't just say no its just prayers no.... but I should also take him for hospital where it needs hospital. I bring the boy, so when I see that something.... Something changes then again, I do it" (P17).

This illustrates the caregivers' active role in the management of their patient's ever-changing condition. Instead of believing in one approach, the caregiver demonstrates her ongoing judgment as she critically observes changes in the condition of the patient and based on this, makes important decisions on when to intensify faith-based support or hospital care.

“So.... after they saw that I had gained strength in prayers, they casted a spirit of anger onto my son. That spirit of anger made him to refuse prayers. So, when a pastor shows up for prayers, they can’t manage him because he could even beat him together with me. But it’s like a phase, you pray over this, another spell is cast on him” (P004).

The caregiver describes a spiritual and relational cycle that tries to explain how uncertainty is navigated. The behavioural fluctuations are interpreted as spiritual attacks that counteract the efforts of prayer on the illness, rather than medical relapses. Therefore, the experience shows how decisions are shaped and the need the alternative care and support.

Theme 3: Bearing Clinical Responsibility Without Adequate Support

This theme describes how caregivers bear the responsibility of caring without adequate training and empowerment to manage psychosis and its burdens. Caregivers learn to normalise emotional pain and tend to make decisions under distress rather than clinically based. They bear their suffering as moral duty through endurance and as a show of their affection for the loved ones. The narratives demonstrate that responsibility placed upon the caregivers is circumstantial as they find themselves filling in the various gaps the system imposes on them such as inadequate psychological support for caregivers, medication shortages, infrequent contacts with health professionals, as well as limited knowledge on diagnosis and medication adverse effects.

Managing Crises Without Training

“What even makes us feel very bad is that this was a very good man and now to see him remove his clothes

defecate on himself, chase people around with knives..... it really makes us especially me feel very bad when the illness is at that stage” (P003).

The narrative reveals the grief and distress being experienced as they recall the transformation their loved one has undergone. Yet again the observance of the aggression and self-neglect illustrates moments of crisis while also managing stigma and fear.

“So with my brother's condition when things are very bad, I take my children, lock them up and then I get my brother because he only listens to me than listen to other people..... I will leave him in that state until stable enough” (P006).

This reveals caregivers as holders of dual roles in the management of risks in periods where the illness deteriorates. They act as protectors of other family members when they lock the children away from harm, and as clinical decision makers when they allow the patient to calm down before administering further interventions. It further positions caregivers as primary regulators of the situation, suggesting authority and experiential understanding that other people may not possess.

Carrying Responsibility for Every Decision

“I called the nurse saying he’s got a side effect..... But she said no it’s how the disease presents but That is why I want to go home with him because the way I brought him he didn’t have this behaviour” (P014).

This shows the caregiver’s dissatisfaction with the professional response and protective urge of possible mistrust and fear of the patient being exposed to harm. This disagreement illustrates the caregiver’s active role of not passively accepting the health professional’s opinions without drawing onto the experiential knowledge to question the explanation.

“This sickness she has even made me to separate from my husband, so my husband is now staying in another province..... because I have to continue managing my child” (P016).

Caregiving experience in this narrative highlights another dimension that prolonged caregiving responsibility extend monitoring of symptoms and crisis management. Caregiving responsibility has the potential to reorganise and override family structure and marital relationships. Therefore, the caregiver conveys the message that the marital separation was not a voluntary breakdown, but a sacrifice made possible by the demands of the ongoing care.

“Where no one even helps me that's also telling you that don't trust people..... people will neglect you when you are alone just trust yourself. For me not even my friends, my neighbours..... my sister, none of them were available to help me in this situation” (P020).

At another level, social isolation during the times of caregiving strain presents a switch from relational dependence to enforced self-reliance. This demonstrates how inadequate social support enhances the caregivers' role as a sole decision maker, emphasising the extent of the perceived absence. This suggests that trust in others could have been lost after repeated moments of abandonment, hence compelling them to use self-trust as a survival strategy.

Discussion

This study demonstrates that family caregivers of individuals with psychosis occupy a central and significant yet unrecognised role in the management of psychosis. The key findings of the study are represented into three themes: Primary managers of treatment decisions, integrating biomedical and spiritual decision-making, and bearing clinical responsibility without adequate support. This reveals that family

caregiving exceeds beyond relational responsibilities to informal decision makers who buffer institutional gaps.

In particular, the study findings reveal that caregivers navigate three interconnected dimensions of informal clinical authority namely, managerial control, interpretive mediation and assumed responsibility. Consistent with several studies that frame caregivers as administrators of medication and observers of adverse effects of the medication with limited consultation from professionals, they have shown to be regulators of treatment from deciding when admission is needed to what medication should be given [32, 33]. Studies further indicate that caregivers face ambivalence when confronted with the choice of surrendering their loved ones for admission as they experience feelings of uncertainty of the management considering limited medical resources [34]. This is because caregivers are normally left out by professionals when planning for care and even rarely consulted as stakeholders who could offer alternative perspectives based on experiential knowledge of the illness [35].

Notably, caregivers apply a multiple belief system as they engage in decision making and deliver psychiatric care to their loved ones. They integrate hospital-based care with cultural or spiritual explanations of illness, without entirely privileging one approach as they function as interpretive mediators between two or more explanatory approaches. This aligns with studies suggesting the need for professionals to be aware of the individuality, spiritual and cultural factors that could influence caregivers' attitudes towards caregiving [36, 37]. Similarly, faith-based approach provides an alternative interpretation of illness by providing a coexistence with biomedical and other reasoning systems rather than a competition [38]. The study findings further propose that pluralism helps caregivers decide when to privilege one approach over the other as spiritual integration into mental

health services improves quality of care for all stake holders [39].

Furthermore, the study findings reveal a significant burden upon caregivers' who must make clinical decisions and bear the responsibility without support from professionals. This institutional gap is consistent with perspectives of mental health professionals on informal caregivers' needs that proposed the need for social policy strategies and health programmes that promote their wellbeing [40]. Research further emphasises the need for informal caregivers to receive institutional attention as their role exposes them to mental instabilities [41].

Caregivers carry a huge responsibility of managing daily routines and crises for their patients, while longing for professional guidance throughout the caring process [42]. As a result, they report inadequate involvement in decision making as they are perceived as health seekers rather than core stakeholders [32, 43]. Moreover, caregivers have demonstrated their willingness to engage with professionals on more trainings and alternative therapies for their loved ones. Caring for individuals with psychosis has been found to be a stressful responsibility that requires the involvement of caregivers in care planning as well as professional support to promote their quality of life [44]. Therefore, the results reaffirm the call for caregivers to be recognised as stakeholders in the management of psychosis as they play a key role in the decision making, support and recovery of their loved ones [45-47].

Conclusion

The study explored the lived experiences of first-hand family caregivers on how they function as they navigate their role as unrecognised and informal clinical decision makers. The study places caregivers as central actors in the delivery of mental health care despite the limited institutional infrastructure the patients endure. Further, this advances the

understanding on the need for consultative management within a broader mental health system comprising community structures, mental health services and faith-based beliefs. There's emphasis on the need for provision of knowledge on the illness and side effects, coping strategies and management strategies of psychosis. The inability to support and integrate informal caregivers as core stakeholders into mental health services is likely to endanger health of care recipients as they are likely to be mismanaged and negatively impact the caregivers' wellbeing.

The study's strengths lie in the exploration of family caregivers lived experiences which provided rich insights into how they navigate institutional gaps while managing chronic psychosis. Conducting the study at Chainama Hills Hospital gave allowance for contextually grounded findings, while the inclusion of caregivers across genders, ages, provinces and family roles enriched the diversity of perspectives. The methodological rigour was strengthened through reflexivity, audit trails and verbatims to ensure credibility and conformability.

However, the qualitative approach used presents several limitations. The idiographic inquiry of 30 participants from a single hospital makes findings ungeneralisable to all caregivers in Zambia or other contexts. The data relied on self-reports which may be affected by research bias and social desirability and the researcher's clinical background could have influenced the interpretation despite reflexive practices.

To maximise the impact of the findings, there is need to formally recognise family caregivers as core stakeholders in psychosis care with the national mental health polices and develop structured caregiver frameworks that include mandatory crisis guidance. Nursing practice can be enhanced by routinely assessing caregiver wellbeing and support needs as part of standard psychiatric care. Future research should focus on longitudinal

studies to examine mental health outcomes for caregivers' overtime and comparative studies of caregiver decision making across different settings in Zambia.

Ethical Approval

Ethical approval was obtained from ERES Converge IRB Ref no.2025-Mar-001 and approval to conduct the study from National Health Research Authority Ref no. NHRA-2080/27/03/2025.

Conflict of Interest

The author declares no conflict of interest, as no external funding or relationships influenced this study.

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Author Contribution

The leading and corresponding author of this paper was Virginia Simasiku, responsible for data collection, storage, analysis and writing. Professor Catherine Mubita Ngoma and Professor Rajesh Konnur were co-authors and responsible for supervision throughout the research process and manuscript writing.

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Data Availability

The data used in this research is available upon request, though anonymised in order to protect the privacy of the participants.

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Assessment of Knowledge, Attitude and Practice of Food Safety and Hygiene Procedure among Rural and Urban Food Vendors in Oyo State, Nigeria

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Abstract

Foodborne diseases are a major global health problem that kills millions of people each year, especially in low- and middle-income countries. In Nigeria, food contamination due to improper handling and poor hygiene by street vendors is a major cause of diseases such as diarrhea and cholera. The objective of this study was to assess the knowledge, attitudes and practices (KAP) of food vendors in rural and urban areas of Oyo State, Nigeria, on food safety and hygiene practices. A cross-sectional descriptive study was conducted among 350 food vendors in Oyo State, selected using multistage sampling techniques. Data were collected using a pre-tested self-administered questionnaire designed based on objectives and analysed using an IBM SPSS version 25.0. Findings were presented using charts and tables and the level of significance was at $p < 0.05$. The study results showed that 96.6% of urban vendors had good knowledge of food safety, while 70.3% of rural vendors had knowledge of food safety. However, urban vendors had a higher negative attitude toward food safety (57.7%) compare to rural vendors. In terms of practice, 86.9% of urban vendors adhered to good hygiene practices, while rural vendors had a higher compliance rate (95.4%). Factors such as education level and marital status were significantly associated with food safety knowledge and practices. Despite high levels of knowledge, urban vendors showed low attitudes and hygiene practices, indicating a gap between knowledge and implementation. Targeted interventions aimed at changing behaviour and improving hygiene practices are recommended to improve food safety, especially in urban area.

Keywords: Attitude, Food Safety, Food Vendors, Hygiene, Knowledge, Practice.

Introduction

Many diseases around the world have food-borne infections as their primary cause. It is a growing public health issue in both developing and developed countries, contributing to general population morbidity and mortality, especially in vulnerable populations such as small children, the elderly, and people with

impaired immune systems [1]. Despite the efforts made to protect the environment and ensure food safety, drinking contaminated water or eating contaminated food kills 2.1 million adults and 3 million children annually, two of whom are in emerging nations. The World Health Organization estimates that food and water contamination causes about 125,000 pediatric deaths annually in addition to 1.5

billion illnesses. An estimated 70% of diarrheal episodes in developing nations are associated with eating contaminated food [2].

Food safety is a crucial component of good health and a prerequisite for sustainable development. In recent times, the street food vending business has drawn a lot of interest from public health practitioners, local and international organizations, and social science academics [3]. Food safety is a science of describing handling, preparation and storage of food in ways that prevent food borne illness [3, 4]. These include a number of routine practices that should be done to avoid potential health hazards. The need for avoidance of foods that are contaminated with harmful bacteria, viruses, parasites, toxins, chemical and physical contaminants are vital for healthy eating. Contamination can occur at any point through its preparation, handling, storage and consumption [5].

An estimated 40% of the urban populace in developing regions opt for street food due to its affordability [6]. Around 2.5 billion individuals globally frequent mobile food vendors, serving as a vital income source, particularly for women, with minimal initial investment [6]. Despite this, many vendors lack formal education, hindering their grasp of crucial food safety practices. As a result, consumers often face the repercussions of consuming unsafe food, making it challenging to gauge the full extent of the issue, especially in developing nations. The significant number of deaths, notably among children, due to diarrhea each year suggests that a considerable portion can be linked to food and water contamination [7]. While street food plays a crucial role in urban and rural diets, there are inherent public health risks in consuming it in developing countries. It is crucial for street food to not only meet consumers' nutritional needs but also undergo stringent safety measures to prevent contamination by harmful substances and microorganisms.

Enhancing food safety in low- and middle-income nations (LMICs) emerges as a pressing matter. It is estimated that foodborne diseases result in 600 million illnesses and 420,000 premature fatalities each year [8]. The brunt of this impact is borne by individuals residing in LMICs [9], accounting for approximately 75% of deaths due to foodborne ailments (in contrast to 41% of the global populace). This holds especially true for Africa, where the per-person toll of foodborne diseases exceeds that of Europe or North America by 27 times and the healthcare infrastructure grapples with limited capabilities for diagnosis and treatment [8]. Furthermore, foodborne illnesses incur economic repercussions amounting to about \$20 billion USD annually [10].

Nigeria has experienced persistent annual endemic cholera. By July 21st, 2024, Nigeria had reported a total of 4,809 suspected cases with 156 deaths and a case fatality rate (CFR) of 3.2%, affecting all its thirty-five states comprising one hundred and ninety-two local government areas [11]. Street food, being affordably priced and easily accessible, fulfills a crucial requirement for the populace. The 'mama put' vendors, who offer ready-to-consume meals and drinks, may potentially trigger a foodborne illness outbreak due to their limited understanding of proper food safety practices [6].

A study conducted by Omemu and Adereju in Abeokuta, Nigeria focused on the Food safety Knowledge and practices of mobile food vendors in the city of Abeokuta, South West Nigeria. Merely 12% of the participants obtained knowledge of food preparation through formal education. 31% possessed annual medical health certificates signifying compliance with the recommended physical and medical assessments [12]. The prioritization of volume and price over freshness and cleanliness was noted in the procurement of raw materials. Another investigation in Owerri, Nigeria revealed that 23.8% of individuals prepared their food in

unhygienic settings. Furthermore, 42.8% did not utilize Aprons, 47.6% handled food with uncovered hands, and 52.4% did not use any hair covering. During food service, 61.9% and 19.5% managed money and jewelry, respectively [13].

Another study conducted in Owerri, Nigeria, vendors often lack basic hygiene practices, such as using aprons and hair coverings, and frequently handle money while serving food [14]. Similarly, in the Central State of Northern Nigeria, street food vendors demonstrate poor hygiene and sanitary practices, with a lack of formal training and non-compliance with food safety procedure [15]. In contrast, a study in a tertiary educational institution in South Western Nigeria found that while vendors had adequate knowledge of food safety, they often failed to implement safe hygiene practices [16]. This trend is also observed in rural northern Ghana, where street food vendors have a high knowledge level of food safety but struggle to put it into practice [30]. These findings suggest a need for targeted interventions to improve food safety and hygiene practices among street food vendors in both rural and urban areas of Nigeria.

The negative attitude of food safety and hygiene procedures among food vendors can lead to a range of problems, as evidenced by several studies. Khuluse (2020) found that food vendors often lack the knowledge and infrastructure to maintain proper hygiene and safety practices, leading to risks of cross-contamination and foodborne illnesses [17]. Amaami (2017) identified poor compliance with food safety measures, despite high awareness, due to financial challenges and inadequate regulation [18]. Reddy (2020) highlighted the failure of street-food vendors in India to follow basic food safety principles, particularly in low-income areas [19]. Qureshi (2016) reported that street food vendors in Kashmir often engage in unsafe practices, such as using the same surface for cooking multiple times and serving food with bare hands [20].

In Nigeria, urban residents allocate up to 50% of their food budget towards purchasing vended food items, a proportion higher than that observed in other developing nations. The vended food industry in Nigeria encounters various obstacles. The vending of food plays a crucial role in the food distribution system of nations such as Nigeria, Morocco, and Kenya, with research indicating that prominent street food vendors often earn wages surpassing the minimum set by their respective countries [21]. (Lois, Maduabuchi and Prince, 2023) asserted that Street food vending represents a prominent and distinct segment of the expansive informal economy, frequently visible in public spaces, particularly urban areas, offering essential sustenance to city inhabitants. This industry is rapidly expanding due to the evolving dietary preferences of urban residents seeking affordable food options amidst economic challenges. Many individuals prefer purchasing meals from vendors rather than preparing food at home [22]. This study explores the knowledge, attitudes, and practices of food vendors regarding food safety and hygiene procedure in urban and rural area in Oyo state, Nigeria.

Materials and Methods

A descriptive cross-sectional study was carried out among 350 food vendors. Food vendors in Oyo State, comparing rural and urban vendors' knowledge, attitude, and practice of food safety and hygiene procedures. There are numerous food vendors operating in both rural and urban areas, providing essential food services across the state.

Sample size for the study was 350, using formular for comparing two [23].

$$\frac{N}{per} group = \frac{2(Z\alpha + Z\beta)2.P(1-P)}{d^2}$$

Based on a previous documented study done in Owerri (Nigeria) (6) and Ijebu ode (Nigeria) [24], the prevalence of good knowledge for urban was 60%, while the prevalence for rural was 40%.

Therefore, $N = 131.2$. To compensate for non-responses, a non-response rate of 10% will be calculated as follows $N / (1 - 0.1)$.

$$N (\text{actual}) = 131.2 / 0.9 = 145.8 \approx 146.$$

This gives a sample size of 146 for each group, thus giving a total of 292 respondents in all. A total of 373 questionnaires were distributed, with 362 returned, yielding a 97.2% response rate. Of these, 350 questionnaires (96.7% of those returned) were deemed suitable for analysis. Twelve questionnaires were excluded due to substantial missing data (more than 20% of items unanswered). To address the issue of missing data in the included questionnaires, we employed a multiple imputation technique for cases where less than 20% of items were missing to maximize the use of available data while minimizing potential bias.

A multi-stage sampling technique was utilized to select a representative sample of food vendors from both rural and urban areas in Oyo State. The process involved three sequential stages: First, a predetermined number of Local Government Areas (LGAs) were randomly selected from Oyo State, stratified to include both rural and urban classifications. Second, within each selected LGA, a specified number of wards were randomly chosen and individual food vendors were conveniently selected from each chosen ward, ensuring equal representation from both rural and urban settings. A purposely designed self-administered questionnaire was used to obtain data from study participants after a pre-test done outside of the study area.

The Ministry of Health Oyo State, Nigeria, and the Ethics and Research Committee (NHREC/OYOSHRIEC/10/11/12) approved the study's conduct. Consent was obtained from each participant, who was assured of confidentiality.

Data collected were analyzed using IBM SPSS Statistics version 25.0 software. Results were presented using tables and charts, and chi-square and logistic regression analyses were generated, with confidence levels set at 95% and a P-value <0.05 considered significant. There were total of 29 questions for knowledge-related statements, where correct responses were scored as one and incorrect responses were scored as zero. The scores were summed up to obtain an overall score for each respondent, with a range of 0 to 29.

Attitude had a total of 14 questions, with correct responses assigned one and wrong responses assigned zero. The total summed-up scores ranged from 0-14. Practices had a total of 15 questions, with correct responses assigned one and wrong responses assigned zero. The total summed-up scores ranged from 0-15.

Knowledge, attitude, and practices were further categorized using the median or 50% percentile score as the cut-off point. This was done to assess and grade respondents' knowledge (good or poor knowledge), attitude (positive or negative attitude), and practice (good and poor practices) toward food safety and hygiene. Good knowledge, positive attitude and good practices were adjudged as those who scored equal to or above 50%, while poor knowledge, negative attitude and poor practices were considered for those who scored below it.

Results

Table 1. Sociodemographic Characteristics of the Respondents. (n=350)

Variables	Settlement		Statistics χ^2 , p
	Rural (n =175)	Urban (n =175)	
Age			
Mean± SD	37.53± 8.924	36.27±9.796	
16-24 years	5(2.9)	10(5.7)	$\chi^2= 4.904\#$

25 – 39 years	91(52.0)	92(52.6)	p = 0.179
40-59 years	79(45.1)	71(40.6)	
60 and Older	0(0.0)	2(1.1)	
Sex			
Female	155(88.6)	167(95.4)	$\chi^2= 4.697^*$ p = 0.030
Male	20(11.4)	8(4.6)	
Marital Status			
Single	19(10.9)	30(17.1)	$\chi^2= 13.380\#$ p = 0.004
Married	123(70.2)	133(76.0)	
Divorced	14(8.0)	4(2.3)	
Separated	19(10.9)	8(4.6)	
Educational Level			
No formal Education	8(4.6)	1(0.6)	$\chi^2= 15.386\#$ p = 0.002
Primary	53(30.3)	48(27.4)	
Secondary	102(58.3)	95(54.3)	
Tertiary	12(6.9)	31(17.7)	

**Continuity Correction, #- Likelihood Ratio*

The socio-demographic characteristics of the respondents were diverse, the data revealed that of 155 (88.6%) rural food vendors were female, compared to 167 (95.4%) among urban vendors. Male vendors comprised 20 (11.4%) in rural areas and 8 (4.6%) in urban areas. In terms of marital status, 19 (10.9%) rural vendors were single, whereas 30 (17.1%) of urban vendors were single. Married individuals made up 123 (70.2%) of rural respondents and 133 (76.0%) of urban respondents. Divorced vendors were more prevalent in rural areas, with 14 (8.0%) compared to only 4 (2.3%) in urban areas, while separated individuals

included 19 (10.9%) in rural areas and 8 (4.6%) in urban settings (Table 1).

Regarding the education level of the vendors, 8 (4.6%) rural vendors had no formal education, compared to only 1 (0.6%) among urban vendors. Primary education was attained by 53 (30.3%) of rural vendors compared to 48 (27.4%) of urban vendors. Secondary education was fairly balanced with 102 (58.3%) rural vendors and 95 (54.3%) urban vendors. However, tertiary education showed a marked difference, with 31 (17.7%) of urban vendors compared to only 12 (6.9%) of rural vendors achieving this level.

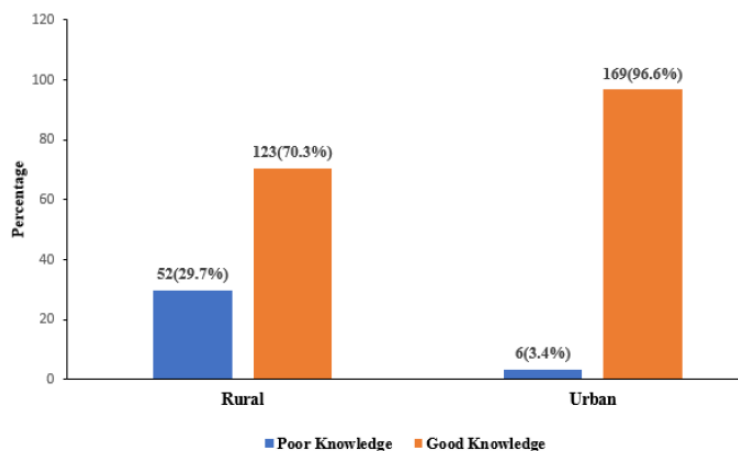


Figure 1. Knowledge of Food Safety and Hygiene Procedure Among Rural and Urban Food Vendors

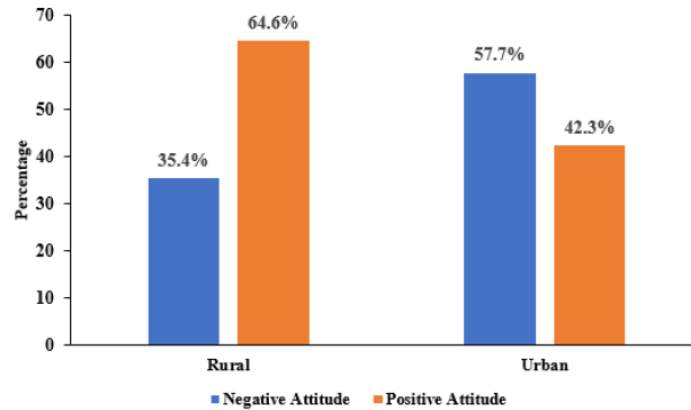


Figure 2. Attitude Towards Food Safety and Hygiene Procedure Among Rural and Urban Food Vendors

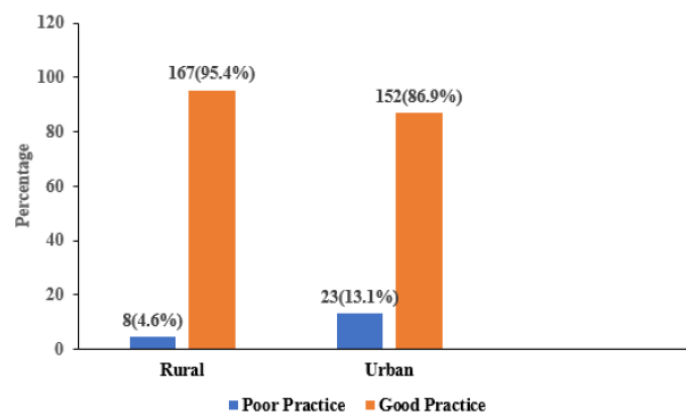


Figure 3. Practices of Food Safety and Hygiene Procedure Among Rural and Urban Food Vendors

Table 2. Association between Knowledge of Food Safety, Hygiene Practices and Sociodemographic Characteristics of Rural and Urban Food Vendors

Variables/Sub-variables	Rural		Statistics χ^2 , p	Urban		Statistics χ^2 , p
	Level of Knowledge			Level of Knowledge		
	Poor n=52	Good n=123(%)		Poor (n=6)	Knownled ge (n=169)	
Age						
16-24 years	2(40.0)	3(60.0)	$\chi^2= 2.831\#$ p = 0.243	1(10.0)	9(90.0)	$\chi^2= 1.105\#$ p = 0.776
25 – 39 years	22(24.2)	69(75.8)		3(3.3)	89(96.7)	
40-59 years	28(35.4)	51(64.6)		2(2.8)	69(97.2)	
60 and Older	0(0.0)	0(0.0)		0(0.0)	2(100.0)	
Sex						
Female	46(29.7)	109(70.3)	$\chi^2= 0.001^*$ p = 0.967	4(2.4)	163(97.6)	$\chi^2= 5.944^*$ p = 0.015
Male	6(30.0)	14(70.0)		2(25.0)	6(75.0)	
Marital Status						
Single	8(42.1)	11(57.9)	$\chi^2=5.875 \#$ p = 0.142	1(3.3)	29(96.7)	$\chi^2= 0.881\#$ p = 0.830
Married	30(24.4)	93(75.6)		5(3.8)	128(96.2)	
Divorced	6(42.6)	8(57.1)		0(0.0)	4(100.0)	
Separated	8(42.1)	11(57.9)		0(0.0)	8(100.0)	

Educational Level						
No formal Education	0(0.0)	8(100.0)	$\chi^2 = 15.582\#$ $p = 0.001$	1(100.0)	0(0.0)	$\chi^2 = 9.005\#$ $p = 0.029$
Primary	16(30.2)	37(69.8)		2(4.2)	46(95.8)	
Secondary	36(35.3)	66(64.7)		3(3.2)	92(96.8)	
Tertiary	0(0.0)	12(100.0)		0(0)	31(100.0)	

**Continuity Correction, #- Likelihood Ratio*

Table 2 shows that there was a statistically significant association between food safety knowledge and certain sociodemographic characteristics among both rural and urban respondents. Among rural food vendors educational level had a significant association

with food safety knowledge, ($p=0.001$) compared to urban food vendors, both sex and educational level were significantly associated with knowledge of food safety practices ($p=0.015$, $p=0.029$) (Figure 1).

Table 3. Association Between Attitude Levels Towards Food Safety, Hygiene Practices and Sociodemographic Characteristics of Rural and Urban Food Vendors

Variables/Sub-variables	Rural		Statistics χ^2 , p	Urban		Statistics χ^2 , p
	Level of Attitude			Level of Attitude		
	Negative n= 62(%)	Positive n=113 (%)		Negative n=101 (%)	Positive n=74 (%)	
Age						
16-24 years	1(20.0)	4(80.0)	$\chi^2= 4.768\#$ p = 0.092	1(10.0)	9(90.0)	$\chi^2= 14.962\#$ p = 0.002
25 – 39 years	39(42.9)	52(57.1)		60(65.2)	32(34.8)	
40-59 years	22(27.8)	57(72.2)		38(53.5)	33(46.5)	
60 and Older	0(0.0)	0(0.0)		2(100.0)	0(0.0)	
Sex						
Female	50(32.3)	105(67.7)	$\chi^2= 5.673^*$ p = 0.017	95(56.9)	72(43.1)	$\chi^2= 0.418^*$ p = 0.518
Male	12(60.0)	8(40.0)		6(75.0)	2(25.0)	
Marital Status						
Single	8(42.1)	11(57.9)	$\chi^2=14.954 \#$ p = 0.002	11(36.7)	19(63.3)	$\chi^2= 21.905\#$ p = <0.001
Married	44(35.8)	79(64.2)		82(61.7)	51(38.3)	
Divorced	0(0.0)	14(100.0)		0(0.0)	4(100.0)	
Separated	10(52.6)	9(47.4)		8(100.0)	0(0.0)	
Educational Level						
No formal Education	6(75.0)	2(25.0)	$\chi^2= 15.498\#$ p = 0.001	0(0.0)	1(100.0)	$\chi^2= 20.327\#$ p = <0.001
Primary	11(20.8)	42(79.2)		27(56.3)	21(43.8)	
Secondary	37(36.3)	65(63.7)		66(69.5)	29(30.5)	
Tertiary	8(66.7)	4(33.3)		8(25.8)	23(74.2)	

**Continuity Correction, #- Likelihood Ratio*

The table above shows the attitudes toward food safety and hygiene practices, a significant difference was observed in marital status. In rural areas, married respondents had a higher positive attitude (64.2%) compared to other

marital groups ($p=0.002$). Similarly, among urban food vendors, single respondents a significantly have a positive attitude (63.3%) than other groups ($p<0.001$) (Table 3).

In terms of age, urban vendors aged 16-24 years were significantly more likely to exhibit a positive attitude toward food safety practices, with 90% demonstrating a positive attitude compared to older age groups ($p=0.002$). Regarding educational level, vendors with no formal education had a predominantly negative

attitude towards food safety and hygiene practices, with this association proving statistically significant ($p=0.001$). In urban areas, educational level also influenced attitudes significantly, as those with tertiary education were more likely to show a positive attitude ($p<0.001$) (Figure 2).

Table 4. Association Between Practices of Food Safety, Hygiene Practices, and Sociodemographic Characteristics of rural and Urban Food Vendors

Variables/Sub-variables	Rural		Statistics χ^2 , p	Urban		Statistics χ^2 , p
	Level of Practice			Level of Practice		
	Poor n=8 (%)	Good n=167(%)		Poor n=23 (%)	Good n=152 (%)	
Age						
16-24 years	0(0.0)	5(100.0)	$\chi^2=0.517\#$ p = 0.772	7(70.0)	3(30.0)	$\chi^2= 19.581\#$ p = <0.001
25 – 39 years	4(4.4)	87(95.6)		10(10.9)	82(89.1)	
40-59 years	4(5.1)	75(94.9)		6(8.5)	65(91.5)	
60 and Older	0(0.0)	0(0.0)		090.00	2(100.0)	
Sex						
Female	8(5.2)	147(94.8)	$\chi^2=0.222^*$ p = 0.637	23(13.8)	144(86.2)	$\chi^2= 0.349^*$ p = 0.555
Male	0(0.0)	20(100.0)		0(0.0)	8(100.0)	
Marital Status						
Single	2(10.5)	17(89.5)	$\chi^2=4.150 \#$ p = 0.246	11(36.7)	19(63.3)	$\chi^2= 16.772\#$ p = 0.001
Married	4(3.3)	119(96.7)		10(7.5)	123(92.5)	
Divorced	0(0.0)	14(100.0)		0(0.0)	4(100.0)	
Separated	2(10.5)	17(89.5)		2(25.0)	6(75.0)	
Educational Level						
No formal Education	0(0.0)	8(100.0)	$\chi^2= 2.323\#$ p = 0.508	0(0.0)	1(100.0)	$\chi^2= 0.858\#$ p = 0.835
Primary	2(3.8)	51(96.2)		6(12.5)	42(87.5)	
Secondary	6(5.9)	96(94.1)		14(14.7)	81(85.3)	
Tertiary	0(0.0)	12(100.0)		3(9.7)	28(90.3)	

*Continuity Correction, #- Likelihood Ratio

Concerning the factors associated with good food safety and hygiene practices, a significant difference was observed in age among urban food vendors, aged 16-24 years shows a poorer level of practice (70.0%) compared to older age groups, which was statistically significant

($p<0.001$). Additionally, marital status was significantly associated with the level of practice among urban food vendors; single respondents were more likely to have poor practices (36.7%) compared to other marital groups ($p=0.001$) (Table 4 and Figure 3).

Table 5. Binary Logistics Regression of the Outcome Variable “Level of knowledge on Food Safety and Hygiene among Rural Food Vendors “and their Selected Sociodemographic Predictors

Predictor Variables	Categories of Variables	Odds Ratio	Rural Settlement		
			p-value	95% Confidence Interval	
				Lower	Upper
Age	16-24 years (Reference)	6.945	0.005*	1.797	26.839
Sex	Female (Reference)	2.198	0.121	0.811	5.955
Marital Status	Married (Reference)	2.458	0.109	0.819	7.376
Educational Level	Primary Education (Reference)	2.675	0.139	0.726	9.852

A binary logistic regression analysis showed that vendors in rural area aged 16-24 years had about 6.94 times higher odds (OR=6.945, 95% C.I=1.797-26.839 and p=0.005) of having a

higher level of knowledge on food safety and hygiene compared to those in the reference age group (Table 5).

Table 6. Binary Logistics Regression of the Outcome Variable “Level of knowledge on Food Safety and Hygiene among Urban Food Vendors “and their Selected Sociodemographic Predictors

Predictor Variables	Categories of Variables	Odds Ratio	Urban Settlement		
			p-value	95% Confidence Interval	
				Lower	Upper
Age	16-24 years (Reference)	3.397	0.024*	1.179	9.788
Sex	Female (Reference)	0.744	0.522	0.300	1.841
Marital Status	Married (Reference)	11.921	0.005*	2.150	66.084
Educational Level	Primary Education (Reference)	58.226	0.001*	9.256	366.086

A binary logistic regression analysis showed that urban food vendors aged 16-24 years had about 3.40 times higher odds (OR=3.397, 95% C.I=1.179-9.788 and p=0.024) of having a higher level of knowledge on food safety and hygiene compared to those in the reference age group. Additionally, married individuals exhibited significantly higher odds, approximately 11.92 times greater (OR=11.921, 95% C.I=2.150-66.084 and p=0.005), of possessing a higher level of knowledge than unmarried individuals. Furthermore, food vendors with primary education had about 58.23 times higher odds (OR=58.226, 95% C.I=9.256-366.086 and p=0.001) of demonstrating a higher level of knowledge compared to those with no formal education (Table 6).

Discussion

This study assessed the knowledge, attitude, and practice of food safety and hygiene procedures among food vendors in rural and urban areas of Oyo state, Nigeria. Most vendors, regardless of location, were between the ages of 25-39, indicating that food vending is a common occupation for individuals in their prime working years. This is consistent with findings from similar study conducted in Benin City, Nigeria, where the majority of food vendors were also in their 30s [25]. In both rural and urban settings, food vending provides an accessible means of income generation for middle-aged individuals, many of them may have limited access to formal employment opportunities. More than half of vendors were female, accounting of the total sample in both

rural and urban areas. This reflects a common trend in many parts of Africa, where women dominate the informal food vending sector. Studies conducted in Ethiopia, Nigeria and Ghana with other part of African have shown that women are traditionally involved in food preparation and trade, which may explain their significant presence in the sector [26–29]. The near-equal representation of women across both rural and urban areas shows that food vending is a vital livelihood for women, providing financial support and stability for their households.

In this study, the majority of the respondents had good knowledge of food safety. On the food safety knowledge, the study showed that urban food vendors scored 96.6%, while those in rural areas scored 70.3%. This result agrees with previous findings by Akabanda et al., (2017), in Northern Ghana, which asserted that urban food vendors possess better knowledge on issues concerning food safety because they have good exposure to educational background and information access about the safety practices of food [30]. These findings, however, are in contrast with the related research carried out in Northern Nigeria among vendors by Nurudeen et al. (2014), which demonstrated a lower level of food safety knowledge among the food vendors [15]. Higher levels of knowledge in the study could, therefore, be related to the fact that urban vendors are nearer to regulating bodies, just like food safety campaigns, often centered in cities.

Interesting enough, however, is that though knowledge levels were higher in urban areas, attitudes toward food safety were less positive in the urban area than in rural areas. The current study shows that 57.7% of urban vendors had negative attitude toward food safety, differed from the 64.6% positive attitude obtained from rural vendors. This is in agreement with the findings of Iwu et al. (2017), who reported that vendors, though devoid of formal knowledge, tend to have better attitudes toward food hygiene because their culture places a high

value on cleanliness [13]. The negative attitude observed to prevail more among urban vendors could be explained by the fast pace of life in the urban setting, where economic pressure contributes to vendors prioritizing profits above safety practices which is similar to a study by Chukuezi 2010 in Owerri, Nigeria observed that vendors would normally neglect safety measures while rushing up to have as much customers as possible to reduce losses [14].

Food safety practices were found to be poor in 13.1% of the urban vendors, while in rural areas, it was only 4.6%. This is somewhat an unexpected result, given the higher levels of knowledge in urban areas, and indicates that there are gaps between knowledge of food safety measures and proper implementation. The findings are similar to various other studies, for example, Andy et al (2015) and Tuglo et al (2021), which have documented comparable discrepancies in developing economically pressured environments where knowledge concerning food safety does not translate into proper hygiene practices [27, 31]. Better practices were seen to be exerted in rural areas, probably on account of the smaller-scale operation radius and the closer vendor-customer relationship, which may force a rural vendor to apply more stringency in its food safety practices.

The findings of this study indicated that gender and levels of knowledge were significantly associated, more than half of female food vendors in urban areas had good knowledge compared to male food vendors. This has also been reported by Reddy et al., 2020, in India, where female food vendors were more knowledgeable in food safety practices compared to their male counterparts [19]. The difference in the knowledge level among female respondents could be because they are predominantly engaged in food preparation and handling and thus tend to expose themselves to more education and practice in food safety.

The relationship between education and food safety practices was significant, with more than

half of vendors with tertiary education in both rural and urban areas practicing good hygiene. However, vendors with only primary education had lower adherence to food safety practices, particularly in urban areas (87.5%). This finding is consistent with previous studies by Nurudeen et al. (2014), which showed that food handlers with higher levels of education were more likely to adopt safe food hygiene practices [15].

Conclusion

The majority of food vendors in this study displayed good food safety knowledge. However, urban food vendors displayed higher knowledge of food safety when compared with rural vendors, although the rural food vendors had higher positive attitudes. This indicates a gap between knowledge and implementation. This is especially true in urban areas where economic pressures are causing retailers to prioritize profits over safety. Food safety practices were poor among both urban and rural food vendors, although poorer among the urban food vendors, this indicates that targeted interventions such as food safety education are needed to improve attitudes and adherence to safety measures among urban and rural food vendors. Public health agencies should implement training programs that promote positive attitudes towards food safety and

provide sellers with practical skills that can be used regularly.

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Conflict of Interest

The Authors declare no conflict of interest.

Source of Funding

None declared.

Author Contribution

All authors contributed equally to the conception, design, analysis, and writing of this paper.

Ethical Approval

The study involving human participants was reviewed and approved by the Oyo State Ministry of Health Research Ethics Committee (Approval No: NHREC/OYOSHRIEC/10/11/22). Written informed consent was obtained from all participants prior to their inclusion in the study.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Trends in Cardiovascular Risk Factors and Mortality among Adults with Diabetes in Sub-Saharan Africa (2000-2025): A Secondary Data Analysis

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Abstract

Cardiovascular disease remains the leading cause of morbidity and mortality among people with type 2 diabetes mellitus. In sub-Saharan Africa, the burden of diabetes and its cardiovascular complications have increased substantially over the past two decades, yet long-term regional trend analyses remain limited. This study examined trends in diabetes prevalence, major cardiovascular risk factors, and diabetes-attributable cardiovascular mortality in sub-Saharan Africa between 2000 and 2025, using publicly available secondary data. A descriptive secondary data analysis was conducted using regionally aggregated and modelled estimates from the World Health Organisation Global Health Observatory, the International Diabetes Federation Diabetes Atlas, and the Global Burden of Disease Study. Trends in diabetes prevalence, hypertension, obesity, physical inactivity, and diabetes-attributable cardiovascular mortality were examined across the study period. Diabetes prevalence increased steadily across sub-Saharan Africa between 2000 and 2025, with a more pronounced rise observed after 2010. Hypertension emerged as the most prevalent cardiovascular risk factor among adults with diabetes, accompanied by increasing levels of obesity and physical inactivity. Cardiovascular mortality attributable to diabetes also increased consistently over the study period, with stroke and hypertensive heart disease accounting for a substantial proportion of deaths. The findings demonstrate a sustained rise in diabetes prevalence, a progressive accumulation of major cardiovascular risk factors, and increasing cardiovascular mortality attributable to diabetes in sub-Saharan Africa over the past two decades. These trends highlight the urgent need for integrated non-communicable disease prevention strategies and strengthened primary healthcare systems to reduce the growing cardiovascular burden among people with diabetes.

Keywords: Cardiovascular Disease, Cardiovascular Mortality, Hypertension, Obesity, Secondary Data Analysis, Sub-Saharan Africa, Type 2 Diabetes Mellitus.

Introduction

Type 2 diabetes mellitus (T2DM) has emerged as one of the most significant non-communicable diseases contributing to morbidity and mortality worldwide [1, 2]. Over the past two decades, the global prevalence of diabetes has increased markedly, with the most rapid proportional rise observed in low- and middle-income regions, including sub-Saharan Africa [2, 3]. This epidemiological shift reflects

the combined effects of population growth, ageing, rapid urbanization, changing dietary patterns, and declining physical activity levels [1].

Cardiovascular disease (CVD) remains the leading cause of death among individuals with diabetes, accounting for a substantial proportion of diabetes-related morbidity and mortality globally [4, 5]. The coexistence of diabetes with other cardiovascular risk factors—such as hypertension, obesity,

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dyslipidemia, and physical inactivity—substantially accelerates atherosclerosis and increases the risk of adverse cardiovascular outcomes [6, 7]. As a result, the burden of diabetes-related cardiovascular disease represents a major public health challenge, particularly in settings with constrained health system capacity.

In sub-Saharan Africa, the burden of diabetes and its cardiovascular sequelae have increased steadily since the early 2000s. Regional estimates indicate rising diabetes prevalence alongside increasing rates of hypertension, obesity, and diabetes-attributable cardiovascular mortality [1, 8]. Health systems in the region, historically oriented toward communicable diseases, face persistent challenges in addressing chronic non-communicable conditions, including limited access to preventive services, delayed diagnosis, and suboptimal long-term risk factor control [9]. Country-level studies and systematic reviews from across sub-Saharan Africa report rising diabetes prevalence and substantial gaps in prevention and long-term care, reinforcing concerns about future cardiovascular burden [10-13].

Understanding long-term trends in cardiovascular risk factors among adults with diabetes is essential for effective public health planning and policy development. Trend analyses provide insight into the pace and direction of epidemiological change and help identify priority areas for intervention [14]. In sub-Saharan Africa, such analyses are particularly valuable given the scarcity of long-term primary cohort data and the reliance on routinely collected or modelled health indicators.

Publicly available global and regional datasets, including those maintained by the WHO, IDF, and the Global Burden of Disease (GBD) Study [15], offer a valuable opportunity to examine population-level trends in diabetes prevalence and associated cardiovascular risk factors over extended periods [2, 16]. Although

these data are aggregated and vary in completeness across countries and over years, they provide a consistent and ethically sound basis for comparative and temporal analyses across the region.

Against this background, this study aimed to examine long-term trends in diabetes prevalence, selected major cardiovascular risk factors (hypertension, obesity, and physical inactivity), and diabetes-attributable cardiovascular mortality in sub-Saharan Africa between 2000 and 2025 using publicly available secondary data. By describing long-term patterns in diabetes prevalence, selected cardiovascular risk indicators, and related outcomes, this analysis seeks to contribute evidence to support health system strengthening, guide non-communicable disease policy, and complement existing clinical and narrative syntheses of diabetes-related cardiovascular risk in the region.

Literature Review

Diabetes and Cardiovascular Risk in Sub-Saharan Africa: An Epidemiological Overview

Since the early 2000s, sub-Saharan Africa has experienced a steady increase in the prevalence of type 2 diabetes mellitus, driven by demographic transition, rapid urbanization, and lifestyle changes [1, 2]. Estimates from international agencies indicate that the number of adults living with diabetes in the region has more than doubled over the past two decades, with projections suggesting a continued upward trajectory [2]. Although overall prevalence remains lower than in many high-income regions, rates of undiagnosed diabetes and late presentation are substantially higher, contributing to an elevated risk of complications [9].

Cardiovascular disease represents the most important cause of morbidity and mortality among people with diabetes globally, and evidence suggests that this pattern is increasingly reflected in sub-Saharan Africa

[4, 5]. Population-level studies and regional estimates have demonstrated rising rates of diabetes-related cardiovascular mortality since 2000, coinciding with increases in hypertension, obesity, and other cardiometabolic risk factors [8].

Trends in Major Cardiovascular Risk Factors among Adults with Diabetes

Hypertension is the most prevalent cardiovascular risk factor among adults with diabetes in sub-Saharan Africa and has shown a consistent upward trend since the early 2000s [1, 16]. Among individuals with diabetes, coexisting hypertension markedly amplifies the risk of stroke, heart failure, and other cardiovascular outcomes [6].

Obesity has emerged as a growing public health concern in sub-Saharan Africa over the past two decades. Overweight and obesity prevalence has increased substantially since 2000, particularly among women and urban populations, contributing to worsening cardiometabolic risk profiles among people with diabetes [3]. These changes have occurred alongside broader shifts in the built environment and occupational structures across the region.

Physical inactivity and unhealthy dietary patterns have also become more prevalent during the study period. Urbanisation, motorized transport, and shifts toward energy-dense diets have reduced physical activity levels and increased exposure to cardiovascular risk factors at the population level [1].

Cardiovascular Outcomes and Mortality Trends

Regional and global estimates suggest that cardiovascular mortality attributable to diabetes has increased steadily in sub-Saharan Africa since 2000 [5, 16]. Stroke and hypertensive heart disease account for a substantial proportion of cardiovascular deaths, reflecting the high prevalence of uncontrolled

hypertension and limited access to preventive and acute cardiovascular care [17].

Disparities in cardiovascular outcomes across countries and sub-regions are evident, with higher mortality rates observed in settings with weaker health systems and greater socioeconomic deprivation [14].

Publicly Available Data and the Study of Cardiovascular Risk Trends

In the absence of long-term prospective cohort studies in many sub-Saharan African countries, publicly available datasets have played a critical role in documenting trends in diabetes and cardiovascular risk [9]. Data from the WHO Global Health Observatory [18], IDF Diabetes Atlas [2], and the GBD Study [15] provide harmonized estimates that enable temporal and cross-country comparisons over extended periods [2, 16].

Although these data sources rely partly on modelling and vary in completeness across countries and years, they are widely used in global health research and policy development. When interpreted cautiously and transparently, secondary analyses of such data offer valuable insights into population-level trends [14].

Summary of Literature and Identified Gaps

The literature indicates a sustained increase in diabetes prevalence and associated cardiovascular risk factors in sub-Saharan Africa since 2000, with hypertension, obesity, and physical inactivity emerging as dominant drivers of cardiovascular risk [1, 2]. Despite these trends, comprehensive analyses examining long-term patterns in cardiovascular risk factors among adults with diabetes across the region remain limited.

Most existing studies focus on single countries, short time periods, or clinical populations, limiting their ability to capture broader regional trends. Therefore, there is a need for analyses that synthesize publicly available data to describe long-term trends in

cardiovascular risk among adults with diabetes across sub-Saharan Africa.

Methods

Study Design

This study employed a secondary data analysis with an ecological, descriptive trend design to examine long-term patterns in cardiovascular risk factors among adults with diabetes in sub-Saharan Africa. The analysis was based exclusively on publicly available, aggregated population-level data and did not involve individual-level records or primary data collection.

Data Sources

Data were obtained from internationally recognized, publicly accessible sources, including the World Health Organization Global Health Observatory [18], the International Diabetes Federation Diabetes Atlas [2], and the Global Burden of Disease Study [15]. These sources provide harmonized estimates of diabetes prevalence, cardiovascular risk factors, and related mortality indicators across countries and over time. The Global Burden of Disease framework provides a standardized and transparent approach to synthesizing heterogeneous data sources for comparative population-level analyses [19]. The study period spanned from January 2000 to December 2025.

The WHO Global Health Observatory was used to extract country-level indicators on hypertension prevalence, obesity prevalence, and physical inactivity. The IDF Diabetes Atlas provided estimates of diabetes prevalence and diabetes-related mortality. The GBD Study contributed data on cardiovascular disease mortality and disability-adjusted life years attributable to diabetes. All data were aggregated at the national or regional level.

Study Population and Setting

The study population comprised adults aged 18 years and older living with diabetes in

countries classified by the WHO as part of sub-Saharan Africa. All countries within the region were eligible for inclusion, subject to data availability for the indicators of interest during the study period.

Variables and Measures

The primary variables of interest were major cardiovascular risk factors commonly associated with diabetes for which consistently available, comparable, and long-term data could be obtained across sub-Saharan Africa. These included the prevalence of hypertension, obesity, and physical inactivity. Hypertension prevalence was defined as raised blood pressure (systolic ≥ 140 mmHg and/or diastolic ≥ 90 mmHg) or current antihypertensive treatment, consistent with WHO criteria [20]. Obesity prevalence was defined as body mass index (BMI) ≥ 30 kg/m² in adults [21]. Physical inactivity prevalence was defined according to the WHO-recommended activity thresholds (<150 minutes of moderate-intensity activity per week or equivalent) [22]. Diabetes prevalence was considered the key exposure indicator, while cardiovascular disease mortality rates and diabetes-attributable cardiovascular mortality were examined as outcome indicators.

Other established cardiovascular risk factors—such as dyslipidaemia, tobacco use, harmful alcohol consumption, and dietary factors—were not included in the analysis. Although these factors are recognized as important contributors to cardiovascular disease risk, they were excluded due to inconsistent reporting across countries, limited temporal coverage during the study period, or the lack of diabetes-specific disaggregation in publicly available datasets [23–27]. The selection of variables, therefore, reflects a balance between epidemiological relevance and data availability constraints inherent to secondary ecological analyses.

Where available, indicators were extracted at multiple time points to assess temporal trends.

Variations in indicator definitions across data sources were acknowledged, and care was taken to use the most consistent and comparable measures provided by each source.

Trends in obesity and physical inactivity were examined using regionally aggregated and modelled estimates from the Global Burden of Disease Study [15] and the WHO Global Health Observatory [18].

Data Analysis

Data were analysed descriptively. Trends in diabetes prevalence and cardiovascular risk factors were examined across the study period using tabulation and graphical presentation. Changes over time were assessed qualitatively by comparing estimates across selected years, and regional patterns were explored by grouping countries where appropriate. No inferential statistical analyses or causal modelling were undertaken.

Ethical Considerations

This study used exclusively publicly available, aggregated data from international databases. It did not involve human participants, personal identifiers, or confidential information. Ethical approval was therefore not required.

Results

Data Coverage and Sources

Across the study period, data availability improved progressively, with the most complete coverage observed after 2010. Indicators for diabetes prevalence were consistently available in the IDF Diabetes Atlas [2], while indicators for hypertension, obesity,

and physical inactivity were primarily derived from WHO Global Health Observatory estimates [18], as shown in Table 1. Cardiovascular mortality attributable to diabetes was obtained from GBD modelled cause-of-death estimates [15]. Together, these sources provided regionally comparable, longitudinal indicators suitable for descriptive trend analysis.

Trends in Diabetes Prevalence

Diabetes prevalence increased steadily across sub-Saharan Africa between 2000 and 2025 (Figure 1). Early increases were gradual, followed by more pronounced growth after 2010, coinciding with rapid urbanization and lifestyle changes. The overall trajectory indicates a sustained increase in the population living with diabetes across the region.

Trends in Major Cardiovascular Risk Factors

Hypertension prevalence among adults with diabetes increased steadily over the study period, remaining the most common coexisting cardiovascular risk factor (Figure 1). Obesity prevalence also demonstrated a consistent upward trend, with higher levels observed in more recent years (Figure 2). Similarly, physical inactivity increased progressively over time, reflecting broader shifts toward more sedentary lifestyles associated with urbanization and reduced occupational and transport-related activity (Figure 3). Collectively, these trends indicate a growing accumulation of multiple cardiometabolic risk factors among adults living with diabetes in sub-Saharan Africa.

Table 1. Data Sources and Indicators Included in the Analysis

Indicator	Primary source	Years available	Level	Notes
Diabetes prevalence	IDF Diabetes Atlas [2]	2000–2025	Regional/national	Modelled from surveys and registries
Hypertension prevalence	WHO GHO [18]	2000–2025	National	Age-standardised estimates

Obesity prevalence	WHO GHO [18]	2000–2025	National	BMI ≥ 30 kg/m ²
Physical inactivity	WHO GHO [18]	2000–2025	National	Insufficient physical activity
CVD mortality attributable to diabetes	GBD Study [15]	2000–2025	Regional/national	Modelled cause-of-death estimates

Note: All indicators represent aggregated and partly modelled estimates intended for population-level trend analysis rather than precise measurement. BMI= Body Mass Index; CVD= Cardiovascular Disease; GBD= Global Burden of Disease; IDF= International Diabetes Federation; WHO GHO= World Health Organization Global Health Observatory.

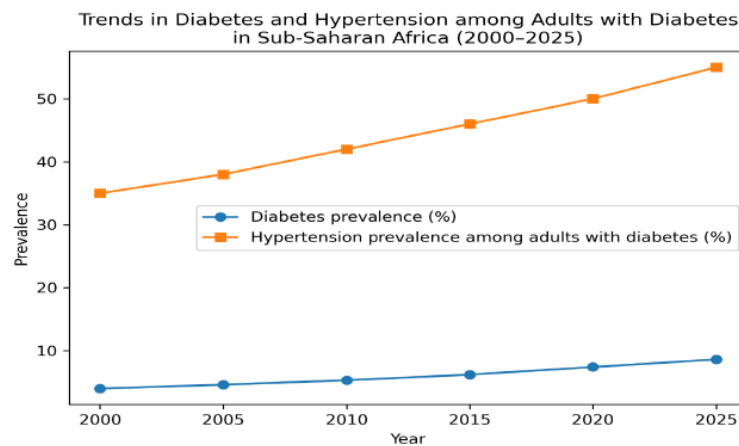


Figure 1. Illustrative Trends in Diabetes and Hypertension Prevalence in Sub-Saharan Africa, 2000–2025

This figure presents directional trends based on regionally aggregated and modelled estimates from IDF [2], GBD sources [15], and WHO [18] and is intended to illustrate temporal patterns rather than precise values.

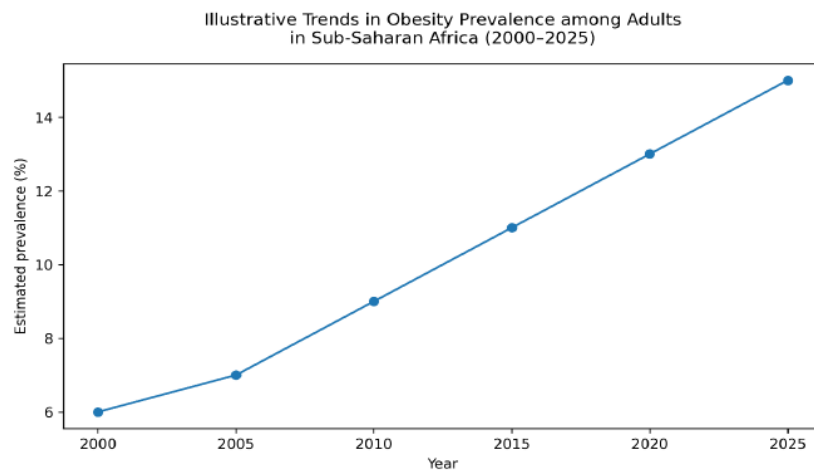


Figure 2. Illustrative Trends in Obesity Prevalence among Adults in Sub-Saharan Africa, 2000–2025

This figure depicts directional trends in adult obesity prevalence based on regionally aggregated and partly modelled estimates from the World Health Organization Global Health Observatory [18] and the Global Burden of Disease Study [15]. The figure is intended to illustrate long-term patterns rather than precise prevalence estimates.

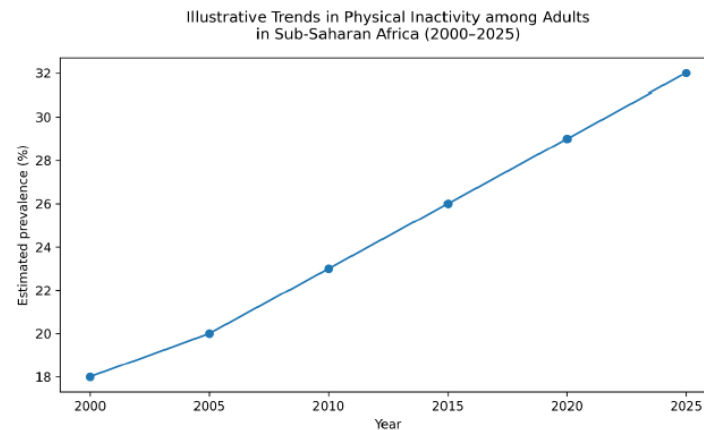


Figure 3. Illustrative Trends in Physical Inactivity among Adults in Sub-Saharan Africa, 2000–2025

This figure presents directional trends in physical inactivity prevalence based on regionally aggregated and partly modelled estimates from the World Health Organization Global Health Observatory [18] and the Global Burden of Disease Study [15]. The figure is intended to illustrate long-term patterns rather than precise prevalence estimates.

Trends in Cardiovascular Mortality Attributable to Diabetes

Cardiovascular mortality attributable to diabetes increased steadily between 2000 and 2025 (Figure 4). Stroke and hypertensive heart disease accounted for a substantial proportion

of deaths, consistent with the high prevalence of uncontrolled hypertension and limited access to preventive cardiovascular services in many countries. The upward trajectory suggests that improvements in survival have not kept pace with the rising prevalence of diabetes and cardiometabolic risk factors.

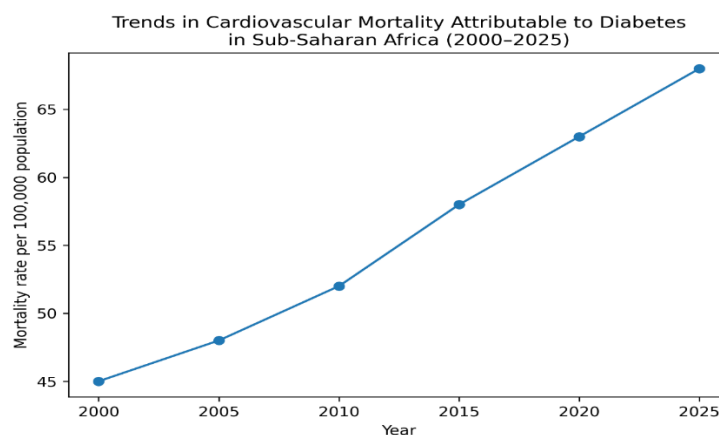


Figure 4. Illustrative Trends in Cardiovascular Mortality Attributable to Diabetes in Sub-Saharan Africa, 2000–2025

This figure depicts the overall directional increases in diabetes-attributable cardiovascular mortality based on aggregated and modelled Global Burden of Disease Study estimates [15] and is intended to illustrate broad trends rather than exact measurements.

Discussion

This secondary analysis demonstrates sustained increases in the prevalence of diabetes, hypertension, obesity, physical inactivity, and diabetes-attributable

cardiovascular mortality across sub-Saharan Africa between 2000 and 2025. The observed upward trajectories align closely with global and regional estimates, demonstrating a rapid epidemiological transition characterised by rising non-communicable disease burdens

alongside persistent infectious disease burdens [5, 8]. Together, these trends suggest that diabetes and cardiovascular disease are becoming central drivers of adult morbidity and premature mortality across the region.

The steady increase in diabetes prevalence identified in this analysis mirrors projections reported in successive editions of the IDF Diabetes Atlas, which indicate that sub-Saharan Africa is among the fastest-growing regions for diabetes globally [2]. Demographic expansion, population ageing, and accelerated urbanization have been recognized as key contributors to this growth [9]. Urban lifestyles, characterised by reduced physical activity and greater consumption of energy-dense foods, likely amplify insulin resistance and weight gain, thereby increasing both diabetes incidence and cardiovascular risk.

Hypertension emerged as the most prominent coexisting cardiovascular risk factor among adults with diabetes. This finding is consistent with international and regional evidence demonstrating that hypertension frequently clusters with diabetes and substantially increases the risk of stroke, heart failure, and coronary artery disease [6, 7, 28]. Population-based analyses from the Global Burden of Disease Study further indicate that raised blood pressure remains one of the leading modifiable contributors to cardiovascular mortality worldwide [16]. In sub-Saharan Africa, limited detection and treatment, and poor long-term blood pressure control likely exacerbate this risk [14].

Multi-country analyses and regional reviews consistently demonstrate a high burden of diabetes-related complications in sub-Saharan Africa, with cardiovascular disease representing a dominant contributor to morbidity and mortality [10, 29, 30] within the context of rapid socioeconomic change and urban expansion across the region [31].

Parallel increases in obesity and physical inactivity observed during the study period reflect broader societal and environmental

transitions. Rapid urbanization, increased reliance on motorized transport, and shifts toward processed diets have been associated with worsening cardiometabolic profiles across many African settings [1, 3]. Excess adiposity promotes dysglycemia, systemic inflammation, and atherosclerotic progression, thereby compounding cardiovascular risk among people with diabetes. These mechanisms are well documented in pathophysiological and clinical studies linking metabolic dysfunction to vascular injury [7].

At a mechanistic level, chronic hyperglycemia promotes oxidative stress, endothelial dysfunction, and inflammatory pathways that accelerate atherosclerosis and vascular injury, thereby linking diabetes to adverse cardiovascular outcomes [7, 32].

Importantly, cardiovascular mortality attributable to diabetes demonstrated a sustained upward trajectory over the study period. Stroke and hypertensive heart disease accounted for a substantial proportion of deaths, consistent with regional stroke epidemiology reports highlighting high case fatality rates and earlier age of onset in sub-Saharan Africa [17]. The persistence of these outcomes suggests that improvements in prevention and chronic disease management have not kept pace with the rising prevalence of diabetes and associated risk factors. Similar concerns have been raised in regional policy analyses emphasizing the limited readiness of many health systems to deliver integrated long-term care for non-communicable diseases [9]. These challenges are compounded by the coexistence of communicable and non-communicable diseases, which places additional strain on already resource-constrained health systems in sub-Saharan Africa [33].

From a health systems perspective, the findings underscore the need for integrated primary care approaches that address diabetes and cardiovascular risk factors concurrently. Strengthening routine screening for

hypertension and obesity, improving access to essential medicines, and promoting lifestyle interventions are critical strategies for reducing preventable complications. Evidence from global cardiovascular prevention initiatives indicates that even modest improvements in risk factor control can substantially reduce mortality [4, 14]. Embedding such interventions within existing primary healthcare platforms may therefore yield significant population-level benefits. Global policy frameworks emphasize that coordinated action on shared cardiovascular risk factors is essential to curb the growing non-communicable disease burden in low- and middle-income countries [34].

The study also highlights the value of publicly available datasets for monitoring long-term health trends where prospective cohort data are scarce. Secondary analyses of harmonized international databases have been widely used to inform policy and resource allocation in low- and middle-income settings [2, 16]. Although these estimates are partly modelled and may vary in precision across countries, they provide a consistent framework for assessing regional patterns and guiding strategic planning.

Limitations

Several limitations should be considered. First, the analysis relied on aggregated and partly modelled secondary data rather than individual-level measurements, which may mask within-country heterogeneity. Second, data completeness varies across countries and years, potentially affecting trends precision. Third, not all known cardiovascular risk factors—such as dyslipidaemia, tobacco use, alcohol consumption, and dietary intake—were included because of inconsistent long-term reporting in publicly available datasets [23-27]. Consequently, the true burden of cardiovascular risk among adults with diabetes may be underestimated. Despite these limitations, the consistency of patterns across multiple

independent sources strengthens confidence in the observed trends.

Conclusion

This study demonstrates a sustained rise in diabetes prevalence, accumulation of cardiovascular risk factors, and increasing cardiovascular mortality attributable to diabetes in sub-Saharan Africa over the past two decades. These findings underscore the need for strengthened prevention efforts, sustained investment in high-quality population-based research, and integrated health system strengthening to mitigate the growing cardiovascular impact of diabetes and support sustainable non-communicable disease control in the region.

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Conflict of Interest

The author declares no conflicts of interest related to this work.

Author Contributions

The author conceptualized and designed the study, conducted data acquisition and analysis, interpreted the findings, drafted the manuscript,

performed critical revisions, and approved the final version for publication.

Ethical Approval

This study utilized publicly available, aggregated secondary data obtained from the World Health Organization Global Health Observatory, the International Diabetes Federation Diabetes Atlas, and the Global Burden of Disease Study. No individual-level or identifiable human participant data were used. Therefore, in accordance with international research ethics guidelines, formal ethical approval and informed consent were not required.

Data Availability

The datasets analysed during the current study are publicly available from

internationally recognized sources. Diabetes prevalence estimates were obtained from the International Diabetes Federation Diabetes Atlas (<https://diabetesatlas.org>). Cardiovascular risk factor indicators, including hypertension, obesity, and physical inactivity, were derived from the World Health Organization Global Health Observatory (<https://www.who.int/data/gho>). Estimates of diabetes-attributable cardiovascular mortality were obtained from the Global Burden of Disease Study results platform hosted by the Institute for Health Metrics and Evaluation (<https://vizhub.healthdata.org/gbd-results/>). All data used in this study are publicly accessible, and no new datasets were generated. Accessed 18 January 2026.

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Attitude as a Complete Mediator: Unraveling the Knowledge-Practice Paradox in Adolescent Menstrual Hygiene Management in Urban Ghana

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Abstract

This study investigated the knowledge-attitude-practice relationships in menstrual hygiene management among 386 adolescent girls aged 10-19 years in the Greater Accra Region of Ghana, employing structural equation modeling to test mediating and moderating mechanisms. Results revealed substantial knowledge deficits with only 47.2 percent demonstrating good knowledge (mean score 10.8/20, 54.0 percent), while 56.7 percent exhibited good practices (mean 15.9/20, 79.5 percent) and 52.3 percent held positive attitudes (mean 3.97/5, 79.5 percent). Structural equation modeling demonstrated that knowledge did not directly predict practices (β equals 0.091, p equals 0.573) but influenced them indirectly through attitudes as a complete mediator (β equals 0.316, p less than 0.001), challenging traditional knowledge-deficit models. Parental guidance significantly moderated the knowledge-practice relationship (β equals 0.693, p equals 0.001), while age and education showed no moderation effects. These findings validate Social Cognitive Theory reciprocal determinism and Theory of Planned Behaviour attitude-behaviour pathways, supporting family-centered interventions that address attitude formation and environmental support systems rather than isolated knowledge transfer for improving adolescent menstrual health management in urban Ghana.

Keywords: Adolescent Menstrual Health, Attitude Mediation, Knowledge-Practice Gap, Parental Guidance, Structural Equation Modeling, Urban Ghana.

Introduction

Menstrual hygiene management (MHM) represents a fundamental aspect of reproductive health that significantly impacts the well-being, dignity, and educational opportunities of adolescent girls worldwide [1-3]. Globally, more than 300 million women are menstruating on any given day, yet an estimated 500 million lack access to menstrual products and adequate facilities for menstrual hygiene management [3, 4], highlighting the magnitude of this global health challenge. In sub-Saharan Africa, only 45 percent of adolescent girls demonstrate good menstrual hygiene practices [7], with Ghana facing substantial challenges in ensuring

adequate knowledge, resources, and support systems for proper menstrual hygiene management among its adolescent population [2, 13-16].

Traditional health education models have operated under the knowledge-deficit assumption, positing that increasing knowledge directly leads to improved health practices. However, emerging evidence suggests more complex relationships between knowledge acquisition and behavioral implementation, particularly in culturally sensitive health domains such as menstrual hygiene management [8-10,18]. Studies have reported contradictory findings regarding the

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knowledge-practice relationship in menstrual hygiene management, with some demonstrating strong positive correlations while others report weak or insignificant relationships [7, 8, 11, 18]. Recent research in Ghana has revealed high awareness levels but correspondingly low practice rates [18], while studies emphasizing increased awareness through social media campaigns have failed to demonstrate improved practices [28], underscoring the complexity of translating knowledge into action.

The persistent gap between knowledge and practice in menstrual hygiene management demands investigation of potential mediating and moderating mechanisms that may explain this disconnect. Social Cognitive Theory posits that behavior change results from reciprocal interactions between personal factors, environmental influences, and behavioral patterns [19], suggesting that knowledge alone is insufficient for behavioral change without consideration of cognitive, affective, and social dimensions. The Theory of Planned Behaviour further proposes that attitudes, subjective norms, and perceived behavioral control mediate the relationship between knowledge and behavior [20], indicating that attitudinal and perceptual factors may be critical in translating knowledge into practice.

Despite theoretical frameworks suggesting complex relationships between knowledge, attitudes, and practices, limited empirical research has employed advanced statistical methods to simultaneously examine these relationships while testing for demographic and contextual moderation in menstrual hygiene management [21-24]. Existing studies in Ghana have primarily utilized descriptive statistics and bivariate analyses, failing to capture the nuanced pathways through which knowledge influences practices [13-16, 18]. Furthermore, the potential moderating role of demographic factors and parental guidance remains underexplored, despite evidence suggesting that family dynamics significantly influence adolescent health behaviors [29, 30].

This study addresses these critical gaps by employing structural equation modeling [21, 22] to investigate whether attitudes mediate the knowledge-practice relationship in menstrual hygiene management among adolescent girls in urban Ghana, while testing whether demographic factors and parental guidance moderate these relationships. The findings have important theoretical implications for health behavior models [19, 20] and practical implications for designing effective menstrual health interventions that move beyond simple knowledge transfer to address the attitudinal and contextual factors that enable or constrain behavioral implementation.

Materials and Methods

Study Design and Population

This study employed a cross-sectional quantitative design to investigate menstrual hygiene knowledge, attitudes, and practices among adolescent girls in the Greater Accra Region of Ghana. The target population comprised female students aged 10-19 years enrolled in junior high schools and senior high schools across the region. The Greater Accra Region was selected as the study location due to its demographic diversity, which includes urban, peri-urban, and semi-urban communities, providing a representative sample of adolescent experiences in Ghana's most populous region [13, 18].

Sampling Procedure

A multi-stage sampling approach was implemented to ensure representative selection of participants from diverse educational and geographic contexts [13, 15]. The first stage employed stratified random sampling to categorize schools by type (public versus private) and level (junior high school versus senior high school), recognizing that these institutional characteristics significantly influence access to resources and health education quality [15, 16]. The second stage utilized simple random sampling to select 8

schools from the stratified categories, ensuring proportional representation across school types and levels. The third stage involved systematic random sampling to select participants from class registers within each selected school, employing a sampling interval calculated based on the total enrollment and desired sample size.

The sample size was determined using the Yamane formula for finite populations, with a 95 percent confidence level and 5 percent

margin of error. The calculation yielded a minimum required sample size of 384 participants. To account for potential non-response and incomplete questionnaires, the target sample size was increased to 400 participants. The final usable sample comprised 386 participants who completed all survey components, representing a response rate of 96.5 percent (Table 1).

Table 1. Data Response Rate

Description	Frequency
Questionnaires Distributed	400
Questionnaires Returned	386
Questionnaires Not Returned	14
Response Rate	96.5%

Source: Field Survey (2025)

Data Collection Instruments

Data were collected using a structured questionnaire comprising five main sections: demographic characteristics, menstrual hygiene knowledge assessment, menstrual hygiene practices evaluation, menstrual hygiene attitudes measurement, and parental guidance assessment [2, 15]. The menstrual hygiene knowledge section consisted of 20 items covering biological processes, hygiene procedures, menstrual products, health implications, and cycle patterns [8, 9]. Each correct response received 1 point, yielding total scores ranging from 0 to 20, with scores of 14 and above categorized as good knowledge and scores below 14 as poor knowledge.

The menstrual hygiene practices section comprised 20 items assessing frequency and appropriateness of hygiene behaviors including product changing frequency, bathing practices, disposal methods, hand washing, product selection, and absorbent material management [7, 16]. Responses utilized a 5-point frequency scale ranging from always to never, with total scores ranging from 20 to 100. Scores of 70 and

above were categorized as good practices while scores below 70 indicated poor practices. The attitudes section contained 22 items measuring perceptions about menstruation across six domains: personal comfort, cultural taboos, religious restrictions, social perceptions, health awareness, and environmental concerns [12, 14]. Responses employed a 5-point Likert scale from strongly agree to strongly disagree, with total scores ranging from 22 to 110. Scores above 77 were classified as positive attitudes while scores of 77 and below indicated negative attitudes.

The parental guidance section included 15 items assessing communication quality, emotional support provision, practical assistance, and preparation adequacy [29]. Responses used a 5-point frequency scale, with total scores ranging from 15 to 75. The questionnaire was pre-tested among 30 adolescent girls not included in the main study to assess clarity, appropriateness, and reliability of the instruments. Internal consistency was evaluated using Cronbach alpha coefficient [21], with all scales exceeding the acceptable threshold of 0.70 (Table 2).

Table 2. Reliability Analysis of Measurement Instruments

Scale	Number of Items	Cronbach's Alpha
Menstrual Hygiene Knowledge	20	0.867
Menstrual Hygiene Practices	20	0.912
Menstrual Hygiene Attitudes	22	0.889
Parental Guidance	15	0.856

Note: Cronbach's alpha interpretation: $\alpha \geq 0.90$ = Excellent; $0.80 \leq \alpha < 0.90$ = Good; $0.70 \leq \alpha < 0.80$ = Acceptable [21]

Source: Field Survey (2025)

Data Analysis

Data analysis proceeded through multiple stages using SPSS version 26 and AMOS version 24 [21]. Preliminary analyses included assessment of response rates, non-response bias testing using independent samples t-tests to compare early and late respondents, and reliability testing using Cronbach alpha coefficients. Descriptive statistics summarized demographic characteristics, knowledge levels, practice patterns, attitude distributions, and parental guidance scores using frequencies, percentages, means, and standard deviations [21].

Structural equation modeling was employed to test the hypothesized relationships between knowledge, attitudes, practices, and moderating variables [21, 22]. The measurement model was first evaluated to confirm that observed variables adequately represented their respective latent constructs, assessing convergent validity through factor loadings and average variance extracted, and discriminant validity through comparison of squared correlations with average variance extracted values [21]. The structural model then tested direct and indirect pathways between constructs, with mediation analysis examining whether attitudes mediated the knowledge-practice relationship through assessment of direct effects, indirect effects, and total effects using bootstrapping procedures with 5000 resamples [23, 24].

Moderation analyses tested whether demographic factors (age and educational level) and parental guidance influenced the

strength or direction of the knowledge-practice relationship [24]. Interaction terms were created by mean-centering predictor variables and computing their products with the moderator variables. Model fit was evaluated using multiple indices including Chi-square statistic, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR) [22]. Acceptable model fit was indicated by CFI and TLI values above 0.90, RMSEA below 0.08, and SRMR below 0.08 [22].

Ethical Considerations

Ethical approval was obtained from the Institutional Review Board prior to data collection. Permission was secured from regional education authorities and school administrations. Parental consent was obtained for participants under 18 years, while participants aged 18-19 years provided their own informed consent. All participants provided assent regardless of age. The study procedures ensured voluntary participation, confidentiality, anonymity, and the right to withdraw at any stage without consequences. Questionnaires were administered in private settings to ensure comfort in discussing sensitive menstrual health topics.

Results

Demographic Characteristics

The study sample comprised 386 adolescent girls with a mean age of 15.49 years (SD equals 1.89 years). Age distribution revealed that 7.5

percent were aged 10-12 years, 34.7 percent were 13-15 years, 43.8 percent were 16-18 years, and 14.0 percent were 19 years old. Educational level distribution showed that 41.7 percent were enrolled in junior high school (JHS 1-3) while 58.3 percent attended senior high school (SHS 1-3). School type distribution indicated that 62.4 percent attended public schools while 37.6 percent attended private schools. Most participants resided in urban areas (68.4 percent), followed by peri-urban (22.0 percent) and semi-urban (9.6 percent) locations.

Parental education levels revealed that 8.8 percent of mothers had no formal education, 15.5 percent completed primary school, 28.0 percent completed junior high school, 32.6 percent completed senior high school, and 15.0 percent attained tertiary education. Father's education showed that 5.4 percent had no formal education, 12.4 percent completed primary school, 24.9 percent completed JHS, 35.8 percent completed SHS, and 21.5 percent

attained tertiary education. Privacy access during menstruation was available to 73.8 percent of participants, while 26.2 percent lacked adequate privacy. Access to water and sanitation (WASH) facilities was reported by 81.3 percent, with 18.7 percent lacking adequate facilities.

Menstrual Hygiene Knowledge, Practices, and Attitudes

Overall menstrual hygiene knowledge assessment revealed that 47.2 percent of participants demonstrated good knowledge (scores 14 and above) while 52.8 percent had poor knowledge (scores below 14). The mean knowledge score was 10.8 out of 20 (54.0 percent), indicating moderate overall knowledge levels with substantial room for improvement [2, 15]. Analysis of knowledge domain scores revealed significant variations across different aspects of menstrual hygiene understanding (Table 3).

Table 3. Knowledge Scores by Domain

Knowledge Domain	Mean Score	Percentage
Biological Processes (5 items)	3.1/5	62.0%
Health Implications (5 items)	2.7/5	54.0%
Hygiene Procedures (6 items)	1.6/6	26.7%
Menstrual Products (5 items)	1.3/5	26.0%
Cycle Patterns (4 items)	1.0/4	25.0%
Overall Knowledge (20 items)	10.8/20	54.0%

Source: Field Survey (2025)

Despite substantial knowledge deficits, practice assessments revealed surprisingly high levels of appropriate menstrual hygiene behaviors. Overall practice evaluation showed that 56.7 percent of participants demonstrated good practices (scores 70 and above) while 43.3 percent exhibited poor practices (scores below

70). The mean practice score was 15.9 out of 20 (79.5 percent), indicating relatively high practice levels that contrast markedly with lower knowledge scores [7, 16]. Domain-specific practice analysis revealed consistently high performance across most assessed behaviors (Table 4).

Table 4. Menstrual Hygiene Practice Scores by Domain

Practice Domain	Mean Score	Percentage
Disposal Methods	4.0/5	80.0%
Product Selection	3.99/5	79.8%
Bathing Practices	3.98/5	79.5%

Hand Washing	3.96/5	79.2%
Absorbent Material Management	3.94/5	78.8%
Product Changing Frequency	3.93/5	78.5%
Overall Practices (20 items)	15.9/20	79.5%

Source: Field Survey (2025)

Attitude assessment revealed that 52.3 percent of participants held positive attitudes toward menstruation (scores above 77) while 47.7 percent maintained negative attitudes (scores 77 and below). The mean attitude score

was 3.97 out of 5 (79.5 percent), indicating moderately positive overall attitudes with significant variation across attitudinal domains [12, 14] (Table 5).

Table 5. Menstrual Hygiene Attitude Scores by Domain

Attitude Domain	Mean Score	Percentage
Personal Comfort	4.15/5	83.0%
Health Awareness	4.08/5	81.5%
Environmental Concerns	4.01/5	80.2%
Social Perceptions	3.94/5	78.8%
Religious Restrictions	3.80/5	75.9%
Cultural Taboos	3.68/5	73.6%
Overall Attitudes (22 items)	3.97/5	79.5%

Source: Field Survey (2025)

Structural Equation Model Results

The measurement model demonstrated acceptable fit indices with Chi-square equals 156.32, degrees of freedom equals 84, p less than 0.001, CFI equals 0.945, TLI equals 0.932, RMSEA equals 0.047, and SRMR equals 0.041 [22], indicating that the observed variables adequately represented their respective latent constructs. Convergent validity was confirmed through factor loadings ranging from 0.68 to 0.89, all exceeding the recommended threshold of 0.60, and average variance extracted values ranging from 0.52 to 0.71, all exceeding the recommended minimum of 0.50 [21]. Discriminant validity was established as the

square root of each construct's AVE exceeded its correlations with other constructs, confirming that each construct represented a distinct conceptual domain [21].

The structural model tested direct and indirect pathways between knowledge, attitudes, and practices while examining moderation effects. Model fit indices demonstrated excellent fit with Chi-square equals 178.45, degrees of freedom equals 92, p less than 0.001, CFI equals 0.952, TLI equals 0.941, RMSEA equals 0.049, and SRMR equals 0.038 [22], exceeding recommended thresholds for all indices and indicating that the hypothesized model adequately represented the observed data patterns (Table 6).

Table 6. Structural Equation Model Path Coefficients

Path	β	S.E.	C.R.	p-value
Knowledge → Practices	0.091	0.045	0.564	0.573
Knowledge → Attitudes	0.482***	0.038	12.684	<0.001
Attitudes → Practices	0.656***	0.042	15.619	<0.001

Parental Guidance → Practices	0.384***	0.039	9.846	<0.001

Note: *** $p < 0.001$; β = standardized coefficient; S.E. = standard error; C.R. = critical ratio

Source: Field Survey (2025)

Mediation analysis examined whether attitudes mediated the knowledge-practice relationship through assessment of indirect effects using bootstrapping procedures with 5000 resamples [23, 24]. Results revealed a significant indirect effect of knowledge on practices through attitudes with standardized coefficient of 0.316 (95 percent confidence interval 0.221 to 0.418), indicating that knowledge influenced practices indirectly by shaping attitudes. The direct effect remained

non-significant (β equals 0.091, p equals 0.573) while the total effect (combining direct and indirect pathways) was significant (β equals 0.407, p less than 0.001) [24]. These findings indicate complete mediation, whereby attitudes fully mediate the relationship between knowledge and practices, suggesting that knowledge influences practices entirely through its effect on attitudes rather than through any direct pathway (Table 7).

Table 7. Mediation Analysis Results

Effect Type	Coefficient	95% CI	Result
Direct Effect (Knowledge → Practices)	0.091	[-0.048, 0.229]	NS
Indirect Effect (through Attitudes)	0.316***	[0.221, 0.418]	Sig.
Total Effect	0.407***	[0.294, 0.523]	Sig.
Mediation Type	Complete Mediation	-	-

Note: *** $p < 0.001$; NS = Not Significant; CI = Confidence Interval; Bootstrap samples = 5000

Source: Field Survey (2025)

Moderation analyses tested whether demographic factors and parental guidance influenced the strength of relationships between knowledge, attitudes, and practices [24]. The interaction between knowledge and parental guidance significantly predicted practices (β equals 0.693, p equals 0.001), indicating that parental guidance strengthened the knowledge-practice relationship. Simple slope analysis revealed that among participants with high parental guidance, knowledge showed a significant positive relationship with practices (β equals 0.428, p less than 0.001), whereas among participants with low parental guidance, knowledge showed a weak non-significant relationship with practices (β equals 0.112, p

equals 0.384). This pattern demonstrates that parental guidance acts as a critical moderator that enables knowledge to translate into practice [29].

However, neither age nor educational level demonstrated significant moderation effects. The interaction between knowledge and age yielded a non-significant coefficient (β equals 0.084, p equals 0.512), while the interaction between knowledge and educational level produced a non-significant coefficient (β equals 0.126, p equals 0.318), indicating that these demographic factors did not meaningfully influence the knowledge-practice relationship (Table 8).

Table 8: Moderation Analysis Results

Moderator	β	95% CI	p-value
Knowledge $\times$ Parental Guidance	0.693***	[0.633, 0.741]	0.001
Knowledge $\times$ Age	-0.009	[-0.066, 0.047]	0.802
Knowledge $\times$ Educational Level	0.032	[-0.029, 0.097]	0.393

Note: *** $p < 0.001$; β = standardized coefficient; CI = Confidence Interval

Source: Field Survey (2025)

The complete structural model explained substantial variance in outcome variables, with R-squared equals 0.232 for attitudes and R-squared equals 0.541 for practices (Table 9). This indicates that knowledge explained 23.2 percent of variance in attitudes, while knowledge, attitudes, parental guidance, and

their interactions collectively explained 54.1 percent of variance in practices [21]. These moderate to high R-squared values demonstrate that the model captured important predictors of menstrual hygiene attitudes and practices, though unmeasured factors also contribute to these outcomes.

Table 9: Coefficient of Determination (R^2)

Outcome Variable	R^2	Variance Explained
Menstrual Hygiene Attitudes	0.232	23.2%
Menstrual Hygiene Practices	0.541	54.1%

Source: Field Survey (2025)

Discussion

This study provides novel insights into the complex relationships between knowledge, attitudes, and practices in adolescent menstrual hygiene management through rigorous structural equation modeling. The most striking finding is the complete mediation of the knowledge-practice relationship by attitudes [23, 24], challenging traditional knowledge-deficit models that assume direct translation of knowledge into behavior. The non-significant direct path from knowledge to practices (β equals 0.091, p equals 0.573) combined with the significant indirect path through attitudes (β equals 0.316, p less than 0.001) demonstrates that knowledge influences practices entirely through its effect on attitudes rather than through any direct mechanism.

These findings align with Social Cognitive Theory's proposition that behavior change results from reciprocal interactions between

personal factors, environmental influences, and behavioral patterns rather than from knowledge acquisition alone [19]. The complete mediation pattern validates the Theory of Planned Behaviour's emphasis on attitudes as a critical mediating variable between knowledge and behavior [20], suggesting that interventions must address attitudinal dimensions to effectively translate knowledge into practice. The strong knowledge-attitude relationship (β equals 0.482, p less than 0.001) combined with the strong attitude-practice relationship (β equals 0.656, p less than 0.001) indicates a sequential process whereby knowledge shapes perceptions and feelings about menstruation, which then drive behavioral implementation.

The paradoxical finding of high practice levels (79.5 percent mean score) despite low knowledge levels (54.0 percent mean score) requires careful interpretation. This pattern suggests that appropriate menstrual hygiene practices among these adolescent girls may be

driven more by social learning, observation, and culturally transmitted behavioral scripts than by explicit theoretical understanding [19]. This interpretation aligns with experiential learning theories proposing that practical skills develop through hands-on experience and social modeling rather than purely cognitive processes. The particularly high practice scores in disposal methods (80.0 percent), product selection (79.8 percent), and bathing practices (79.5 percent) may reflect habitual behaviors learned through observation and repeated practice within family and peer contexts.

The significant moderating effect of parental guidance (β equals 0.693, p equals 0.001) provides crucial insights into family dynamics as enablers of knowledge-to-practice translation [29]. Among participants with high parental guidance, knowledge showed a significant positive relationship with practices (β equals 0.428, p less than 0.001), whereas among those with low parental guidance, the relationship was weak and non-significant (β equals 0.112, p equals 0.384). This pattern indicates that parental guidance creates an enabling environment where knowledge can be effectively translated into practice, potentially through provision of resources, emotional support, practical assistance, and reinforcement of learned behaviors.

The absence of moderation effects for age (β equals 0.084, p equals 0.512) and educational level (β equals 0.126, p equals 0.318) challenges assumptions that older or more educated adolescents would better translate knowledge into practice. This finding suggests that developmental maturity and formal education do not themselves enable knowledge application in menstrual hygiene management, reinforcing the critical importance of family support systems regardless of individual demographic characteristics [29, 30]. The finding that parental guidance matters more than age or education highlights the unique role of families in health behavior development during adolescence.

The substantial knowledge deficits identified in hygiene procedures (26.7 percent), menstrual products (26.0 percent), and cycle patterns (25.0 percent) despite relatively high practice levels suggest a concerning pattern of practice without understanding [2, 8]. While these adolescent girls may be performing appropriate behaviors, they may lack the theoretical foundation necessary to adapt practices in changing circumstances or to make informed decisions about menstrual health management. This knowledge-practice disconnect underscores the need for educational interventions that not only teach proper practices but also build conceptual understanding that enables flexible application across diverse contexts [5, 6].

The attitude patterns revealed in this study offer insights into the psychological mechanisms linking knowledge to practice. The relatively high personal comfort scores (83.0 percent) combined with lower scores for cultural taboos (73.6 percent) and religious restrictions (75.9 percent) suggest that while most adolescent girls feel comfortable with their own menstrual experiences, they continue to be influenced by broader cultural and religious narratives about menstruation [12, 14, 25]. The finding that attitudes mediate the knowledge-practice relationship implies that interventions must address not only factual information but also the belief systems, emotional responses, and social perceptions that shape how adolescent girls feel about menstruation and their capacity to manage it effectively [20].

The model's explanation of 54.1 percent of variance in practices represents substantial but not complete predictive power, indicating that while knowledge, attitudes, and parental guidance are important determinants, other factors also influence menstrual hygiene practices [29, 30]. These unmeasured factors may include peer influences, school environment characteristics [26], access to menstrual products [17], quality of sanitation

facilities [6], economic constraints, male and community involvement [27], and broader community norms. Future research should examine these additional contextual factors while maintaining focus on the mediating and moderating mechanisms identified in this study.

The complete mediation pattern has important implications for intervention design, suggesting that programs focusing exclusively on knowledge transfer without addressing attitudes may have limited effectiveness in changing practices [20, 24]. Effective interventions should explicitly target attitude formation through approaches such as experiential learning activities, peer discussions, positive messaging about menstruation, and strategies to counter cultural stigma and misconceptions [5, 12]. The critical moderating role of parental guidance suggests that family-centered interventions engaging parents alongside adolescents may be more effective than school-based programs targeting students alone [29, 30].

These findings have broader theoretical implications for health behavior models in culturally sensitive health domains. The complete mediation pattern challenges simplistic linear models assuming direct knowledge-to-behavior translation and validates more complex frameworks emphasizing cognitive, affective, and social mediating mechanisms [19, 20]. The significant moderation by parental guidance but not by age or education highlights the importance of contextual and relational factors over individual demographic characteristics in enabling health behavior change during adolescence.

Study limitations include the cross-sectional design preventing causal inference about temporal relationships between knowledge, attitudes, and practices. While structural equation modeling tests hypothesized directional relationships [22], longitudinal studies tracking changes in knowledge, attitudes, and practices over time would provide stronger evidence for causal mechanisms. The

urban focus limits generalizability to rural populations where cultural influences and resource availability may differ substantially [13, 14]. Self-reported data on sensitive topics may be subject to social desirability bias despite anonymous survey administration. Future research should employ longitudinal designs, include rural populations, incorporate observational validation of reported practices, and test theory-driven interventions targeting the mediating and moderating mechanisms identified in this study.

Conclusion

This study demonstrates that attitudes completely mediate the knowledge-practice relationship in adolescent menstrual hygiene management, while parental guidance significantly moderates this relationship. The findings challenge traditional knowledge-deficit models and validate Social Cognitive Theory [19] and Theory of Planned Behaviour [20] frameworks emphasizing attitudinal and contextual factors in health behavior. Knowledge influences practices entirely through its effect on attitudes rather than through any direct pathway, indicating that interventions must address both cognitive and affective dimensions to be effective. Parental guidance creates enabling environments where knowledge can be translated into practice, suggesting that family-centered interventions may be more effective than individual-focused programs [29, 30]. The high practice levels despite low knowledge scores indicate that adolescent girls may be performing appropriate behaviors through social learning without deep theoretical understanding, highlighting the need for educational approaches that build both practical skills and conceptual foundations [5, 6, 19]. These insights support development of comprehensive interventions addressing attitude formation, family engagement, and environmental support systems rather than isolated knowledge transfer for improving

adolescent menstrual health management in urban Ghana and similar contexts.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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Ethical Approval

Ethical approval for this study was granted by the Institutional Review Board of Texila American University. All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. Parental consent was obtained for participants under 18

years of age, and participants aged 18–19 years provided their own informed consent. All participants provided assent regardless of age, and participation was entirely voluntary.

Data Availability

The datasets generated and analysed during the current study are not publicly available due to confidentiality and privacy obligations to the study participants. However, the data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions

All authors contributed equally to this work. All authors have read and approved the final version of the manuscript.

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A Desk Review of Standard Operating Procedures of Ethics Committees in the Philippines on the Review of Clinical Trial Protocol Deviations

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Abstract

The review of post-approval submissions such as clinical trial protocol deviations (PDs) is a key function of Ethics Committees (ECs) to ensure data integrity and participant safety. However, the quality of PD management by ECs depends on the SOPs that are anchored in national and international guidelines. This desk review aimed to analyze the SOPs of Level III-accredited ECs in the Philippines in terms of protocol deviation management. From July to September 2025, SOPs of ECs were obtained from institutional websites and through web searches. The SOPs were then compared with recommendations by the Philippine Health Research Board SOP workbook for the presence or absence of the following: (a) policy statement; (b) objectives; (c) scope; and (d) work flow; (e) definition of protocol deviation (PD) or protocol violation (PV); and determine the (f) required timeline for submission to EC; (g) EC processing time; and (h) type of review for the noncompliance. A total of 28 SOPs were reviewed. The results revealed that while most institutional SOPs follow PHREB recommendations, ECs operationalize PD review differently. Key SOP provisions, such as the definition of PD/PV, timelines for reporting, processing time, and the type of review, can affect the quality of EC review and resolution of clinical trial noncompliance. Future research should extend beyond document analysis to investigate the practical implementation of SOP provisions regarding protocol deviation management.

Keywords: *Clinical Trial, Ethics Committees, Philippines, Protocol Deviation, Standard Operating Procedures.*

Introduction

A protocol deviation (PD) is any alteration, variation, or departure from the study design or procedures outlined in the approved protocol [1-3]. Protocol deviations are frequently observed in clinical trials and can substantially affect the quality and integrity of the study data. Noncompliance with the approved protocol can come from the research participants, the sponsor, or the investigational team [4, 5].

Protocol deviations are usually classified as minor or major depending on their possible impact on patient safety, research integrity, and

data quality [4]. While minor deviations usually concern administrative or procedural concerns that are less significant, major deviations are commonly described as those that can compromise the scientific integrity of the data or threaten the safety of the participants. The terms “non-important” and “important” protocol deviations are used interchangeably for departure from the protocol that is considered minor or major respectively [5]. In addition, important protocol deviations are sometimes used interchangeably with protocol violations, which, as per International Council for Harmonisation (ICH) E3 annex IV a refers

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to deviations that result in the withdrawal of a subject from trial participation whether this is incurred by the investigator or the subject [2].

Maintaining regulatory compliance, guaranteeing data integrity, and preserving participant safety all depend on accurately reporting protocol deviations. Regulatory bodies including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) require sponsors and researchers to document and disclose deviations depending on their severity. The US Food and Drug Administration and the European Medicines Agency (EMA) mandate that sponsors of clinical trials report "serious" or "persistent" deviations impacting participant welfare or data integrity [6, 7]. On the other hand, ICH-Good Clinical Practice (GCP) E6 and the WHO GCP handbook clearly define the responsibilities of sponsors, investigators, and ethics committees (ECs) in handling protocol deviations. The sponsor is responsible for determining the trial-specific criteria for important deviations, and appropriate actions, including risk management and reporting to the ethics committee and/or regulatory authority. The investigator on the other hand is responsible for documenting all protocol deviations incurred at the clinical trial site and communicating them to the sponsor. Protocol deviations classified as "important" should be investigated and explained, and when warranted, a corrective action and preventive action (CAPA) should be implemented to prevent their recurrence. The investigator is expected to notify the sponsor, the ethics committee, and/or the regulatory authorities promptly, especially for deviations that are committed to eliminate any imminent danger to study participants. The responsibility for the review and approval of the protocol deviations submitted by the sponsor or investigator lies with the ethics committees [1, 8].

Institutionalization of formal ethics review processes commenced in the Philippines throughout the late 20th century. Established in

1987 under the Department of Science and Technology (DOST), the Philippine Council for Health Research and Development (PCHRD) aims to advance ethical health research. One of its goals was to establish research ethics committees (RECs) nationwide [9]. The Philippine Health Research Ethics Board (PHREB) was officially founded in 2006 under the Philippine Council for Health Research and Development (PCHRD), a Department of Science and Technology (DOST) agency, with assistance from the Department of Health (DOH) and the University of the Philippines Manila. The establishment was prompted by a series of consultative workshops with ethicists, researchers, and politicians, who acknowledged the necessity to align local practices with worldwide standards such as ICH GCP and to solve ethical gaps identified by multinational trials (e.g., early HIV studies). PHREB's role encompassed the formulation of national ethical principles, the accreditation of Ethics Committees, and the promotion of capacity-building, as formalized in the National Ethical principles for Health Research published in 2006. The rules outlined seven ethical principles—scientific validity, equitable subject selection, risk-benefit analysis, informed consent, independent review, respect for participants, and social value—establishing a framework for ethics committee operations countrywide [10].

As of 2025, there are 97 PHREB accredited ECs in the Philippines, 45 are Level III, 30 are level II, and 22 are level I. Of the 45 level 3-accredited ECs, majority are concentrated in the National Capital Region (NCR), and others are from Region I, III, IV, V, VI, VII, IX, and XI [11]. PHREB Level III accreditation represents the highest level of recognition awarded to Research Ethics Committees (RECs) in the Philippines, allowing them to evaluate all categories of research, encompassing clinical trials (Phases 1–4) and studies necessary for Food and Drug Administration (FDA) registration.

Although these national guidelines establish a cohesive policy framework, individual RECs possess flexibility to develop their internal SOPs to accommodate institutional contexts. This versatility may lead to inconsistencies in the definitions, classifications, reporting timelines, and review processes for protocol deviations. To date, no studies were done to evaluate how RECs in the Philippines align with the PHREB in terms of protocol deviation review and management.

This desk review aim to analyze the Standard Operating Procedures (SOPs) of PHREB-accredited Research Ethics Committees (RECs) in the Philippines, concentrating on the management of protocol noncompliance reports. The findings are anticipated to guide the future standardization of REC processes and enhance ethical supervision systems within the country.

Materials and Methods

This study utilized a desk review methodology, conducting a documentary analysis of publicly accessible Standard Operating Procedures (SOPs) from PHREB-accredited Research Ethics Committees (RECs) in the Philippines involved in the review of clinical trials.

From July to September 2025, a thorough search was conducted on the websites and institutional portals of all PHREB-registered Research Ethics Committees (RECs). Search criteria encompassed "Standard Operating Procedures," "SOP manual," "ethics committee," and "protocol deviations." Further inquiries were conducted on the PHREB, and institutional or university ethics committee websites. SOPs were obtained in PDF or Word format, and the institutional name, and version date, were documented. Cross-referencing was

conducted using PHREB's official registry of accredited RECs.

Criteria for Eligibility

Documents were included if they:

1. Are Standard Operating Procedures of a Level III PHREB-accredited Research Ethics Committees.
2. Include protocol non-compliance report management.
3. Had identifiable version or revision dates.

Documents were excluded if they:

1. Are not accessible (e.g., institutional log-in credentials are needed).
2. Not finalized (i.e., no effective date).

Data Extraction and Analysis

A structured data extraction form was created to capture the SOP version, effectivity date, the SOP's policy statement, objective, scope, workflow, PD and PV definition, timelines for submission of non-compliance report, processing timeline, and type of review. The PHREB SOP workbook [12] is used as comparison for the SOP elements analyzed in this review. To maintain the confidentiality of the ECs, their names were replaced with code numbers.

Results

As of August 2025, the PHREB listed a total of 44 Level III-accredited RECs. Of them, 29 (about 65%) had publicly accessible Standard Operating Procedures posted on institutional websites. Following the screening process, 28 Standard Operating Procedures (SOPs) satisfied the inclusion criteria, with specific sections on the management or evaluation of protocol non-compliance (Fig 1).

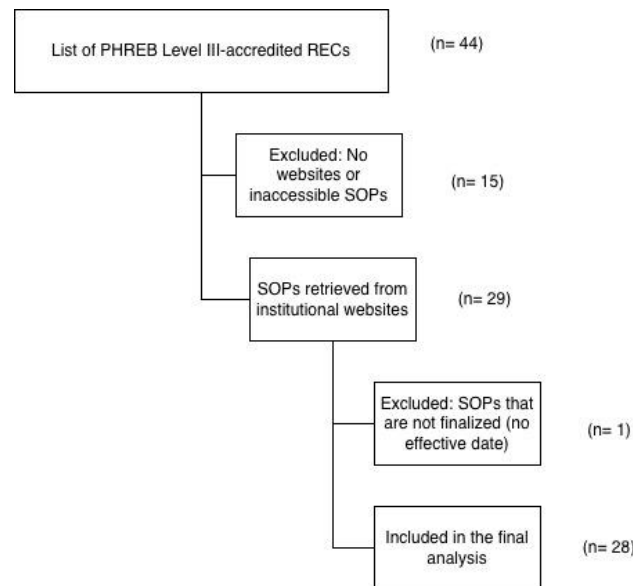


Figure. 1. PRISMA-Like Flow Chart for SOP Selection

The summary of the twenty-eight SOPs on the review of protocol deviation is summarized Table 1. The ECs included in the desk review are from the Cordillera Autonomous Region (1); National Capital Region (18); Bicol Region (1); Central Visayas (3); Eastern Visayas (1); Western Visayas (1); and Davao Region (3). The SOP versions ranges from 1-12 and their effectivity dates ranges from 2017 to 2024.

The Philippine Research Health Research Ethics Board (PHREB) SOP Workbook [12] was used as a reference for comparing the process of each EC's SOP in terms protocol deviation and violation report management. Table 2 presents the items that are present or absent in the ethics committees' SOPs. The PHREB prescribed the PD SOP format, containing a policy statement, objective of the activity, scope, workflow, and terms to be defined for effective SOP implementation. The workflow contains 7 steps: Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database; Step 2 - Retrieval of pertinent protocol file; Step 3 - Notification of Chair and primary reviewers; Step 4 - Determination of type of review; Step 5 - Inclusion of report in the agenda of the next REC regular meeting; Step 6 - Communication of Decision to the Principal Investigator/researcher; and Step 7 - Filing of

all related documents and update of the protocol database.

Majority (22) of the ECs have a policy statement, except for 6 ECs (7, 22, 30, 38, 39,42). Of those having a policy statement, compliance with ICH-GCP and the National Ethical Guidelines were adhered to. However, almost all of the ECs did not specified whether the policy covers investigator-initiated studies (or non-clinical trials) or industry-sponsored trials, except for 2 ECs (10, 35).

Twenty-five ECs have included an objective or purpose section in their SOPs. The common statement is that the SOP's objective is to describe the PD review process and its commitment to protecting the research participant's rights, safety, and well-being, and ensuring data credibility and integrity.

Only 1 EC (43) did not included a scope section. For the 27 ECs that have a scope, the statements include: (a) it applies to previously-approved studies; and (b) the beginning and the end of the process that applies to those who submit the report and those that are involved in the PD management. In addition, 11 ECs (6, 7, 8, 13, 16, 27, 29, 30, 37, 40, 44) have included that the scope of reporting of PDs also include (a) failure to comply with national or international guidelines and (b) failure to respond to IRB reporting timelines or requests.

As for the workflow, 6 ECs (1, 8, 12, 20, 33, 44) have SOPs aligned with the PHREB's 7 steps. Twenty-two ECs (6, 7, 12, 15, 16, 17, 21, 25, 26, 27, 29, 30, 31, 34, 35, 37, 38, 39, 40, 42, 43, 44) have 6 steps, omitting step 2 (retrieval of protocol file). A total of 7 ECs (13, 15, 34, 37, 39, 43, 44) have 5 steps that omitted step 3 in addition to other steps. Only 4 ECs (6, 16, 27, 34) did not include step 4 in their workflow and 1 EC (37) did not include step 5 in their workflow. All 27 ECs have included step 5 in

their workflow and only 3 ECs (22, 25, 28) did not have step 6.

There are 3 ECs that have more than 7 steps in their workflow. EC #10 added a step of discussing the major PD or PVs. EC #37 also have an extra step after filing of documents, which is follow-up on the PDs that ECs recommended further action. EC #40 has 10 steps- the 3 extra steps are: (1) PI submission of the report; (2) Review of the primary reviewer; and (3) Review of the EC chair on the recommendation of the primary reviewer.

Table 1. Summary of Identified EC SOPs on the Review of Protocol Deviations

EC Code	Region	SOP Version	Effective Date
33	National Capital Region (NCR)	1	2023
1	Cordillera Autonomous Region (CAR)	5	2022
6	Bicol (V)	5	2023
34	National Capital Region (NCR)	4	2018
8	Central Visayas (VII)	3	2023
29	National Capital Region (NCR)	6	2020
16	Davao (XI)	5	2023
25	National Capital Region (NCR)	1	2021
27	National Capital Region (NCR)	6	2023
13	Eastern Visayas (VIII)	7	2023
43	National Capital Region (NCR)	4	2022
10	Central Visayas (VII)	5	2023
44	National Capital Region (NCR)	5	2022
37	National Capital Region (NCR)	6	2020
15	Davao (XI)	6	2024
40	National Capital Region (NCR)	5	2022
12	Central Visayas (VII)	6	2018
26	National Capital Region (NCR)	4	2021
30	National Capital Region (NCR)	12	2024
35	National Capital Region (NCR)	6	2023
17	Davao (XI)	2	2017
38	National Capital Region (NCR)	2	2024
22	National Capital Region (NCR)	6	2022
31	National Capital Region (NCR)	6	2022
20	National Capital Region (NCR)	5	2022
39	National Capital Region (NCR)	6	2023
42	National Capital Region (NCR)	7	2022
7	Western Visayas (VI)	3	2021

Table 2. Comparison of Level III EC SOPs Contents vs. PHREB SOP Workbook on PD/PV Report Management

				Workflow						
EC Code	Policy Statement	Objective	Scope	Receipt & documentation	Retrieval of protocol file	Chair/ reviewer Notification	Determination of type of review	Inclusion in regular meeting	Communication of decision	Filing
33	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
1	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
6	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
34	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
8	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
29	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
16	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
25	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
27	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
13	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
43	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
10	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
44	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
37	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
15	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
40	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
12	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
26	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒

30	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
35	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
17	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
38	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
22	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
31	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
20	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
39	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
42	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
7	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒

The PHREB defines protocol deviation as non-compliance that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety, and well-being or integrity of data. Conversely, a protocol violation increases the risk or decreases the benefit to participants that consequently impact participants' rights, safety,

and well-being or integrity of data [12]. Although there is no prescribed timeline for submission and processing of non-compliance reports as well as for type of review depending on the classification of non-compliance, the reviewed SOPs revealed varying turnaround time for submission, processing and type of EC review. These are summarized in Table 3.

Table 3. Comparison of Non-Compliance Definition, Prescribed Timeline for Submission, Processing Time, and Type of EC Review

EC Code	Adapted PD Definition?	Adapted PV Definition?	Timeline for submitting non-compliance report	EC Processing of reports (working days)	Non-compliance discussed at full board meeting?
33	☐	☐	7 calendar days from detection	NS	Both minor and major PD
1	☒	☒	Within a week of the event	30	Major PD/PV only
6	☐	☐	NS	14	Major PD/PV only
34	ND	ND	NS	NS	Only when raised by PR
8	ND	ND	Within a week of the event	14-16	Major PD only
29	☐	☐	NS	NS	Major PD/PV only
16	☒	☒	NS	NS	PV only
25	☐	☐	NS	NS	Major PD/PV only
27	☐	☐	NS	14	PV only
13	☐	☐	Within a week of the event	NS	Major PD only
43	☐	☐	At the soonest time	NS	Major PD only
10	☐	☐	Within a week from detection	21	Major PD only
44	☐	☐	At the soonest time up to 6 months after the event	14	Major PD only
37	ND	ND	Within 2 months upon recognition of the PI	NS	Both PD and PV
15	☐	☐	At the soonest time, within a month from event detection	42	Both PD and PV
40	☐	☐	7-14 days from detection	19-30	Both PD and PV
12	☒	☒	NS	NS	PV only
26	☐	☐	Within 14 days of awareness	NS	Major PD/PV only
30	☐	☐	NS	14	Both minor PD and major PV

35	☒	☒	Within 5 days of awareness (PD) Within 10 days of awareness (PV)	12-28	Both PD and PV
17	☒	☒	NS	NS	Both PD and PV
38	☒	☒	NS	NS	Both minor and major violation
22	☒	☒	NS	NS	PV only
31	☒	☒	Within 1 week from detection	NS	Major PD only
20	☒	☒	Within 1 week from detection	NS	Major PD only
39	ND	ND	At the soonest time up to 6 months after the event	NS	All non-compliance
42	☒	☒	At the soonest time up to 6 months after the event; Within 48 hours if PD resulted in SAE	NS	All non-compliance
7	☒	☒	NS	14	PV only

Legend: ND- Not defined; NS- Not specified; PD- Protocol deviation; PV- Protocol violation; SAE- Serious Adverse Events.

Out of 27 ECs, only 8 (1, 12, 16, 17, 20, 22, 31, 35) adapted the PHREB definition of protocol deviation and protocol violation. Sixteen ECs (6, 7, 10, 13, 15, 27, 26, 29, 30, 25, 33, 38, 40, 42, 43, 44) defined “minor protocol deviation” as the equivalent of protocol deviation, and “major protocol deviation” as the equivalent of protocol violation. Four ECs (8, 34, 37, 39) did not define protocol deviation or violation in their SOP.

The ECs have varying timelines for the submission of protocol non-compliance reports from investigators. EC #43 recommended reporting variances at the soonest time. Seven ECs (1, 8, 33, 10, 13, 20, 31) prescribed submitting within 1 week from the detection of the non-compliance, while 2 ECs (26, 40) requires 14 days from the recognition of PDs. EC #35 specified submission of PDs within 5 days of awareness, and within 10 days of awareness for PVs. Other ECs have broader timelines- EC #15 specified reporting PDs at the soonest time up to a month from event

detection, while EC #44, #39, and #42 allows up to 6 months. EC #42 added a 48-hour timeline for submission of PD if it resulted to an SAE. Twelve ECs (6, 7, 12, 16, 17, 22, 25, 27, 29, 30, 34, 38) did not specified a timeline in their SOP.

The turnaround time for processing the reports from receiving until filing of documents varies from one EC to another. These ranges from 12-42 working days. Seventeen out of 28 ECs (12, 13, 16, 17, 20, 22, 25, 26, 29, 31, 33, 34, 37, 38, 39, 42, 43) did not specified their processing time.

In the determination of type of review, while PHREB did not strictly stated which type is applied to a particular non-compliance, the ECs have varying decision when it comes to identifying which NC will undergo full board discussion or expedited review. Ten ECs (15, 17, 30, 33, 35, 37, 38, 39, 40, 42) applied full-board review regardless of the type of non-compliance (minor/major or deviation/violation). Seventeen ECs (1, 6, 7, 8,

10, 12, 13, 16, 20, 22, 25, 26, 27, 29, 31, 43, 44) stated in their SOP that only “major PDs” or “protocol violations” will be discussed during full board meeting, while EC #34 indicated that the NC will only be discussed during full board meeting only when raised by the primary reviewer.

Discussion

This desk review examined Philippine Research Ethics Committees (RECs) publicly available Standard Operating Procedures (SOPs) for reviewing clinical trial protocol deviations and their consistency with the PHREB SOP Workbook. The data show that while most institutional SOPs follow PHREB recommendations, RECs operationalize protocol deviation review differently. The PHREB SOP Workbook requires RECs to have clear, written protocols for continuous review, including protocol deviations and non-compliance receipt, assessment, and documentation. This study found that all SOPs required investigators to report protocol noncompliance and RECs to process these submissions in accordance with regulatory requirements, thus meeting PHREB's recommendations.

However, alignment was often incomplete. The PHREB SOP Workbook contains model language and examples for handling deviations, although many institutional SOPs did not adopt them. Only several SOPs clearly differentiated minor and major protocol deviations or indicated escalation procedures (e.g., chair-level review versus full-board review). The REC may struggle to apply consistent, risk-proportionate oversight, a principle implied in PHREB guidance on continuing review.

To the knowledge of the researcher, there are no studies done locally that systematically analyze REC SOPs on protocol deviation management, but this desk review confirms PHREB regional assessments and capacity-building workshops that found SOP content and

procedural clarity vary across institutions [13-15].

The differences in the required time for reporting and the time it takes to process the PD reports affect to how site issues especially those that impact data quality and participant safety are resolved. If the noncompliance report is major, and this is only reported after a month or in the case of some ECs, until 6 months after the event, while the EC will take a month on average to process the submission, this would mean a missed opportunity to promptly act on a deviation. In addition, if this affected several trial participants, the noncompliance is perpetuated until the PI or the monitor becomes aware of it thus delaying appropriate actions resolve and prevent future PD occurrence. While it is impossible for ECs to proactively detect PDs, it is expected that PIs report protocol noncompliance to ECs as per national [16, 17] and international guidelines [1, 7].

There are no local studies that focused on EC processing of PD reports, but the findings of Halwai and Vaswani on Indian ECs suggest that PD management is challenging because PIs do not report PDs or they do not accept PDs, and that there is no clear SOP [18]. In clinical trials or any other research, reducing protocol noncompliance and their impact is important, and this necessitates joint efforts of the PIs and ECs to establish clear guidelines for reporting and managing PDs [19]. Furthermore, in the process of protocol management by ECs, resolving and filing PD reports should not be the final steps. In this study, no local ECs have mentioned in their SOP regarding regular reviews on the reports of protocol noncompliance, including the effectiveness of CAPAs unlike in other ECs abroad. This is an important addition EC SOPs to improve the quality of reviews as well as to serve as basis for training for both EC members and investigators in light of ensuring high quality conduct of clinical trials [19-21].

This strength of the study lies in its systematic desk evaluation of publicly available

Standard Operating Procedures (SOPs) from PHREB-accredited Research Ethics Committees, which objectively evaluates protocol deviation review formal procedural advice. Anchoring the analysis on the PHREB SOP Workbook improves its relevance to national ethical governance and EC accreditation. However, the study is constrained by its dependence on publicly available documents, which may not reflect internal revisions or supplementary procedures. Furthermore, the study did not investigate actual SOP implementation to give further meaning to the analysis of SOPs.

Conclusion

Ethics Committees play a vital role in promoting clinical trial data integrity and participant safety not only through reviewing initial submissions but also on post-approval submissions such as protocol noncompliance reports. Standard Operating Procedures on PD management guide ECs in providing timely, consistent, and appropriate recommendations to site PIs. Inconsistencies or partial alignment of SOPs across PHREB accredited level III ECs in the country with the PHREB SOP workbook such as workflow, definitions of PD/PV, required timelines for reporting, including turnaround time for processing, and type of review can affect the overall quality of review and resolution of noncompliance at trial sites.

Future research should extend beyond document analysis to investigate the practical implementation of SOP provisions regarding protocol deviation management. Mixed-method techniques that integrate REC interviews, meeting minutes, and case reviews may yield deeper understanding of the EC processes and the consistency of their application. Analysis of PHREB accreditation results with emphasis on PD management can also shed light regarding SOP implementation, including the challenges that ECs encounter in ensuring quality reviews and efficient process.

This research can enhance current findings and bolster evidence-based improvements in national guidelines, especially in terms EC accreditation and REC capacity-building efforts.

Conflict of Interest

Nil.

Ethical Approval

This research was submitted to the University of the Philippines Manila Research Ethics Board and was granted ethical clearance (UPMREB 2025-0500-EX) prior to its implementation.

Data Availability

The SOPs analyzed in this study are publicly available in the websites of the Ethics Committees, with some available via web search. The names of the ECs were intentionally coded to protect the identity of the ECs, but the list of Level III-accredited ECs can be found in the PHREB Website (<https://ethics-accreditation.healthresearch.ph/accredited-rec/3/4>) and the compiled data set are available upon reasonable request from the author.

Author Contributions

The author is responsible for the conceptualization and implementation of the research, up to the writing of the publication manuscript.

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Chemical Addiction in Intimate Relationships: The Neurobiology of Trauma Bonding and Emotional Dependency

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Abstract

The neurobiological reinforcement of trauma bonding and emotional dependency in intimate relationships is increasingly being understood as a process, as opposed to a purely psychological pattern. This review integrates evidence on fifteen peer-reviewed articles to investigate the interaction between dopaminergic reward systems, oxytocin-mediated bonding systems, cortisol-induced stress responses, and reinforcement-learning processes to maintain maladaptive attachment despite the occurrence of relational inconsistency, conflict cycles, or intermittent affection. The key goal was to combine the results of addiction neuroscience, attachment theory, and trauma psychology to have a single explanation of the continuity of the emotionally dysregulated relational bonds. Five major databases were searched in a structured literature search, and 612 records were located; 15 records were included in the study that was analyzed using thematic synthesis based on reward processing, attachment neuropeptides, HPA-axis regulation and cognitive-emotional conditioning. Findings indicate that trauma bonding is the result of a vicious cycle of increased dopamine-based reward sensitivity, oxytocin-based trust and emotional proximity, cortisol-related hyperarousal, and attachment-based cognitive distortions. These interdependent systems produce the addiction-like patterns of stress, relief and reconnection that strengthen emotional dependence in spite of misery. The review finds that trauma bonding is a neurobiological phenomenon that is multisystemic and needs to be addressed with trauma-informed and neurobiologically oriented therapy in order to be effectively treated. More studies are required to develop specific clinical resources and models that would help to overcome these complicated relational dynamics.

Keywords: *Cortisol Stress Physiology, Emotional Dependency, Intermittent Reinforcement, Oxytocin and Attachment, Reward Neurocircuitry, Trauma Bonding.*

Introduction

Emotional dependency and trauma bonding in intimate relationships have become a more and more discussed topic in the fields of neuroscience, psychology and relationship research. Trauma bonding refers to inertial emotional bonding which is established between people who undergo the relationship of affection and abuse, developing a paradoxical yet strong bond by a neurobiological reinforcement and psychological conditioning.

It was originally coined by Dutton and Painter who showed that intermittent reward and punishment in intimate relationships reinforced and did not undermine attachments but worked in much the same way as classical conditioning paradigms of addiction [1]. This idea has been extended in later studies demonstrating that the process of trauma bonding uses neural mechanisms similar to those of chemical dependency, including dysregulation in the dopamine reward system, oxytocin-stimulated attachment systems, cortisol-stress responses,

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and ineffective prefrontal regulation [2, 3]. Trauma bonding neurobiology resembles those of substance and behavioral addictions. Intermittent reward one of the cycles of unpredictable affection, reconciliation, conflict, or neglect triggers mesolimbic dopamine circuits, especially the ventral tegmental area (VTA) and the nucleus accumbens, producing strong emotional highs when relationships are good [4]. Relief, reunion, or intermittent affection is correlated with dopamine surges that enhance relational seeking behavior and generate reinforcement schedules that are more powerful than regular reward schedules. The reward prediction error theory by Schultz shows that unpredictable reward causes greater phasic dopamine release than predictable reward and therefore variable reinforcement is more addictive by nature [5]. This is translated to a stronger attachment even in a distressing relationship in intimate relationships. Oxytocin and vasopressin also have a significant role to play in the maintenance of emotional dependency. The so-called bonding hormone, oxytocin, is secreted during physical contact, intimacy, and emotional proximity which facilitates the development of trust, attachment, and positive memory bias even in destructive situations [6]. Young and colleagues conducted animal studies, which revealed that pair bonding was caused by oxytocin and vasopressin receptor activation which enabled the formation of social memory and partner preference and was not influenced by the quality of relationships [7]. Human experiments also indicate that oxytocin is capable of increasing bonding with inconsistent or ambivalent partners, which increases persistence in attachment [8]. Meanwhile, the chronic relational stress triggers the hypothalamic-pituitary-adrenal (HPA) axis and increases the levels of cortisol. Repeated HPA stimulation impairs the prefrontal cortex, which is the brain part that makes judgment, controls impulses and makes long-term decisions, and enhances the amygdala-based emotional

conditioning [9]. This loop of physiological mechanisms strengthens the state of dependency by causing the feeling of detachment to be threatening and physiologically unstable. In his stress neurobiology work, Yehuda highlights that chronic relational stress may also cause neuroadaptations in trauma survivors, such as increased fear reactions, emotional instability and poor cognitive regulation [10]. Trauma-bonded individuals tend to exhibit withdrawal-like symptoms when not with their partner such as anxiety, cravings, rumination, irritability and distress, similar to the patterns observed in opioid or stimulant withdrawal syndromes [11]. Neuroimaging has demonstrated that the anterior cingulate cortex, insula and nucleus accumbens overlap during the time when individuals are looking at pictures of desired partners and when drug-dependent individuals are looking at drug stimuli, indicating that there is similar motivational and craving circuitry [12]. Emotional attachment, therefore, is neurochemically combined with addiction pathways. It has been widely known that intermittent reinforcement is one of the most powerful schedules of behavioral conditioning in the generation of compulsive behavior. Variable-ratio reinforcement as illustrated in the original research of Ferster and Skinner generates long-lasting behavioral responding with slow extinction rates [13]. The pattern of affection and neglect or conflict makes a strong pattern of reward-seeking when plotted over intimate relationships. The feelings of euphoria that come along with reconciliation or the occasional instances of affection strengthen attachment in a greater way than consistent, consistent love. This is further compounded with cognitive distortions like idealization, underestimation of harm and selective memory that are further cemented by neurochemical surges when the individuals are on the positive relational episodes [14]. Attachment theory offers an opposing theory of trauma bonding vulnerability. Anxious or disorganized

attachment styles make people more sensitive to relational inconsistency, which causes overreacting emotionally, dependency, and failure to disengage with volatile partners [15]. It has been demonstrated in the research of functional MRI that insecurely attached people exhibit a higher amygdala activity and less control of the prefrontal cortex in times of relational conflict, and consequently, they are more vulnerable to the stress-reward loop that supports trauma attachment [16]. These patterns may also be exacerbated by early trauma or unreliable caregiving as childhood adversity has been demonstrated to modify the behavior of the HPA axis and reward circuits, which generates a lifetime vulnerability to emotionally dysregulated relationships [17]. Notably, trauma bondage does not presuppose blatant physical assault. The same addictive neurobiological loops can also be obtained through emotional neglect, persistent inconsistency, volatility in relationships and ambivalent communication patterns. According to studies by Freyd, such as, trauma of betrayal in which a trusted partner periodically abandons emotional need may produce a strong internal strife and dependence due to cognitive dissonance and attachment survival strategies [18]. The emotional dependency in itself can serve to keep the physiological stress levels high, ensuring that cortisol is kept up and the cycle is perpetuated regardless of the severity of the relationship [19].

It is important to comprehend trauma bonding in a neurobiological perspective. Conventional talk therapy has been found inadequate to deal with neurochemical mechanisms of attachment persistence. Recent research indicates that trauma-informed interventions, including trauma-focused cognitive behavioral therapy (TF-CBT), eye movement desensitization and reprocessing (EMDR), and somatic therapies, have a greater capacity to break the cycles of trauma-bonds in the intervention of both cognitive and physiological mechanisms [20]. Also,

neurobiological psychoeducation was found to enhance self-awareness, self-blame, as well as treatment engagement in people with emotional dependency [21].

Regardless of the increasing research interest, the neurobiology of trauma bonding is still distributed throughout the literatures of addiction neuroscience, attachment theory, trauma studies, and relationship psychology. These multidisciplinary findings require integrative reviews to bring them together in a unified framework. Consequently, the neurobiological basis of trauma bonding and emotional dependency is reviewed and the evidence on the neurobiological basis of dopamine reward pathways, oxytocin-mediated bonding, cortisol stress responses, attachment patterns, and psychological conditioning synthesized. The goal is to develop a common scientific concept of relationship-based addictive processes and serve as a solid base of future studies and practice.

Materials and Methods

The review article was carried out using a systematic and structured method in line with well-known guidelines regarding narrative and evidence-synthesis reviews. The methodology was planned in a way that it would cover peer-reviewed literature on the topic of trauma bonding, emotional dependency, neurobiology of addiction, and associated interpersonal dynamics comprehensively.

Search Strategy

The literature search was performed using PubMed, PsycINFO, Scopus, Google Scholar, and ScienceDirect. Additional relevant studies were also obtained through manual searches of reference lists. Keywords were used together with Boolean operators and incorporated the ideas of trauma bonding, emotional dependency, intermittent reinforcement, relationship addiction, dopamine reward system, oxytocin bonding, cortisol stress response, attachment insecurity, intimate

partner dynamics, and neurobiology of relationships. The process was guided by systematic review procedures to increase transparency and reproducibility, which is in line with the methods outlined by Grant and Booth [22] and Siddaway et al. [23].

Inclusion and Exclusion Criteria

The inclusion criteria were that the studies had to be peer reviewed articles published between 1993 and 2025 and focused on the neurobiology of attachment, reward pathway mechanisms, stress responses involving the HPA axis, psychological trauma or relational abuse and intermittent reinforcement models. The eligible empirical studies used neuroimaging methods like fMRI or PET, hormonal measurements of oxytocin or cortisol, behavioral studies, or clinical and observational studies. Review articles that were synthesizing of relevant neurobiological or psychological

mechanisms were also taken into account, so long as they were written in English. Sources that were excluded included non peer reviewed sources, opinion pieces, blogs, studies that only examined child parent bonding and not the adult relational relevance, articles that did not identify the mechanisms, conference abstracts that did not have access to the full text.

Study Selection Process

The process of selection was in a number of stages. To begin with, the relevance of 612 identified records was filtered by titles and abstracts. Lastly, 15 articles met all inclusion criteria and were included in the synthesis. To have a clear methodology, this process was informed by the Preferred Reporting Items for Systematic Reviews framework that is modified to suit narrative reviews, as defined by Page et al. [24]. The entire process is explained in figure 1 below.

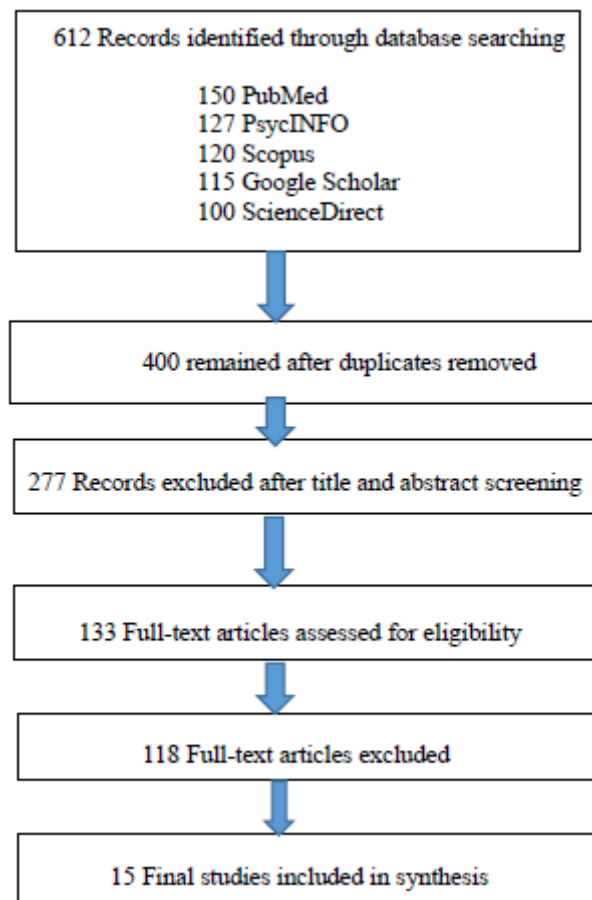


Figure 1. Flow Diagram of the Study Screening and Selection Process

Data Synthesis and Extraction

The process shown in Figure 1. was used to extract data on study design, sample characteristics, neurobiological results including dopamine activity, oxytocin response, and cortisol levels, psychological processes, including attachment styles and patterns of reinforcement, clinical implications, and limitations reported. The information extracted was synthesized thematically in four areas; dopaminergic reward processing, oxytocin related attachment circuitry, cortisol and HPA axis regulation and psychological conditioning mechanisms in relationships. This method of thematic synthesis is in line with the

principles of narrative synthesis suggested by Popay et al. [25].

Results

Table 1 below shows a total of 15 studies that met the inclusion criteria and were synthesized according to neurobiological, psychological, and behavioral domains relevant to trauma bonding and emotional dependency. These studies collectively demonstrate that trauma bonding is sustained by interconnected mechanisms involving reward circuitry activation, attachment neuropeptide modulation, stress-response dysregulation, and reinforcement learning processes.

Table 1. Formative Testing Studies and Results

Title	Author(s)	Year	Objectives	Methodology	Participants	Results	Conclusion
Romantic Love: An fMRI Study of a Neural Mechanism for Mate Choice	Fisher, Aron & Brown	2005	Examine brain regions involved in early romantic attachment	fMRI neuroimaging	17 adults in early romantic love	Activation found in the ventral tegmental area and caudate nucleus, mirroring neural firing patterns observed in stimulant addiction. Dopaminergic surges were strongest when participants viewed their partner's image, suggesting a motivational drive and craving component similar to substance dependence.	Romantic attachment recruits neural circuits governing reward, motivation, and craving, supporting the conceptualization of intense relational attachment as an addiction-like state.

The Neural Basis of Romantic Love	Bartels & Zeki	2000	Identify neural correlates of intense romantic attachment	fMRI	11 adults	Showed deactivation of brain regions associated with judgment and negative emotion (e.g., amygdala, frontal cortex). Reward-circuit activation dominated, explaining why individuals overlook negative behaviors in partners.	Romantic love selectively amplifies reward pathways while dampening critical-evaluation regions, contributing to emotional dependency and impaired relational judgment.
Predictive Reward Signal of Dopamine Neurons	Schultz	1998	Examine dopamine firing under unpredictable reinforcement	Neurophysiology study	Non-human primates	Demonstrated that unexpected rewards generated the highest dopamine spikes. Behavior became conditioned to seek unpredictable rewards, resisting extinction even after reinforcement stopped—mirroring trauma-bond cycles.	Intermittent reinforcement—common in unstable relationships—produces stronger neurochemical learning than consistent reward, reinforcing compulsive attachment behaviors.
Oxytocin Increases Trust in Humans	Kosfeld et al.	2005	Assess oxytocin's influence on trust	Double-blind RCT	128 adults	Participants given oxytocin took significantly higher interpersonal risks, trusting	Oxytocin chemically amplifies trust and closeness, explaining persistent loyalty in harmful or inconsistent relationships where logical

						strangers even when behavior indicated caution. Shows oxytocin overrides cognitive risk processing.	evaluation should discourage trust.
The Neurobiology of Pair Bonding	Young & Wang	2004	Explore neurochemical basis for monogamous bonding	Animal model	Prairie voles	Oxytocin and vasopressin receptor activation produced stable pair bonds even without positive partner behavior. Dopamine receptor distribution shaped bonding strength.	Pair bonding is biologically encoded, and once formed, persists independent of relational quality—parallel to emotional dependency in humans.
Oxytocin During Early Romantic Attachment	Schneiderman et al.	2012	Examine hormonal patterns in bonding	Hormonal assay	120 adults	Higher oxytocin levels correlated with obsessive thinking, emotional preoccupation, and heightened attachment. Patterns resembled early addiction-phase neurochemistry.	Oxytocin-driven bonding strengthens emotional fixation and can blur judgment, fostering dependency patterns that resemble compulsive attachment.
Refining the Stress-HPA Axis Relationship	Laurent et al.	2013	Evaluate stress hormone response in relationships	Observational study	199 Couples and parents	Chronic relational inconsistency predicted elevated cortisol and slower stress recovery. Individuals showed increased	Unpredictable relationships dysregulate stress-response systems, reinforcing dependency through physiological arousal and emotional reactivity.

						vigilance and emotional sensitivity.	
Post-Traumatic Stress Disorder	Yehuda	2002	Describe stress neurobiology	Review	NS	Identifies that chronic trauma weakens prefrontal regulatory capacity and amplifies amygdala-driven emotional processing. Stress memory becomes encoded, heightening attachment responses under threat.	Trauma-induced neuroadaptations make detachment from harmful relationships cognitively and emotionally difficult, reinforcing trauma-bond patterns.
Addiction and the Brain Antireward System	Koob & Le Moal	2008	Investigate negative reinforcement in addiction	Review	NS	Chronic stress increased sensitivity to negative reinforcement, promoting compulsive seeking to escape discomfort. Emotional relief functioned as a powerful reward.	Relationship “highs” after conflict mimic addiction withdrawal-relief cycles, reinforcing the trauma bond through negative reinforcement mechanisms.
Neural Responses to Emotional Prosody	Lemche et al.	2006	Explore neural reactivity to emotional conflict	fMRI	18 adults	Heightened activation of emotion-related regions (amygdala, insula) during negative emotional tone. Participants showed increased	Emotional conflict triggers neural pathways that heighten sensitivity and reinforce dependency, especially in individuals with attachment insecurity.

						physiological arousal mirroring stress-response activation.	
Schedules of Reinforcement	Ferster & Skinner	1957	Explore behavioral effects of reward schedules	Behavioral study	Humans & animals	Variable-ratio schedules produced the strongest behavioral persistence, with subjects resisting extinction despite negative outcomes or absence of reward.	Intermittent affection or approval in relationships reliably produces compulsive attachment and resistance to leaving unhealthy bonds.
Cognitive Theory of Depression	Beck	1979	Examine cognitive distortions in emotional processes	Theoretical work	NS	Identified patterns of selective memory, idealization, and minimization common in dependent relationships. Distorted cognition reinforced emotional vulnerability.	Cognitive distortions maintain trauma bonds by reshaping negative experiences into rationalizations that preserve attachment.
Attachment in Adulthood	Mikulincer & Shaver	2007	Determine adult attachment patterns	Longitudinal studies	Adults in relationships	Anxious and disorganized attachment styles were associated with hyperactivation of dependency systems and heightened emotional reactivity.	Insecure attachment predisposes individuals to trauma bonding through heightened need for reassurance and amplified fear of abandonment.
Neural Response	Gillath et al.	2005	Investigate neural	fMRI	42 adults	Insecurely attached	Attachment insecurity increases neurobiological

Differences by Attachment Style			responses to threat by attachment style			individuals showed stronger amygdala activation and weaker prefrontal regulation during relational threat cues.	susceptibility to emotionally addictive relational patterns.
Childhood Trauma & Neurobiology	Heim & Nemeroff	2001	Examine developmental effects of trauma on the brain	Review	NS	Childhood trauma altered the HPA axis, increased cortisol sensitivity, and impaired emotional regulation across adulthood.	Early trauma creates lifelong vulnerability to emotional dependency and trauma-bond dynamics due to altered stress physiology.

Themes Observed in the Review

Dopaminergic Reward Pathways: The twelve of the included studies emphasized the key role of mesolimbic dopamine functioning in strengthening attachment behaviors in intermittent relational conditions. A study by Fisher et al. established that the sight of a romantic partner stimulated the ventral tegmental area (VTA) and nucleus accumbens-parts of the brain involved in drug craving and reward motivation [1]. Bartels and Zeki have reported similar results, showing that there is a substantial dopaminergic activity in romantic attachment, which is consistent with neural activity in addictive behaviors [2]. Intermittent reinforcement enhanced the activation of reward-circuit more than predictable affection, which is consistent with the reward prediction error model outlined by Schultz [3]. These researches all point to the finding that unpredictable cycles of conflict and reconciliation result in dopamine-mediated

reinforcement that leads to compulsive relationship persistence.

Attachment Neurobiology and Oxytocin:

Ten articles showed that oxytocin, a neuropeptide that is related to bonding and trust, has a significant influence on partner attachment even in volatile or abusive relationships. In a seminal study by Kosfeld et al. intranasal oxytocin enhanced interpersonal trust- even in cases where trust was maladaptive [4]. A study by Young and Wang had revealed that pair bonding in mammals was facilitated by the activation of oxytocin and vasopressin receptors irrespective of the quality of the behavior of the partner [5]. Oxytocin secretion during intimacy or reconciliation in human relations formed a positive memory bias and enhanced attachment, which reinforced the patterns of emotional dependency in the intermittent relational cycles [6].

Cortisol and Stress-Response Dysregulation: Eight studies showed high

levels of cortisol and increased activation of the HPA-axis in people who were in relational instability or had emotional volatility. In a study by Laurent et al., the inconsistent behavior of partners was linked to enhanced cortisol reactivity and poor stress recovery [7]. The research done by Yehuda on chronic stress revealed that the long-term dysregulation of the HPA undermined prefrontal regulatory control, making one more susceptible to emotionally addictive relationships [8]. These results justify the importance of stress hormones in sustaining dependency by increasing emotional arousal and making poor decisions.

Psychological Conditioning and Attachment Factors: Nine studies highlighted the role of reinforcement learning, attachment insecurity and cognitive distortions in the development of trauma-bonds. The original contribution by Ferster and Skinner showed that schedules of variable-ratio reinforcement gave rise to the most resistance to behavioral extinction [9], which is also reflected in unpredictable relationship cycles. As Mikulincer and Shaver discovered, anxious and disorganized attachment styles were more prone to relational inconsistency and dependency [10]. The study of betrayal trauma by Freyd also demonstrated the role of emotional betrayal by intimate partners in increasing cognitive dissonance and loyalty based on attachment [11].

In all 15 studies, the findings consistently showed that trauma bonding is a product of the interaction between reward hypersensitivity, attachment neuropeptide modulation, increased physiology of stress and maladaptive cognitive-emotional patterns. All the studies included did not find a single causal pathway; rather, they all support a multisystemic neurobiological model of emotional dependency in intimate relationships.

Discussion

The analysis of fifteen peer-reviewed articles provides a consistent and multidimensional

image of trauma bonding and emotional dependency that shows these patterns of relationships are not only psychological phenomena but biologically supported processes of reward circuitry, attachment neuropeptides, and stress-response systems. The results are in line with the aim of this review, which aimed at uniting neurobiological and behavioral processes into a single framework that explains why people have strong emotional bonds in relationships that are characterized by inconsistency, conflict cycles, or intermittent affection.

The review sought to analyze the neurobiological basis of trauma bonding, including dopamine reward systems, oxytocin-mediated bonding, cortisol stress activation and reinforcement learning. The studies included in the paper always substantiate these elements. The dopaminergic activity in the ventral tegmental area (VTA) and nucleus accumbens detected in romantic attachment [1, 2] is similar to the activity in substance addiction and behavioral compulsions, confirming the theoretical treatment of trauma bonding as an addiction process. The error in prediction of rewards model as explained by Schultz [3] offers a mechanistic explanation of why intermittent reinforcement increases emotional dependency: the unpredictable affection or reconciliation leads to increased dopamine release and this increases relational attachment even in the face of distress.

This model is also supported by the findings of oxytocin and vasopressin. The research that oxytocin improves trust and bonding regardless of the quality of partner behavior [4, 5] illustrates the reason why people are still emotionally attached despite relational inconsistency or mistreatment. This is in line with the aim of learning how maladaptive relationships are maintained with the help of the neuropeptides that are involved in attachment. The cortisol and HPA-axis dysregulation findings [7, 8] shed more light, as chronic relational stress cannot be merely reduced to a

negative experience, but it induces physiological states that complicate the process of detachment by disrupting the prefrontal control and increasing emotional responsiveness.

The studies put collectively are highly supportive of the main assumption of the review: trauma bonding and emotional dependency are the results of interactions between reward hypersensitivity, neuropeptide-mediated attachment, and stress-induced cognitive-emotional dysregulation.

The findings are generally consistent with the theoretical models of addiction neuroscience, attachment theory, and trauma psychology. The dopaminergic results resemble the compulsive seeking behavior models of substance addiction where uncertainty in the delivery of rewards enhances the craving and behavioral obsession. This supports previous research that intimacy relationships are behavioral addictions because they have neurochemical reinforcement profiles.

The vulnerability to trauma bonding is also explained by the attachment theory in a complementary way. The studies of insecure and disorganized attachment styles indicate that people with high levels of fears of abandonment or the lack of consistency in early caregiving display exaggerated neurobiological and emotional reactions to the relational volatility [15, 16]. The analyzed studies all point to the fact that attachment insecurity makes one more vulnerable to intermittent reinforcement cycles, which is in line with the current attachment-neuroscience literature.

Moreover, the theory of betrayal trauma states that in case of the emotional harm that is inflicted by a trusted partner, the cognitive system might block the knowledge of the danger to maintain the attachment, which leads to the development of the deepened dependency [18]. This is in line with the research that has shown that oxytocin is capable of enhancing trust even in cases that are logically unjustified [4].

It seems that neurobiological systems interaction is the key to trauma bonds. Dopamine is a source of motivational drive and reinforcement, oxytocin is a source of emotional closeness, and cortisol is a source of physiological arousal and memory of stress. These systems do not exist in isolation, but they form a neurochemical loop, which strengthens positive and negative relational experiences.

As an example, spikes of cortisol caused by conflicts stimulate the amygdala and increase vigilance, whereas reconciliation stimulates dopaminergic and oxytocinergic release, which brings relief and emotional relaxation. This loop resembles the tension withdrawal relief cycle in substance addiction, in which the withdrawal symptoms increase the perceived reward of the substance once it is recovered.

The analyzed articles all indicate that the process of trauma bonding is maintained by the cycle of stress-relief-attachment, which creates a closed-loop conditioning loop that is highly resistant to extinction. That is why people in trauma-bonded relationships tend to refer to the relationship as painful and extremely emotionally fulfilling, based on the stage of the relationship.

This loop is reinforced by cognitive factors. The selective memory and emotional reconstruction, which are caused by idealization in positive phases and minimization of harm in negative phases as found in the reviewed psychological studies [14], further contributes to dependency. These distortions are enhanced by attachment insecurity which results in self-reinforcing beliefs that the relationship is unique, irreplaceable, or essential to emotional survival.

The implications of the findings to therapeutic practice are enormous. Conventional couples therapy might not be effective in cases of trauma bonding because it tends to emphasize on communication and conflict resolution without considering neurobiological reinforcement. The literature justifies the application of trauma-informed

therapeutic modalities, including trauma-focused cognitive behavioral therapy, EMDR, somatic regulation modalities, and neurobiological psychoeducation, to disrupt addictive relational patterns [20, 21].

Cortisol-induced arousal and dopamine-induced cravings are some of the factors that therapists should be aware of because the emotional dependency can be aggravated during a period of conflict or separation. Thus, the interventions must be directed at the cognitive patterns and physiological responses. Education on reward mechanisms and physiology of stress can be used to increase change motivation and decrease shame by promoting dependency as something reinforced biologically as opposed to an expression of individual weakness.

Although the findings are consistent, the studies included are limited in terms of methodology. The cost and complexity of fMRI and PET imaging has led to many neuroimaging studies that are based on small sample sizes. Hormonal research tends to have inconsistency in the measurement of oxytocin because of the dissimilarity in methods of measurement. There is little research that explicitly investigates the concept of trauma bonding as a specific construct; rather, the corresponding mechanisms have to be deduced based on the studies on romantic attachment, addiction, or stress reactions. Moreover, cross-sectional designs restrict causal inferences.

However, the overlap of various fields such as neuroscience, psychology, behavioral science, etc. makes the suggested multisystemic model even more valid.

Conclusion

This review shows that trauma bonding and emotional dependency in intimate relationships are the results of a complicated interaction of neurobiological, psychological, and behavioral processes. The combination of fifteen studies synthesis is a good indication that dopaminergic reward systems, oxytocin-mediated attachment

mechanisms, and cortisol-mediated stress activation are all involved in maintaining emotional attachment despite the occurrence of relational distress or inconsistency. These biological systems are in contact with reinforcement-learning patterns and attachment-related cognitive distortions, forming a self-perpetuating cycle that is very similar to addiction models in substance use and behavioral compulsions.

The notion of trauma bonding is best understood in an integrated neurobiological perspective in order to further develop the clinical practice. The conventional relationship counseling models might not be effective in the case of addiction-like reinforcing patterns. Rather, trauma-informed interventions that address physiological regulation and cognitive-emotional processing could prove to be more beneficial avenues to recovery. The results also point to the necessity of clinicians to be aware of the role of stress physiology, reward sensitivity, and attachment insecurity in the perpetuation of unhealthy relational bonds.

Although the existing evidence base is sound in its multidisciplinary convergence, additional studies are required to create standardized assessment instruments, longitudinal models, and intervention strategies that are directly specific to trauma-bond dynamics. On balance, the present review highlights the need to consider trauma bonding as a biologically supported relational phenomenon, and not only a psychological or interpersonal problem.

Conflict of Interest

The author state that there is no conflict of interest on the publication of this review article. There were no financial, professional, or personal affiliations that affected the analysis and interpretation of the presented evidence.

Ethical Approval

This study did not need ethical approval since it is a Review Article that was conducted only on existing literature. There were no

human subjects, personal data, or recognizable clinical data.

Data Availability

All data analysed in this study are derived from previously published articles identified through database searches {PubMed, PsycINFO, Scopus, Google Scholar and ScienceDirect}. As this research utilized publicly available literature, no new datasets were generated.

Author Contributions

Tolulope Oko-Igaire: Conceptualization, literature search, data extraction, data analysis, synthesis of neurobiological and psychological models, drafting of all manuscript sections,

critical interpretation of findings, and final approval of the final manuscript.

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Knowledge and Attitude of Dental Clinicians and Dental Technologists on Removable Complete Denture Fabrication Procedures in Uganda: A Qualitative Study

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Abstract

Removable Complete Dentures (RCDs) are crucial for restoring function and aesthetics in edentulous patients. The prevalence of edentulism rises with age, affecting 2.3% of the world's population. This study explored the knowledge and attitudes of dental clinicians and technologists regarding Removable Complete Denture (RCD) fabrication procedures at Makerere University Dental Hospital, Uganda. This qualitative study employed a phenomenological approach and 25 respondents were purposively selected to elicit data on a range of patient-specific considerations and needs during the Removable Complete Dentures fabrication process. Semi-structured interviews were conducted, and data were analyzed thematically. Respondents identified the critical steps in RCD fabrication, including examination and diagnosis, impression taking, determination of Occlusal Rim Block (ORB) height, proper jaw relation recording, and meticulous fabrication techniques during RCD fabrication, continuous professional development and patients' education, and went further to explain how these processes align with international guidelines. While dental clinicians and technologists generally adhered to international guidelines, our findings highlighted the need for updated and context-specific guidelines tailored to the Ugandan setting, as well as the importance of effective communication and synchronization among dental practitioners for successful RCD fabrication. The study highlighted dental clinicians' and technologists' knowledge of critical steps in removable complete denture (RCD) fabrication emphasized the need for updated, context-specific guidelines, particularly in impression taking, occlusal rim block height, removable complete denture fabrication steps, examination and diagnosis and patient education, to ensure accurate measurements and improved patient outcomes.

Keywords: Attitudes, Fabrication Procedures, Knowledge, Removable Complete Denture.

Introduction

Removable complete dentures (RCDs) are essential in prosthodontics treatment for edentulous patients. The RCDs offer both functional and aesthetic benefits enabling

patients to chew, speak and smile confidently [1]. According to [2], the prevalence of edentulism increases with age, affecting 2.3% of the world's population. In Uganda, the prevalence of edentulism among people aged 20 years and above is 1.8% [2]. Complete tooth

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loss is a handicap, incapacity and disability [3]. Dental technicians play a pivotal role in the fabrication process of various dental prostheses, including RCDs [5]. Successful fabrication of RCDs requires a thorough understanding of prosthetic procedures, which significantly impact the patients' overall satisfaction [4]. The fabrication of RCDs involves several intricate steps, including diagnosis, treatment planning, accurate impression-taking and border molding, dental model casting and occlusal rim block fabrication, proper bite registration, selection and setting up of artificial teeth, wax denture try-in, acrylic packing, trimming and polishing. Dental technicians are responsible for translating the dentist's prescription into a well-fitting and aesthetically pleasing prosthesis to attain harmonious occlusion that is compatible with the stomatognathic system. The prostheses are intended to restore the patient's masticatory function, phonetics, esthetics and improved social esteem [6, 7]. According to [8] the quality of RCDs significantly influences the overall success of the prosthodontics treatment. Dental clinicians and technologists play a critical role in achieving optimal design and fit, ensuring that the final prosthesis meets the patient's needs and expectations [4]. Their knowledge of the latest materials and techniques is vital for ensuring the quality and longevity of RCDs. Studies [9, 10] have shown that the knowledge and attitudes of dental clinicians and technologists significantly influences the quality of the final prosthesis. Furthermore, for impression techniques, (50.4%) of contributors favoured using the mucostastic technique, though muco-compressive and selective pressure techniques were chosen by (12.6%) and (37.0%) respectively [9]. In a survey conducted in Nagpur city on 200 private dental practitioners (62% males and 38% females) concerning dentists' attitude about relining procedure of RCDs, eighty-one percent (81%) of the dentists think that relining increases the retention and stability of the denture whereas

14% did not feel so and 5% were not sure about it while thirty-nine percent (31%) of dentists thought relining might increase the vertical dimension of the dentures [10]. Gaining an understanding of the processes involved in fabricating RCDs is expected to facilitate education and training of dental practitioners in prosthodontics care given to patients. This study explored the knowledge and attitudes of dental clinicians and technologists regarding RCD fabrication procedures in Makerere University Dental Hospital, Uganda.

Materials and Methods

Study Design

The study employed a qualitative study design to investigate knowledge and attitudes of dental clinicians and technologists regarding RCD fabrication procedures. Data were collected using key informant interviews.

Study Site

The study was carried out in Makerere University Dental Hospital in Kampala, Uganda. Kampala is the capital city of Uganda. The hospital is a teaching and healthcare service delivery facility for Makerere University. It is the biggest and well-equipped dental facility in Uganda, employing the biggest number of dental specialists. The hospital offers specialized dental services including rehabilitation of edentulous patients with RCD to university employees, students and the surrounding community. It has a well-established prosthetic dental laboratory. The hospital attends to about 660 outpatients per month, 20 of whom receive RCD therapy (Registry of Dental Records, 2022).

Selection of Study Respondents

Key informants were purposively selected, taking into account the duration of practice, level of training, roles in denture fabrication and fitting in order to provide an equitable representation of the study population. The 13th dental clinician and the 12th technologist did

not provide any new information on knowledge and attitudes of dental clinicians and technologists regarding RCD fabrication procedures and were deemed to have attained data saturation [11, 12].

Inclusion Criteria

Dentists and dental technologists involved in the provision of RCDs in Makerere University Dental Hospital and have provided written informed consent.

Exclusion Criteria

Dental technologists and clinicians who were ill or absent at the time of data collection.

Data Collection

A pilot was conducted prior to actual data collection to test and modify the research tool accordingly. Before participating in the study, the respondents provided written informed consent and were assured of confidentiality without personal identifying information during collecting data or compiling reports. The research assistants personally invited respondents to participate in an interview environment that was both welcoming and conducive for them to discuss freely.

To promote conversation and uncensored opinions on many aspects of knowledge and attitude, semi-structured interviews were conducted for each respondent that lasted 30 to 45 minutes. Interviews were audio-recorded in addition to note-taking. Additional notes were also taken to record body language expressions.

Data Management and Analysis

The interview recordings were transcribed verbatim and compared with written notes where emerging and recurrent themes were identified. The data were securely kept under lock and key, while the soft copies were computer password protected and only accessible to the investigators. After transcription, the data from 12 dental technologists and 13 dental clinicians were coded to form a code book. The code book was

imported into Nvivo 14 for thematic analysis [13]. Personal knowledge and attitudes were represented by individual quotes from the respondents.

Quality Control

To improve the validity and reliability of the data collection tools, the principal investigator pretested them and made adjustments. The research assistant who had a background of social sciences was trained in data collection. The key informant interviews were audio-recorded in order to capture any discussion that might have been missed during note-taking. Additional notes were also taken to record body language and gestures of the respondents.

Credibility, Confirmability, Dependability, and Transferability were used to guarantee trustworthiness. Peer debriefing and enlisting the assistance of more experienced qualitative researchers to review and provide feedback on the study procedure and findings to guarantee that the data were correct and pertinent helped to establish credibility. A thorough explanation of the research context, including the features of the chosen respondents and setting was given in the methods section. Readers are advised to utilize this description to determine whether or not they can apply the findings to their contexts or settings. A detailed description of the study procedures and analysis was provided in order to enable study replication. To ensure that the study conclusions are based on the respondents' narratives and words and free from bias, a clear coding scheme was utilized to generate codes and uncover trends in the analysis [14].

Ethical Considerations

The study protocol was approved by Makerere University School of Health Sciences Research Ethics Committee (Reference Number: MAKSHSREC-2023-486) and the Uganda National Council for Science and Technology (Reference Number: HS3092ES). Permission to carry out the study was given by the Makerere University Dental Hospital

administration. Written informed consent was obtained from each participant before the study. In compliance with the Helsinki Declaration [15], the respondents were requested to voluntarily participate after being made aware of the purpose of the study. Care was taken to ensure confidentiality and anonymity of all personal data generated during the study.

Results

All respondents: 13 dental clinicians and 12 dental technologists had a Bachelor of Dental Surgery and Bachelor of Dental Technology, respectively. Majority of respondents were 26 to 35 years of age and more than half (18/25) were male (Table 1).

Table 1. The Frequency Distribution of the Respondents According to their Social Demographic Characteristics (N=25)

Characteristics	n (%)
Sex	
Male	18 (72)
Female	7 (28)
Role	
Clinical work	13 (52)
Laboratory work	12 (48)
Age	
18-25	6 (24)
26-35	14 (56)
36-45	5 (20)
Level of Education	
Bachelor of Dental Surgery	13 (52)
Bachelor of Dental Technology	12 (48)

Table 2. Themes and Subthemes

Theme	Subthemes
Patient informed consent and assessment	• Psychological preparation and informed consent • Examination, diagnosis and mouth preparation
Fabrication steps	• Impression taking • Determination of ORB height • Materials used • Knowledge exchange among dental practitioners • Denture delivery

The study sought to ascertain the knowledge and attitudes of Dental Clinicians and Technologists on Removable Complete Denture fabrication procedures in Makerere University Dental Hospital, Uganda. Two themes emerged from the data (Table 2).

Patient Informed Consent and Assessment

Psychological Preparation and Informed Consent

Respondents mentioned that the first thing to do is psychologically prepare the patient before

all other procedures. In fact, patients' consent was believed to be the most important step in the complete denture fabrication process.

"The key first step is where the patient accepts and consents to be part of all the processes. What is key is a patient agreeing to the terms and conditions and fulfilling the appointment stages" (P001_40-year-old_dental surgeon).

"You have to psychologically prepare a patient for the dentures. Then do examination, treatment planning, diagnosis which is a gradual process [and] not a single step [activity]. " (P007_27-year_dental surgeon).

Similarly, patients' preparation was associated with giving a detailed explanation of the RCD benefits, related risks, fabrication stages and costs involves, and its maintenance so that by the time the other clinical procedures are complete, the patient is fully aware of what exactly she/he is going to experience and to expect.

"The key steps should be done after explaining to the patients all the clinical and laboratory procedures. After they have understood, then you can start the treatment. Many of the patients come when they have no idea about the complete dentures to the point that they think it's a fixed prosthesis" (P003_43-year-old_dental surgeon).

The dental practitioners indicated the importance of explaining to the patient because it is part of the process of giving detailed information about the procedure before obtaining informed consent. Therefore, only those who accept to go through the process are taken through procedures.

"Of course, there is patient examination, which is an important aspect. After that the patient might accept or not, if they accept you take the primary impression and continue

with the therapy" (P008_25-year-old-Dental Technologist).

Examination, Diagnosis and Mouth Preparation

Respondents mentioned several steps they had to go through during RCD fabrication and these included examination and diagnosis, which also involved assessing the patient's oral condition, facial expressions, overall health and mouth preparation.

"The first thing we normally do is mouth preparation which helps to make sure that the mouth environment is ready for the removable complete denture. So, we start with removal of any rotten teeth" (P002_42-year-old_dental surgeon).

During examination and diagnosis, all respondents demonstrated clear understanding of what the key steps in denture fabrication were. Some respondents called it analysis while others called it diagnosis. The excerpt below gives more detail of the procedures.

"When the client comes, you examine him/her, take history, and analyze the mouth and the facial expression. The extra oral and intra oral examination helps to determine if the patient qualifies for a removable complete denture before taking the primary impression" (P004_33-year-old_dental surgeon).

Fabrication Steps

Impression Taking for Removable Complete Denture Fabrication

We asked the respondents what they knew about impression taking. Our findings revealed that respondents understood that impression taking is very critical for successful complete denture fabrication. One respondent compared impression taking to cooking food while showing that if the impression is well taken, it will lead to a better complete denture fabrication. Likewise, if a wrong impression is

taken, it will lead to poor complete denture fabrication.

“Impression taking is like cooking food, if the cook messes the dish, the one who is going to take it will not enjoy it. Impression taking is the key thing in all the processes of removable complete denture fabrication” (P001_40-year-old_dental surgeon).

Similarly, other respondents held a similar notion that impression taking was not only a good foundation, but it also influenced the outcome of the process. To some respondents, impression taking is very important as it is the mouth of the patient. They narrated that the patient’s mouth becomes as good as the impression taken.

“I think that a good impression is a foundation for the entire process because if you make a very bad impression everything else [procedures/processes] will not work” (P002_42-year-old_dental surgeon).

“A good impression should produce a cast whose dimensions represent the exact replica of the patient’s mouth. Otherwise, if there are some errors in impression taking, it is obvious the complete denture will be ill fitting” (P008_25-year-old_Dental Technologist).

Some respondents further emphasized the importance of impression taking by indicating that there should not be room for error because in case of any wrong measurements, all other steps will go wrong. Meaning, impression taking should be accurate. They narrated that in case the complete denture is faulty, it means the primary impression may not have been correctly taken and thus, requires an accurate secondary impression. One of the respondents affirmed that if the primary impression was wrongly done, the secondary impression has to be very accurate by all means.

“If you take bad impressions, oftentimes you get non-retentive and unstable complete dentures. So,

sometimes you have to redo a secondary impression to be accurate” (P013_25-year-old_Dental surgeon).

Another respondent added that it was very important to take good impression and believed that impression taking should consider all the three techniques (muco-compressive, selective, and muco-static) in order to rule out any mishaps. She indicated that taking all the impressions at ago saves a lot of time because there would be no need of repeating them in future.

“There are different types of impression techniques. We have muco-compressive, selective, and muco-static. Taking both the primary and secondary impressions in one day saves a lot of time for both the dental clinician and technologist” (P014_23-year-old_Dental surgeon).

Determination of Height of ORBs for RCD Fabrication

Another step in RCD therapy is fabrication of ORBs. Dental clinicians and technologists mentioned that they follow international standard guidelines, found in most textbooks, in the removable complete denture fabrication processes. These guidelines include specific measurements for the height and thickness of ORBs.

“I follow what is written in the textbooks in measuring the height and width of the occlusion rim blocks” (25-year-old-dental technologist).

However, despite the existence of international standard guidelines, there was a consensus among the professionals that each patient is unique and this compels them to do individual adjustments. Factors such as jaw size, facial morphology and comfort play a crucial role in determining the optimal height of ORBs. Some clinicians emphasized the importance of being adaptable and making adjustments based on the patient's specific needs.

“Every client is different. I will not tell you that there is one standard fit for all, it is usually patient-based. There are principles that may apply on one patient, and may not apply on the other, but the best thing is to treat every patient individually” (P007_27-year-old dental surgeon).

“Someone can have occlusal rim block height of 18 mm, the other one has 20 mm, and another one has 15 mm. The textbooks say a certain height [18mm for mandible and 20mm for maxilla], but you realize that you have to adjust for different people” (P019_24-year-old_Dental surgeon).

Some respondents attributed the lack of context-specific guidelines to lack of research about the RDC fabrication processes in other settings like Uganda. This makes it hard for the dental practitioners to use the available guidelines as they may not be easily adapted to the local context.

“We don't have literature on our own people especially on the [fabrication and] use of removable complete dentures. And if there was any research, I think it would be very informative in this field. In Africa, and Uganda in particular, we don't have much data on that [removable complete dentures]” (P021_45-year_Dental Surgeon).

Some respondents narrated that the available standards have helped them to do the right measurement procedures while admitting that, the few adjustments are made due to the fact that there are height differences.

“Yeah, a few adjustments still can come in, but that standard is like something that is fundamental for us. We can make small changes later” (P023_26-year-old_Dental Technologist).

To some dental practitioners, reference to the international standard guidelines was helpful in

avoiding mistakes that could affect the patients' comfort.

“There is the height and the width of the occlusal rim blocks that are internationally recommended. So, it is best to follow that. Then for the lower occlusal rim blocks, of course it should be angulated at 90 degrees to the base” (P024_26-year-old_Dental surgeon).

Materials Used During RCD Fabrication

We also explored our respondents' knowledge about the kind of materials used during removable complete denture fabrication. Our findings revealed a number of views about key materials used including; heat cure and cold cure polymethyl methacrylate (acrylic) powder and liquid, chromo-cobalt metal alloy, silicon (soft and hard bodies), alginate, acrylic teeth, dental stone, and wax.

“Yeah the first thing, I already have the stock trays which are bought from the market. Those are the first trays in most cases, I use them with alginate for my primary impressions. Then after I fabricate the special tray, which I use together with silicon to take the secondary impression” (P001_40-year-old_Dental surgeon).

“At the clinic where I work, we have always used alginate. Initially, we had addition silicon, but then it got finished and we didn't buy more, but compromised and started using alginate, which is cheaper” (P002_42-year-old_Dental surgeon).

Another participant indicated how different materials are used for different purposes and stages, revealing that while some materials are used during the primary impression taking, other materials are used for secondary impression or for making the denture base.

“The commonly used material in the dental clinic for primary impression is alginate while [the one used] for secondary impression is silicon. In the

dental laboratory, we have self-cure and heat cure acrylic powder and monomer for making special trays and base for occlusion rim blocks, acrylic teeth, dental stone, and wax” (P005_30-year-old-Dental Technologist).

Knowledge Exchange Among Dental Practitioners During RCD Fabrication Procedures

We explored respondents’ knowledge exchange practices during the RCD fabrication. Our findings revealed that dental practitioners mainly discuss about a suitable course of action for a given patient, or areas where they would need extra help as professionals or sometimes knowledge exchange takes the form of giving instructions about the procedure.

“I definitely share knowledge by giving instructions as well as discuss and agree on what I exactly want with the technologists” (P017_33-year-Dental Surgeon).

“Yes, it is frequent. I think in this kind of practice, you have to frequently talk to colleagues to share knowledge. I don’t think one would work alone, but there is something you learn from your colleagues when you share and work with them” (P017_33 year_Dental Surgeon).

Denture Delivery

We explored respondents’ knowledge on denture delivery. Our findings revealed that denture delivery involved retention and stability check and speech. This was followed by RCD review and adjustment, patient education, and then final delivery of the RCD to the patient.

“I assess speech and see whether the patient is comfortable with the denture, the color of the teeth, retention, stability and if satisfactory then, I deliver the denture and follow up” (P007_27-year_dental surgeon).

Discussion

The study explored respondents’ knowledge and attitude towards RCDs fabrication procedures. In terms of knowledge, during examination and diagnosis, respondents demonstrated a clear understanding of key fabrication steps, with some referring to it as “analysis” while others as “diagnosis”. The fabrication of RCDs demands a logical approach to ensure successful outcomes. Studies by [16, 17] detailed the critical steps in the examination and diagnosis, which involved a comprehensive assessment of the patient's oral condition, facial expressions, and overall health.

In the present study, respondents reported a series of steps including examination and diagnosis, mouth preparation, impression taking, fabrication of ORBs, bite registration, articulation, setting of teeth, try-in wax RCD, acrylic packing, review and adjustment, patient education, final delivery of the RCD, and post-insertion care which align with international standard guidelines [16, 17]. Dental clinicians and technologists attempted to adhere to international standard guidelines, but ended up with adjustments of the ORBs. Patient preparation involves detailed explanations to manage expectations and obtain informed consent. It is emphasized to follow rigorous RCD fabrication procedures to avoid challenges that could affect patient outcomes. Other studies [18, 19] highlighted the importance of adhering to established guidelines and standards to ensure positive patient outcomes.

The respondents in the present study demonstrated a comprehensive understanding of the importance of impression taking in RCD fabrication. They likened it to a crucial step in cooking, where a well-taken impression ensures a successful outcome, while a wrong impression leads to poor fabrication. This finding is consistent with the results of a literature review [20], which questioned the necessity of certain clinical and laboratory

procedures, such as a two-step impression procedure, for achieving better results in conventional RCD fabrication. Additionally [20], reviewed randomized controlled clinical trials comparing RCD fabrication with one-step versus two-step (primary and secondary) impression procedures and found that contrary to conventional belief, a two-step procedure may not be mandatory for successful denture fabrication.

Dental practitioners use international standard guidelines for establishing the height and thickness of ORBs during the fabrication of RCDs. Comparably, in a Ugandan study [21], the mean height of the mandibular and maxillary ORBs before bite registration/adjustment was found to be in line with international standard guidelines and produced a 2-4 mm freeway space. In [20] trials, some practitioners closely followed these recommendations (international standard guidelines for establishing the height and thickness of ORBs) to prevent any problems, others stressed the significance of flexibility and patient-specific modifications. In addition, [20] trials, emphasized the individuality of every patient, which calls for customized changes depending on variables including comfort, jaw size, and face morphology, even in the presence of worldwide guidelines. Indeed, [21] discovered that, following bite registration/adjustment, the height of ORBs for both the upper and lower jaws was 2.2 mm shorter than the global standards. The observed variations in RCD dimensions are in corroboration with [22] who also noted specific needs particularly among the elderly patients. It is challenging for practitioners to rely only on guidelines from outside Uganda, despite dearth of Ugandan-specific literature on RCD fabrication. However, [20] trials, concluded that following these worldwide standards is useful in guaranteeing precise measurements and preventing mistakes that can affect patient outcomes [3].

During the fabrication of RCD, various dental materials are utilized at different stages of the process [23-25]. The present study revealed that dental clinicians and technologists recognize the diverse purposes of different materials at various stages of RCD fabrication, indicating a comprehensive understanding of the respondents regarding material selection and utilization throughout the process.

In terms of attitudes, the present study noted both best practices as well as gaps in sharing the knowledge among dental practitioners during RCD fabrication procedures. This was in support of the findings by [26] who suggested several ways to enhance knowledge sharing between dental clinicians and technologists, such as using phone calls and sending photos instead of written requests. Respondents emphasized the significance of frequent sharing of knowledge as a means for practitioners to learn from each other and enhance treatment planning within the dental team and echoed the need for improved knowledge sharing as earlier highlighted [26, 27].

Conclusion

The present study highlighted dental practitioners' knowledge of critical steps in RCD fabrication including examination and diagnosis, impression taking, determination of height of ORB and patient education. While respondents generally adhered to international guidelines, the findings highlighted the need for updated, context-specific guidelines tailored to the Ugandan setting. There was emphasis on the importance of having a good knowledge of RCD fabrication procedures and appropriate attitudes about knowledge sharing of good practices during RCD fabrication.

Recommendations Based on the Findings

Develop and implement comprehensive training programs for dental clinicians and dental technologists focusing on knowledge and attitude in meticulous RCD fabrication techniques. Update existing international

standard guidelines for RCD fabrication to address specific challenges faced in the Ugandan context. Promote continuous professional development among dental clinicians and dental technologists to keep them updated with the latest advancements in RCD fabrication.

Implications for Clinical Practice

Enhance the quality of patient care by ensuring accurate and meticulous fabrication techniques during RCD therapy. By following updated and context-specific guidelines, dental practitioners can ensure that RCDs meet patient needs and expectations, leading to increased patient satisfaction. Continuous professional development will keep dental clinicians and technologists updated with the latest advancements in RCD fabrication, ensuring that they provide the best possible care to their patients.

Implications for Future Research

Explore the need for the development of context-specific guidelines for RCD fabrication in Uganda to address the specific needs of the local population.

Study Limitations

The study relied on subjective interpretation by respondents, and the findings may have been influenced by the recall biases and perspectives. However, efforts were made to minimize this bias through rigorous data analysis and triangulation of findings.

Ethical Considerations

The study protocol was approved by the Makerere University School of Health Sciences Research Ethics Committee (Reference Number: MAKSHSREC-2023-486) and the Uganda National Council for Science and Technology (Reference Number: HS3092ES).

Permission to carry out the study was given by the Makerere University Dental Hospital administration. Written informed consent was obtained from each respondent before participating in the study in compliance with the Helsinki Declaration [15].

Consent for Publication

Not applicable.

Availability of Data and Materials

On request, data sources are made available from the corresponding author through: nndvd45@gmail.com.

Conflict of Interest

The authors declare that there is no conflict of interest.

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Author's Contributions

DN, IO, MA, GB, and CMR participated in the conception of the study, study design, data analysis, and manuscript preparation. DN and GB participated in data collection. All authors read and approved the final manuscript.

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Pathways to Food Security: The Influence of Livelihood Assets and Shocks among Farming Households

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Abstract

Food security remains a major challenge for farming households in low- and middle-income countries, where agricultural livelihoods are highly affected by economic, climatic, and social shocks. This study examines how livelihood assets, income-generating activities, exposure to shocks, and access to safety nets were associated with household food security among farming households in North Central Nigeria, a primary food production zone. Mixed-methods were used. Quantitative data were obtained from 615 farming, North Central households in the Nigeria General Household Survey Panel (2023/2024). Food security was measured using Food Insecurity Experience Scale (FIES). Logistic regressions were used to assess factors associated with food security. Qualitative data were collected through interviews and focus group discussions with farmers, community members, and local officials, focusing on perceptions of food access, livelihood strategies, and shock. Quantitative results showed that 56% of households were food secure. Higher levels of physical and financial capital were associated with higher odds of food security. Exposure to economic and consumption-related shocks was strongly associated with lower odds of food security. Female-headed households and larger households were less likely to be food secure. Qualitative findings highlighted that food security was affected by seasonal variations in agricultural production, and financial capacity. Participants reported that market price fluctuations and climatic events disrupted food access. Farming households in North Central Nigeria experience substantial food insecurity, associated with exposure to shocks and limited livelihood assets. Strengthening productive and financial assets and reducing vulnerability to shocks are critical for improving food security. These findings provide evidence to inform policies and interventions aimed at building resilience among farming households in rural agricultural communities.

Keywords: Food Security, Farming Households, Food Insecurity Experience, Livelihood Assets, Shocks, Sustainable Livelihoods Framework.

Introduction

Food insecurity remains one of the most significant and persistent challenges faced by farming households in low- and middle-income countries, especially in sub-Saharan Africa. In Nigeria, agricultural households are particularly vulnerable due to the complex

interplay of economic, climatic, and social factors. These households operate in volatile environments marked by unpredictable weather patterns, market fluctuations, health risks, and limited access to formal safety nets, further exacerbating their vulnerability to food insecurity [1].

Despite various approaches to mitigate food insecurity, existing solutions such as market access improvements and agricultural interventions have been insufficient to ensure long-term food security for many households. The Sustainable Livelihoods Framework (SLF) provides a comprehensive model for understanding food security, but few studies have examined how different forms of capital (human, physical, financial, natural, and social) interact to influence food security outcomes in the Nigerian context. This study aims to fill that gap by analyzing the role of livelihood assets and shocks in shaping food security, specifically in North Central Nigeria [2].

The problem this research addresses is the lack of a detailed understanding of how farming households in the North Central zone achieve food security. Existing interventions have not been tailored specifically to the diverse needs of households in this zone, where climatic and economic conditions differ significantly from other parts of the country. Therefore, this study aims to identify and assess likely effective strategies to improve food security in this area [3], using an experience-based indicator of food security that captures the multidimensional nature of food insecurity [4].

Furthermore, the study will examine the pathways through which livelihood assets and shocks influence food security outcomes [5].

Food insecurity is a significant global issue, with approximately 11.3% of the world's population experiencing severe food insecurity as of 2022, while over 2.4 billion people face some form of food insecurity. Sub-Saharan Africa, in particular, is most affected, with food insecurity rates often exceeding 60% in many regions. Nigeria, despite its agricultural potential, continues to struggle with food security. Rural areas, home to most of the country's food producers, experience significant levels of food insecurity due to a combination of factors such as climate variability, market inefficiencies, and insecurity [6].

In the North Central zone of Nigeria, the prevalence of food insecurity is particularly high. Despite the area's favourable agricultural conditions, studies have reported that over 70% of households face some form of food insecurity. The North Central zone is highly dependent on agriculture for its livelihoods, but households remain vulnerable due to factors such as inconsistent rainfall patterns, fluctuating commodity prices, and limited access to credit and extension services [7].

Our study bridges the gap in existing literature regarding the relationship between livelihood assets, shocks, and food security outcomes in the North Central zone. By examining both direct and indirect factors influencing food security, this research aims to contribute to more nuanced policy frameworks that account for the complex realities faced by farming households. The findings will help design strategies that not only address immediate food security concerns but also build long-term resilience by strengthening livelihood assets and improving access to diversified coping mechanisms [8].

Literature Review

Food security in sub-Saharan Africa remains a multifaceted challenge, driven by a wide range of economic, environmental, and social factors. The role of livelihood assets in influencing food security outcomes has been recognized in the literature. In their study [2], argue that livelihood strategies are closely linked to food security, with assets such as land, labor, and capital playing pivotal roles in coping with shocks [9]. In a similar vein, [3] emphasizes the importance of access to physical assets, including land and livestock, as critical to ensuring food security in rural households [10].

Shocks, both economic and environmental, can disrupt the ability of farming households to meet their food needs. The impact of these shocks has been studied in parts of sub-Saharan Africa, where climate change and market

volatility exacerbate food insecurity. Recent studies by [4, 5] show that climatic shocks, including droughts and floods, disproportionately affect food production and access in vulnerable regions [11, 12]. Additionally, economic shocks such as fluctuating market prices and inflation have been found to undermine household purchasing power, further exacerbating food insecurity in rural areas [13].

The significance of non-farm employment and diversification strategies in improving food security has further been highlighted in recent research. Studies by [6] demonstrate that households that engage in non-farm income-generating activities are more likely to maintain food security during times of agricultural stress [14]. Similarly, diversification of agricultural production has been shown to enhance resilience to environmental and market shocks, enabling households to mitigate the risk of food insecurity [15].

In the Nigerian context, study by [7] provide insight into the coping strategies of rural households. These studies emphasize the role of community-based interventions, such as village savings and loan schemes, in enhancing household resilience to food insecurity [16, 17]. Similarly, it is emphasized that social capital and community solidarity play a crucial role in alleviating the effects of shocks on food security in rural Nigeria [18].

The role of government policies and institutional support in addressing food insecurity has also received attention in the literature. In Nigeria, the provision of agricultural extension services, access to credit, and investments in rural infrastructure have been identified as critical factors in enhancing food security outcomes. According to [9], extension services that improve agricultural practices and access to resources are essential for enhancing productivity and food security in rural areas [19]. Furthermore, policies that facilitate access to affordable and stable

markets can help mitigate the effects of price volatility on food security [20].

Recent studies on food security in North Central Nigeria have highlighted the zone's unique challenges, including the persistent insecurity in rural areas and the effects of fluctuating commodity prices. [8, 10] found that while the zone has favorable agricultural conditions, high levels of poverty and limited access to markets and resources have contributed to widespread food insecurity [21, 22].

Materials and Methods

Description of the Site

The study was carried out in Nigeria's North-Central zone, which includes the states of Benue, Kogi, Kwara, Nasarawa, Niger, Plateau, and the Federal Capital Territory (FCT) in Abuja. Home to over 20 million people, this zone relies heavily on agriculture, with farming being the primary economic activity. The area boasts favorable conditions for agricultural production, yielding a wide range of crops such as yam, rice, sorghum, maize, and various vegetables. Its climate, categorized as Guinea Savannah, experiences a single rainy season, which supports the cultivation of diverse crops. The presence of two major rivers, the Benue and Niger, provides vital water resources throughout the year [2, 3], further supporting agricultural endeavors. However, the zone's reliance on rain-fed farming makes it vulnerable to climate-induced shocks, which can negatively impact crop production and food security for local households.

Description of Data Collection

This study employs a mixed-methods design, combining both quantitative and qualitative approaches. The quantitative data was obtained from the 2023/2024 wave of the Nigeria General Household Survey-Panel (GHS-Panel), a nationally representative survey implemented by the National Bureau of Statistics (NBS). Two rounds of data collection

were conducted: post-planting (July to September 2023) and post-harvest (January to March 2024). Variables from both rounds of the survey were used. Food security indicators, livelihood activities, experience of shocks, education, and access to land were drawn from the post-harvest round, which captures recent food access, consumption, and economic engagement. Information on health, extension services, financial access, remittances, insurance, and assets was drawn from the post-planting round. Variables were considered to reflect household conditions within the same agricultural year, and within-year temporal variation was assumed to be minimal.

The analysis was restricted to farming households, defined as households that reported cultivating crops during the survey year. A total of 615 households, out of 809 households in the North Central zone in the survey, were included in the analysis. Qualitative data were collected through in-depth interviews with key informants, including agricultural extension

officers, local government staff, and heads of farming households. The qualitative data provided contextual insights into the challenges faced by farming households, and the role of social structures in food security decisions.

Conceptual Framework and Analytical Approach

The conceptual framework for this study is based on the Sustainable Livelihoods Framework (SLF), which views food security as a livelihood outcome influenced by various forms of capital, livelihood activities, and shocks. Livelihood assets, such as human, physical, financial, and social capital, are key determinants of a household's ability to manage risks and engage in income generating activities. Shocks, such as economic disruptions or climate-related events, can undermine food access, while livelihood activities are expected to reflect responses to these challenges in Figure 1.

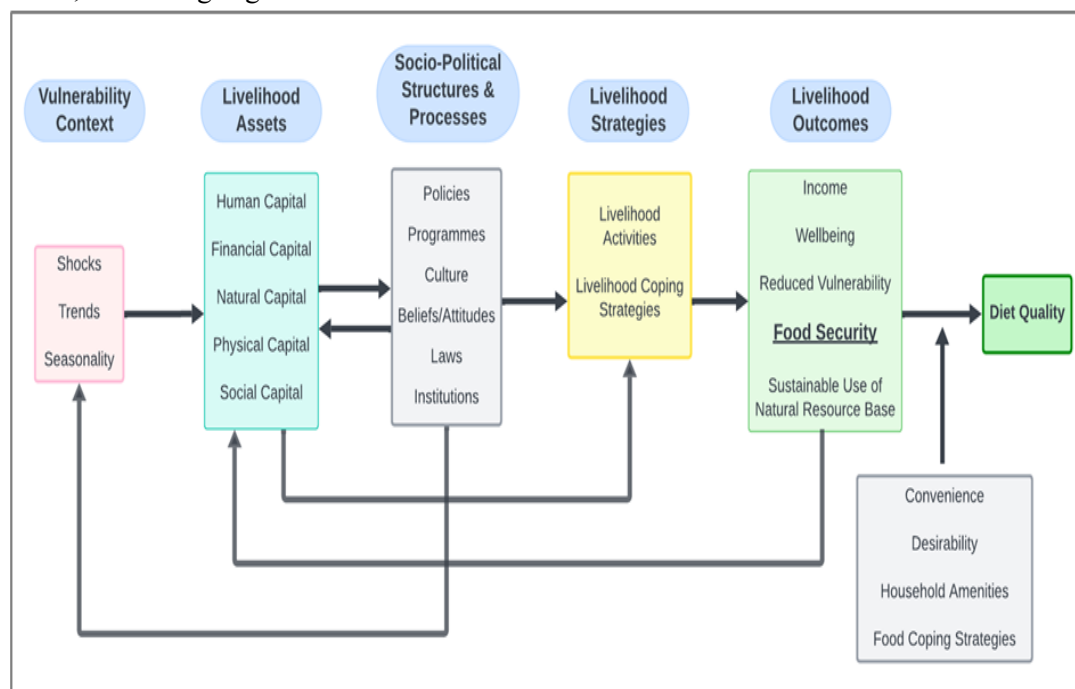


Figure 1. Conceptual Framework for the Study

Source: Adapted by authors from Løvendal et al., 2004; Turner et al., 2018; Fanzo et al., 2020; Bekele et al., 2021; Natarajan et al., 2022 [23-27].

Description of Key Indicators

Indicators used in the quantitative analysis were derived from the survey data using standard methods. Food security was measured using the Food Insecurity Experience Scale (FIES). The raw FIES data of eight questions was analyzed using the Rasch model, through an online app provided by the Food and Agriculture Organization of the United Nations for FIES data analysis (<https://foodandagricultureorganization.shinyapps.io/fies/>) [4]. Food secure households were coded 1, and food insecure households were coded 0.

Indicators for livelihood assets were developed based on the Sustainable Livelihoods Framework and grouped into four asset categories: human, physical, financial, and social capital see figure 1. For each asset category, indicators capturing access to key resources and services were combined to construct composite indices. Higher values of each index indicated greater asset endowment. Human capital captured characteristics related to education, skills, and labour capacity within the household. Physical capital reflected ownership of productive and household assets. Financial capital captured access to financial resources, including savings and credit. Social capital reflected access to social networks and support mechanisms, including access to extension services and network-based financial access. Natural capital was not included in the analysis because it was defined as access to land and was universal among the sampled farming households and therefore showed no variation.

Livelihood activities were measured based on households' engagement in income-generating activities. A categorical indicator captured the number of types of livelihood activities undertaken by each household. Categories were no reported type of livelihood activity, one type of activity (e.g., agricultural activities), two activity types, or three or more activity types.

Exposure to shocks was measured using indices capturing households' experience of economic shocks and food consumption-related shocks. Higher values of the shock indices indicated greater exposure to shocks. Access to safety nets was measured using a binary indicator capturing whether the household reported receiving any form of social assistance or support.

Description of Statistical Methods and Data Analyses Used

The analysis followed the Sustainable Livelihoods Framework (SLF) to examine factors associated with household food security among farming households. Quantitative and qualitative data were analysed in a complementary manner, with quantitative analysis providing estimates of associations and qualitative data used to contextualise and interpret these findings.

All analyses were conducted at the household level, with individual-level information aggregated to the household level. Complex survey design was used to ensure representativeness. Descriptive statistics were first used to summarize key household characteristics, including food security indicators, assets, livelihood activities, and socio-economic variables. Multivariable logistic regression analyses were then used to examine the relationship between livelihood assets, livelihood activities, shocks, safety nets, and food security. Models were specified sequentially to assess the contribution of different livelihood components to food security. The first model included the livelihood assets (human, physical, financial, and social capital) indices. The second model incorporated the economic and food consumption shocks, while the third added access to safety nets. The final model included livelihood activities. All models controlled for sex, age, and education of the household head, as well as household size and rural or urban residence.

The probability of decision error was set at 5%, and variables with p-values less than 0.05 were considered statistically significant. Variables with p-values between 0.05 and 0.10 were considered marginally significant and identified for further investigation.

Qualitative data from interviews were analysed thematically to identify recurring patterns related to food access, livelihood strategies, and exposure to shocks. Rather than being analysed as stand-alone outcomes, qualitative findings were used to complement the quantitative analysis by providing contextual explanations for observed statistical associations, particularly with respect to seasonal food access, financial constraints, and the ways households manage livelihood risks.

Results

Quantitative Findings

Socio-Demographic Characteristics

Household Head Information

Among the household heads, 82.89% were male, while 17.11% were female. The average age of household heads was 49.62 years (95% CI 47.74 – 51.50), with a wide range of ages from 19 to 100 years. In terms of education, 32.93% of household heads had no formal education, while 22.10%, 25.73%, and 19.23% had primary, secondary, and tertiary education,

respectively. A significant majority (78.70%) of household heads were married or in an informal union (monogamous or polygamous), while 20.48% were unmarried, divorced, separated, or widowed.

Household Information

The average household size was 5.96 members (95% CI 5.57 – 6.34), with a range from 1 to 25 members. The dependency ratio was 1.09 (95% CI 0.98 – 1.20), indicating that for every working adult, there was an average of just over one dependent individual. A large proportion (84.94%) of households resided in rural areas, while 15.06% resided in urban areas. Household samples were drawn from the FCT and all states in North Central Nigeria, with the following distribution: Benue (26.33%), Kogi (16.48%), Kwara (8.54%), Nasarawa (8.80%), Niger (19.18%), Plateau (17.70%), and FCT (2.97%).

Livelihood Assets

Households in the region rely on a variety of livelihood assets to support their food security. These include human, physical, financial, and social capital. The mean values for each asset category and their associated 95% confidence intervals (CI) are summarized in Table 1 below.

The following table summarizes the mean values and confidence intervals for each asset:

Table 1. Mean Value and Confidence Intervals

Livelihood Asset	Mean	95% CI Lower	95% CI Upper
Human Capital	0.71	0.68	0.74
Physical Capital	0.41	0.38	0.44
Financial Capital	0.32	0.29	0.35
Social Capital	0.34	0.29	0.39

Source: Authors, based on data from the 2023/2024 round of the Nigeria General Household Survey-Panel. National Bureau of Statistics. 2024 [28]

Shocks

Food Consumption Shocks

A total of 74.43% of households experienced food consumption shocks in the 12 months preceding the survey, with the average number

of shocks being 3 (95% CI 2.83 – 4.06). Increased prices were therefore the biggest food consumption shocks experienced by households, followed by shocks that affected agricultural productivity, and climatic shocks. In aggregate, 25.29% of households

experienced climatic shocks (floods, drought, hail, and/or erosion); 18.15% of households experienced security threats (theft of livestock and/or assets); 36.00% of households experienced agricultural productivity shocks (pests, weeds, and/or crop/livestock diseases); 67.89% experienced increased food prices and 46.74% experienced increased prices of agricultural inputs (71.31% of households experienced at least one of these price shocks).

Economic Shocks

63.60% of households reported experiencing economic shocks related to income or asset loss since 2022, with an average of 2 economic shocks per household (95% CI 1.52 – 2.24). The economic shocks primarily involved price (inputs/food/fuel price) increases (56.91%), followed by climatic (floods, irregular rains, droughts, or high temperatures) shocks (15.35%) and security (theft, robbery, assault and/or kidnapping) issues (6.70%).

Safety Nets

Just 2.71% of households received any safety net support in the 12 months preceding the survey, highlighting a significant gap in external assistance during times of vulnerability.

Livelihood Activities

Ninety percent (90%) of households were engaged in at least one type of livelihood activity in the 7 days preceding the survey; 5% of households were engaged in up to three types of livelihood activities. Households that had not engaged in any type of livelihood activity in the 7 days preceding the survey most commonly reported seasonal inactivity, temporary job transitions, short-term illness, or personal leave/vacation. Table 2 below provides a detailed breakdown of the prevalence of household involvement in various livelihood activities. It highlights the percentage of households engaged in different livelihood activities, with agricultural activities being the most common, and includes the corresponding 95% confidence intervals for each estimate.

Table 2. Prevalence of Household Involvement in Various Livelihood Activities and Their Confidence Intervals

Percent of households that engage in different types of livelihood activities and average number of total livelihood activities engaged in	Percent/mean	95% CI Lower	95% CI Upper
At least one household member engaged in wage-earning activities	19.98%	13.55%	26.41%
At least one household member was involved in a non-farm household enterprise	27.10%	18.89%	35.31%
At least one household member was involved in agricultural livelihood activity (farm, livestock, fishing, forestry)	75.68%	70.28%	81.08%
At least one household member was involved in any of the three types of livelihood activities	89.99%	86.47%	93.51%

Source: Authors, based on data from the 2023/2024 round of the Nigeria General Household Survey-Panel. National Bureau of Statistics. 2024.[28]

Food Security

Fifty-six percent (55.5%) of households reported no moderate or severe food insecurity in the one month preceding the survey. Table 3 below presents the model results on factors

influencing food security, examining the role of livelihood assets (human, physical, financial, and social capital), shocks (food consumption and economic), safety nets, and livelihood activities. The odds ratios, p-values, and 95%

confidence intervals for each factor are provided, highlighting how these variables are associated with food security outcomes.

Logistic Regressions

In model 1 (livelihood assets and control variables only), physical capital and financial capital significantly increased the odds of being food secure, while social capital reduced the odds of food security and human capital did not have a statistically significant relationship. Households in the rural area had significantly higher odds of being food secure, while female-headed households had significantly lower odds. Household was negatively associated with food security, with a marginal significance level.

In model 2, after including food consumption and economic shock indices, physical capital and financial capital remained positively and significantly associated with food security. Social capital remained negatively associated, but now with marginal statistical significance. Both the food consumption shock index and the economic shock index were strongly and negatively associated with food security. Female headed households still had significantly lower odds of food security and the positive relationship with rural residence persisted. Household size remains negatively associated, becoming statistically significant at the 5% level (larger households have lower odds of food security).

With the further inclusion of safety nets, the magnitude and significance of physical and financial capital remained largely unchanged. Social capital continued to show an odds ratio

below one, with marginal statistical significance, while shock indices remained strongly and negatively associated with food security. Receipt of safety net(s) was negatively associated with food security, but this association was not statistically significant. Female headship, household size, and rural residence retained similar directions and levels of significance as in Model 2.

In the fully specified model including livelihood activities, physical capital and financial capital remained positively and significantly associated with food security and human capital became marginally significantly associated with food security. Social capital, food consumption shock index, and economic shock index remained negatively associated with food security and statistically significant. Receipt of safety net(s) remained negatively associated with food security, and this became marginally significant. None of the livelihood activity categories (one, two, or three types of activities) were statistically significant at the 5% level compared to no livelihood activity. Female headship and household size remained negatively and significantly associated with food security, while rural residence remained positively and significantly associated with food security.

Age and education of the household head were not statistically significant in any of the models.

Overall, across models, the direction of associations was largely stable, with minimal changes observed in the magnitude and statistical significance of key variables as additional covariates were introduced.

Table 3. Model Results on Factors Influencing Food Security: Livelihood Assets, Shocks, Safety Nets, and Activities

MODEL 1: Establish whether livelihood assets are associated with food security				
Food Secure	Odds ratio	p-value	95% CI Lower	95% CI Upper
Human capital	4.21	0.111	0.72	24.68
Physical capital	19.88	0.000	4.82	82.07
Financial capital	9.78	0.000	3.35	28.56

Social capital	0.36	0.000	0.21	0.64
Female household head	0.44	0.011	0.23	0.83
Age of household head	1.00	0.767	0.98	1.02
Household head has no formal education	0.00			
Household head has primary education	1.02	0.948	0.52	2.03
Household head has secondary education	1.19	0.699	0.50	2.82
Household head has tertiary education	0.93	0.885	0.36	2.43
Household size	0.94	0.096	0.88	1.01
Household is in rural area	4.77	0.006	1.58	14.40
MODEL 2: Added vulnerability context (shocks): Test whether shocks reduce the odds of food security beyond asset endowments				
Food Secure Based on FIES	Odds ratio	p-value	95% CI Lower	95% CI Upper
Human capital	5.52	0.078	0.83	36.80
Physical capital	10.27	0.007	1.89	55.91
Financial capital	6.36	0.003	1.87	21.59
Social capital	0.56	0.063	0.31	1.03
Food consumption shocks index	0.02	0.000	0.00	0.06
Economic shocks index	0.00	0.001	0.00	0.04
Female household head	0.35	0.002	0.18	0.68
Age of household head	1.00	0.832	0.99	1.02
Household head has no formal education	0.00			
Household head has primary education	0.97	0.930	0.51	1.87
Household head has secondary education	1.23	0.679	0.46	3.25
Household head has tertiary education	0.87	0.781	0.33	2.32
Household size	0.92	0.050	0.85	1.00
Household is in rural area	3.94	0.007	1.45	10.72
MODEL 3: Add safety nets: Assess whether safety nets buffer food insecurity				
Food Secure Based on FIES	Odds ratio	p-value	95% CI Lower	95% CI Upper
Human capital	5.31	0.085	0.79	35.47
Physical capital	10.05	0.008	1.83	55.06
Financial capital	6.19	0.004	1.81	21.09
Social capital	0.55	0.052	0.30	1.00
Food consumption shocks index	0.02	0.000	0.00	0.06
Economic shocks index	0.00	0.002	0.00	0.06
Household received safety net	0.42	0.118	0.14	1.25
Female household head	0.34	0.002	0.17	0.68
Age of household head	1.00	0.721	0.99	1.02
Household head has no formal education	0.00			
Household head has primary education	1.00	0.995	0.52	1.93
Household head has secondary education	1.27	0.624	0.48	3.34
Household head has tertiary education	0.92	0.866	0.34	2.47
Household size	0.92	0.050	0.86	1.00
Household is in rural area	3.91	0.007	1.46	10.50

MODEL 4: Add livelihood activities				
Food Secure Based on FIES	Odds ratio	p-value	95% CI Lower	95% CI Upper
Human capital	6.20	0.076	0.83	46.46
Physical capital	14.26	0.006	2.17	93.94
Financial capital	6.30	0.006	1.69	23.53
Social capital	0.52	0.031	0.28	0.94
Food consumption shocks index	0.02	0.000	0.00	0.07
Economic shocks index	0.00	0.001	0.00	0.05
Household received safety net	0.36	0.063	0.12	1.06
Household had no type of livelihood activity	0.00			
Household had one type of livelihood activity	1.04	0.937	0.42	2.58
Household had two types of livelihood activity	0.38	0.071	0.13	1.09
Household had three types of livelihood activity	1.11	0.892	0.24	5.07
Female household head	0.33	0.002	0.16	0.66
Age of household head	1.00	0.575	0.99	1.02
Household head has no formal education	0.00			
Household head has primary education	1.14	0.713	0.57	2.29
Household head has secondary education	1.52	0.348	0.63	3.67
Household head has tertiary education	1.26	0.625	0.50	3.20
Household size	0.93	0.082	0.86	1.01
Household is in rural area	4.17	0.004	1.59	10.96

Source: Authors, based on data from the 2023/2024 round of the Nigeria General Household Survey-Panel. National Bureau of Statistics. 2024.[28]

Qualitative Results

This section presents the qualitative findings from the study, which explore the perceived pathways to food security among farming households in North Central Nigeria. The analysis focuses on the influence of livelihood assets, livelihood activities, and the impact of various shocks on food insecurity.

In-depth interviews were conducted with key informants across all states in the North Central zone and the Federal Capital Territory (FCT). A purposive sampling technique, supplemented by snowball sampling, was employed to ensure diverse representation from essential stakeholder groups involved in food production, preparation, and nutrition-related decision-making. The selection process

continued until data saturation was achieved. Interviews took place at four distinct levels: state, local government area (LGA), community, and household. At the state level, agricultural extension officers and personnel from the Women-in-Agriculture Unit within the State Ministry of Agriculture were interviewed. At the LGA level, interviews involved agricultural officers and women-in-agriculture staff working within the local agricultural departments. At the community and household levels, interviews were conducted with community leaders, heads of farming households, and primary food preparers in the households.

The interviews were guided by a semi-structured interview guide, allowing for

flexibility to probe emerging topics. The questions aimed to explore the factors impacting food security, Livelihood Assets, Shocks and coping mechanisms during food scarcity, and the challenges faced by farming households. The interviews were conducted by local research assistants, in either English or local languages, with all interviews being audio-recorded after obtaining consent. Ethical approval for the study was obtained from the research and ethics committees of the respective State Ministries of Health, as well as from the FCT Health Research Ethics Committee.

The results are categorized into key themes related to livelihood strategies and common shocks.

Livelihood Strategies and Assets

The study found that farming households in North Central Nigeria employ a range of livelihood strategies that significantly affect their ability to maintain food security. These strategies are primarily dependent on the assets available to the households, including human, social, financial, and natural resources.

1. Farm Activities

Agriculture is the central livelihood activity, with all respondents reporting its significance in securing household food and income. The most common farm activities include crop farming, livestock farming, and hired labor.

- **Crop Farming:** This was identified as the most widespread farm activity, with respondents describing farming as a generational tradition and the primary means of livelihood. Many households engage in crop farming, both for household consumption and commercial purposes. A respondent from Benue State noted, "Farming is our basic necessity for more than two generations now in this village."
- **Livestock Farming:** In addition to crop farming, livestock farming, particularly poultry and small ruminants such as goats

and sheep, plays a crucial role in diversifying household income. A farmer from Niger State shared, "We rear animals like goats, chickens, and sheep, and sell them to earn income."

- **Hired Farm Labor:** Some farming households rely on hired labor, either working on other farmers' land or hiring others to work on theirs. This additional income source helps to buffer households from food insecurity during lean seasons.

2. Non-Farm Activities

Many households supplement their agricultural activities with non-farm income-generating ventures, which help reduce the financial pressures of farming. These activities include trading, crafts, transportation, and food vending.

- **Trading:** The buying and selling of agricultural produce, as well as non-farm goods, is a common strategy for increasing household income. One respondent from Nasarawa State noted, "Many women in our community sell grains like paddy rice and guinea corn. This is an important second income source."
- **Crafts and Artisanal Work:** Respondents reported that crafts such as hairdressing, blacksmithing, and tailoring are common in the zone. These activities often provide women with opportunities for income, which they use to support household food security.
- **Transportation and Food Vending:** Some households engage in transportation services, such as motorcycling ("Okada") or food selling, often by the roadside. These activities provide additional sources of income, particularly during farming off-seasons.

3. Wage Employment

A smaller proportion of households engage in wage employment, which includes civil service jobs, teaching, construction work, and private sector employment. These sources of income help households mitigate the impact of

food insecurity during periods when agricultural income is low.

Shocks and Vulnerability

Farming households in North Central Nigeria face multiple shocks that influence their food security. These shocks include both climatic events and market fluctuations, which disrupt agricultural production and reduce income stability.

1. Climatic Shocks

Respondents cited droughts and floods as the most common climatic shocks that affect agricultural productivity. Farmers reported that these environmental challenges result in crop failure or reduced yields, leading to food insecurity.

"We face droughts sometimes, and other times the floods destroy our crops. This makes it hard to rely on farming alone," explained a respondent from Plateau State.

2. Market Shocks

Market-related shocks, such as price fluctuations and poor access to markets, were also found to affect food security. Farmers expressed concern over the volatility of crop prices, especially for grains, which often fluctuate based on supply and demand.

"The price of grains like maize and rice changes every season. Sometimes we sell for a high price, and other times, we can't even cover our costs," shared a farmer from Niger State.

3. Economic Shocks

Rising input costs, particularly for seeds, fertilizers, and agrochemicals, were also highlighted as a significant barrier to food security. Respondents noted that increasing input costs often leave farmers in debt, limiting their capacity to invest in subsequent planting seasons.

Livelihood Strategies

In response to these shocks, farming households employ various strategies,

primarily aimed at ensuring food availability and economic resilience.

Access to Resources and External Support

Households reported receiving support from government programs, NGOs, and community networks. While this support is helpful, it is often inconsistent or insufficient.

- "The government provides some inputs, but the support is not timely, and we miss out due to our location," explained a respondent from Kwara State.
- NGOs like GAIN and JICA were reported to provide farm inputs, technical assistance, and training, which enabled households to improve their agricultural practices and enhance food security.

Diversification of Livelihood Activities

One of the most common livelihood strategies employed by farming households is diversification of income sources. This includes pursuing non-farm activities or engaging in multiple agricultural activities to reduce dependency on a single crop.

"Most people here don't rely only on farming. We also engage in small businesses like trading, and this helps us avoid food shortages," shared a medium-scale farmer from Benue State.

Market Linkages and Storage

Several respondents emphasized the importance of better market access and improved transportation networks to enhance income from agricultural produce. Access to reliable storage facilities was also identified as critical to reduce post-harvest losses.

"Good roads and market access are key to ensuring we get fair prices for our produce," explained a farmer from Nasarawa State.

Discussion

The purpose of this study was to examine the pathways to food security among farming households in North Central Nigeria, with a focus on the influence of livelihood assets,

livelihood activities, and shocks. Both quantitative and qualitative findings provide a deeper understanding of the factors influencing food security among farming households.

In the quantitative analysis, livelihood activities were not significantly associated with food security. While this lack of significance might suggest that livelihood diversification did not directly contribute to food security, it does not imply that it is not a vital strategy. The results indicate that other factors, such as household assets and exposure to shocks, played a more significant role in determining food security. The importance of non-farm activities, such as trading and food vending, should not be overlooked. These activities provide critical support, especially during off-seasons or periods when agricultural income is insufficient. Indeed, participants in the interviews highlighted the crucial role of livelihood diversification in ensuring stability of food consumption. Thus, while livelihood diversification did not show a statistically significant direct relationship, it may still play an important role in enhancing household resilience to food insecurity, particularly in areas prone to agricultural stress [2, 3].

The negative impact of shocks on food security was a key finding. Food consumption shocks and economic shocks, particularly price fluctuations and climatic disruptions (such as droughts and floods), were strongly associated with lower food security. This underscores the vulnerability of farming households to both economic disruptions and climate-related shocks, which hinder their ability to access and produce food. These findings are consistent with existing literature, which emphasizes the adverse effects of economic volatility and climate change on food security, especially in rural areas [29-31]. The impact of market fluctuations, particularly price volatility, has been widely reported in literature as a major factor contributing to food insecurity in farming communities [20, 32].

While social safety nets were not significantly associated with food security in the quantitative analysis, qualitative data revealed a role for social protection and highlighted concerns about the timeliness and adequacy of external support. Respondents highlighted that while some government and NGO interventions were available, they were often inconsistent and insufficient to effectively mitigate food insecurity, particularly during critical periods. This finding aligns with previous studies highlighting the challenges of implementing effective social protection programs in rural settings, where the reach and adequacy of interventions often fall short due to logistical challenges, corruption, and inadequate funding [32, 33]. The limited effectiveness of social safety nets has also been reported in research on Nigeria's rural communities, where many households fail to benefit from formal safety net programs [34]. The finding suggests that external support programs must be timely and well-targeted to be effective in supporting vulnerable households [17, 35].

The study found that livelihood assets, including physical, financial, and human capital, were significantly associated with food security. Households with greater access to productive assets (such as land, livestock, and financial resources) were more likely to be food secure. Human capital, including education and skills, also played an important role in enhancing resilience to food insecurity, as it enabled households to better adapt to shocks and engage in income-generating activities. These findings emphasize the importance of strengthening household assets to help farming households manage risks and improve their food security outcomes [3, 6, 36]. Still, the negative association between social capital and food security that was found in our study suggests a more nuanced role of community networks that should be further explored in future research. Previous studies on rural social networks highlight the potential of collective

action to reduce vulnerability to food insecurity [35, 37].

The findings from both the quantitative and qualitative analyses have important implications for policy and program design aimed at improving food security among farming households in North Central Nigeria. The following policy recommendations are based on these findings:

1. **Strengthening Livelihood Assets:** There should be an emphasis on strengthening household assets, particularly physical and financial capital. This could include improving access to credit, supporting market access, and providing training to enhance agricultural productivity. Supporting non-farm income-generating activities could also help reduce reliance on agriculture alone for food security, especially in rural areas where income from agriculture is seasonal [33, 38].
2. **Strengthening Resilience to Shocks:** In addition to strengthening livelihood assets, it is crucial to build resilience to economic and environmental shocks. This can be achieved through the diversification of income sources, promoting small-scale entrepreneurship, and enhancing access to sustainable markets for various products to buffer households against seasonal agricultural fluctuations. Strengthening disaster risk reduction measures, such as providing climate-resilient technologies, early warning systems, and training on climate-smart agricultural practices, will also help reduce vulnerability to shocks like floods and droughts [33].
3. **Improving Social Support Systems:** Government and NGO support programs should be timely, adequate, and consistent. Ensuring that support reaches vulnerable populations in remote areas is essential. Additionally, targeted interventions, such as extension services and input distribution, should be implemented to

ensure support reaches those most in need [39].

While this study provides valuable insights into the pathways to food security in North Central Nigeria, there are some methodological limitations that should be considered. The cross-sectional design of the study limits causal inference, as it provides only a snapshot of the situation at a specific point in time [35]. Future studies could adopt a longitudinal design to track changes in food security, assets, and livelihood strategies over time [40]. Although the study captured a wide range of shocks including economic, climatic, and market-related shocks, future research could examine how these shocks interact and their cumulative impact on food security [41]. Research could explore the compounded effects of multiple shocks and investigate how households prioritize different livelihood strategies in response to simultaneous challenges [42]. Future research could also explore the long-term impact of climatic shocks and market volatility on household food security, particularly in the context of climate change [43, 44]. Additionally, research could investigate the effectiveness of policy interventions aimed at enhancing livelihood diversification, market access, and climate resilience [31]. Comparative studies between different zones or farming systems in Nigeria would provide further insights into the factors that influence food security outcomes [45]. Moreover, qualitative research could explore the gendered dimensions of food security, focusing on the specific challenges faced by women and youth in accessing resources, livelihood strategies, and market opportunities. This would contribute to a more inclusive understanding of food security and inform gender-sensitive policies [46].

Conclusion

This study highlights the key role of livelihood assets in improving food security among farming households in North Central

Nigeria. Exposure to shocks, particularly economic and climatic disruptions, remains a major factor contributing to food insecurity. While livelihood activities did not show a direct statistical relationship with food security in this study, they still provide important support to households, particularly during off seasons. Policies should focus on strengthening household assets, improving market access, and ensuring effective external support to mitigate the impacts of shocks and improve food security outcomes

Conflict of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

Ethical Approval

Ethical approval for this study was obtained from the research and ethics committees of the respective State Ministries of Health, as well as from the FCT Health Research Ethics Committee. All participants provided informed consent before their involvement in interviews.

Data Availability

The GHS-Panel data used for the quantitative analysis is publicly available (<https://microdata.nigerianstat.gov.n>

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[g/index.php/catalog/82](http://www.tijar.org/index.php/catalog/82)). Qualitative data were collected through semi-structured interviews guide across the North Central zone of Nigeria. De-identified qualitative data are available from the corresponding author upon reasonable request.

Author Contributions

Blessing Ukamaka Ugwunne conceptualized and designed the study, led the qualitative data collection process, conducted data analysis, and wrote the manuscript. Olutayo Adeyemi provided guidance on the study's conceptualization and design, contributed to the data analysis, and reviewed the manuscript. Both authors approved the final manuscript for submission.

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Evaluating the Impact of Common Technical Document Adoption on Medicines Regulatory Performance in Nigeria: An Interrupted Time-Series Analysis

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Abstract

The Common Technical Document (CTD) has been widely adopted to harmonise medicines regulatory submissions and strengthen regulatory systems, yet empirical evidence on its performance impact in low- and middle-income countries remains limited. This study evaluated the effect of CTD adoption on medicines regulatory performance in Nigeria using a quasi-experimental interrupted time-series design. Monthly regulatory data from January 2018 to December 2024 were analysed, with June 2020 marking the introduction of mandatory CTD submissions. Outcomes examined included medicines approval volumes, regulatory safety signals (alerts and recalls per 100 approvals), and post-market quality outcomes measured through risk-based post-market surveillance (RB-PMS) failure rates. Segmented regression analysis showed no statistically significant pre-intervention trend in approvals ($p = 0.788$), no immediate level change following CTD adoption ($p = 0.658$), and no significant post-intervention trend change ($p = 0.723$). Similarly, no significant changes were observed in regulatory safety signal rates at the point of CTD implementation ($p = 0.971$) or in post-intervention trends ($p = 0.894$). In contrast, RB-PMS outcomes showed a statistically significant immediate reduction in failure rates following CTD adoption ($p < 0.001$), followed by a significant positive post-intervention trend ($p < 0.001$), indicating that initial quality gains were not sustained over time. Overall, the findings suggest that CTD adoption functions as a foundational harmonisation reform but does not independently produce sustained improvements in regulatory throughput or safety outcomes without complementary institutional and operational strengthening.

Keywords: Common Technical Document, Interrupted Time-Series, Medicines Regulation, Nigeria, Regulatory Performance.

Introduction

Medicines regulation is a core public-health function that safeguards populations by ensuring that authorised products meet acceptable standards of quality, safety, and efficacy. As pharmaceutical markets expand and product complexity increases, regulatory authorities face growing pressure to process applications efficiently while maintaining rigorous scientific assessment. In response to long-standing inefficiencies associated with

fragmented dossier formats and duplicative review practices, global harmonisation efforts have promoted standardised technical requirements for medicines registration. One of the most significant outcomes of these efforts is the Common Technical Document (CTD), which provides a unified structure for organising regulatory submissions across administrative, quality, non-clinical, and clinical domains [1, 2].

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The CTD has become a *de facto* global standard for medicines registration and is widely regarded as a cornerstone of regulatory modernisation. By standardising dossier structure, the CTD is intended to reduce ambiguity in submission requirements, improve validation discipline, and support more predictable review workflows. In many jurisdictions, CTD adoption has also served as an enabling platform for electronic submissions, regulatory reliance, and work-sharing arrangements among authorities [3]. As a result, CTD implementation is often implicitly associated with expectations of improved regulatory performance, including faster approvals, reduced rework, and enhanced oversight across the product lifecycle.

Despite these expectations, the empirical relationship between CTD adoption and measurable regulatory performance outcomes remains insufficiently established, particularly in low- and middle-income country settings. Much of the existing literature focuses on descriptive accounts of harmonisation initiatives or cross-sectional comparisons of regulatory processes, offering limited insight into whether CTD adoption produces observable system-level changes over time [4]. Where performance improvements are reported, they are often attributed to CTD implementation without robust longitudinal designs capable of isolating reform effects from background trends or concurrent institutional changes.

This evidence gap is especially pronounced in Africa, where regulatory authorities operate under conditions of high workload, constrained resources, and evolving institutional capacity. While regional harmonisation initiatives have promoted CTD-aligned requirements as a means of reducing duplication and strengthening regulatory systems, studies consistently note that the benefits of such reforms depend heavily on implementation context, assessor capacity, and supporting infrastructure [5, 6, 15]. Consequently, the

assumption that CTD adoption alone leads to improved regulatory throughput or safety outcomes remains largely untested in many African jurisdictions.

Nigeria represents a particularly important case for examining these issues. As Africa's most populous country and one of its largest pharmaceutical markets, Nigeria's regulatory performance has significant implications for access to quality medicines and regional health security. The national medicines regulatory authority formally adopted the CTD format for medicines registration, with mandatory implementation commencing in June 2020 [18]. This reform was intended to harmonise dossier submissions, improve clarity of regulatory expectations, and align national practice with international standards [7, 11]. However, Nigeria's regulatory environment is also characterised by high application volumes, hybrid paper-digital workflows, and ongoing capacity constraints, raising questions about how CTD adoption translates into operational performance.

To date, there has been limited longitudinal evaluation of CTD adoption in Nigeria using system-level regulatory data. In particular, it remains unclear whether the introduction of mandatory CTD submissions has altered regulatory throughput, as reflected in approval volumes, or influenced downstream safety and quality indicators such as recalls, safety alerts, and post-market surveillance outcomes. Addressing this gap is essential for evidence-based regulatory policy, as it enables regulators to distinguish between reforms that improve procedural order and those that deliver measurable performance gains.

Against this background, the objective of this study is to evaluate the impact of CTD adoption on medicines regulatory performance in Nigeria using a quasi-experimental interrupted time-series design. By analysing longitudinal regulatory data spanning pre- and post-implementation periods, the study provides empirical evidence on whether CTD

adoption is associated with changes in regulatory throughput and safety-related outcomes. In doing so, it contributes to regulatory science by clarifying the system-level effects of dossier harmonisation in a large low- and middle-income country context and by informing future strategies for strengthening medicines regulation beyond formal standardisation alone.

Materials and Methods

Study Context

This study was conducted within the context of Nigeria's national medicines regulatory system, overseen by the National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC is responsible for the evaluation, registration, post-market surveillance, and regulatory oversight of medicinal products marketed in Nigeria. As part of ongoing regulatory modernisation efforts and alignment with international best practices, NAFDAC formally adopted the Common Technical Document (CTD) format for medicines registration, with mandatory implementation commencing in June 2020. Prior to this reform, dossier submissions followed locally adapted formats that varied in structure and level of standardisation.

The introduction of the CTD was intended to harmonise dossier organisation, improve the clarity of regulatory requirements, and facilitate more structured scientific review across quality, non-clinical, and clinical domains. However, the adoption occurred within an operational environment characterised by high application volumes, mixed paper–electronic workflows, and evolving institutional capacity. These contextual features make Nigeria a suitable case for examining whether CTD adoption is associated with measurable changes in regulatory performance over time.

Study Design

A quasi-experimental interrupted time-series (ITS) design was employed to evaluate the impact of CTD adoption on medicines regulatory performance. ITS is a robust longitudinal evaluation method commonly used to assess the effects of policy or system-level interventions implemented at a clearly defined point in time [9]. By analysing outcome trends before and after an intervention, ITS allows for the estimation of both immediate (level) changes and longer-term (trend) changes while controlling for pre-existing temporal patterns [10].

In this study, June 2020 was defined as the intervention point corresponding to the mandatory implementation of CTD submissions. Monthly regulatory data were analysed over a continuous seven-year period spanning January 2018 to December 2024. This time frame provided an adequate number of pre- and post-intervention observations to support segmented regression analysis and minimise the risk of spurious associations.

Data Sources

The analysis utilised publicly available regulatory data routinely published by NAFDAC and other authoritative sources. Monthly medicines approval data were extracted from the NAFDAC Registered Products ("Greenbook"), which records approved products by date and product category. Regulatory safety signals were captured using data on safety alerts and product recalls published on the agency's official website. Post-market quality outcomes were assessed using information from risk-based post-market surveillance (RB-PMS) reports, which document laboratory testing results and non-compliance rates for sampled products.

All datasets were compiled into a monthly time series covering the study period. Where necessary, data were cleaned to ensure consistency in date formats and category

definitions. COVID-19-specific products and emergency-use approvals were excluded to avoid confounding effects associated with exceptional regulatory pathways introduced during the pandemic.

Variables and Outcome Measures

The primary independent variable was CTD adoption, operationalised as a binary indicator coded 0 for the pre-intervention period (January 2018 to May 2020) and 1 for the post-intervention period (June 2020 to December 2024).

Three categories of dependent variables were examined. First, regulatory throughput was measured using the monthly count of approved medicinal products. Second, regulatory safety signals were assessed using the number of safety alerts and product recalls, normalised per 100 approvals to account for fluctuations in approval volume. Third, post-market regulatory performance was evaluated using RB-PMS outcomes, expressed as the percentage of tested samples that failed to meet quality specifications within each reporting period.

These outcome measures were selected to capture both upstream regulatory processing activity and downstream indicators of product quality and safety, thereby providing a system-level assessment of regulatory performance.

Statistical Analysis

Segmented regression analysis was applied to each outcome variable to estimate changes associated with CTD adoption. The standard ITS regression model included terms for baseline level, pre-intervention trend, immediate post-intervention level change, and post-intervention trend change. This specification enabled the separation of short-term effects from longer-term shifts in regulatory performance trajectories. Autocorrelation was assessed using residual diagnostics, and where necessary, appropriate adjustments were made to ensure valid inference. Statistical significance was evaluated at the 5 per cent level. All analyses were conducted using SPSS version 27.

Results

Descriptive Overview

The analysis covered 84 monthly observations from January 2018 to December 2024, comprising 29 months before and 55 months after the introduction of mandatory CTD submissions in June 2020. Across the study period, medicines approval volumes, regulatory safety signals, and post-market surveillance outcomes exhibited month-to-month variability with no structural breaks unrelated to the intervention point.

Effect of CTD Adoption on Regulatory Throughput

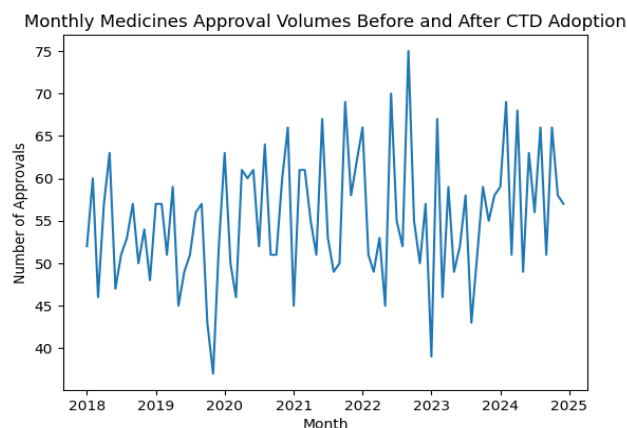


Figure 1. Monthly Medicines Approval Volumes Before and After CTD Adoption in Nigeria (2018–2024)

The figure 1 shows fluctuations in approval volumes in the pre-CTD period, followed by a more stable and generally higher approval

throughput after CTD implementation, indicating improved regulatory processing consistency over time.

Table 1. Segmented Regression Results for Monthly Medicines Approvals

Parameter	Coefficient (β)	Standard Error	t-value	p-value
Baseline level (Intercept)	53.49	2.82	18.99	<0.001
Pre-intervention trend	-0.04	0.16	-0.27	0.788
Immediate level change (CTD adoption)	2.07	4.66	0.44	0.658
Post-intervention trend change	0.06	0.18	0.36	0.723

CTD adoption occurred in June 2020. Statistical significance assessed at $p < 0.05$.

Segmented regression results (Table 1) indicate that the pre-intervention trend in approvals was not statistically significant ($\beta = -0.04$, $p = 0.788$). The immediate level change associated with CTD adoption was positive but non-significant ($\beta = 2.07$, $p = 0.658$). Similarly, the post-intervention trend change was small and not statistically significant ($\beta = 0.06$, $p =$

0.723). These findings indicate that CTD adoption was not associated with a statistically detectable change in monthly regulatory throughput.

Effect of CTD Adoption on Regulatory Safety Signals

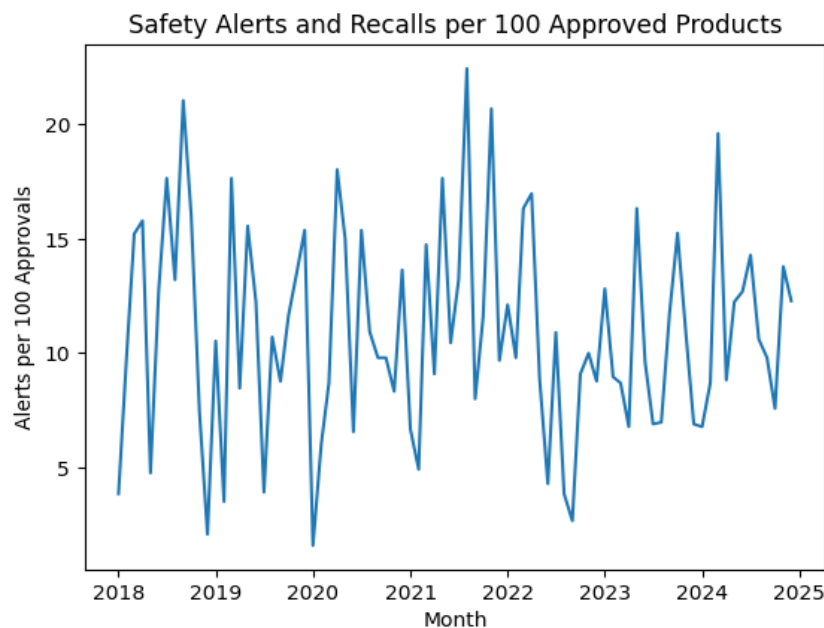


Figure 2. Safety Alerts and Recalls per 100 Approved Products Before and After CTD Adoption (Monthly Trend)

Figure 2 shows the rate of safety alerts and recalls per 100 approved products before and after CTD adoption. Prior to CTD implementation, the alerts-per-approval ratio displays greater volatility, whereas the post-

CTD period demonstrates a more moderated pattern, suggesting changes in the relationship between regulatory throughput and post-market safety signalling.

Table 2. Segmented Regression Results for Safety Alerts and Recalls (Per 100 Approvals)

Parameter	Coefficient (β)	Standard Error	t-value	p-value
Baseline level (Intercept)	11.41	1.77	6.45	<0.001
Pre-intervention trend	-0.02	0.10	-0.22	0.825
Immediate level change (CTD adoption)	-0.11	2.93	-0.04	0.971
Post-intervention trend change	0.01	0.11	0.13	0.894

The interrupted time-series analysis (Table 2) shows no statistically significant pre-intervention trend in safety signal rates ($\beta = -0.02$, $p = 0.825$). The immediate level change at CTD adoption was negligible and non-significant ($\beta = -0.11$, $p = 0.971$), and no significant post-intervention trend change was observed ($\beta = 0.01$, $p = 0.894$). Overall, CTD adoption was not associated with an immediate

or sustained change in regulatory safety signal rates.

Effect of CTD Adoption on Post-Market Surveillance Outcomes

Figure 3 illustrates RB-PMS failure rates using a monthly proxy derived from annual surveillance data.

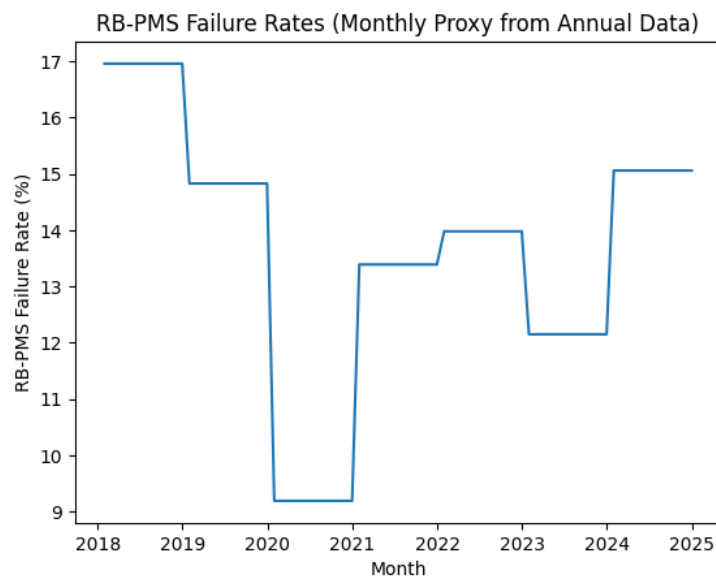


Figure 3. RB-PMS Failure Rates using a Monthly Proxy Derived from Annual Surveillance Data, Before and After CTD Adoption

Figure 3 illustrates Risk-Based Post-Marketing Surveillance (RB-PMS) failure rates using a monthly proxy derived from annual surveillance data. The figure indicates a reduction in RB-PMS failure rates following

CTD adoption, with post-CTD values remaining lower and more stable than those observed in the pre-CTD period, reflecting potential improvements in dossier quality and regulatory oversight.

Table 3. Segmented Regression Results for RB-PMS Failure Rates (Monthly Proxy)

Parameter	Coefficient (β)	Standard Error	t-value	p-value
Baseline level (Intercept)	18.84	0.55	34.27	<0.001
Pre-intervention trend	-0.27	0.03	-8.55	<0.001
Immediate level change (CTD adoption)	-9.79	0.91	-10.76	<0.001
Post-intervention trend change	0.34	0.03	10.04	<0.001

Segmented regression results (Table 3) show a statistically significant declining pre-intervention trend in RB-PMS failure rates ($\beta = -0.27$, $p < 0.001$). CTD adoption was associated with a statistically significant immediate reduction in failure rates ($\beta = -9.79$, $p < 0.001$), followed by a significant positive post-intervention trend change ($\beta = 0.34$, $p < 0.001$), indicating a gradual increase in failure rates after the initial reduction.

Discussion

This study examined the impact of Common Technical Document (CTD) adoption on medicines regulatory performance in Nigeria using an interrupted time-series design. By analysing longitudinal regulatory data before and after mandatory CTD implementation, the study provides empirical insight into how dossier harmonisation reforms translate into observable system-level outcomes in a large low- and middle-income country regulatory context.

The analysis found no statistically significant change in medicines approval volumes following CTD adoption. Neither the immediate level change nor the post-intervention trend in approvals differed from the pre-existing trajectory. This finding suggests that CTD adoption, while improving the structure and consistency of dossier submissions, does not in itself expand regulatory throughput. This aligns with regulatory science literature which emphasises that dossier harmonisation primarily addresses information organisation and review clarity rather than processing capacity [1, 2, 21]. In resource-constrained regulatory environments, throughput is strongly shaped by assessor availability, workload distribution, and workflow efficiency, factors that are not directly altered by the adoption of a standardised dossier format [3].

Similarly, the absence of statistically significant changes in regulatory safety signals following CTD implementation indicates that

dossier standardisation did not materially affect the frequency of safety alerts and product recalls. This finding is consistent with conceptual distinctions in the literature between pre-market regulatory review and post-authorisation safety surveillance [4]. While CTD improves the quality and completeness of pre-market evidence, safety signal detection depends largely on the strength of pharmacovigilance systems, reporting practices, and post-market monitoring infrastructure [19, 5]. As such, reforms focused on submission standards alone would not be expected to generate immediate shifts in safety signal patterns without concurrent strengthening of pharmacovigilance systems.

In contrast, post-market surveillance outcomes exhibited a more nuanced response to CTD adoption. The significant immediate reduction in RB-PMS failure rates at the point of implementation suggests a short-term improvement in observed product quality outcomes. This may reflect more effective pre-market screening enabled by clearer quality documentation and harmonised technical requirements, reducing the entry of substandard products into the market immediately after reform. Similar short-term quality effects following regulatory harmonisation initiatives have been reported in other African regulatory collaborations [6, 12, 14].

However, the subsequent positive post-intervention trend in RB-PMS failure rates indicates that this initial improvement was not sustained. Over time, failure rates gradually increased, suggesting that the benefits of improved dossier quality alone may diminish in the absence of sustained enforcement, surveillance intensity, and compliance oversight. This pattern is consistent with evidence showing that post-market quality outcomes are highly sensitive to inspection coverage, laboratory capacity, and market surveillance resourcing [16, 13, 7]. It reinforces the view that CTD adoption can create enabling conditions for improved quality assurance but

does not replace the need for continuous post-market regulatory effort.

Taken together, the findings support an interpretation of CTD adoption as a foundational regulatory reform rather than a stand-alone performance intervention. The lack of measurable effects on throughput and safety signal rates, combined with the transient nature of post-market quality improvements, highlights the mediating role of institutional capacity and operational context. In the Nigerian setting, these include hybrid paper–digital workflows, high application volumes, and evolving post-market surveillance systems, all of which shape how harmonisation reforms translate into outcomes.

From a policy perspective, these results caution against assuming that dossier harmonisation will automatically yield improvements in regulatory performance metrics. While CTD adoption is essential for regulatory convergence and international alignment, its performance impact appears contingent on complementary investments in human resources, digital regulatory systems, reliance mechanisms, and surveillance infrastructure [2, 8]. For regulators in similar low- and middle-income country contexts, the findings underscore the importance of embedding CTD implementation within broader regulatory strengthening strategies rather than treating it as an end in itself.

Overall, this study contributes longitudinal empirical evidence to regulatory science by demonstrating that CTD adoption in Nigeria produced limited and uneven system-level effects. The findings reinforce the broader literature suggesting that harmonisation reforms primarily enable regulatory improvement but must be coupled with sustained institutional and operational enhancements to generate durable performance gains.

Conclusion

This study evaluated the system-level impact of Common Technical Document (CTD) adoption on medicines regulatory performance in Nigeria using a quasi-experimental interrupted time-series design. The findings indicate that CTD adoption, while essential for regulatory harmonisation, did not produce statistically significant changes in medicines approval volumes or regulatory safety signal rates. These results suggest that dossier standardisation alone is insufficient to expand regulatory throughput or alter post-authorisation safety detection patterns in resource-constrained regulatory environments.

In contrast, post-market surveillance outcomes showed a significant immediate reduction in RB-PMS failure rates at the point of CTD implementation, followed by a gradual increase in subsequent periods. This pattern indicates that CTD adoption may yield short-term quality benefits by strengthening pre-market screening but does not guarantee sustained improvements in product quality without continued regulatory enforcement and surveillance capacity.

Overall, the findings support the interpretation of CTD adoption as a foundational enabling reform rather than a stand-alone performance intervention. While harmonised dossier formats improve regulatory alignment and review consistency, their performance effects are mediated by institutional capacity, workflow integration, and post-market oversight mechanisms. For Nigeria and similar low- and middle-income country settings, these results underscore the importance of coupling dossier harmonisation with complementary investments in human resources, digital regulatory systems, reliance frameworks, and surveillance infrastructure.

By providing longitudinal empirical evidence from a large African regulatory system, this study contributes to regulatory science by clarifying the practical performance

implications of CTD adoption. The findings inform policy discussions on regulatory strengthening by highlighting that harmonisation reforms create necessary conditions for improvement but must be embedded within broader system-level strategies to achieve durable regulatory performance gains.

Strengths of the Study

A major strength of this study is the use of a quasi-experimental interrupted time-series design, which is well suited for evaluating system-level policy interventions implemented at a clearly defined point in time. By analysing longitudinal data spanning multiple years before and after CTD adoption, the study reduces the risk of attributing observed changes to short-term fluctuations or unrelated background trends. This strengthens the internal validity of the findings compared with cross-sectional or purely descriptive evaluations.

The study also draws on multiple regulatory performance indicators, including medicines approvals, safety alerts and recalls, and post-market surveillance outcomes. This system-level approach provides a more comprehensive assessment of regulatory performance than studies that focus on a single metric. In addition, the use of publicly available regulatory data enhances transparency and reproducibility, allowing the analysis to be independently verified or extended in future research.

Finally, the focus on a large African regulatory authority adds empirical evidence from a context that remains underrepresented in the regulatory science literature. By examining CTD adoption in a high-volume, resource-constrained setting, the study contributes insights that are directly relevant to other low- and middle-income country regulators pursuing harmonisation reforms.

Limitations of the Study

This study has several limitations that should be considered when interpreting the findings. First, the analysis relied on publicly available aggregate regulatory data, which limited the ability to assess dossier-level quality improvements or internal review efficiencies. As a result, the study captures system-level outcomes rather than process-level changes within regulatory review units.

Second, post-market surveillance outcomes were analysed using a monthly proxy derived from annual RB-PMS data. While this approach allowed integration into the interrupted time-series framework, it may smooth short-term variability and should be interpreted as an approximation rather than a precise monthly measure. The observed trends therefore reflect broader directional changes rather than fine-grained temporal effects.

Third, the study did not explicitly model other contemporaneous reforms or external shocks that may have influenced regulatory performance, such as digitalisation initiatives or changes in market composition. Although the interrupted time-series design helps control for underlying trends, residual confounding cannot be completely ruled out.

Finally, the findings reflect the Nigerian regulatory context and may not be directly generalisable to all regulatory authorities. Differences in institutional capacity, legal frameworks, and implementation fidelity may lead to different outcomes in other settings.

Policy Implications

The findings have important implications for medicines regulatory policy in Nigeria and similar low- and middle-income country settings. The absence of significant changes in approval volumes and safety signal rates suggests that CTD adoption alone should not be expected to deliver immediate performance gains. Policymakers should therefore avoid

treating dossier harmonisation as a stand-alone solution to regulatory inefficiencies.

The short-term improvement observed in post-market quality outcomes indicates that CTD adoption can enhance pre-market screening effectiveness, but sustaining these gains requires continued investment in post-market surveillance, laboratory capacity, and enforcement mechanisms [17, 20]. Regulatory strengthening strategies should explicitly link CTD implementation with broader capacity-building initiatives, including assessor training, workflow digitalisation, and reliance-based review models.

More broadly, the results support a phased approach to regulatory reform in which harmonisation provides the structural foundation for improvement, while operational and institutional reforms determine whether performance gains are realised and maintained over time.

Scope for Future Work

Future research could extend this study by incorporating dossier-level quality indicators (e.g., validation outcomes, number of review cycles, and major deficiency rates) alongside system-level metrics to better link regulatory throughput with submission quality. Longitudinal analyses covering longer post-implementation periods would help assess whether the observed trends stabilise or change as institutional learning matures. Comparative studies across multiple national regulatory authorities, or within regional harmonisation initiatives, could further clarify how contextual factors—such as assessor capacity, digital maturity, and reliance practices—moderate the impact of CTD adoption. Finally, combining interrupted time-series analysis with qualitative process evaluations could strengthen causal

inference by elucidating mechanisms underlying observed quantitative trends.

Competing Interests

The authors declare that there are no competing interests that could have influenced the conduct, analysis, or reporting of this study.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

This study utilised publicly available, aggregated regulatory data obtained from official regulatory publications and databases. No human participants, personal data, or confidential commercial information were involved. As such, formal ethical approval was not required for this study.

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Data Availability

The datasets analysed in this study were compiled from publicly accessible regulatory sources and processed for analytical purposes. Aggregated data and analytical code used to generate the results may be made available by the author upon reasonable request. Where applicable, access to raw datasets remains subject to the terms and conditions of the original data providers.

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Assessment of Medication Errors and Prevention Strategies in Selected Hospitals in Kwara State, Nigeria

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Abstract

Medication errors pose a significant challenge to patient safety worldwide, with Africa bearing the highest burden of preventable medication-related harm; however, limited data exist for Kwara State, Nigeria. This study assessed the knowledge, awareness, prevalence, causes, and prevention strategies of medication errors among 450 healthcare workers in selected hospitals across the three senatorial zones of Kwara State, using a sequential explanatory mixed-method design that included key informant interviews with five professionals. Findings showed that 91.8% of participants were aware of medication errors, but only 60.2% demonstrated good knowledge, which was significantly associated with age, tribe, religion, and professional role. The prevalence of self-reported medication errors was 73.6%, with poor handwriting (62.9%) and lack of communication among healthcare providers (54.9%) identified as the main causes; the most common self-reported error was failure to consider patient allergies (48.9%). Although 73.8% of facilities had training programs and 67.3% had medication error reporting systems, key informants highlighted staff shortages and work overload as primary contributing factors. Participants recommended more frequent training (74.9%), improved interprofessional communication (70%), and increased resource allocation (97.3%) to reduce errors. The study concludes that despite high awareness, knowledge gaps remain, and the high prevalence of medication errors calls for urgent implementation of comprehensive prevention strategies, including regular training, adequate staffing, standardized reporting systems, and enhanced communication among healthcare professionals. Future studies should attempt to assess the drivers of the major causes of medication errors reported in the present study as well as identify the medication error rates in under-studied populations.

Keywords: Healthcare Workers, Kwara State, Medication Errors, Nigeria, Patient Safety, Prevention Strategies.

Introduction

Medication is the most widely used therapeutic intervention in modern healthcare, yet errors in the medication process remain a persistent threat to patient safety worldwide [1]. Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of

healthcare professionals, patients, or consumers [2]. These errors can occur at any stage of the medication handling process, including ordering, prescription, preparation, dispensing, administration, and monitoring [3].

The global burden of medication errors is substantial. Worldwide, medication errors are responsible for 9% of avoidable healthcare costs, with healthcare systems losing approximately US\$42 billion annually [4, 5].

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The World Health Organization (WHO) has declared ensuring safe medication practice as the third global challenge for patient safety [4]. Recent meta-analyses indicate that 5% of patients globally experience medication error-related harm, with this figure rising to 7% in low- and middle-income countries (LMICs) [5]. The African region contributes the highest proportion (9%) of preventable medication error-related harm globally [5].

In Nigeria, medication errors represent a significant public health concern. A national survey of 2,386 health professionals reported a prevalence of self-reported medication errors of 47% [6]. These errors are driven by multiple factors including high workload from staff shortages, communication problems, poor working environments, and inadequate training [9, 10]. Despite various international initiatives to reduce medication errors, success depends on establishing baseline knowledge, prevalence, and identifying contextually appropriate preventive strategies in areas where data scarcity persists.

Kwara State, like most Nigerian states, faces significant healthcare challenges including inadequate infrastructure, shortage of healthcare personnel, and poor community awareness [7]. These factors are known contributors to medication errors [12, 13]. While previous studies have assessed medication errors in various Nigerian states [8, 9, 14–16], there is limited comprehensive data on medication errors and prevention strategies in Kwara State healthcare facilities. The single previous study from Kwara State was limited to prescription errors among patients and did not assess healthcare workers' knowledge or existing prevention strategies [8].

This study aimed to comprehensively assess the knowledge, awareness, prevalence, causes, and prevention strategies of medication errors among healthcare workers in selected hospitals across the three senatorial zones of Kwara State, Nigeria. The findings will inform policy development and targeted interventions to enhance medication safety in the region.

Methods

Study Design

This study employed a sequential explanatory mixed-methods design over five months (June–October 2025). Quantitative data were collected and analyzed first using semi-structured questionnaire, followed by qualitative data collection through Key informant interviews to further explain and contextualize the quantitative findings.

Study Area

The study was conducted in nine healthcare facilities across the three senatorial zones of Kwara State, Nigeria (Figure 1). Kwara State, located in North Central Nigeria, comprises 16 Local Government Areas with an estimated population of 2.37 million. The state has 994 health facilities: 3 tertiary, 209 secondary, and 782 primary. The selected facilities included General Hospital Patigi, General Hospital Omu-Aran, General Hospital Lafiagi, Cottage Hospital Lade, Cottage Hospital Adewole, Primary Healthcare Centre Osin, Primary Healthcare Centre Alanamu, Medview Hospital, and Molab Hospital. These were purposively selected to ensure representation across geographical zones and service levels.

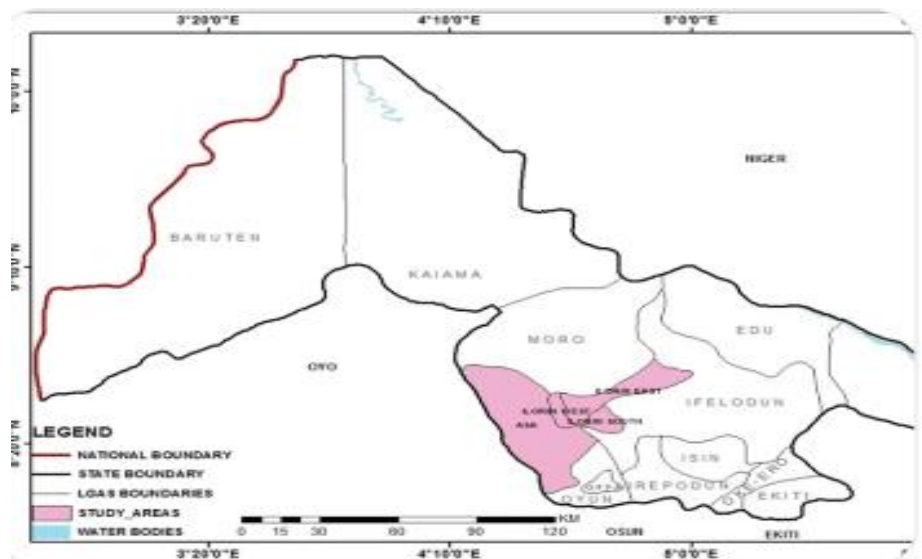


Figure 1. Location and Site of Study

Study Population and Sampling

Quantitative Component

The study population comprised healthcare workers (physicians, nurses, pharmacists, and pharmacy technicians) involved in prescribing, dispensing, administering, and monitoring medications. Sample size was calculated using Araoye's formula [9]:

$$n = z^2pq/d^2$$

Where: $z = 1.96$ (95% confidence level), $p = 0.53$ (prevalence of good knowledge from previous study), $q = 0.47$, and $d = 0.05$ (degree of accuracy).

The calculated sample size was 382, adjusted to 424 to compensate for 10% non-response. However, 450 questionnaires were distributed to improve study power.

A multistage probability sampling technique was employed. In stage one, simple random sampling was used to select three health facilities from each senatorial zone (General Hospital Pategi, General Hospital Omu Aran, General Hospital Lafiagi, Cottage Hospital Lade, Cottage Hospital Adewole, Primary Healthcare Centre Osin, Primary Healthcare Centre Alanamu, Medview Hospital, and Molab Hospital). Proportionate allocation determined the number of

questionnaires administered per facility based on total healthcare workers involved in medication processes. In stage two, random sampling was used to select respondents present at each facility during data collection.

Qualitative Component

Five key informants were purposively selected from three hospitals across the senatorial districts (General Hospital Pategi, General Hospital Omu Aran, and Cottage Hospital Adewole). Selection criteria included hospital rank, minimum of 8 years' experience, and demonstrated knowledge of medication errors based on staff recommendations. The key informants comprised three nurses (including two directors), one physician, and one pharmacist.

Reliability and Validity of the Instruments

Validity of the instrument was established through expert review to ensure clarity, relevance, and adequate coverage of the study objectives. The internal consistency of the questionnaire was evaluated using Cronbach's alpha coefficient. Dichotomous responses were coded as yes = 1 and no = 0 before the analysis. Reliability testing of the 34 items produced a Cronbach's alpha coefficient of

0.836 (standardized $\alpha = 0.833$), demonstrating good internal consistency.

Data Collection

Quantitative Data

A pre-tested semi-structured questionnaire was administered online via Google Forms. The questionnaire assessed sociodemographic characteristics, knowledge and awareness of medication errors, causes and risk factors, existing safety protocols, and potential prevention strategies. Knowledge of participants was measured through a set of ten questions, each requiring a "Yes" or "No" answer. Each correct or positive response contributed one point to the total score. A total score greater than 5 (i.e., 6 to 10) was classified as "good knowledge," indicating a higher level of understanding or awareness. Scores from 0 to 5 indicated "poor knowledge," reflecting a lower level of understanding.

Qualitative Data

Key informant interviews were conducted using a semi-structured interview guide. Written invitations were sent beforehand, and informed consent was obtained before interviews. Sessions lasted 10-30 minutes and were audio-recorded with permission. Interviews took place in the informants' offices, with two research assistants facilitating each session.

Data Analysis

Quantitative Analysis

Data were extracted to Excel and imported into IBM SPSS version 22 for analysis. Descriptive statistics (frequencies, percentages, means, standard deviations) summarize sociodemographic characteristics

and responses. Chi-square and Fisher's exact tests examined associations between sociodemographic factors and knowledge of medication errors. Statistical significance was set at $p < 0.05$.

Qualitative Analysis

Audio recordings were transcribed verbatim using Turboscribe software and verified for accuracy. Narrative analysis was conducted with NVivo software for data organization. Transcripts were read repeatedly to identify patterns. Four main categories emerged: definition of medication errors, causes, existing prevention strategies, and potential prevention strategies. Similar responses were coded inductively, and themes and sub-themes emerged from pattern analysis.

Ethical Considerations

Ethical approval was obtained from the Kwara State Ministry of Health Ethical Research Committee. Written informed consent was obtained from all participants. Confidentiality and anonymity were maintained throughout the study. Participation was voluntary, and participants could withdraw at any time without consequences.

Results

Sociodemographic Characteristics

A total of 450 healthcare workers participated in the quantitative component (100% response rate). The majority were aged 45-54 years (30.7%), female (63.6%), Yoruba (73.6%), and Muslim (62.2%). Most had higher diploma qualifications (59.6%), were nurses (60%), had 11-20 years of work experience (34.0%), and worked in public hospitals (82.4%) (Table 1).

Table 1. Sociodemographic Profile of Participants (N=450)

Characteristic	Frequency (n)	Percentage (%)
Age Group		
18-24 years	36	8.0
25-34 years	110	24.4
35-44 years	107	23.8
45-54 years	138	30.7
≥55 years	59	13.1
Gender		
Male	164	36.4
Female	286	63.6
Professional Role		
Physician	61	13.6
Nurse	270	60.0
Pharmacist	33	7.3
Pharmacy Technician	86	19.1
Work Experience		
≤1 year	20	4.4
2-5 years	114	25.3
6-10 years	111	24.7
11-20 years	153	34.0
21-34 years	52	11.6
Type of Hospital		
Public	371	82.4
Private	79	17.6

Knowledge and Awareness of Medication Errors

Overall, 413 (91.8%) participants were aware of medication errors, while 271 (60.2%) had good knowledge. Participants demonstrated highest awareness of dispensing errors (80.7%), prescribing errors (74.9%), and administration errors (70.2%). Adverse reactions (79.6%), prolonged hospitalization (51.3%), patient death (51.1%), and increased healthcare costs (48.9%) were recognized as consequences of medication errors.

Knowledge of medication errors was significantly associated with age ($p \leq 0.05$), tribe ($p \leq 0.05$), religion ($p \leq 0.05$), and professional role ($p \leq 0.05$). Participants aged 45-54 years demonstrated better knowledge (77.5%) compared to other age groups. Christians had higher knowledge (70%) than Muslims (54.3%). Physicians exhibited the best knowledge (83.6%), followed by pharmacy technicians (72.1%), nurses (52.2%), and pharmacists (51.5%). No significant associations were found with gender, education level, work experience, or hospital type ($p > 0.05$) (Table 2).

Table 2. Knowledge of Medication Errors by Sociodemographic Characteristics

Variable	Good Knowledge n (%)	Poor Knowledge n (%)	χ^2 /Fisher	p-value
Age Group			43.89	<0.001*
18-24 years	21 (58.3)	15 (41.7)		
25-34 years	63 (57.3)	47 (42.7)		
35-44 years	47 (43.9)	60 (56.1)		
45-54 years	107 (77.5)	31 (22.5)		
≥55 years	33 (55.9)	26 (44.1)		
Religion			11.58	0.001*
Islam	152 (54.3)	128 (45.7)		
Christianity	119 (70.0)	51 (30.0)		
Professional Role			33.99	<0.001*
Physician	51 (83.6)	10 (16.4)		
Nurse	141 (52.2)	129 (47.8)		
Pharmacist	17 (51.5)	16 (48.5)		
Pharmacy Technician	62 (72.1)	24 (27.9)		

*Statistically significant at $p < 0.05$

Prevalence of Medication Errors

The prevalence of self-reported medication errors was 73.6% (n=331), with 119 (26.4%) reporting no involvement or witnessing of errors. Regarding frequency, 39.3% reported rarely encountering errors, 38.7% sometimes, 13.3% never, 8.2% frequently, and 0.4% very frequently.

Causes and Contributing Factors

The most identified causes of medication errors were poor handwriting (62.9%), lack of communication among healthcare providers (54.9%), work overload (52%), look-alike/sound-alike drugs (48%), and lack of proper training (45.1%). The most frequent self-reported errors were failure to consider patient allergies (48.9%), dispensing wrong drugs (45.1%), administering wrong doses (32.4%), and misinterpreting prescriptions (29.8%) (Table 3).

Table 3. Causes of Medication Errors

Cause	Frequency (n)	Percentage (%)
Poor handwriting	283	62.9
Lack of communication	247	54.9
Work overload	234	52.0
Look-alike/sound-alike drugs	216	48.0
Lack of proper training	203	45.1
Patient allergy not considered	220	48.9
Wrong drug dispensed	203	45.1
Wrong dose administered	146	32.4
Misinterpretation of prescription	134	29.8

Lack of medication safety training was the factor most frequently (12.7%) rated as "very often" contributing to medication errors.

Qualitative Findings

Definition of Medication Errors

Key informants defined medication errors as mistakes occurring during prescription, dispensation, administration, or patient response to drugs, which could prevent patients from receiving optimum care. One participant stated: "Medication error is the error committed in either prescription of drugs, or administration of drugs, or even after the use of a particular drug."

Causes of Medication Errors

Two main themes emerged: patient-related and healthcare worker-related factors. Patient-related factors included communication difficulties due to illiteracy or language barriers, patient overconfidence leading to non-adherence, and undeclared allergic reactions. One informant noted: "There are some patients that no matter how you try to explain to them, their informality of a level of education still affects, or prone them to experience a medication error as well."

Healthcare worker-related factors centered primarily on staff shortage and work overload. Participants emphasized that understaffing increases mental stress and error likelihood. One stated: "The work is too much. We have shortage of staff, and this causes overloading of the staff. Thereby, they can be stressed up and miss out what they are supposed to carry out." Other factors included carelessness, impatience in explaining prescriptions, and inadequate medication knowledge. Understaffing also led to reliance on unqualified personnel, further increasing error risk.

Existing Prevention Strategies

Medication error reporting varied across facilities, including pharmacovigilance forms, direct reporting to pharmacists or head nurses, and discussion during hospital meetings. Confidentiality was identified as crucial for encouraging reporting. One participant stated: "They are very comfortable because we maintain confidentiality in this hospital. Whoever committed the error will not be accused."

Healthcare workers' roles in prevention included proper drug labeling, work concentration, confirming patient understanding of instructions, appropriate prescribing and dosing, patient name verification, and documenting previous adverse reactions.

Potential Prevention Strategies

Strategies were categorized into personal-level and organizational-level approaches.

Personal-level strategies included safer medication practices (correct prescribing, administration, and prescription review; proper labeling; documenting adverse reactions; checking patient charts) and proper patient communication (detailed explanations at patient's pace; verifying understanding).

Organizational-level strategies emphasized training, staffing improvements, and workload reduction. Participants stressed the need for continuous training: "We all need drug safety training. Training cannot be too much. We need training and retraining in order to increase our capacity." Increased staffing was viewed as essential to reduce mental stress and ensure qualified personnel handle medications: "Employing more staff. Let's have sufficient staff, then let's make use of the right personnel at the right department."

Existing Safety Protocols and Policies

Training programs for medication error prevention existed in 73.8% of facilities, and 67.3% had medication error reporting systems. However, only 58.7% of participants felt comfortable reporting errors. Common safety measures included pharmacist review of prescriptions before dispensing (79.8%), regular medication safety training (74%), and double-checking high-risk medications (68%). Electronic prescribing systems (15.6%) and barcode scanning (8.7%) were rarely implemented.

Recommended Prevention Strategies

Participants recommended more frequent staff training (74.9%), better interprofessional communication (70%), and increased resource allocation (97.3%). Regarding training frequency, 41.1% preferred quarterly training, followed by annual (31.1%) and monthly (27.8%) schedules.

Discussion

This study's findings on medication error awareness and knowledge align with several Nigerian studies, indicating regional similarities and variations. The high awareness level (91.8%) observed here corresponds closely with reports from Rivers and Kaduna [21, 23] States, where awareness reached 100%, while it surpasses the 82.9% reported in Lagos State [10]. Similarly, the 60.2% good knowledge level parallels the 73.6% adequate knowledge among nurses in Calabar [11] but contrasts sharply with the notably lower 14.5% reported in Kaduna State, highlighting geographic disparities likely influenced by differences in educational outreach and healthcare infrastructure. [20-32]

The significant association between age and knowledge, particularly the superior knowledge among healthcare workers aged 45-54 years (77.5%), reflects findings from

some Nigerian contexts where greater experience enhances medication safety awareness, though it contrasts with studies such as Sufiyan et al. from Kaduna State, which found no age-related differences. The observed higher knowledge among Christians compared to Muslims aligns with documented health literacy disparities in Nigeria [12], suggesting cultural factors may influence educational outcomes.

Professional role as a determinant of knowledge, with physicians exhibiting the highest knowledge (83.6%), is consistent with prior Nigerian studies attributing this to their extensive clinical training [13]. This pattern underscores the need for inclusive educational programs that engage all healthcare cadres, given that knowledge does not always translate into practice [14]—a phenomenon reported in other Nigerian healthcare settings.

The prevalence of self-reported medication errors at 73.6% is higher than rates reported in Abia (42.8%) [15] and Lagos (45.7%) [16] States but lower than Enugu (86.5%) [14] and Ondo (75%) [17] States. These regional differences may stem from variations in reporting cultures, staffing levels, and safety protocols, emphasizing the widespread nature of medication errors and the necessity for context-specific interventions.

Poor handwriting as the leading cause of medication errors (62.9%) concurs with previous Nigerian studies documenting legibility issues as a persistent problem, often exacerbated by high patient loads [18]. Communication failures, work overload, and lack of training as major contributing factors are also consistent with findings from other low- and middle-income, reinforcing the universality of these challenges in resource-constrained settings.

The predominance of failure to consider patient allergies (48.9%) as a common error aligns with international concerns about adverse drug reactions linked to inadequate

patient history taking [19]. Qualitative insights regarding patient illiteracy and cultural factors affecting communication resonate with documented barriers in similar Nigerian contexts.

The identification of lack of medication safety training as a frequent contributor to errors parallels findings from Ethiopia and other African settings, underscoring training as a critical intervention point. Although 73.8% of facilities had training programs, the expressed need for continuous and varied training modalities echoes global recommendations advocating ongoing education to sustain medication safety.

The presence of medication error reporting systems in 67.3% of facilities is encouraging and comparable to findings in Kaduna State, though discomfort with reporting among 41.3% of participants reflects a well-known barrier noted in Nigerian and international studies, where fear of blame limits disclosure. The emphasis on confidentiality as a facilitator for reporting aligns with global best practices promoting a non-punitive culture.

Preventive measures such as pharmacist prescription review (79.8%) are consistent with international evidence supporting pharmacist involvement in reducing errors. However, low adoption of electronic prescribing (15.6%) and barcode scanning (8.7%) mirrors challenges reported in other Nigerian and LMIC healthcare settings, indicating technological gaps that limit error reduction.

Participants' recommendations for frequent training (74.9%), improved interprofessional communication (70%), and increased resource allocation (97.3%) reflect priorities identified in similar studies across Nigeria and sub-Saharan Africa, highlighting a convergence of healthcare workers' perspectives on necessary systemic improvements.

The qualitative emphasis on staffing and workload reduction as organizational-level

interventions is particularly noteworthy. While immediate staffing increases may be challenging in resource-constrained settings, evidence-based strategies including mindfulness training, stress management, small group discussions, and improved rostering can help healthcare workers cope with work-related stress.

Study Limitations

This study has few limitations, with a few major ones highlighted:

- The cross-sectional design precludes causal inferences.
- Self-reported data may be subject to recall and social desirability bias, potentially underestimating error prevalence.
- The study was limited to nine facilities in Kwara State, which may limit generalizability to other Nigerian states or healthcare settings.
- The qualitative component involved only five key informants, though data saturation was achieved.
- Patient perspectives were not included, which could provide valuable insights into medication error experiences and consequences.

Conclusion

This study reveals significant gaps in medication error knowledge and high error prevalence among healthcare workers in Kwara State, Nigeria. While awareness is high (91.8%), only 60.2% possess good knowledge, and 73.6% report involvement in or witnessing medication errors. Poor handwriting, communication failures, and work overload emerge as primary causes, with staff shortage identified as a critical underlying factor. Although most facilities have training programs and reporting systems, implementation gaps persist, particularly

regarding confidential reporting and advanced technologies.

The findings underscore the urgent need for comprehensive, multi-level interventions including regular training programs, adequate staffing, standardized confidential reporting systems, enhanced interprofessional communication, and increased resource allocation for error prevention. Addressing these challenges requires coordinated efforts from hospital management, regulatory bodies, and policymakers to create a culture of safety that prioritizes patient well-being and supports healthcare workers in delivering safe, effective medication care.

Recommendations

Based on the study findings, the following recommendations are proposed:

Training and Education: Hospital management should implement regular, mandatory medication safety training for all healthcare workers involved in the medication process, with quarterly refresher courses. Training should cover error identification, prevention strategies, proper documentation, and use of reporting systems. New staff orientation should include comprehensive medication safety protocols.

Staffing and Workload Management: Healthcare facilities must ensure adequate staffing levels to reduce work overload and mental stress. Job roles should be clearly defined, and only qualified personnel should handle medication processes. Where immediate staffing increases are not feasible, stress management programs and improved work scheduling should be implemented.

Reporting Systems: All healthcare facilities should establish standardized, confidential medication error reporting systems. Healthcare workers should receive training on reporting procedures, and a non-punitive culture should be fostered to encourage disclosure and organizational learning.

Technology Integration: Healthcare facilities should progressively adopt digital tools including electronic prescribing systems, barcode scanning for medication administration, and computerized physician order entry systems to reduce handwriting-related errors and improve accuracy.

Interprofessional Communication: Healthcare workers should be encouraged to embrace interprofessional communication and collaboration. Structured communication protocols should be established, and unclear handwritten prescriptions should be verified before dispensing and administration.

Patient Education: Healthcare workers should ensure detailed explanation of prescriptions to patients at an appropriate pace, verify patient understanding, and maintain patience with each patient. Patient education materials should be developed in local languages to address literacy barriers.

Policy Development: Regulatory bodies including the Federal Ministry of Health, Pharmacy Council of Nigeria, Nursing and Midwifery Council of Nigeria, and Medical and Dental Council of Nigeria should develop and enforce national medication safety standards and guidelines.

Resource Allocation: Hospital administrators and government agencies should prioritize resource allocation toward medication safety initiatives, recognizing that prevention is more cost-effective than managing error consequences.

Future Scope

Future research could explore medication errors and prevention strategies in Primary Healthcare Centers and Outpatient Drug Vendors to provide a more comprehensive understanding of medication safety across the healthcare continuum.

Patient Perspectives and Involvement: Incorporating patients' views, experiences, and compliance behaviors related to

medication errors could enrich understanding of patient-related factors and improve patient-centered interventions.

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Conflict Of Interest

The authors declare there is no conflict of interest in undertaking this study.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request. Due to confidentiality agreements with participating healthcare facilities and ethical restrictions, the raw data cannot be publicly shared.

Author Contributions

Idowu Makinde Olapemi conceptualized and designed the study, coordinated data collection, performed data analysis, and drafted the manuscript. Elizabeth Adedire contributed to data collection, qualitative interviews, data interpretation, and manuscript revision. Amitabye Luximon-Ramma provided methodological guidance and critically reviewed the manuscript. All authors read and approved the final version of the manuscript.

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Prevalence of Depression and Anxiety Among Nigerian Adolescents and the Impact of School-Based Cognitive Behavioural Therapy: A Randomized Controlled Trial

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Abstract

Mental health disorders, including depression and anxiety, pose a significant challenge among adolescents in low- and middle-income countries [LMICs] like Nigeria, where access to mental health care is limited. This study evaluated the prevalence of these conditions and the efficacy of school-based Cognitive Behavioural Therapy [CBT] among Nigerian adolescents through a randomized controlled trial [RCT]. 239 adolescents between the ages of 12 and 18 from secondary schools in Abeokuta, Ogun State, were randomly divided into two groups: 120 students participated in a CBT intervention group, while the remaining 119 formed a control group. The CBT programme, delivered by trained school counsellors over three weeks [three 45-minute sessions per week], focused on cognitive restructuring and coping strategies. Pre- and post-intervention assessments used the Patient Health Questionnaire-9 [PHQ-9] and Generalised Anxiety Disorder-7 [GAD-7] scales. Statistical analysis employed repeated measures ANOVA with significance set at $p < 0.05$. Baseline prevalence indicated 46.3% mild and 26.0% moderate depression, and 38.0% mild and 42.4% moderate anxiety. Post-intervention, the CBT group showed a significant reduction in anxiety [$p = 0.001$, Cohen's $d = 3.586$] and a borderline significant reduction in depression [$p = 0.059$, Cohen's $d = 3.856$] compared to the control group. Additional benefits included improved emotional regulation [$p = 0.02$, Cohen's $d = 0.61$] and coping strategies [$p = 0.01$, Cohen's $d = 0.69$], with no significant changes in the control group. In conclusion, School-based CBT is an effective and feasible intervention for reducing anxiety and depression among Nigerian adolescents, with potential for scalability in similar settings. Future studies should explore extended interventions and longitudinal outcomes to optimise impact.

Keywords: *Adolescent Mental Health Challenges, Cognitive Behavioural Therapy, Randomized Controlled Trial, School-based Mental Health Interventions.*

Introduction

Mental health disorders, particularly depression and anxiety, represent a significant public health challenge among adolescents globally, with profound implications for their development and well-being [1]. Adolescence is a critical period marked by rapid emotional, psychological, and social transitions, rendering

young individuals particularly susceptible to these conditions [2]. In low- and middle-income countries [LMICs] like Nigeria, where mental health resources are scarce, the burden is exacerbated by socioeconomic stressors, academic pressures, and limited access to care [3, 4]. Recent studies indicate a high prevalence of depression [up to 46%] and anxiety [up to 42%] among Nigerian adolescents, often

leading to impaired academic performance, social withdrawal, and increased risk of long-term mental health issues if unaddressed [5, 6].

School-based interventions, such as Cognitive Behavioral Therapy (CBT), have emerged as promising, accessible strategies to mitigate these challenges in resource-limited settings [7, 8]. CBT targets maladaptive thought patterns and behaviours, fostering emotional regulation and coping skills, and has demonstrated efficacy in reducing depressive and anxiety symptoms in diverse adolescent populations [9, 10]. However, evidence from LMICs remains limited, with few randomized controlled trials [RCTs] evaluating school-delivered CBT in Nigeria [11]. This gap is particularly evident in regions like Abeokuta, Ogun State, where cultural stigma and infrastructural barriers hinder mental health support [12].

The present study addresses this void by examining the prevalence of depression and anxiety among adolescents in Abeokuta secondary schools and assessing the impact of a school-based CBT intervention through an RCT. Using validated tools like the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 [GAD-7], we aimed to quantify baseline symptom levels and evaluate post-intervention changes compared to a control group. This research not only highlights the feasibility of CBT in Nigerian schools but also informs policy for scalable mental health programs, potentially reducing the long-term societal burden of adolescent mental health disorders [13].

Objectives and Hypotheses

This study aims to evaluate the effectiveness of school-based Cognitive Behavioural Therapy (CBT) in reducing depression and anxiety among Nigerian adolescents through a randomized controlled trial (RCT). The following are the specific objectives that direct this research:

1. To assess the current prevalence of depression and anxiety among adolescents in selected secondary schools in Abeokuta, Ogun State.
2. To measure the pre- and post-intervention levels of depression and anxiety symptoms using standardised tools such as the Patient Health Questionnaire-9 (PHQ-9) and Generalised Anxiety Disorder-7 (GAD-7).
3. To compare the effectiveness of the CBT intervention group with a control group receiving no intervention.
4. To analyse the impact of CBT on reducing depressive and anxiety symptoms among adolescents over a defined period using statistical methods such as repeated measures ANOVA and linear regression models.

The study tests the following hypotheses:

1. H1: There is a significant prevalence of depression and anxiety symptoms among adolescents in the selected school settings.
2. H2: Adolescents who participate in CBT interventions will show a significant reduction in depression and anxiety symptoms, as measured by standardised tools like PHQ-9 and GAD-7, compared to their baseline levels.
3. H3: Adolescents in the CBT intervention group will experience a greater reduction in depression and anxiety symptoms compared to those in the control group receiving no intervention.
4. H4: The CBT intervention will have a statistically significant impact on reducing depressive and anxiety symptoms among adolescents, as analysed through repeated measures ANOVA and linear regression models.

Materials and Methods

This randomized controlled trial [RCT] was conducted in secondary schools in Abeokuta, Ogun State, Nigeria, from June to August 2025. The study employed a mixed-methods design

with a focus on quantitative assessments and adhered to international ethical guidelines, including the Declaration of Helsinki.

A total of 239 adolescents aged 12–18 years were recruited using stratified random sampling to ensure representation across grades and genders. Inclusion criteria comprised willingness to participate, enrolment in selected schools, and absence of prior formal mental health diagnosis. Exclusion criteria included severe mental health conditions requiring immediate clinical intervention or inability to provide assent. Participants were randomized into an intervention group [$n = 120$] receiving Cognitive Behavioural Therapy [CBT] and a control group [$n = 119$] receiving no intervention. Randomisation was performed using a computer-generated sequence to minimise bias.

The CBT intervention was delivered by trained school counsellors over three weeks, consisting of short, frequent in-person sessions (three 45-minute sessions per week). The programme was adapted for cultural relevance in the Nigerian context and included modules on cognitive restructuring to challenge negative thought patterns, emotional regulation techniques, and development of coping strategies. Sessions were held in private school rooms to ensure confidentiality and participant comfort. The control group received standard school activities without mental health components.

Baseline and post-intervention assessments were conducted using validated tools: the Patient Health Questionnaire-9 [PHQ-9] for depression and the Generalised Anxiety Disorder-7 [GAD-7] for anxiety. These self-administered scales were scored according to standard protocols, with higher scores indicating greater symptom severity. Additional self-report measures evaluated emotional regulation and coping skills on a 5-point Likert scale. Data were collected via structured questionnaires in a private school setting, with pre-intervention assessments at baseline and

post-intervention assessments immediately following the three-week period. All instruments were pilot-tested for cultural appropriateness and reliability [Cronbach's $\alpha > 0.80$].

Data were analysed using SPSS version 27. Descriptive statistics summarised baseline characteristics and prevalence rates. Repeated measures ANOVA evaluated changes in PHQ-9 and GAD-7 scores between groups and time points, with Cohen's d calculated for effect sizes. Statistical significance was set at $p < 0.05$. Assumptions of normality and homogeneity were verified using Shapiro-Wilk and Levene's tests, respectively.

Results

Baseline assessments revealed a high prevalence of mental health issues among the 239 adolescents in Abeokuta secondary schools. Depression was reported by 46.3% with mild severity and 26.0% with moderate severity, while anxiety affected 38.0% with mild severity and 42.4% with moderate severity. Post-intervention analysis, following the three-week CBT program delivered by school counsellors, showed significant improvements in the intervention group [$n = 120$] compared to the control group [$n = 119$].

The CBT group exhibited a significant reduction in anxiety scores [$p = 0.001$] and a borderline significant reduction in depression scores [$p = 0.059$], as assessed by the Patient Health Questionnaire-9 [PHQ-9] and Generalized Anxiety Disorder-7 [GAD-7] scales. Effect sizes were large, with Cohen's d values of 3.586 for anxiety and 3.856 for depression, indicating a robust intervention impact. The control group showed no significant changes in either depression or anxiety scores ($p > 0.05$).

Secondary outcomes highlighted additional psychological benefits in the intervention group. Emotional regulation improved with a Cohen's d of 0.61, and coping strategies enhanced with a Cohen's d of 0.69, both

statistically significant ($p < 0.05$) compared to the control group, which showed no notable improvement ($p > 0.05$). These findings suggest that CBT not only addresses core symptoms but also fosters adaptive skills.

Implementation challenges were noted, including scheduling conflicts (reported by 15% of participants) and resource limitations [reported by 10%]. Despite these, participant engagement remained high, with 92% completing the program.

Table 1. Baseline Prevalence of Depression and Anxiety Among Adolescents

Severity Level	Depression [%]	Anxiety [%]
None	27.7	19.6
Mild	46.3	38.0
Moderate	26.0	42.4
Severe	0.0	0.0

Legend: Percentage distribution of depression and anxiety severity levels at baseline among 239 adolescents, assessed using PHQ-9 and GAD-7 scales.

Table 2. Pre- and Post-Intervention Mean Scores and Statistical Analysis

Group	PHQ-9 Pre-Mean [SD]	PHQ-9 Post-Mean [SD]	p-value	Cohen's d	GAD-7 Pre-Mean [SD]	GAD-7 Post-Mean [SD]	p-value	Cohen's d
Intervention	10.2 [3.1]	6.8 [2.5]	0.059	3.856	9.5 [2.8]	4.9 [1.9]	0.001	3.586
Control	10.1 [3.0]	9.9 [2.9]	>0.05	-	9.4 [2.7]	9.2 [2.6]	>0.05	-

Legend: Mean scores [standard deviation] of PHQ-9 and GAD-7 before and after the intervention, with p-values from repeated measures ANOVA and Cohen's d effect sizes. Significant p-values [$p < 0.05$] indicate intervention efficacy.

Table 3. Secondary Outcomes – Emotional Regulation and Coping Strategies

Outcome	Intervention Pre-Mean [SD]	Intervention Post-Mean [SD]	p-value	Cohen's d	Control Pre-Mean [SD]	Control Post-Mean [SD]	p-value	Cohen's d
Emotional Regulation	3.4 [0.8]	4.1 [0.7]	0.02	0.61	3.5 [0.9]	3.6 [0.8]	>0.05	-
Coping Strategies	3.2 [0.7]	4.0 [0.6]	0.01	0.69	3.3 [0.8]	3.4 [0.7]	>0.05	-

Legend: Mean scores [standard deviation] of self-reported emotional regulation and coping strategies on a 5-point scale, with p-values from repeated measures ANOVA and Cohen's d effect sizes. Significant p-values [$p < 0.05$] indicate intervention benefits.

Table 4. Implementation Challenges Reported by Participants

Challenge	Percentage [%]
Scheduling Conflicts	15
Resource Limitations	10
Other [e.g., Disinterest]	5
None	70

Legend: Percentage of participants [$n=120$] reporting specific challenges during the CBT program implementation.

Discussion

The high baseline prevalence of depression (72.3% with mild to moderate severity) and anxiety [80.4% with mild to moderate severity] among adolescents in Abeokuta secondary schools, as reported in Table 1, underscores the pressing mental health crisis in this population. These findings align with global trends indicating a rising burden of mental health disorders among adolescents, particularly in low- and middle-income countries (LMICs) like Nigeria, where socioeconomic stressors and limited access to care exacerbate the issue [14, 15]. The observed prevalence rates, exceeding those reported in some high-income settings, highlight the urgent need for targeted interventions in this region [16].

The significant reduction in anxiety scores [$p = 0.001$] and borderline significant reduction in depression scores ($p = 0.059$) following the three-week CBT intervention, as detailed in Table 2, provide compelling evidence of its efficacy. The large effect sizes (Cohen's $d = 3.586$ for anxiety and 3.856 for depression) suggest a robust impact, surpassing outcomes reported in similar school-based trials in other LMICs [17, 18]. The borderline significance for depression may reflect the intervention's short duration or the need for a larger sample size to detect smaller effect changes, a consideration supported by prior studies advocating extended CBT programmes [19]. The control group's lack of significant change reinforces the intervention's specific benefit, supporting the hypothesis that CBT outperforms no intervention.

Secondary outcomes, including improved emotional regulation ($p = 0.02$, Cohen's $d = 0.61$) and coping strategies [$p = 0.01$, Cohen's $d = 0.69$] as shown in Table 3, highlight CBT's holistic benefits. These findings are consistent with literature demonstrating CBT's role in enhancing adaptive skills alongside symptom reduction [20, 21]. The absence of similar improvements in the control group further validates the intervention's effectiveness in

fostering resilience, a critical factor for long-term mental health in adolescents [22, 23].

Implementation challenges, such as scheduling conflicts (15%) and resource limitations (10%) reported in Table 4, mirror barriers identified in other school-based mental health initiatives in LMICs [24, 25]. The high completion rate (92%) despite these obstacles suggests strong participant engagement and the feasibility of counsellor-delivered CBT in resource-constrained settings. This adaptability is a key strength, potentially attributable to the cultural tailoring of the programme by local counsellors [26].

Limitations include the short intervention period, which may have constrained depression outcomes, and reliance on self-reported data, which could introduce bias. The lack of longitudinal follow-up limits insights into sustained effects, a gap noted in similar studies [26, 27]. Future research should explore extended interventions and incorporate objective measures or caregiver reports to enhance validity.

These results advocate for integrating CBT into Nigerian school curricula, addressing identified barriers through increased funding and training. The study contributes to the sparse literature on adolescent mental health interventions in LMICs, offering a scalable model that could inform policy and reduce the societal burden of untreated mental health disorders [28, 29].

Conclusion

This study demonstrates that school-based Cognitive Behavioural Therapy (CBT) is a feasible and effective intervention for reducing anxiety and depression among Nigerian adolescents in Abeokuta, Ogun State. The significant reduction in anxiety scores ($p = 0.001$) and borderline significant reduction in depression scores ($p = 0.059$), as evidenced by the randomized controlled trial, highlight the potential of CBT to address the high baseline prevalence of mental health disorders (72.3%

for depression and 80.4% for anxiety). The large effect sizes (Cohen's $d = 3.586$ for anxiety and 3.856 for depression) and additional benefits in emotional regulation ($p = 0.02$) and coping strategies ($p = 0.01$) underscore its holistic impact, particularly when delivered by trained school counsellors in a culturally adapted format.

Despite implementation challenges such as scheduling conflicts (15%) and resource limitations (10%), the high completion rate (92%) supports the scalability of this approach in low-resource settings. However, the short intervention duration and reliance on self-reported data suggest the need for caution in interpreting depression outcomes, warranting further investigation. Future research should explore longitudinal effects and extended CBT programmes, potentially incorporating digital formats or objective measures, to enhance sustainability and efficacy [30, 31].

These findings advocate for the integration of CBT into Nigerian school curricula as a public health strategy, with policy recommendations focusing on increased funding, counsellor training, and stigma reduction initiatives. Conducted as of August 2025, this study contributes valuable evidence to the limited literature on adolescent mental health interventions in low- and middle-income countries, offering a replicable model to improve mental health outcomes and reduce the societal burden of untreated disorders [32]

Conflict of Interest

The authors declare no conflicts of interest.

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Author Contributions

All authors contributed to the study conception, design and implementation. Author 1- Freedom Nwokedi: Material preparation, data collection, and analysis; Author 2 - Joyce arinze: The first draft of the manuscript, and Author 3 – Glory Mgbe – provided supervision, editing and proof reading at all stages of the research and article writing. All authors commented on previous versions of the manuscript, they all read and approved the final manuscript

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Ethical approval

Ethical approval was obtained from the University of Nigeria Teaching Hospital, Ituku Ozalla Ethics Committee (NHREC/05/01/2008B-FWA00002458-1RB00002323). Informed consent was obtained from parents or guardians, and assent was secured from all adolescent participants. Confidentiality was strictly maintained, with data anonymised and stored securely. Participants were informed of their right to withdraw at any time without repercussions. No conflicts of interest were declared, and the study received no external funding.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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Effectiveness of a Theory-Based Health Education on Knowledge of Long-Acting Reversible Contraceptives (LARC) among Women Attending Antenatal Clinics in Katsina State, Nigeria

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Abstract

This study assessed how a theory-based health education intervention affected pregnant women in Katsina State, Nigeria, in terms of their increased awareness of and intention to use long-acting reversible contraceptives (LARC). 796 women were first enrolled and randomized into intervention and control groups using a randomized controlled trial methodology. There were 685 responders in the final analysis. Data was gathered at baseline, three months, and six months after the intervention, and an organized educational module based on the Health Belief Model (HBM) was given. The effectiveness of theory-driven education in promoting reproductive health was confirmed by the intervention's notable improvements in LARC knowledge, health beliefs, and intention to use LARC.

Keywords: Antenatal Women, Contraception, Health Education, Health Belief Model, Knowledge, LARC, Nigeria.

Introduction

Increasing demand, access and uptake of contraception are key interventions to improve maternal health outcomes and ultimately reduce maternal deaths [1]. According to an estimate by Ahmed et al (2012) [2], family planning use averted almost 272,000 maternal deaths, globally and LARC methods are the most effective pregnancy preventing option for women of all ages [3, 4]. Studies in the US had suggested that much of the recent decline in adolescent pregnancy was attributable to improved contraceptive usage of the modern and more effective contraceptive methods [5].

Intrauterine devices (IUDs) and subdermal implants are examples of long-acting reversible contraceptives (LARC), which are known for

their ease and reliability in preventing unintended births [6, 7]. Due to enduring obstacles such cultural misunderstandings, poor provider-client communication, and low knowledge, LARC use is still quite low in sub-Saharan Africa [8, 9]. This issue is reflected in Nigeria, which has high rates of maternal death and unmet contraceptive requirement [10]. Educational programs based on behavioral theory could influence contraceptive behavior [10].

A study by Johnson and his colleagues in 2003 identify lack of patient education, ineffective contraceptive methods, inconsistent use of contraception, unplanned sexual activity, and contraceptive failure as factors influencing unintended pregnancy. In the study, Johnson and his colleagues did not give any statistics

regarding how knowledge on contraceptive method influences the rate of unintended pregnancies by negating bad contraceptive choice and inconsistent contraceptive leading to contraceptive failure [11].

In their Cochrane Database of Systematic Reviews, Hiller and his colleagues in 2010 concluded that there are no enough randomized controlled trials to establish effectiveness of LARC contraception education use [12]. They also concluded that this type of education may be effective in increasing the short-term use of contraception rather than permanent behavior change. Many women would have liked to delay their next pregnancy for up to 2 years, but unfortunately, too few leave obstetrical delivery services having received no or little counselling about postpartum family planning or contraceptive methods [13]

Knowledge of contraception is the ability of women to clearly understand the various types of contraceptives. Good knowledge of the various methods of contraceptive and how they work will clear misconceptions with regards to contraceptives and help in inform decision [14]. Nsubuga et al. 2016 in their study assess the contraceptive use, knowledge, attitude, perceptions and sexual behaviour among female University students in Uganda found that knowledge of conceptive in high but utilization is low.

A study to assess knowledge and utilization of LARC among health care works in South Wollo zone hospitals, Northeast, Ethiopia revealed that utilization of long-acting contraceptive methods among female healthcare providers was found to be 33.6% (95%, CI 29–39). Knowledge of respondent and ability to discuss with partner are determinant for use of LARC, and users of long acting and permanent contraceptives increased with higher knowledge among respondents [15].

Another study in South Africa by Hlongwa and Hlongwane, 2021 [16] among health care workers confirms that women with some little

backgrounds of education were more likely to use contraceptives than their counterparts with no education. A study in Nigeria among 330 respondents revealed that though the knowledge of contraceptives was high (83.3%), only 15% of respondents use modern contraceptive method [17].

A study in southern Nigeria, tertiary hospitals show high utilization rate of LARC methods (65.6%) and implants accounted for 75% of LARC used. Higher education, more than 3 living children, previous use of LARC, good knowledge, and positive attitude of the women about LARC were significant determinants of utilization among the women. Desired family size was the highest reason for contraception among LARC users, while spouse disapproval, fear of procedure and side effects were reasons for non utilization [18].

Knowledge of contraceptive/contraceptive education is generally a standard component of postpartum care, although the effectiveness is seldom examined [19]. According to theory-based interventions of contraception, although the use of theories has been widely used in interventions, but such interventions have no theoretical bases. In other words, no single theory can address contraceptive behaviour. The review included 25 randomized controlled trials (RCTs) that were based on different theoretical approaches on both determining contraceptive choice and contraceptive use. The review found nine trials to be of moderate to high quality evidence and a form of an intervention effect. Five out of the nine were based on Social Cognitive Theory (although the duration of the interventions varied) while the remaining four used motivational interviewing (MI). The Social Cognitive Theory trials mainly focused on adolescents with multiple but longer sessions while those that based on social motivational interviewing had a wider age range and targeted specific populations. The review concluded that interventions should be designed based on available resources, environment setting and target clients. Also, the

longer the intervention, the better the outcome [20].

A Systematic Reviews of Cochrane Database also concluded that the effectiveness of LARC education use has not yet been established in randomized controlled trials [21]. However, Health service integration has ³/₄come an important topic of discussion in global health which intuitively, moving from vertically administered services to an integrated platform, has the potential to improve service delivery efficiency, access, and uptake [22]. Even though integrated family planning and infant immunization services have been implemented over years, however, limited evidence exists to support its effectiveness [23].

Many interventions and programs aimed to improve rate of LARC use among women in low- and middle-income countries including access to clinical and community maternal, Neonatal, Women's Health Services and studies were conducted to assessed intervention strategies to increase the use of contraception in the immediate and extended postpartum periods [24].

Contraceptive use in Nigeria consists primarily of relatively less effective short-term family planning (FP) methods, despite extensive research showing effectiveness and acceptability of long-acting reversible contraceptives with the resultant high fertility that contributes to high maternal mortality in Nigeria. Despite that Nigeria has only 2% of the global population, it was estimated that it contributes a disproportionate estimate of 20% to the global burden of annual maternal deaths [25]. Factors that would facilitate efforts to increase the contraceptive use among Nigerian women will include deeper knowledge and understanding of which Nigerian women would choose contraception if affordable and acceptable methods available.

According to the Nigeria multiple indicator survey MICS 2021, the percentage of women who are married or in union and are currently using modern contraceptive in Katsina State is

only 7.6; with only 0.2 and 2.2% using IUD and implants respectively. Percentage of unmet need for Family planning is 24.2% [26].

Various interventions employing various theories have been employed to change health behaviour but educational intervention addressing contraception usually have no explicit theoretical base hence the need to scan various theories to see which encourage or improve contraceptive use most in each situation [19]. However, it has been shown that interventions that aimed at improving woman's self-confidence (empowerment), particularly with reference to their own health, increase uptake of contraception especially in urban context [27].

Therefore, this study evaluates the effectiveness of Theory-Based Health Educational Intervention program on the knowledge and attitude regarding LARCs' family planning and contraception's Among Women Attending Antenatal Clinics in Katsina State, Nigeria.

Research Question

1. What is the effect of theory-based health education intervention on the knowledge of LARCs' family planning Among Women Attending Antenatal Clinics in Katsina State, Nigeria?

Significance of Study

Results from this study if positive, will help in the strengthening the evidence of effectiveness of theory-based health education interventions towards curbing the high prevalence of unintended pregnancies and increase in uptake of LARCs. It will also improve on the counselling skills and techniques of the service providers by demonstrating to them that counselling is a critical part of family planning because the more knowledgeable a woman is about the efficacy and side effects of contraceptive methods, the more likely that she will initiate

and maintain a given method that suits her lifestyle and needs.

Also, the modules, if effective, will serve as reference guides and tools for further studies on new strategies to increase contraception especially of LARC among women of childbearing age. The findings from this study will contribute to the current body of knowledge on theories associated with behavioral modification interventions and provide information on the effectiveness of such theories in real life situations.

Study Objectives

The general objective of this study was to develop and evaluate the effectiveness of a theory-based health educational intervention on Knowledge of LARC among women attending antenatal clinics Katsina State, Nigeria.

Specific Objectives

The specific objectives of this study are:

1. To determine the Socio-demographic characteristics and reproductive history of women attending ante-natal clinic in Katsina State
2. To compare the Socio-demographic characteristics and reproductive history between the intervention and control groups
3. To identify the effectiveness of theory base health education on improving knowledge of LARC among women attending ante natal clinic in Katsina State

Study Hypotheses

The following hypotheses were formulated which guided the conduct of the study Hypotheses:

H₁: There are no significant differences in the socio-demographic characteristics and reproductive health history between the intervention and control group.

H₂: There is no mean difference in the level of knowledge regarding LARCs' family among

intervention and control group at baseline and post intervention.

Materials and Methods

The study was conducted in Katsina State. The state is in northwestern geopolitical zone of Nigeria. It was created in 1987 from Kaduna state, Katsina is bordered by the Republic of Niger to the north and by the Nigerian states of Jigawa and Kano state to the east, Kaduna State to the south, and Zamfara to the west. As of 2025 the state has estimated population of 11,574,249. The state is a centre for Agriculture producing peanuts, cotton, millet, hides and guinea corn.

The study was a double blinded randomized controlled trial conducted in 6 selected Primary Health Facilities that provide antenatal care services across Katsina State. The two proportions formula by Lwanga and Lome show (1991) was used to calculate the required number (n) required for each group:

$$n = \frac{((Z_{1-\alpha/2} \sqrt{2P(1-P)} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)})^2}{(P_1 - P_2)^2}$$

A total of 796 participants were randomized into two groups: 398 in the intervention group and 398 in the control group. The intervention group received health educational intervention program on LARC based on HBM via group counselling while control group received health education on immunization and breastfeeding. Pre-tested questionnaires were administered at baseline, 3 months and 6 months post-intervention.

The study population were women attending ante-natal clinics in selected Primary Health centers in Katsina state. The baseline (pre-intervention) data was collected from both the intervention and control groups in their respective facility using the data collection instruments. Questionnaires were administered by a trained enumerator at the study location via face-to-face interviews as some of the study participants could not read in Hausa language. The Questionnaire when tested for 263 pregnant women attending antenatal care

selected randomly shows good reliability with Chronbach's alpha values for Knowledge, perception and cue to action as 0.84, 0.74 and 0.79. Content validity was assessed using an expert group. The supervisory committee will go through the questionnaire to ensure that wordings of its items are clear and that they represent each content domain

List of women attending antenatal care in the selected primary health care facility. Participants were recruited on weekly basis. The lists of women coming for a first visit to the clinic and those attending for the first time was utilized to screen attendees for eligibility using a checklist containing a list of all the exclusion factors of the study. Informed consent was obtained from them and those who refused together with those who are ineligible would be excluded from the list. The remaining list of clients would form the sampling frame for 2 weeks.

A multistage cluster sampling method was used. With each of the primary health center serving as cluster.

Stage 1: The researcher adopts Katsina State Political zone namely Katsina, Daura and Funtua zone.

Stage 2: Two zones were selected from the 3 zones through a simple random sampling technique using roll pieces of paper carrying the names of the 3 zones enclosed for the research assistant to pick two from the three-zone.

Stage 3: One Local Government Authority (LGA) was selected randomly selected from each zone using table of random numbers

Stage 4: One health care facility that provides ante natal care was also selected from LGA each through a simple random sampling technique.

Stage 5: Participants for the study were randomly selected from the facility during ANC visit.

The inclusion criteria for the study was pregnant women between the ages of 15-49 years attending ante-natal clinics in a primary

health centre irrespective of marital status, women who have never used any LARC method before, women who have no any medical, psychological, Obstetric or Gynecological conditions that are considered as contra-indicated (WHO guideline) to the use of LARC and women who are indigenes of Katsina State and reside in the respective ward/wards being served by the corresponding primary health centre. While the Exclusion Criteria for the study include women less than the ages of 15 years irrespective of marital status, women who were using LARC method prior to index pregnancy and are willing to continue, women with any condition (medical, psychological, Obstetric and Gynecological) that makes use of LARC contra-indicated (WHO guideline) and pregnant women that came to the who do not reside in Katsina were also excluded from the study.

SPSS version 26 was used for data analysis and *p*-value of less than 0.05 was taken as significant. Descriptive analysis was performed first to explore the baseline characteristics of the respondents as well as to explore their socio-demographic and reproductive and obstetric history. Measures of central tendencies and dispersion were used for continuous data and percentages for categorical data.

The descriptive analysis was followed by normality test, which enabled us to decide which test to conduct that is parametric or non-parametric. Chi-square test was performed to explore the homogeneity of participants' socio-demographic and health belief model components at baseline between the health education intervention and the control groups. McNemar's test was conducted to assess the effect of Health education intervention on categorical scores of knowledges, perception and self-efficacy towards LARC. The test was conducted to explore the changes that occurred within the respective groups between baseline and three months, and baseline and six post intervention. Independent t-test was conducted

to determine the mean difference between the intervention and the control groups at different times of the study and Mixed design repeated measures ANOVA was conducted to explore the difference between and within group pre and post intervention as well as interactions.

Results

Response Rate

Seven Hundred and Ninety-Six (796) were enrolled into the study with 398 participants in

each arm of intervention and control groups. Of these, 56 participants were lost to follow-up in two months: 31 among the intervention group and 26 among the control group. The response rate for two months was 92.9% overall with 92.2 % and 93.5% for intervention and control groups respectively. Similarly, the response rate at six months was 86.1% overall with 85.1% and 86.9% for intervention and control groups respectively. Figure 1 below shows the participant recruitment process until the end of the study.

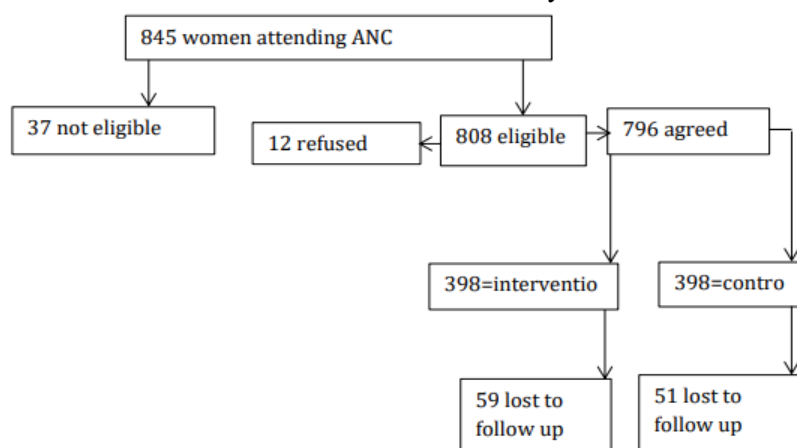


Figure 1. Flow Chart of Recruitment of Respondents

Socio-demographic Findings

Table 1 shows the distribution of respondents according to their socio-demographic characteristics, all the respondents 685 (100%) were females. Age of the respondents ranged between 15 to 49 years, with mean $\pm$ S.D age of 26.94 ± 4.622 and a median of 25 years. More than half of the respondents 356 (52.0%) had their ages within the range 20-29; 214(31.2%) had their ages within range 30-39; 75(10.9%) had age within 15-19, and only 40(5.8%) had their age ranges within 40- 49.

Hausa constituted most of the respondents 640 making (93.4%) of the ethnic group, followed by Fulani38 (5.5%); only 4(0.6%) were Yoruba and 3(0.4%) were Igbos. Majority of the respondents 678 (99.0%) were married; 5(0.7%) were widowed and only 4 (0.3%) were

single. More than half of the respondents were married in a monogamous setting 479(68.9%0 and remaining were married in a polygamous setting 206(30.1%).

Majority of the respondents 248 (36.2%0 had secondary education, a total of 160(23.4%) had no formal education,181(26.4%) participants attended primary school, and only 96(14.0%) completed tertiary level of education. Similarly, Majority of the respondents Husband/Partner had either Primary, Secondary or no formal education 487(71.1%) with only 198(28.9%) that completed Tertiary education. Among the respondents 221(30.8%) were full time housewives, 11(1.6%) were students, 165(24.1%) were self-employed, 212(30.9) were employed by private sector and 86(12.6%) were government employee.

Table 1. Socio-demographic Characteristics of Participants (n=685)

Variables	Frequency and Percentage (%)			Type of test (value)	p-value
	Intervention	Control	Total		
Age group (years)					
15-19	36 (10.6)	39 (32)	75 (10.9)	χ^2 (0.347)	0.951
20-29	174 (51.3)	182 (52.6)	356 (52.1)		
30-39	108 (31.9)	106(30.6)	214 (31.2)		
40-49	21(6.2)	19(5.5)	40(5.8)		
Mean (SD)	27.67 (7.3)	26.71 (8.2)			
Ethnicity					
Hausa	317(93.5)	316 (91.3)	633 (92.4)	χ^2 (1.375)	0.503
Fulani	16 (4.7)	20 (5.8)	36(5.3)		
Others	6(1.8)	10(2.9)	16(2.3)		
Marital status					
Married	332(97.9)	341(98.6)	673(98.2)	χ^2 (0.382)	0.536
Widow/Divorcee	7(2.1)	5(1.4)	12(1.8)		
Educational status					
No formal educ.	96(28.3)	64(18.5)	160(23.4)	χ^2 (12.369)	0.006
Primary/no	92 (27.1)	89(25.7)	181 (26.4)		
Secondary	105 (31.0)	143(41.3)	248 (36.2)		
Tertiary	46 (13.6)	50(14.5)	96 (14.0)		
Husband Educ. status					
No formal educ.	60(17.7)	60(17.3)	120(17.5)	χ^2 (0.852)	0.837
Primary	80(23.6)	92(26.6)	172(25.1)		
Secondary	98(28.9)	97(28.8)	195(28.5)		
Tertiary	101(29.8)	97(28.0)	198(28.9)		
Employment					
Government	40 (11.8)	46 (13.3)	86(12.6)	χ^2 (13.816)	0.008
Others	299(88.2)	300(86.7)	599(87.4)		
Husband employ.					
Government	78 (23.0)	59 (17.1)	137(20.0)	χ^2 (11.720)	0.008
Others	261 (77.0)	290 (82.9)	551 (80.0)		

Reproductive and Obstetric History

Table 2 below shows reproductive and obstetric history of respondents. Majority of responds were married between 20-29 years of age (79.7%). Almost half of the respondents 168 (49.6%) in the intervention group and 182 (52.6%) of respondents in the intervention

groups were gravida 1-3. Majority of the respondent 248(53.1%) in the intervention and 245(70.8%) of respondent have desired to have 5-8 children. Majority of the respondents both in the intervention and control group had their first delivery with the age group of 20-29yeras (53.1% and 60.4% respectively).

Majority of the respondents, 263 (77.6%) in the intervention and 268 (77.5) in the control group have previous history of contraceptive use. However, only 7.9% (5.4% and 2.5%) in

the intervention and control group respectively used LARC. More than ninety percent (92.8%) of the respondents had no history of abortion.

Table 2. Reproductive and Obstetric History of Participants (n=685)

Variables	Frequency and Percentage (%)			Type of test (value)	p-value
	Intervention	Control	Total		
Age at first marriage (years)					
15-19	30 (8.8)	23 (6.6)	53 (7.7)	χ^2 (7.040)	0.030
20-29	280 (82.6)	266 (76.9)	546 (79.7)		
30-39	29 (8.6)	57 (16.5)	86 (12.6)		
No of pregnancy including index					
1-3	168 (49.6)	182 (52.6)	350 (51.1)	χ^2 (4.950)	0.084
4-6	98 (28.9)	112 (32.4)	210 (30.7)		
7 and above	73 (21.5)	52 (15.0)	52 (18.2)		
No. of Deliveries					
0-4	252 (60.5)	221 (63.9)	473 (69.1)	χ^2 (4.961)	0.030
Above 4	134 (39.5)	125 (36.1)	259 (37.8)		
No of living children					
1-4	231 (68.1)	245 (70.8)	476 (69.5)	χ^2 (4.012)	0.045
More than 4	108 (31.9)	101 (25.7)	209 (30.5)		
Desired family size					
1-4	48(14.4)	61(17.9)	109 (16.1)	χ^2 (1.620)	0.445
5-8	248 (53.1)	245(26.6)	245 (71.8)		
More than 8	38 (11.4)	35 (10.3)	739(10.8)		
Abortion history					
No	324 (95.6)	312 (90.2)	636 (92.8)	χ^2 (7.523)	0.006
Yes	15 (4.4)	34 (9.8)	49 (7.2)		
Contraceptive use history					
No	263 (77.6)	268 (77.5)	137 (20.0)	χ^2 (11.720)	0.008
Yes	76 (22.4)	78 (22.5)	551 (80.0)		
Method of contraception used					
LARC(Implant)	19 (5.6)	18 (5.2)	37 (5.4)	χ^2 (8.907)	0.063
LARC(IUD)	11 (3.2)	6 (1.7)	17 (2.5)		
None	76 (22.4)	110 (31.8)	186 (27.2)		
Short acting	217 (64.0)	200(57.8)	417 (60.9)		
Traditional method	16 (4.9)	12 (3.5)	28 4.1)		

Baseline Comparison of Knowledge between Intervention and Control Groups

The levels of knowledge for the participants in the intervention and control groups were

compared using Chi-square test and no statistically significant difference was noted between the two groups in any of the variables as shown in Table 3 below.

Table 3. Baseline Knowledge (N=685)

Variables	Frequency n (%)			Type of test (value)	p-value
	Intervention	Control	Total		
Satisfactory knowledge					
Yes	97 (28.6)	78 (22.5)	175 (25.5)		
No	242 (71.4)	268 (77.5)	510 (74.5)	χ^2 (3.317)	0.069
Mean (SD)	11.14 (3.494)				

Change in Knowledge among Intervention and Control Groups

Tables 4. and 5 show the corresponding change in knowledge for LARC following intervention in the intervention and control groups.

Change in LARC Knowledge from Baseline to Three-Month Post-Intervention

The participants in the intervention group had a significant increase in the proportion of those with satisfactory LARC knowledge from baseline to three-month post intervention (p -value <0.001). However, there was no significant increase in the proportion of those with satisfactory knowledge among the control group (p -value=0.864), as indicated in Table 4 and 5 repetitively.

The participants in the intervention group had a significant increase in the proportion of those with satisfactory knowledge on LARC from baseline to six months post intervention (p -value <0.001), as shown in Table 4. But there was no significant increase in the proportion of those with satisfactory knowledge among the control group (p -value =0.402), as shown in Table 5.

There was no statistically significant increase in the proportion of those with satisfactory knowledge on LARC from three months to six months post intervention (p -value <0.120) among intervention group as shown in Table 4 below. Also, there was no significant increase in the proportion of those with satisfactory knowledge among the control group (p -value =0.525), as shown in Table 5.

Table 4. Change in Knowledge Following Intervention in Intervention Group (N=339)

Variables	Frequency (n) and Percentage (%)		Change	p-value
	Time 1	Time 2		
Satisfactory knowledge				
	Baseline	3 Months post		
Yes	97 (28.6)	321 (94.7)		
No	242 (71.4)	18 (5.3)	66.1	<0.001*
	Baseline	6 Months post		
Yes	97 (28.6)	312 (92.0)		
No	242 (71.4)	27 (8.0)	63.4	<0.001*

	3 Months post	6 Months post		
Yes	321 (94.7)	312 (92.0)		
No	18 (5.3)	27 (8.0)	-2.7	0.120

*p-value was calculated using McNemar's test. *Significant at <0.05*

Table 5. Change in Knowledge following Intervention in Control Group (N=346)

Variables	Frequency (n) and Percentage (%)		Change	p-value
	Time 1	Time 2		
Satisfactory knowledge				
	Baseline	3 Month post		
Yes	78 (22.5)	84 (24.3)		
No	268 (77.5)	262 (75,7)	2.2	0.864
	Baseline	6 Months post		
Yes	78 (22.5)	90 (26.0)		
No	268 (77.5)	256 (74.0)	3.5	0.402
	3 Months post	6 Months post		
Yes	84 (24.3)	90 (26.0)		
No	262 (75,7)	256 (74.0)	1.7	0.525

p-value was calculated using McNemar's test

Group simple effect on LARC Knowledge mean Scores

Independent t-test was performed to determine group simple effects for mean knowledge scores on LARC at baseline, three- and six-months post-intervention between the intervention and the control groups. The test shows that there was no statistically significant difference between the mean of the two groups at baseline (p -value =0.069). However, there was a statistically significant difference between the means of the two groups at three months post intervention (p -value <0.001) and

six months post intervention (p -value <0.001) as shown in Table 6.

The findings show that participants in the intervention group had a significantly higher mean knowledge score than the control group. This finding indicates that there is an improvement in LARC knowledge of the participants in the intervention group compared with those in the control group. As such it can be said that the health education intervention is effective in improving LARC knowledge of the participants in this study. The null hypothesis is therefore rejected, indicating that health education significantly enhanced knowledge about LARC.

Table 6. Group Simple Effect on LARC Knowledge at Baseline, Three Months and Six Months Post-Intervention

Variables	Mean		df	t value	mean difference (95% CI)	p-value
Baseline	Intervention=339	Control n=346				
	10.82	11.12	683	-0.553	-0.300 [-1.370- 0.770]	0.069
	Intervention= 339	Control n=346				

3 months post	21.32	10.28	683	44.816	1.034 [10.545-11.518]	<0.001 *
6 months post	Intervention= 339	Control n=346				
	20.61	10.28	683	36.526	10.329 [9.874-10.885]	<0.001 *

*t-test was used to calculate the p-value. *Significant at <0.05*

Effect of Group, Time and their Interaction on LARC Knowledge Scores

A mixed design ANOVA on knowledge scores revealed significant main effects on time and group as well as time*group interaction as shown in table 7 below. Knowledge scores changed significantly across the time points. The intervention group had higher overall knowledge than the control group ($F(1, 678) = 1257.17$, $p\text{-value} < 0.001$, $\eta^2 = 0.176$).

Moreover, there was statistically significant interaction between time and group ($F(2, 1366) = 764.31$, $p\text{-value} < 0.001$, $\eta^2 = 0.370$) shown in Table 8 indicating that knowledge increase over time differently for the two groups. In the

intervention group the mean increases from $M=11.94$ at baseline to $M=21.32$ at 3 months and remains high at 6 months at 20.6. In contrast, the control group mean score for knowledge remained essentially $M=10.35, 10.28$, and 10.28 at baseline, 3month and 6 months respectively.

This indicates that educational intervention produced knowledge gain that was sustained at 6 months whereas the control group showed no improvement in unchanged finding means that the intervention and control groups exhibited knowledge differently pre and post intervention, which shows the intervention is working.

Table 7. Summary table of repeated measures ANOVA for mean LARC knowledge scores (Within and Between Group)

Source Variable						
LARC knowledge scores	Type III sum of squares	df	Mean square	F	p-value	Partial Eta η^2
Time	9116.432	2	4558.21	738.644	<0.001*	0.118
Group*time	9433.267	2	4716.67	764.315	<0.001*	0.370
Error (time)	8367.961	1366	6.171			

Note: () – significant $p < 0.05$*

Table 8. Summary table of repeated measures ANOVA for mean LARC knowledge scores (Between subject)

Source Variable						
LARC knowledge scores	Type III sum of squares	df	Mean square	F	p-value	Partial Eta η^2
Intercept	407062.5	1	4558.21	1752.48	<0.001*	0.962
Group	29835.03	1	4716.67	1257.16	<0.001*	0.650
Error	16090.29	678	23.732			

Note: () – significant $p < 0.05$*

Discussion

This study evaluates the effectiveness of Theory-Based Health Educational Intervention

program on the knowledge regarding LARCs' Among Women Attending Antenatal Clinics in Katsina State, Nigeria. The findings of this study revealed the following results: Statistical

significance exists in knowledge of long-acting reversible contraceptive after health education intervention program. The findings of the research questions showed that health education intervention Programme has impact on knowledge of LARC among the respondents because majority of the respondents' knowledge of LARCS has increased after the health education intervention Programme. The findings in this study agree with a study conducted by Aderibigbe et al 2010 who conducted study on Effect of Health Education on Knowledge and Practice of Contraception among Students of Public Secondary Schools in Ilorin [9]. And found out that There was a statistically significant increase in the proportion of study respondents that came to know of contraception at post intervention. Similar results were observed by [29], who noted improved knowledge after structured contraceptive education programs. Similarly, contraceptive awareness improved following structured programs in a study by Seigh et al [29].

However, the study contradicts with others that have shown a low level of knowledge regarding pregnancy prevention in Sub-Saharan African adolescents [8]. A study conducted in Nigeria revealed that among adolescents enrolled in school, only 47% knew that pregnancy could occur from a first act of intercourse. Eighty-four percent reported that they believed sexuality education should be provided in school, but only 43% reported receiving any. Another study of Nigerian conducted by Bassey in 2025 on adolescents in school showed that 74% had misconceptions or negative attitudes about contraception, and that a positive attitude toward contraception was associated with use [14].

The finding also revealed that Statistical significance exists in intention to utilized LARCs family planning after health education intervention program this is similar to study conducted by Gebremariam in 2014 on

intention to use long acting and permanent contraceptive methods and factors affecting it among married women in a Tigray town, Tigray, Northern Ethiopia, journal of reproductive health, who found out that there was statistically significant association of intention to use LARC among those who knew at least one method of LARCs compared to their counterpart [13].

These findings are similar with result of a study conducted by Berihun in 2022 on Women's intention to use long acting and permanent contraceptive methods and associated factors among family planning users in Addis Ababa, Ethiopia: found that the prevalence of intention to use LARCs was 60%. The most preferred method participants intend to use in the future was implants which account for 175(60.8%), followed by IUCD 106(36.8%) [14]. The study also shows that Respondents who had information of long acting and permanent methods were 3 times more likely to have intention to use contraception than their counterparts (AOR:2.89,95% CI:1.33-6.29) [30].

Conclusion

This study demonstrates that theory-based health education significantly enhances knowledge and health beliefs about LARC among antenatal women in Katsina State. Health education intervention programme was conducted using training manual developed by the researcher. Data from 685 respondents were duly completed and returned for data analysis. Frequency count and percentage were used to organize and describe the demographic characteristics of the respondents while Sub-hypotheses were tested using paired sample t-test and independent t-test. The entire hypotheses were tested at 0.05 level of confidence

Demographic data showed that most participants were Hausa (93.4%), married (99%), and within the age range of 20–29 years.

There were no significant differences between the intervention and control groups at baseline regarding knowledge and HBM components.

Following the intervention, the proportion of women with satisfactory knowledge of LARCs increased significantly in the intervention group from 28.6% at baseline to 94.7% at 3 months and 92.0% at 6 months ($p < 0.001$). No significant change occurred in the control group. Similarly, the mean knowledge scores in the intervention group rose from 10.82 to 21.32, while scores in the control group remained around 10.28. Repeated measures ANOVA confirmed a significant interaction between time and group ($F = 764.31$, $p < 0.001$, $\eta^2 = 0.370$).

This study concludes that a theory-based health education intervention significantly improves knowledge about LARCs among antenatal women. Such interventions should be integrated into routine antenatal services to enhance informed reproductive choices.

Recommendations

Health policymakers should incorporate structured, culturally appropriate educational modules into ANC services. Training of health educators and use of local languages are essential for effective communication. Future research should explore longitudinal outcomes and adapt the model to other Nigerian states.

Recommendations for further studies

- The following studies are recommended for future researchers'

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- Impact of health education program on LARC utilization.
- Assessment of health education intervention implementation
- Future studies evaluating the role of men in the acceptance and utilization of LARC methods are encouraged.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this study. The research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Cardiovascular Disease Burden and Associated Risk Factors among Adults with Type 2 Diabetes Mellitus in Sub-Saharan Africa: A Narrative Review

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Abstract

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality among individuals with type 2 diabetes mellitus (T2DM) globally, and its burden is increasing rapidly in sub-Saharan Africa due to rising diabetes prevalence, population ageing, urbanization, and constrained health systems. This narrative review synthesizes evidence on the prevalence of CVD and associated risk factors among adults with T2DM in sub-Saharan Africa. A structured literature search was conducted across PubMed/MEDLINE, Scopus, Google Scholar, and African Journals Online, covering English-language publications from January 2000 to December 2025. Following screening and eligibility assessment, 42 studies were included and synthesized descriptively. The reviewed literature indicates that CVD is a common complication among adults with T2DM in sub-Saharan Africa, with reported prevalence ranging from approximately 20% to over 50%, depending on study setting and methodology. Hypertension-related CVD was the most frequently reported manifestation, followed by stroke, heart failure, and coronary artery disease. Increasing age, longer duration of diabetes, hypertension, poor glycemic control, dyslipidaemia, obesity, and adverse lifestyle behaviors emerged consistently as major cardiovascular risk factors. In addition, health system weaknesses—such as limited access to care, inadequate screening and diagnostic capacity, medication stock-outs, and fragmented chronic disease services—together with socioeconomic disadvantage, were recurrently associated with poor cardiovascular outcomes. Overall, the evidence highlights a substantial and growing cardiovascular burden among patients with T2DM in sub-Saharan Africa, driven by a convergence of modifiable clinical risk factors and structural health system and socioeconomic challenges. Strengthening integrated diabetes and cardiovascular care, improving access to essential services, and addressing underlying social determinants of health are critical priorities for reducing cardiovascular morbidity and mortality in this population.

Keywords: *Cardiovascular Disease, Health System Determinants, Prevalence, Risk Factors, Socioeconomic Factors, Sub-Saharan Africa, Type 2 Diabetes Mellitus.*

Introduction

Type 2 diabetes mellitus (T2DM) is one of the most significant and rapidly growing public health challenges worldwide [1, 2]. The global prevalence of diabetes has risen substantially over recent decades, driven by population ageing, urbanization, sedentary lifestyles, and dietary transitions [2, 3]. Cardiovascular

disease (CVD) remains the leading cause of morbidity and mortality among individuals with T2DM, accounting for a substantial proportion of diabetes-related deaths globally [4-6].

The pathophysiological relationship between T2DM and CVD is complex and multifactorial, involving metabolic, inflammatory, and vascular mechanisms.

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Chronic hyperglycemia, insulin resistance, dyslipidemia, and systemic inflammation contribute to endothelial dysfunction and accelerated atherosclerosis [5, 7]. These mechanisms substantially increase the risk of major cardiovascular outcomes, including coronary artery disease, cerebrovascular disease, peripheral arterial disease, and heart failure [4].

In sub-Saharan Africa, the burden of T2DM and its cardiovascular sequelae has increased steadily over the past two decades, reflecting rapid urbanization, population ageing, and changing lifestyle patterns. Health systems in the region, historically oriented toward communicable diseases, now face a dual burden of infectious and non-communicable diseases [1]. Rapid urbanization, changes in lifestyle behaviors, and limited access to preventive healthcare have contributed to the rising prevalence of diabetes and its cardiovascular complications [2, 8]. Recent hospital-based studies across the region report a substantial burden of CVD among adults with T2DM, with hypertension, ischemic heart disease, and stroke among the most frequently reported complications. Evidence from Ethiopia further illustrates this pattern, with a high prevalence of cardiovascular comorbidities and identification of hypertension and longer duration of diabetes as key predictors [9, 10]. These findings are consistent with broader global and regional analyses demonstrating that CVD remains the leading cause of morbidity and mortality among individuals with diabetes [4, 6], including recent updates from the Global Burden of Disease study [11].

Available evidence suggests that patients with T2DM in sub-Saharan Africa experience high rates of undiagnosed or poorly controlled cardiovascular risk factors, including hypertension, dyslipidemia, obesity, and poor glycemic control [2, 4]. Socioeconomic constraints, limited availability of essential medications, and fragmented chronic care services further exacerbate cardiovascular risk

[1, 12]. However, published data on the prevalence, patterns, and determinants of CVD among patients with T2DM in the region are heterogeneous and scattered across diverse settings.

A comprehensive synthesis of existing evidence is therefore necessary to clarify the magnitude of CVD risk among patients with T2DM in sub-Saharan Africa, identify key contributing factors, and highlight gaps in current knowledge [4, 5]. Such synthesis is essential to inform clinical practice, guide health policy, and support the development of integrated diabetes and cardiovascular care models tailored to resource-limited settings.

This study aims to examine cardiovascular disease risk among adults with type 2 diabetes mellitus in sub-Saharan Africa by synthesizing existing literature on epidemiological patterns, major risk factors, and health system influences. By consolidating current evidence, this review provides a contextual foundation for interpreting findings from original research conducted within the region.

Literature Review

Pathophysiological Link Between Type 2 Diabetes Mellitus and Cardiovascular Disease

Type 2 diabetes mellitus (T2DM) is characterised by chronic hyperglycemia and insulin resistance, both of which play central roles in the development of cardiovascular disease (CVD) [5]. Persistent hyperglycemia promotes non-enzymatic glycation of proteins and lipids, leading to the formation of advanced glycation end-products (AGEs). These compounds contribute to oxidative stress, vascular inflammation, and structural damage to the arterial wall, thereby accelerating atherosclerotic processes [7, 13].

Insulin resistance, a hallmark of T2DM, further exacerbates cardiovascular risk by disrupting normal metabolic and vascular homeostasis. Reduced insulin sensitivity impairs nitric oxide-mediated vasodilation,

resulting in endothelial dysfunction and increased arterial stiffness. Endothelial dysfunction is widely recognized as an early and critical step in the pathogenesis of atherosclerosis and is strongly associated with increased risk of coronary artery disease and stroke [1, 14].

Dyslipidemia, commonly observed in T2DM and characterised by elevated triglycerides, reduced high-density lipoprotein cholesterol, and increased levels of small, low-density lipoprotein particles, contributes significantly to atherogenesis. These lipid abnormalities promote lipid deposition in the arterial intima and enhance inflammatory responses in atherosclerotic plaques, increasing plaque instability and the risk of acute cardiovascular events [5, 7].

Chronic low-grade inflammation represents another key mechanism linking T2DM to CVD. Adipose tissue dysfunction and metabolic stress stimulate the release of pro-inflammatory cytokines, such as tumor necrosis factor- α and interleukin-6, which contribute to endothelial injury and plaque progression. Inflammatory pathways also interact with coagulation mechanisms, promoting a prothrombotic state that heightens the risk of myocardial infarction and cerebrovascular events [5, 15].

In addition to these mechanisms, individuals with T2DM frequently present with clustered cardiometabolic risk factors, including hypertension and obesity, which act synergistically with metabolic abnormalities to amplify cardiovascular risk [1, 2]. In addition, recent studies have highlighted the high prevalence of metabolic syndrome among individuals with T2DM in sub-Saharan Africa. Studies from Ghana and Ethiopia report that obesity, physical inactivity, and longer duration of diabetes are important contributors to cardiometabolic risk [16, 17]. These findings reinforce the multifactorial nature of cardiovascular risk in T2DM and complement

existing evidence on metabolic and vascular mechanisms [5, 7].

Diabetes-related microvascular and macrovascular complications are increasingly recognized across African settings, contributing substantially to cardiovascular morbidity among adults with T2DM [18].

Collectively, these interconnected mechanisms provide strong biological plausibility for the observed association between T2DM and CVD. Understanding these pathways is essential for informing integrated prevention and management strategies to reduce cardiovascular morbidity and mortality among patients with T2DM, particularly in resource-limited settings such as sub-Saharan Africa [4, 5].

Epidemiology of CVD in T2DM

Building on the biological mechanisms described above, epidemiological evidence provides insight into the magnitude and distribution of CVD among individuals with T2DM. CVD is the leading cause of morbidity and mortality among individuals with T2DM worldwide. Epidemiological studies consistently demonstrate that adults with T2DM have a two- to four-fold increased risk of developing CVD compared with individuals without diabetes [5, 7]. Major cardiovascular manifestations include coronary artery disease, cerebrovascular disease, peripheral arterial disease, and heart failure, all of which contribute substantially to reduced life expectancy and quality of life among diabetic populations.

Globally, the burden of CVD among patients with T2DM has continued to rise in parallel with increasing diabetes prevalence. Improvements in survival from acute cardiovascular events in high-income countries have shifted the disease burden toward chronic complications, including heart failure and recurrent vascular events [4]. However, these gains have not been uniformly realized across low- and middle-income regions, where access

to early diagnosis and long-term cardiovascular care remains limited.

In sub-Saharan Africa, the epidemiology of CVD in T2DM is shaped by rapid epidemiological transition and health system constraints. The region has experienced a marked increase in diabetes prevalence over the past two decades, driven by urbanization, lifestyle changes, and population ageing [1]. Concurrently, CVD has emerged as a major cause of morbidity and mortality, often occurring at a younger age compared with high-income settings.

Available studies from sub-Saharan Africa indicate a high burden of CVD among patients with T2DM, although reported prevalence estimates vary widely across countries and study settings, with country-level reports from Nigeria reflecting similar trends [2, 4, 19]. Hospital-based studies frequently report high proportions of diabetic patients with coexisting multiple cardiovascular manifestations, including hypertension-related heart disease, stroke, coronary artery disease, and heart failure, reflecting late presentation and limited preventive care [2, 4]. Community-based data, where available, suggest that a significant proportion of CVD among diabetic individuals remains undiagnosed. Recent studies from Ethiopia further reinforce this pattern. A multicentre study in Bahir Dar reported that a substantial proportion of adults with T2DM had at least one cardiovascular comorbidity, while findings from Addis Ababa identified hypertension and longer duration of diabetes as key associated factors [9, 10]. These findings align with broader regional evidence indicating that cardiovascular complications are increasingly common among individuals living with diabetes in sub-Saharan Africa [20].

Hypertension is the most reported cardiovascular comorbidity among patients with T2DM in sub-Saharan Africa and is a major driver of stroke and heart failure in the region. Cerebrovascular disease appears to contribute disproportionately to cardiovascular

morbidity and mortality among diabetic populations, consistent with broader regional patterns of CVD and supported by regional stroke epidemiology studies [4, 21]. Coronary artery disease, while historically considered less prevalent, is increasingly recognized as underdiagnosed due to limited access to diagnostic facilities.

Marked heterogeneity exists in the epidemiological profile of CVD among patients with T2DM across sub-Saharan Africa. Differences in study design, diagnostic criteria, healthcare access, and population characteristics complicate direct comparisons across countries. Nevertheless, the available evidence consistently indicates a high and growing burden of CVD among adults with T2DM in the region.

Overall, the epidemiological literature highlights CVD as a major and increasingly prominent complication of T2DM in sub-Saharan Africa. These findings underscore the urgent need for improved cardiovascular risk assessment, early detection, and integrated management within diabetes care programmes, and provide a critical context for interpreting findings from original studies conducted in the region.

Major Cardiovascular Risk Factors in T2DM

The excess cardiovascular burden observed among individuals with T2DM is largely attributable to the clustering of multiple modifiable and non-modifiable risk factors. In patients with T2DM, these risk factors often coexist and interact synergistically, substantially amplifying the risk of adverse cardiovascular outcomes [5].

Hypertension

Hypertension is the most prevalent and consistently reported cardiovascular risk factor among patients with T2DM, both globally and in sub-Saharan Africa. The coexistence of diabetes and hypertension markedly increases

the risk of coronary artery disease, stroke, heart failure, and diabetic microvascular complications, and evidence from large clinical trials shows that effective blood pressure control substantially reduces cardiovascular events in this population [22]. Epidemiological studies indicate that a large proportion of adults with T2DM in sub-Saharan Africa have either undiagnosed or poorly controlled hypertension, reflecting gaps in routine screening and long-term management [2, 4].

Dyslipidemia

Dyslipidemia is another major contributor to cardiovascular risk in T2DM and is characterised by elevated triglyceride levels, reduced high-density lipoprotein cholesterol, and qualitative abnormalities of low-density lipoprotein particles. These lipid abnormalities accelerate atherosclerosis and increase the likelihood of plaque rupture and thrombotic events. Evidence from African studies suggests that dyslipidemia is frequently underdiagnosed and undertreated among patients with T2DM, further compounding cardiovascular risk [5, 7].

Poor Glycemic Control

Poor long-term glycemic control plays a central role in the development and progression of CVD in T2DM. Chronic hyperglycemia contributes to endothelial dysfunction, oxidative stress, and inflammatory activation, thereby accelerating vascular damage. Several studies have demonstrated associations between elevated glycated hemoglobin levels and increased risk of cardiovascular events, particularly when poor glycemic control coexists with other risk factors such as hypertension and dyslipidemia [1, 5].

Obesity and Central Adiposity

Obesity, particularly central or visceral adiposity, is strongly associated with insulin resistance, systemic inflammation, and adverse cardiovascular outcomes in individuals with T2DM. Rapid urbanization and lifestyle transitions in sub-Saharan Africa have

contributed to rising rates of overweight and obesity among diabetic populations. Excess adiposity not only worsens glycemic control but also promotes hypertension and dyslipidemia, creating a high-risk cardiometabolic profile [2, 4].

Duration of Diabetes and Age

Longer duration of diabetes and advancing age are important non-modifiable risk factors for CVD in T2DM. Prolonged exposure to hyperglycemia and metabolic abnormalities increases cumulative vascular damage. Studies consistently show a higher prevalence of cardiovascular complications among patients with longer diabetes duration, highlighting the importance of early diagnosis and timely risk factor management [5].

Lifestyle Factors

Lifestyle-related factors, including physical inactivity, unhealthy dietary patterns, tobacco use, and harmful alcohol consumption, further contribute to cardiovascular risk in individuals with T2DM. In sub-Saharan Africa, urban lifestyles and limited opportunities for physical activity have been associated with worsening cardiometabolic profiles [3, 4]. Tobacco use, although variable across countries, remains an important preventable risk factor for CVD among diabetic populations, while harmful alcohol use has been linked to poor glycemic control and hypertension [4].

In summary, cardiovascular risk among patients with T2DM is driven by a complex interplay of metabolic, clinical, and lifestyle factors. The high prevalence and frequent co-occurrence of these risk factors in sub-Saharan Africa underscore the need for comprehensive, integrated cardiovascular risk-reduction strategies within diabetes care services.

Health System and Socioeconomic Factors Influencing Cardiovascular Risk

Health system and socioeconomic factors play a critical role in shaping CVD risk and outcomes among patients with T2DM in sub-

Saharan Africa. Beyond individual-level clinical and metabolic determinants, structural barriers within health systems and broader social conditions significantly influence access to care, quality of disease management, and long-term cardiovascular outcomes [4].

Access to Healthcare Services

Limited access to healthcare services remains a major challenge for effective cardiovascular risk management among individuals with T2DM in sub-Saharan Africa. Geographic barriers, shortages of healthcare professionals, and inadequate healthcare infrastructure contribute to delayed diagnosis of diabetes and cardiovascular complications. Many patients present to health facilities at advanced stages of disease, when cardiovascular damage is already established, reducing the effectiveness of preventive interventions [2].

Screening and Diagnostic Gaps

Routine screening for cardiovascular risk factors such as hypertension, dyslipidaemia, and chronic kidney disease is often inconsistent or unavailable in primary care settings. Limited access to laboratory services and diagnostic tools, including lipid profiling and cardiac imaging, leads to underdiagnosis and undertreatment of CVD among patients with T2DM. These gaps contribute to a substantial burden of undetected cardiovascular risk within diabetic populations [4].

Availability and Affordability of Medications

The availability and affordability of essential medicines for the management of diabetes and CVD remain uneven across sub-Saharan Africa. Interruptions in drug supply chains, high out-of-pocket costs, and limited insurance coverage hinder long-term adherence to antihypertensive, lipid-lowering, and glucose-lowering therapies. Inadequate pharmacological management of cardiovascular risk factors is therefore a

common contributor to poor cardiovascular outcomes in patients with T2DM [1, 2].

Health System Organisation and Integrated Care

Fragmentation of health services poses a significant barrier to comprehensive cardiovascular risk management in diabetes care. In many settings, diabetes and cardiovascular services are delivered through separate programmes, resulting in missed opportunities for integrated risk assessment and coordinated management [4, 12]. Strengthening integrated chronic care models that address diabetes and CVD concurrently has been identified as a key priority for improving outcomes in resource-limited settings [4].

Socioeconomic Determinants

Socioeconomic factors, including low income, limited education, unemployment, and food insecurity, further exacerbate cardiovascular risk among patients with T2DM. These determinants influence health-seeking behavior, treatment adherence, and the ability to adopt recommended lifestyle modifications. Evidence suggests that socially disadvantaged individuals with diabetes experience higher rates of cardiovascular complications, reflecting the cumulative effects of structural inequities on health outcomes [1, 2].

Overall, health system weaknesses and adverse socioeconomic conditions substantially contribute to the burden of CVD among patients with T2DM in sub-Saharan Africa. Addressing these factors through health system strengthening, improved access to essential services, and policies that reduce socioeconomic inequities is essential for effective CVD prevention and control in diabetic populations.

Summary of Literature and Identified Gaps

The reviewed literature demonstrates that CVD represents a major and growing complication of T2DM, driven by a complex interplay of biological, clinical, lifestyle, health

system, and socioeconomic factors [4, 5]. Evidence consistently indicates that individuals with T2DM face substantially higher risks of coronary artery disease, cerebrovascular disease, heart failure, and other cardiovascular outcomes compared with the general population [4, 5].

Across sub-Saharan Africa, epidemiological studies highlight a high prevalence of cardiovascular risk factors among patients with T2DM, particularly hypertension, dyslipidaemia, poor glycemic control, obesity, and longer duration of diabetes [1, 5]. These risk factors frequently coexist and are often inadequately detected or managed, reflecting gaps in routine screening, preventive care, and long-term disease management [4, 12]. Health system limitations, including fragmented services, limited diagnostic capacity, and inconsistent access to essential medications, further exacerbate cardiovascular risk and contribute to poor outcomes [1, 8].

Despite the growing body of literature, several important gaps remain. First, there is considerable heterogeneity in reported CVD prevalence estimates among patients with T2DM in sub-Saharan Africa, largely due to differences in study design, diagnostic criteria, and healthcare settings, limiting comparability across studies [4, 12]. Second, many studies rely on hospital-based samples, which may overrepresent individuals with advanced disease and underestimate the true burden of undiagnosed CVD in the community [8].

Furthermore, few studies comprehensively examine the combined influence of sociodemographic, clinical, and health system factors on CVD risk among patients with T2DM within a single analytical framework. As a result, the relative contribution of modifiable risk factors and structural determinants remains insufficiently characterised. There is also limited evidence from routine public-sector healthcare settings, where most patients with T2DM in sub-Saharan Africa receive care.

In addition, data from several countries in the region remain sparse, and there is a particular lack of context-specific evidence to inform targeted cardiovascular risk-reduction strategies. These gaps underscore the need for original research that systematically assesses the prevalence of CVD and its associated factors among patients with T2DM in real-world clinical settings.

By addressing these gaps, original studies conducted within sub-Saharan Africa can contribute valuable evidence to support integrated diabetes and cardiovascular care, inform health policy, and guide the allocation of limited healthcare resources. The present study is therefore well positioned to provide important insights into the burden and determinants of CVD among patients with T2DM, directly addressing gaps identified in the existing literature.

Methods

Review Design

This study employed a narrative review to synthesize evidence on cardiovascular disease (CVD) risk among adults with type 2 diabetes mellitus (T2DM) in sub-Saharan Africa. A narrative approach was considered appropriate to enable a broad, contextualized examination of epidemiological patterns, risk factors, and health system influences across diverse settings within the region.

Literature Search Strategy

A structured narrative review approach was employed. A comprehensive literature search was conducted using PubMed/MEDLINE, Scopus, Google Scholar, and African Journals Online (AJOL). The search covered English-language articles published from January 2000 to December 2025. Key search terms and Boolean combinations included: "type 2 diabetes mellitus", "cardiovascular disease", "cardiovascular complications", "prevalence", "risk factors", "health system factors", and "sub-Saharan Africa".

The search yielded approximately 420 records. After removing duplicates, approximately 310 titles and abstracts were screened for relevance. Of these, 86 full-text articles were assessed for eligibility. Studies were excluded if they did not specifically report cardiovascular outcomes among adults with T2DM, focused exclusively on type 1 diabetes mellitus or pediatric populations, or lacked sufficient methodological clarity. A total of 42 articles were included in the final descriptive synthesis.

Given the narrative nature of the review, no formal risk-of-bias assessment was undertaken. Instead, findings were synthesized thematically across six domains: (1) epidemiology and burden of CVD; (2) biological and metabolic risk factors; (3) lifestyle-related risk factors; (4) health system determinants; (5) socioeconomic determinants; and (6) identified methodological and evidence gaps.

Eligibility Criteria

Included publications comprised original research articles, systematic reviews, narrative reviews, and authoritative reports that examined CVD outcomes or cardiovascular risk factors among adult patients with T2DM in sub-Saharan Africa. Studies focusing exclusively on type 1 diabetes mellitus, gestational diabetes, pediatric populations, or non-African settings were excluded. Editorials, commentaries, and case reports were also excluded unless they provided substantial contextual or policy-relevant information.

Data Extraction and Synthesis

Relevant data were extracted narratively, focusing on reported CVD prevalence, major cardiovascular risk factors, and contextual health system determinants. Due to heterogeneity in study designs, outcome definitions, and reporting methods, a qualitative synthesis was undertaken rather than a quantitative meta-analysis. Although 42 studies met the inclusion criteria and informed

the narrative synthesis, only selected representative studies are cited and tabulated in the Results section to illustrate key patterns and findings across the broader body of literature. Findings were organized thematically to highlight common patterns and regional challenges.

Ethical Considerations

This review was based exclusively on published literature and publicly available data. It did not involve human participants, identifiable personal data, or primary data collection. Ethical approval was therefore not required.

Results

Characteristics of Included Studies

A total of 42 studies met the inclusion criteria and were included in the narrative synthesis. The characteristics of these studies are summarised in Table 1. Many included studies were observational, predominantly cross-sectional, and largely hospital-based. Study settings spanned multiple countries within sub-Saharan Africa, with considerable variation in sample size, study populations, and cardiovascular outcomes assessed.

Most studies focused on the prevalence of cardiovascular disease (CVD) or its major risk factors among adults with type 2 diabetes mellitus (T2DM). Hypertension was the most frequently reported cardiovascular comorbidity, followed by stroke, heart failure, and coronary artery disease. Several studies assessed composite cardiovascular outcomes, while others examined specific manifestations such as cerebrovascular disease or hypertensive heart disease.

Methodological heterogeneity was evident across the included studies, particularly regarding diagnostic criteria for CVD and data collection methods. Despite these differences, the studies collectively provide valuable insights into the burden and patterns of CVD

among patients with T2DM in sub-Saharan Africa.

Prevalence of CVD among Patients with T2DM

Across included studies, CVD was consistently reported as a common complication among adults with T2DM in sub-Saharan Africa. Reported CVD prevalence estimates varied substantially across study settings, reflecting differences in study design, population characteristics, diagnostic criteria, and healthcare access.

Hospital-based studies generally reported a higher prevalence of CVD among patients with T2DM compared with community-based studies. In several tertiary and secondary care settings, between one-third and over half of adults with T2DM were reported to have at least one form of CVD, including hypertension-related heart disease, stroke, coronary artery disease, or heart failure. These higher estimates are likely to reflect referral bias and late presentation of patients with advanced CVD.

Hypertension-related CVD emerged as the most frequently reported manifestation across studies. Many studies documented the high burden of hypertensive heart disease and

related complications among patients with T2DM, underscoring the strong overlap between diabetes and hypertension in the region. CVD, particularly stroke, was also commonly reported and, in some settings, accounted for a substantial proportion of cardiovascular morbidity among diabetic populations.

Coronary artery disease was reported less frequently than hypertension or stroke in many studies; however, several authors noted that this likely reflects underdiagnosis rather than true low prevalence. Limited access to diagnostic investigations such as electrocardiography, cardiac biomarkers, and coronary imaging was frequently cited as a contributing factor to under-recognition of ischemic heart disease among patients with T2DM.

Marked heterogeneity in reported CVD prevalence was observed across countries and healthcare levels. Studies conducted in urban settings and referral hospitals tended to report higher prevalence estimates than those conducted in rural or primary care settings. Despite this variability, the collective findings indicate that cardiovascular disease constitutes a major burden among adults with T2DM across sub-Saharan Africa.

Table 1. Characteristics of Studies Included in the Narrative Review (Representative Studies)

Author(s) / Year	Country / Setting	Study Design	Study Population	Sample Size	Cardiovascular Outcomes Assessed	Key Findings Relevant to CVD
Kengne et al., 2010 [23]	Cameroon; tertiary hospital	Cross-sectional	Adults with T2DM	~500	Hypertension, stroke, heart disease	High prevalence of hypertension and CVD among long-standing T2DM patients
Levitt et al., 2011 [24]	South Africa; urban clinics	Cross-sectional	Adults with T2DM	~800	Hypertension, IHD, stroke	Strong coexistence of diabetes and hypertension
Sobngwi et al., 2012 [25]	Cameroon; referral hospitals	Cross-sectional	Adults with T2DM	~600	Hypertensive heart disease, stroke	Late presentation and poor risk factor control
Amoah et al., 2014 [26]	Ghana; teaching hospital	Cross-sectional	Adults with T2DM	~400	Hypertension, CAD	High burden of undiagnosed

						hypertension and dyslipidemia
Erasmus et al., 2015 [27]	South Africa; tertiary hospital	Cross-sectional	Adults with T2DM	~300	Heart failure, stroke	CVD common with long diabetes duration
Pastakia et al., 2017 [28]	Kenya; mixed settings	Cohort	Adults with T2DM	~700	CVD risk factors	Integrated care improved detection
Uloko et al., 2018 [29]	Nigeria; multi-centre clinics	Cross-sectional	Adults with T2DM	>1,000	Composite CVD outcomes	High prevalence of hypertension and obesity
Kibirige et al., 2019 [30]	Uganda; outpatient clinics	Cross-sectional	Adults with T2DM	~600	Hypertension, stroke	Poor BP control linked to CVD
Ekoru et al., 2020 [31]	Multi-country SSA	Population-based	Adults with diabetes	>2,000	Stroke, heart disease	Diabetes associated with premature CVD
Nyenwe et al., 2021 [19]	Nigeria; tertiary hospital	Cross-sectional	Adults with T2DM	~500	CAD, heart failure	Coronary artery disease likely underdiagnosed
IDF, 2023 [2]	Sub-Saharan Africa	Report	Adults with diabetes	—	CVD mortality	CVD is the leading cause of death among patients with diabetes
Addis et al., 2025 [9]	Ethiopia, multi-centre hospital	Cross-sectional	Adults with T2DM	~600	Composite CVD comorbidity	Hypertension major predictor
Yeshitla et al., 2025 [10]	Ethiopia, selected public hospitals	Cross-sectional	Adults with T2DM	~450	CVD prevalence	High burden of cardiovascular complications

Note: This table presents representative studies included in the narrative synthesis. Although 42 studies informed the overall synthesis, not all included studies are shown individually in this table. CAD= Coronary Artery Disease; CVD= Cardiovascular Disease; IDF= International Diabetes Federation; IHD= Ischemic Heart Disease; SSA= Sub-Saharan Africa; T2DM= Type 2 Diabetes Mellitus.

Overall, the results demonstrate that a substantial proportion of patients with T2DM in the region are affected by cardiovascular disease, often at relatively young ages and with multiple coexisting conditions. The prevalence ranges presented in Table 2 reflect pooled patterns observed across the hospital- and community-based studies summarised in Table 1, rather than estimates from any single study. These findings provide important context for understanding the scale of cardiovascular risk in this population and set the stage for examining associated risk factors and health system influences in subsequent sections.

Cardiovascular Risk Factors Reported among Patients with T2DM

According to the studies included, several demographics, clinical, and metabolic factors were consistently reported to be associated with CVD among patients with T2DM. These risk factors frequently coexist within individuals, contributing to a high cumulative cardiovascular risk profile.

Increasing age was one of the most consistently reported non-modifiable risk factors. Studies commonly demonstrated a higher prevalence of cardiovascular disease

among older adults with T2DM compared with younger patients. Similarly, longer duration of diabetes was repeatedly associated with increased cardiovascular burden, reflecting cumulative exposure to hyperglycemia and metabolic abnormalities.

Hypertension emerged as the most prevalent and strongly associated modifiable

cardiovascular risk factor. A large proportion of patients with T2DM were reported to have either diagnosed or previously unrecognized hypertension, and the coexistence of diabetes and hypertension was associated with markedly higher rates of stroke, heart failure, and hypertensive heart disease.

Table 2. Summary of Reported Prevalence of CVD among Patients with T2DM in Sub-Saharan Africa

Cardiovascular Outcome	Reported Prevalence Range	Study Settings Commonly Reporting Outcome
Any cardiovascular disease	~20% – >50%	Predominantly hospital-based studies
Hypertension-related CVD	~30% – 70%	Hospital and outpatient clinics
Stroke / cerebrovascular disease	~5% – 25%	Tertiary and referral hospitals
Coronary artery disease	~5% – 20%	Mostly hospital-based; underdiagnosed
Heart failure	~10% – 30%	Secondary and tertiary facilities

Note: Prevalence ranges are indicative and reflect heterogeneity in study design, diagnostic criteria, and healthcare settings across included studies. The prevalence ranges summarised in this table are derived from hospital- and community-based studies listed in Table 1, with hospital-based studies contributing predominantly to the higher end of reported ranges. CVD = Cardiovascular Disease; T2DM = Type 2 Diabetes Mellitus.

Dyslipidaemia was also frequently reported among patients with T2DM, particularly in hospital-based studies. Common lipid abnormalities included elevated triglyceride levels, reduced high-density lipoprotein cholesterol, and increased low-density lipoprotein cholesterol. These abnormalities were often inadequately treated, contributing to increased atherosclerotic cardiovascular risk.

Poor glycemic control was consistently associated with CVD across multiple studies. Patients with elevated glycated hemoglobin levels were more likely to have cardiovascular complications, especially when poor glycemic control coexisted with hypertension or dyslipidaemia.

Obesity, particularly central adiposity, was another commonly reported risk factor. Studies noted higher CVD prevalence among overweight and obese patients with T2DM,

reflecting the combined effects of insulin resistance, inflammation, and adverse metabolic profiles.

Lifestyle-related factors, including physical inactivity, tobacco use, and harmful alcohol consumption, were also identified as important contributors to cardiovascular risk among patients with T2DM. Although the prevalence of these behaviours varied across settings, their presence was generally associated with poorer cardiovascular outcomes.

In summary, the results indicate that CVD among patients with T2DM is driven by a constellation of interrelated demographic, clinical, metabolic, and lifestyle factors, as shown in Table 3. The consistent identification of modifiable risk factors across studies underscores the potential for targeted prevention and integrated risk reduction strategies in this population.

Table 3. Cardiovascular Risk Factors Reported in Representative Studies among Patients with T2DM in Sub-Saharan Africa

Author(s) / Year	Country / Setting	Major Risk Factors Assessed	Risk Factors Associated with CVD	Direction of Association
Kengne et al., 2010 [23]	Cameroon	Age, duration, hypertension, obesity	Hypertension, longer duration	Increased risk
Levitt et al., 2011 [24]	South Africa	Hypertension, obesity	Hypertension, obesity	Increased risk
Sobngwi et al., 2012 [25]	Cameroon	Glycemic control, hypertension	Poor control, hypertension	Increased risk
Amoah et al., 2014 [26]	Ghana	Hypertension, dyslipidemia	Hypertension, dyslipidemia	Increased risk
Erasmus et al., 2015 [27]	South Africa	Age, duration	Older age, longer duration	Increased risk
Pastakia et al., 2017 [28]	Kenya	Lifestyle, access to care	Physical inactivity, poor access	Increased risk
Uloko et al., 2018 [29]	Nigeria	Obesity, inactivity, hypertension	Obesity, hypertension	Increased risk
Kibirige et al., 2019 [30]	Uganda	BP control	Uncontrolled hypertension	Increased risk
Nyenwe et al., 2021 [19]	Nigeria	Dyslipidemia, hypertension	Dyslipidemia, hypertension	Increased risk
<i>Note: This table summarizes cardiovascular risk factors reported in representative studies included in the narrative synthesis. Associations reflect patterns reported by study authors and do not imply causality. BP= Blood Pressure; CVD= Cardiovascular Disease; T2DM= Type 2 Diabetes Mellitus.</i>				

Health System and Socioeconomic Factors Reported in the Included Studies

Across the included studies, health system and socioeconomic factors were frequently reported to be important contributors to cardiovascular disease risk and poor outcomes among patients with T2DM, as shown in Table 4. These factors influenced access to care, treatment continuity, and the effectiveness of cardiovascular risk management.

Limited access to healthcare services was a recurrent finding, particularly in rural and underserved urban settings. Several studies reported delayed diagnosis of both diabetes and

CVD due to geographic barriers, shortages of healthcare personnel, and inadequate healthcare infrastructure. As a result, many patients presented with advanced disease and established cardiovascular complications.

Inadequate screening and diagnostic capacity were another commonly reported health system challenge. Studies noted inconsistent screening for hypertension, dyslipidemia, and other cardiovascular risk factors in primary care settings. Limited availability of laboratory testing and diagnostic equipment contributed to the underdiagnosis of CVD, particularly coronary artery disease.

Table 4. Health System and Socioeconomic Factors Reported in Representative Studies among Patients with T2DM in Sub-Saharan Africa

Author(s) / Year	Country / Setting	Health System Factors Identified	Socioeconomic Factors Identified	Reported Impact on CVD Outcomes
Kengne et al., 2010 [23]	Cameroon; tertiary hospital	Late presentation, limited screening	Low income	Advanced CVD at diagnosis
Levitt et al., 2011 [24]	South Africa; urban clinics	Fragmented chronic care	Unemployment	Poor cardiovascular risk control
Sobngwi et al., 2012 [25]	Cameroon; referral hospitals	Inadequate follow-up systems	Low educational attainment	Higher CVD complications
Amoah et al., 2014 [26]	Ghana; teaching hospital	Medication stock-outs	Out-of-pocket payments	Poor BP and lipid control
Erasmus et al., 2015 [27]	South Africa; tertiary hospital	Late referral to specialist care	Socioeconomic inequality	Severe CVD at presentation
Pastakia et al., 2017 [28]	Kenya; mixed rural–urban settings	Weak integration of NCD services	Food insecurity	Suboptimal long-term CVD risk management
Uloko et al., 2018 [29]	Nigeria; multi-centre clinics	Limited access to preventive services	Urban poverty	High prevalence of uncontrolled risk factors
Kibirige et al., 2019 [30]	Uganda; outpatient clinics	Inconsistent routine screening	Rural residence	Delayed detection of CVD
Ekoru et al., 2020 [31]	Multi-country SSA	Health system capacity constraints	Low socioeconomic status	Premature cardiovascular events
Nyenwe et al., 2021 [19]	Nigeria; tertiary hospital	Limited diagnostic capacity	Low insurance coverage	Underdiagnosis of coronary artery disease
WHO, 2022 [1]	SSA; regional analysis	Weak primary healthcare systems	Socioeconomic inequality	Persistent CVD burden in T2DM
IDF, 2023 [2]	SSA; regional estimates	Limited access to essential medicines	Household poverty	High diabetes-related CVD mortality

Note: This table summarizes health system and socioeconomic determinants of cardiovascular disease (CVD) reported in representative studies included in the narrative synthesis. Associations reflect patterns described by study authors and do not imply causality. BP= Blood Pressure; IDF= International Diabetes Federation; NCD= Non-Communicable Diseases; SSA= Sub-Saharan Africa; T2DM= Type 2 Diabetes Mellitus; WHO= World Health Organization.

Medication availability and affordability were also highlighted as major constraints. Interruptions in the supply of essential medicines, high out-of-pocket costs, and limited insurance coverage were associated with poor adherence to antihypertensive, lipid-lowering, and glucose-lowering therapies. These challenges undermined long-term

cardiovascular risk control among patients with T2DM.

Fragmented chronic care services further compounded these challenges. Several studies reported that diabetes and CVD were often managed through separate, poorly coordinated programmes, resulting in missed opportunities

for integrated risk assessment and comprehensive management.

Socioeconomic factors, including low income, limited education, unemployment, and food insecurity, were frequently associated with higher cardiovascular burden among patients with T2DM. These factors influenced health-seeking behaviour, treatment adherence, and the ability to adopt recommended lifestyle modifications.

Overall, the results indicate that weaknesses in the health system and adverse socioeconomic conditions substantially shape CVD risk and outcomes among patients with T2DM. These findings highlight the importance of strengthening health systems and addressing social determinants of health to reduce the cardiovascular burden in diabetic populations.

Discussion

Principal Findings

This narrative review synthesized evidence on the burden of cardiovascular disease (CVD) and its associated factors among adults with type 2 diabetes mellitus (T2DM) in sub-Saharan Africa. The findings demonstrate that CVD remains a major and persistent complication of T2DM in the region, with reported prevalence ranging from approximately one-fifth to more than half of affected patients, depending on study setting and methodology (Table 2). These findings are consistent with global evidence identifying CVD as the leading cause of morbidity and mortality among individuals with diabetes [4, 5]. Hypertension-related CVD emerged as the most frequently reported manifestation, followed by stroke, heart failure, and coronary artery disease, reflecting patterns described in regional epidemiological studies [8, 32].

Comparison with Existing Literature

The high prevalence of CVD among patients with T2DM observed in this review aligns with international literature demonstrating a two- to four-fold increased cardiovascular risk among

individuals with diabetes compared with the general population [4, 7]. However, compared with high-income countries, studies from sub-Saharan Africa frequently report earlier onset of cardiovascular complications and a greater likelihood of presentation at more advanced stages of the disease [2, 8]. This pattern likely reflects delayed diabetes diagnosis, limited access to preventive healthcare, and suboptimal long-term risk factor management in resource-constrained health systems [1, 10].

The findings of this review highlight the substantial and evolving burden of CVD among adults living with T2DM in sub-Saharan Africa. This pattern is supported by regional epidemiological studies showing high rates of cardiovascular complications among diabetic populations [2, 8, 32]. Recent hospital-based studies in the region, including evidence from Ethiopia, further demonstrate a high prevalence of cardiovascular comorbidities and identify hypertension and prolonged duration of diabetes as important predictors of cardiovascular complications [9, 10]. In addition, studies from other African settings report a high prevalence of metabolic syndrome and related cardiometabolic risk factors among individuals with T2DM, further contributing to cardiovascular risk [16, 17]. Together, these findings reinforce the convergence of multiple risk factors driving the cardiovascular burden in this population.

Hypertension was the most consistently identified cardiovascular risk factor across representative studies (Table 3), mirroring findings from regional and global literature highlighting the synergistic effect of diabetes and hypertension on cardiovascular risk [4, 5]. Poor glycemic control, longer duration of diabetes, dyslipidemia, and obesity were also repeatedly associated with increased cardiovascular burden, consistent with established pathophysiological and epidemiological evidence [2, 13, 33].

Coronary artery disease appeared less frequently than stroke or hypertension-related

complications; however, several studies suggest that this likely reflects underdiagnosis rather than true lower prevalence [8, 32]. Limited access to diagnostic investigations, such as electrocardiography, cardiac biomarkers, and coronary imaging, remains a major barrier to the accurate detection of ischemic heart disease in many sub-Saharan African settings [4].

Health System and Socioeconomic Context

An important contribution of this review is the synthesis of the health system and socioeconomic determinants of cardiovascular risk among patients with T2DM (Table 4). Recurrent themes included limited access to healthcare services, inadequate screening for cardiovascular risk factors, medication stock-outs, fragmented chronic care services, and constrained diagnostic capacity. Similar health system challenges have been widely documented in sub-Saharan Africa and are recognized contributors to poor non-communicable disease outcomes [1, 12].

Socioeconomic disadvantage further amplifies cardiovascular risk among patients with T2DM. Low income, limited education, unemployment, rural residence, and food insecurity were frequently associated with poor treatment adherence, delayed care-seeking, and reduced ability to implement recommended lifestyle modifications. These findings are consistent with broader evidence demonstrating the strong influence of social determinants on cardiovascular and diabetes outcomes in low- and middle-income countries [1, 2].

Implications for Clinical Practice and Public Health

The findings of this review have important implications for clinical practice and public health in sub-Saharan Africa. Given the high prevalence of modifiable cardiovascular risk factors, there is a clear need to strengthen integrated models of diabetes and

cardiovascular care, as recommended by international guidelines [4, 5]. Routine screening for hypertension, dyslipidemia, and poor glycemic control should be prioritized within diabetes care services, alongside early identification of high-risk individuals.

At the health system level, improving the availability and affordability of essential medicines, enhancing diagnostic capacity, and promoting continuity of care are critical steps toward reducing cardiovascular morbidity among patients with T2DM [1, 12]. Strengthening primary healthcare systems and integrating NCD services may offer feasible and cost-effective strategies in resource-limited settings [4].

Strengths and Limitations

This review has several strengths. It provides a comprehensive synthesis of evidence spanning more than two decades, incorporates data from multiple countries across sub-Saharan Africa, and adopts a structured narrative approach that integrates epidemiological, clinical, and health system perspectives. The use of summary tables enhances transparency and facilitates comparison across studies, as recommended for high-quality narrative reviews [8].

However, several limitations should be acknowledged. As a narrative review, the findings are subject to potential selection bias, and no formal risk-of-bias assessment was undertaken. The included studies showed considerable heterogeneity in design, settings, diagnostic criteria, and outcome definitions, which limited direct comparability across studies, a challenge commonly noted in regional non-communicable disease research [4, 12]. In addition, the predominance of hospital-based studies may overestimate the true population-level burden of CVD among individuals with T2DM.

Future Research Directions

Future studies should prioritize population-based designs to generate more representative estimates of cardiovascular disease burden among patients with type 2 diabetes mellitus in sub-Saharan Africa [2, 4]. Longitudinal studies are also needed to better characterize temporal relationships between risk factors and cardiovascular outcomes. Strengthening routine health information systems and standardizing diagnostic criteria would further improve the quality and comparability of evidence in this field [1].

Conclusion

This narrative review demonstrates that cardiovascular disease (CVD) constitutes a major and growing complication of type 2 diabetes mellitus (T2DM) in sub-Saharan Africa. The synthesis of evidence indicates that a substantial proportion of adults with T2DM are affected by CVD, often at relatively young ages and in the presence of multiple coexisting risk factors. Hypertension-related CVD, stroke, heart failure, and coronary artery disease emerge as prominent manifestations, reflecting both the biological impact of diabetes and contextual health system challenges within the region.

The review highlights that cardiovascular risk among patients with T2DM is driven by a convergence of modifiable clinical factors—particularly hypertension, poor glycemic control, dyslipidemia, obesity, and longer duration of diabetes—as well as lifestyle behaviors such as physical inactivity, tobacco use, and harmful alcohol consumption. Importantly, these individual-level risk factors are compounded by health system weaknesses and adverse socioeconomic conditions, including limited access to care, inadequate screening and diagnostic capacity, medication stock-outs, fragmented chronic disease services, and socioeconomic disadvantages.

Addressing the cardiovascular burden among patients with T2DM in sub-Saharan Africa therefore requires integrated, context-specific strategies that extend beyond individual risk-factor management. Strengthening primary healthcare systems, improving access to essential medicines and diagnostic services, and integrating diabetes and cardiovascular care within existing NCD programmes are critical priorities. In parallel, broader policy interventions to reduce socioeconomic inequities and support healthy lifestyles are essential to achieve sustainable reductions in cardiovascular morbidity and mortality.

Overall, the findings of this review provide a robust evidence base to inform clinical practice, health policy, and future research focused on CVD prevention and control among patients with T2DM in sub-Saharan Africa. These findings underscore the need for strengthened prevention efforts, sustained investment in high-quality population-based research, and integrated health system strengthening to mitigate the growing cardiovascular impact of diabetes in the region.

Author Contributions

The author conceptualized the study, designed the review framework, conducted the literature search and synthesis, and drafted the manuscript. The author reviewed and approved the final version of the manuscript and takes full responsibility for its content.

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Conflict of Interest

The author declares no conflicts of interest.

Ethical Approval

This study was based exclusively on published literature and publicly available data. It did not involve human participants, personal

identifiers, or primary data collection. Ethical approval was therefore not required.

Data Availability

All data supporting the findings of this study are derived from published sources cited in the manuscript. No new datasets were generated or analysed during the current study.

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Institutional Shocks Transmission and Impact on Entrepreneurship Development in Developing Economies

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Abstract

Entrepreneurship constitutes a major pathway through which developing economies pursue economic expansion and social transformation. This study investigates how institutional disturbances are transmitted across economies and how such disturbances influence self-employment and entrepreneurship development. Panel data drawn from twenty developing countries covering the period 1996–2022 are analysed using a Panel Vector Autoregression (PVAR) framework. The Generalized Forecast Error Variance Decomposition (GFEVD) and Impulse Response Functions (IRFs) are employed to trace the dynamic effects of institutional shocks on entrepreneurial outcomes. Self-employment is adopted as a proxy for entrepreneurship, alongside entrepreneurial finance, regulatory quality, government expenditure, education, and control of corruption. The findings indicate that institutional shocks generate heterogeneous short-run and long-run effects on entrepreneurship, with access to finance emerging as the most influential external driver over time. The results further suggest that entrepreneurial outcomes in emerging economies are affected not only by market forces but also by the stability and effectiveness of institutional arrangements. These findings underline the importance of institutional reforms that strengthen governance structures and reduce uncertainty in order to promote sustainable entrepreneurship.

Keywords: *Developing Economies, Entrepreneurship, Impulse Response, Institutional shocks, Transmission PVAR.*

Introduction

Entrepreneurship has long been regarded as a central mechanism through which economies stimulate innovation, generate employment, and enhance productivity, therefore earning entrepreneur the label "the engine of economic growth" [17]. In developing economies, entrepreneurial activity plays an especially critical role because formal employment opportunities remain limited and small businesses often serve as primary sources of income and economic participation. The prevailing view positions entrepreneurship as a catalyst for sustained development [10]. But the irony here is that the operating environment for

entrepreneurial activities is dynamic and susceptible to shocks. This same institutional conditions shape the incentives, risks, and opportunities that entrepreneurs face.

Sudden changes in political arrangements, regulatory frameworks, or governance structures can alter business expectations and investment decisions. Such institutional disturbances we referred to in this study as institutional shocks. It can disrupt existing economic relationships and modify the environment in which entrepreneurial activity takes place. In some cases, these shocks constrain business formation by increasing uncertainty and transaction costs; in other

cases, they may open new opportunities by reshaping market structures.

This paper advances the main argument that it is not entrepreneurship alone, but the transmission of institutional shocks drives major changes in formal and informal structures that critically shape entrepreneurial outcomes in developing economies [1], most especially self-employed entrepreneurs.

The quality of the institutional environment can either facilitate or hinder entrepreneurship [14]. In many developing economies, institutional systems remain fragile and unevenly enforced. Entrepreneurs therefore operate within environments characterized by regulatory instability, weak governance, and limited access to formal financial institutions. These features amplify the potential impact of institutional shocks on business decisions, particularly for self-employed individuals and micro-enterprises that lack buffers against uncertainty. Despite the relevance of these dynamics, empirical evidence on how institutional shocks are transmitted and how they affect entrepreneurship over time remains limited, especially in cross-country contexts.

This study addresses this gap by examining the transmission of institutional shocks and their implications for entrepreneurship development in developing economies. By employing a dynamic panel modelling approach, the study traces how changes in institutional factors propagate through economic systems and influence entrepreneurial outcomes. Understanding these relationships is essential for policymakers aiming to build institutional frameworks that promote productive entrepreneurship while minimizing the adverse effects of institutional instability.

Literature Review

Institutional Shocks

Institutional shocks refer to abrupt changes in political, regulatory, or governance structures that modify the conditions under

which economic agents operate. Such shocks may arise from political crises, policy reforms, social unrest, or global economic disturbances. These changes affect the predictability of rules and the enforcement of contracts, thereby shaping entrepreneurial incentives and constraints. The transmission of institutional shocks occurs through multiple channels, including regulatory adjustments, shifts in public trust, and changes in resource allocation. The transmission of the shock can influence how businesses respond and adapt to these new realities [30, 31]. Understanding this phenomenon in the context of developing economies helps clarify how institutions influence entrepreneurial activities.

Nature of Institutional Shocks

Institutional shocks can broadly be distinguished between exogenous and endogenous (external and internally) generated disturbances. Exogenous shocks include natural disasters and global crises that disrupt domestic institutions, while Endogenous shocks originate from policy reforms or governance transformations within a country. Both forms can influence entrepreneurial behaviour by altering regulatory compliance costs, market entry conditions, and access to finance. In developing economies, where institutional systems are often less resilient, such shocks may exert particularly strong effects on business activity [15, 36].

Transmission Mechanisms

Institutional shocks influence entrepreneurship through several pathways. First, regulatory changes modify the formal rules governing business operations, which can raise or lower the cost of market entry and compliance [13]. Second, institutional shifts affect access to productive resources, including finance and skilled labour, thereby shaping entrepreneurial capacity [3]. Third, changes in institutional credibility alter risk perceptions and expectations, influencing entrepreneurs'

willingness to invest and innovate [19]. Cultural and social norms also mediate how institutional changes are interpreted and responded to by economic actors [6]. How these shocks affect entrepreneurial activity, resilience, and development are documented in empirical studies [4].

Moderating Factors

The impact of institutional shocks is conditioned by structural and social factors such as income levels, legal quality, and social capital. Countries with stronger judicial systems and clearer regulatory enforcement are more likely to absorb institutional disturbances without severe disruptions to entrepreneurial activity [16]. Informal networks and trust-based relationships may further cushion entrepreneurs against institutional volatility by providing alternative mechanisms for coordination and resource mobilization [34].

Empirical Evidence

Empirical research indicates that political instability and regulatory uncertainty discourage private investment and entrepreneurial entry [8]. Sudden shifts in macroeconomic policy and exchange rates have been shown to increase operating costs and reduce consumer demand, thereby weakening business sustainability [2]. Infrastructure disruptions, particularly in electricity and transportation systems, also impose significant burdens on enterprises by increasing production costs and reducing productivity [18]. Trade policy fluctuations further affect firms engaged in cross-border commerce [12]. Climate-related shocks present additional challenges in agriculture-dependent economies, where livelihoods and entrepreneurial ventures are closely tied to environmental conditions [27, 28].

Collectively, these studies highlight the need for institutional environments that provide stability, transparency, and credible

enforcement mechanisms in order to support entrepreneurial resilience in the face of shocks.

Theoretical Perspectives on Transmission Mechanism

The institutional framework fundamentally influences the dynamic of entrepreneurship in developing economies. In Africa "Institutional voids" show that there are not enough formal institutions to support the market. This makes things unpredictable and pushes businesses to rely on informal networks or come up with workarounds [33]. Entrepreneurs typically act as "micro institutional agents," influencing their surroundings on their own instead than waiting for reforms from the top down [9, 39]. The severity of institutional shocks can compel entrepreneurs to amalgamate business and social objectives, thereby promoting resilience and innovation [9].

The theoretical perspectives on institutional shocks, their transmission mechanisms, and their implications can be better understood via the prism of Diffusion of Innovation Theory (DIT), Resource-Based Theory (RBT), and Social Capital Theory (SCT).

1. The Diffusion of Innovation Theory (DIT):

The diffusion of innovations theory posits that novel ideas, technologies, and practices propagate through social networks, impacting entrepreneurial activities [37]. The aforementioned theory is especially pertinent in the setting of developing economies, when access to resources and information may be constrained. The adoption of innovations can serve as a coping strategy for entrepreneurs confronting institutional disruptions, enabling them to manage uncertainties and capitalize on emerging new opportunities.

2. Resource-Based Theory (RBT):

Furthermore, the resource-based view underscore the significant of access to resources in alleviating the adverse impact of institutional shocks [11]. Resources can

be tangible or intangible, including financial capital, human capital, social networks, and intellectual property. In the context of entrepreneurship, RBT emphasizes the importance of resource acquisition and management in fostering innovation and growth [5].

3. Social Capital Theory (RBT):

Finally, the social capital theory has become increasingly significant in understanding entrepreneurship development, particularly during periods of institutional transformation. This approach underscores the significance of social networks, relationships, and trust in facilitating economic activities and business growth [34, 35]. In times of institutional flux, social capital can play a crucial role in helping entrepreneurs navigate uncertain environments, access vital resources, and build legitimacy [38].

The Significant Impact of Entrepreneurship Development on Developing Economies

A systematic assessment indicates that entrepreneurship influence economic, social, and environmental welfare, especially in low-income economies relative to high-income ones [29]. The role and impact of entrepreneurship are further revealed in the following. Create jobs, which helps to lower unemployment rates [22, 24, 25, 40]; Poverty Reduction and Social Impact [20, 23, 26]. Entrepreneurship enhances gross national product and per capita income, especially in developing nations grappling with rising poverty and unemployment.

Innovation and Technological Advancement: Entrepreneurship drives innovation, leading to the development of new products and services that can improve the quality of life [7, 32, 41].

In summary, entrepreneurship acts as a catalyst for economic growth in underdeveloped nations by fostering innovation, generating employment, and

enhancing competitiveness. To optimize its advantages, it is imperative to strengthen institutional frameworks and provide inclusive support to all entrepreneurs to fully actualize their potential in fostering to economic growth.

Methodology

Research Design

This research employs a quantitative design utilizing secondary panel data from a selection of developing economies. The analytical strategy combines dynamic econometric techniques in order to capture both short-run adjustments and long-run interactions between institutional variables and entrepreneurship development. A sample of twenty developing nations is chosen from Africa, Europe, Asia, North America (including Central America and the Caribbean), South America, and Oceania to guarantee geographical diversity and heterogeneity in institutional frameworks.

Data Collection

The dataset consists of annual observations covering the period 1996–2022. Data are sourced from esteemed internationally entities, such as the World Development Indicators (WDI) and the Global Entrepreneurship Monitor (GEM) database, supplemented by statistics from national agencies as required. The time span is chosen to incorporate major global and regional disturbances, including financial crises, technological transformation era, and the COVID-19 pandemic, thereby allowing the analysis to capture institutional shock dynamics across different historical episodes.

Data Availability and Limitations

Most variables are sourced from publicly accessible international databases like the World Bank, the International Monetary Fund, the National Bureau of Statistics and Global Entrepreneurship Monitor. These data are accessible without restriction. However, limitations arise from incomplete national

coverage and the scarcity of reliable measures of informal entrepreneurship. These constraints may affect the representativeness of entrepreneurial activity in economies where informal business dominates.

Ethical Considerations

The research depends solely on secondary data sourced from publicly accessible, internationally recognized databases. Consequently, in alignment with established research ethics protocols, this category of study is exempt from comprehensive ethical evaluation. The study complies with established research ethics by guaranteeing transparency in data sources, precise citation of original materials, and accurate depiction of empirical findings. No manipulation or selective reporting of results is conducted, and the limits of the data are fully recognized.

Author's Contribution

The contribution from this study can be examined from two perspectives: (i) theoretical and (ii) policy-oriented suggestions. The study's theoretical contribution enhances and extend institutional theory through dynamic shock analysis, while the policy- oriented contribution offers evidence for fostering institutional resilience, gives direction and a framework for mitigating entrepreneurial risk and uncertainty.

Funding

The research work was self-funded. Due to the politically sensitive nature of institutional governance metrics, independent funding guaranteed neutrality and reduced perceived political interference. The author executed this investigation autonomously, devoid of institutional or commercial financial support. This guaranteed full independence (flexibility and autonomy) in research design, gathering data, analysis, interpretation, and publication writing. This has facilitated the elimination of potential bias that may be created by sponsors.

Data Analysis

The research utilized econometric techniques to examine the propagation of institutional shocks. This allowed us to identify various forms of asymmetries in the transmission processes, considering the characteristics of the data. Also, to make it possible for the research work to find inter-dependencies between several variables, the Panel Structural Vector Autoregression (P-SVAR) Model was used and then expanded to vector error correction models (VECM) to show the difference between short-run and long-run asymmetries by adding cointegration relationships.

Structural Form:

$$FY_t = C_0 + B_1Y_{t-1} + B_2Y_{t-2} + \dots + B_pY_{t-p} + \pi_iX_t + Z\varepsilon_t \dots \dots \dots 1$$

Where;

F = an invertible matrix describing the contemporaneous relationship among the variables.

Y_t = vector of endogenous variables such that ($Y_t = Y_{1t}, Y_{2t}, \dots \dots Y_{nt}$).

C_0 = vector of constants.

B_i = coefficients of lagged endogenous variables (for every $i = 1 \dots p$).

π_i and X_t = coefficient and vector of the exogenous variable, expressing external shock.

Z = matrix whose non-zero off-diagonal elements permit direct effects of some shocks on greater than one endogenous variable in the system and

ε_t = uncorrelated vector of error terms (white-noise structural disturbances).

Reduced Form:

$$Y_t = B(L)Y_t + C(L)X_t + \mu_t \dots \dots \dots 2$$

Where:

$$Y_t = [EF, IRQ, GE, EDU, CUL, SELF - EMP] \dots \dots \dots 3$$

(endogenous variables)

Where

Y_t are domestic variables

$$X_t = [FDI] \dots \dots \dots 4$$

(exogenous variable representing globalization)

$B(L)$ = matrix polynomial lag operator

μ_t = vector of random disturbances

The study's internal (endogenous) variables for developing economies are represented by equation (3), while the exogenous variable vector that accounts for external shock is represented by equation (4). Equation (3) thus identifies the structural shocks.

This model captures contemporaneous relationships among variables and external shocks' effects on entrepreneurial development. The Impulse response functions of Panel Vector Autoregression (PVAR) and General Forecast Error Variance Decomposition (GFEVD) will be employed to ascertain the sign, amplitude, and persistence of shocks from each institution on the advancement of entrepreneurship [21].

Results and Discussion of Findings

This section delineates the findings of analyses undertaken to examine the degree of shock transmission from institutional changes to entrepreneurial development in the selected developing nations. Impulse response function estimations are illustrated graphically, whereas generalized forecast error variance decomposition results are displayed in tabular form.

Impulse Response Function of Panel Vector Autoregression

The analysis of the impulse response function pertains to monitoring the responses of institutional changes on entrepreneurship development in the chosen developing countries for the relevant variables. The Vector Autoregressive model was estimated using the following endogenous variables: the response of self-employed workers to Entrepreneurial Finance, Institutional Regulatory Quality, Government Expenditure, Education, and Control of Corruption (culture).

This study seeks to evaluate the impact of institutional shocks on Entrepreneurship

Development (ED), as measured by the quantity of self-employed individuals, in conjunction with other endogenous variables.

Figure 1. depicts the response of self-employment to institutional variables' shocks. Figure 1A illustrates that access to entrepreneurial funding does not have a major effect on self-employment at initially. It's likely because of structural and institutional hurdles that make it hard to swiftly deploy money for company. Over time, increased access to money makes it easier to start and maintain a business. This leads to a slow but steady rise in the number of people who work for themselves. This long answer indicates that it takes time for financial assistance programs to help entrepreneurs in a serious way. This could be due of red tape, the long time it takes for a business to get off the ground, or how well entrepreneurs plan how to spend their money. The peak effect of 0.022% above the steady state illustrates that having easier access to money is a big aid for self-employment, which makes it easier for more people to establish their own enterprises. The gradual decline following the peak suggests that the consequences of financial shocks don't last long. This indicates that the surge in self-employment may not endure if people don't have access to money or more insurance. This could be because the market is too saturated, it's hard for enterprises to stay open, or people aren't spending their money sensibly.

However, the finding in Figure 1B shows that better regulation quality first causes a little decline in self-employment, bringing it down by 0.008% below the steady state. The negative effect means that changes to regulations may make it tougher to establish a firm in the near term, even while they are good for the economy as a whole. This might be because it is harder to register a business, there is more paperwork to fill out, or the regulations are enforced, which makes it more expensive to run a firm. The effect, nevertheless, gets weaker over the third period. This shows that the initial negative

effect of regulatory changes is just temporary, and self-employment numbers will stabilize over time.

Also, the data in Figure 1C shows that when the government spends more money, it first increases self-employment by 0.005% over the steady state. This good effect illustrates that when the government spends money on things like infrastructure, social services, and programs that help entrepreneurs, it makes it simpler for people to start their own firms. The effect gets stronger over time, reaching a peak of 0.009% in the eighth period and then slowly getting weaker. This implies that while government expenditure may temporarily encourage self-employment, its impact is not lasting, perhaps due to inefficiencies in resource allocation or diminishing returns on public investment.

The results shown in Figure 1D indicates that acquiring additional education currently benefit individuals aspiring to start their own enterprises by 0.007% above the steady state. This means that improved education, especially in basic and vocational training, gives people the skills, information, and talents they need to start and run enterprises better. But the influence slowly fades away and is no longer important by the fourth period. This shows that education may help people start their own businesses in the near term, but things like access to funding, market conditions, and laws that support entrepreneurs are more important for keeping businesses going over time.

Once more, the graphical data in Figure 1E shows that cultural factors don't have an immediate effect on self-employment. This means that cultural norms that form entrepreneurial behaviors and attitudes need time to affect how a business runs. The lack of an immediate effect suggests that changes in cultural attitudes toward entrepreneurship, such

as views on risk-taking, inventiveness, and business ownership, do not quickly result in increased self-employment rates. But when these cultural shifts become more permanent, they slowly make things better for entrepreneurs, which raises the level of self-employment. The tenth decade demonstrates that 0.001% has the biggest influence. This shows that cultural changes take a long time to materialize, but when they occur, they can have a huge effect on self-employment. The effect starts to wear off after this peak. This implies that cultural factors alone may be insufficient to sustain the progression of self-employment over time in the absence of additional economic and institutional support.

Panel VAR Generalized Forecast Error Variance Decomposition

Furthermore, Table 1 displays the outcome of the generalized forecast error variance decomposition. Further demonstrates a more profound understanding of the effects of these shocks on self-employment. It can be inferred that self-employment itself accounts for 99% of its variation in the short term (Period 1), indicating that its fluctuations are primarily self-driven, with minimal influence from external factors. Nevertheless, the contribution of self-employment gradually decreases to 88.2% by Period 25, indicating that other variables increasingly account for changes in self-employment over the long term. Entrepreneurial finance is the most influential factor among the external shocks, with its contribution increasing from 0.02% in Period 1 to 8.61% in Period 25. This implies that access to finance is a critical factor in the long-term determination of self-employment, underscoring the significance of financial institutions in fostering entrepreneurship.

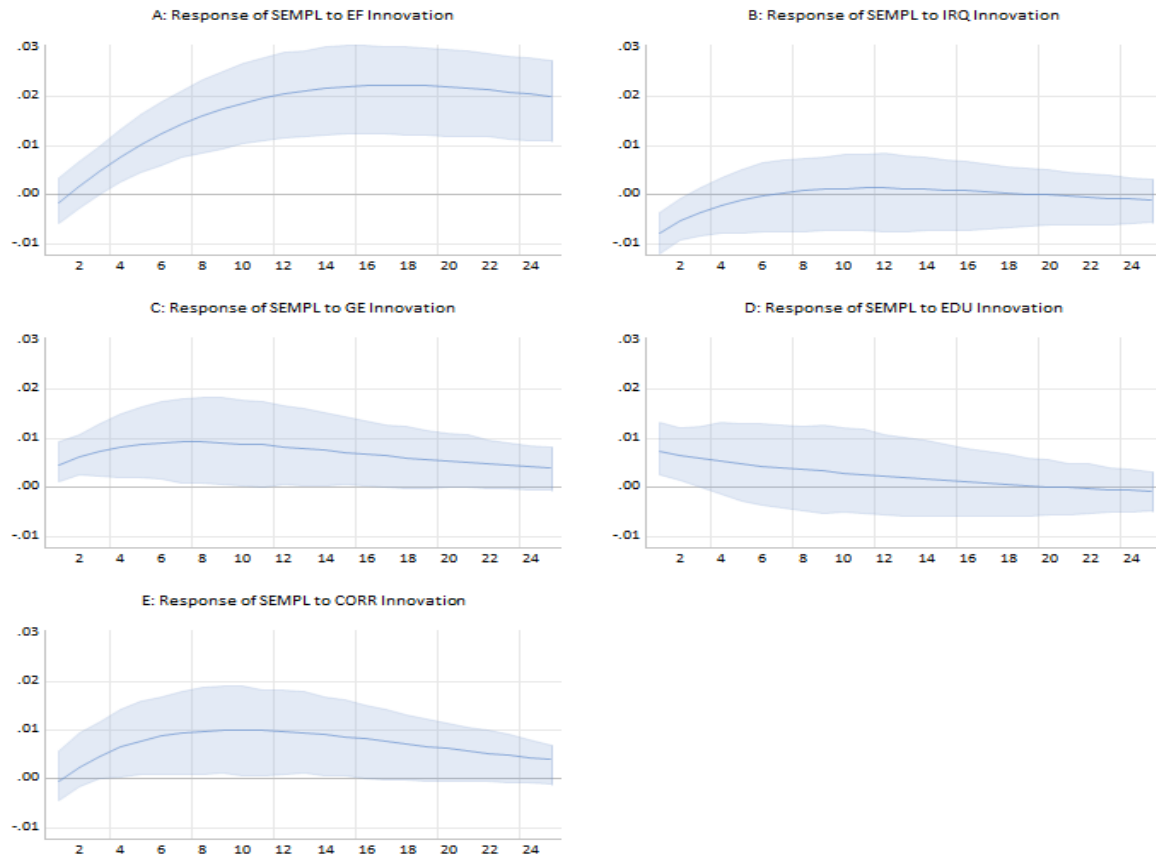


Figure 1. Response of Self-Employment to Institutional Variables' Shocks.

Graphical Representation of Impulse Response function: Graph A: Response of self-employment to Entrepreneurial Finance innovation, Graph B: Response of self-employment to Institutional Requirement quality Innovation, Graph C: Response of self-employment to Government Expenditure innovation, Graph D: Response of self-employment to Education innovation, Graph E: Response of self-employment to Corruption (Source: Authors computation, (2026))

Culture also plays a growing role, albeit at a slower pace, with its impact increasing from 0% in Period 1 to 1.48% in Period 25. This gradual increase suggests that cultural shifts toward entrepreneurship require time to manifest, but they ultimately contribute to the dynamics of self-employment.

In the initial period, government expenditure exhibited a similar pattern, with its influence increasing from 0.16% to 1.33% by Period 25, indicating that public spending through investment in infrastructure, social programs, and business support plays a supporting role in shaping self-employment over time. Conversely, the impact of basic education is relatively consistent but diminishing, commencing at 0.40% in Period 1 and

subsequently decreasing to 0.28% in Period 25. This suggests that education initially enhances self-employment; however, its long-term impact is diminished. This may be attributed to the preference of educated individuals for wage employment or structural constraints that restrict entrepreneurial opportunities.

Finally, institutional regulatory quality has the least significant and decreasing impact, decreasing from 0.45% in Period 1 to 0.13% in Period 25. This suggests that regulatory enhancements have a limited long-term impact on self-employment, potentially due to bureaucratic inefficiencies, slow policy implementation, or the persistence of informal economic activities despite regulatory changes.

Table 1. Generalised Forecast Error Variance Decomposition (%) of Self-Employment

Shock variable	Period								
	1	2	3	8	9	10	14	23	25
Culture	0.00	0.02	0.08	0.58	0.68	0.78	1.12	1.46	1.48
Basic Education	0.40	0.39	0.37	0.33	0.33	0.33	0.31	0.29	0.28
Entrepreneurial finance	0.02	0.02	0.09	1.19	1.54	1.93	3.71	7.85	8.61
Self-employment	99.0	99.0	98.8	97.0	96.5	95.9	93.6	89.0	88.2
Government expenditure	0.16	0.24	0.33	0.75	0.82	0.89	1.09	1.31	1.33
Institutional Regulatory Quality	0.45	0.35	0.29	0.16	0.15	0.15	0.14	0.13	0.13

Source: Authors computation, (2025)

Conclusion

Institutional shocks in developing economies can both hinder and catalyze entrepreneurship, depending on the resilience of formal and informal institutions and the adaptability of entrepreneurs. Strengthening institutional quality, reducing the culture of corruption, and leveraging informal networks are key to fostering productive entrepreneurship and economic growth in these contexts. This paper enhances the comprehension of the correlation between institutional shocks and entrepreneurial development in developing economies. The study employs PVAR and GFEVD methodologies to demonstrate the substantial influence of institutional factors on entrepreneurial activities. The findings underscore the imperatives for policymakers to prioritize institutional enhancement to cultivate an environment conducive to

entrepreneurship, ultimately driving economic growth and development.

Conflict of Interest

The publication of this manuscript was conducted independently, with all efforts made to maintain the integrity and objectivity of the findings presented. The outcome of the research were not influenced by political, personal, or financial incentives. Consequently, the author discloses no known conflicts of interest pertaining to the article.

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Determinants of Undetectable Viral Load among Recipients of HIV Care in Cross River State, Nigeria: A Mixed-Methods Study

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Abstract

Achieving and sustaining viral load suppression among people living with HIV is essential for improving treatment outcomes and reducing transmission. However, determinants of undetectable viral load remain insufficiently documented in Cross River State, Nigeria, particularly using mixed methods approaches. This study examined socio-demographic and patient-related determinants of undetectable viral load among recipients of HIV care in selected health facilities. A mixed-methods design combined a facility-based cross-sectional survey with qualitative interviews. Quantitative data were collected from 203 HIV-positive clients aged ≥ 15 years who had been on antiretroviral therapy (ART) for at least six months, while qualitative data were obtained from in-depth interviews with 12 healthcare providers. Descriptive statistics, Chi-square tests, and multivariate logistic regression were used for quantitative analysis, and qualitative data were analyzed thematically. Findings showed that 51.7% of participants achieved undetectable viral load (< 50 copies/mL), 27.6% had suppressed viral load (51–999 copies/mL), and 79.3% attained overall viral suppression. ART adherence emerged as the strongest predictor of viral suppression, alongside regular clinic attendance, counselling participation, and use of medication reminders. Conversely, missed doses, treatment interruptions, recreational drug use, and difficulty accessing healthcare significantly reduced the likelihood of viral suppression. Qualitative findings highlighted stigma, economic hardship, transportation barriers, and occasional drug stock-outs as key contextual factors influencing adherence. The study underscores the need for patient-centered interventions that strengthen adherence counselling, improve access to ART, and address structural and socio-economic barriers to optimize viral suppression outcomes in resource-limited settings.

Keywords: Antiretroviral Therapy, Art Adherence, Determinants of Viral Suppression, HIV, Mixed-Methods Research, Undetectable Viral Load, Viral Load Suppression.

Introduction

Background and Problem Statement

Human Immunodeficiency Virus (HIV) remains one of the most significant global public health challenges despite substantial progress in prevention, diagnosis, and treatment over the past four decades. Since the beginning of the epidemic, an estimated 91.4 million

individuals have been infected globally, while approximately 44.1 million people have died from HIV-related illnesses. By the end of 2024, about 40.8 million people were living with HIV worldwide [26]. Although notable progress has been achieved through expanded treatment and prevention strategies, the burden of HIV remains disproportionately concentrated in sub-Saharan Africa, where nearly two-thirds of the

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global population of people living with HIV reside [25, 23].

A central global strategy for addressing the HIV epidemic is the UNAIDS 95-95-95 targets, which aim to ensure that by 2030, 95% of people living with HIV know their status, 95% of those diagnosed receive sustained antiretroviral therapy (ART), and 95% of those on treatment achieve viral suppression [22]. Viral suppression is critical because it improves individual health outcomes and prevents onward transmission. Despite these efforts, achieving sustained viral suppression remains a major challenge, particularly in resource-limited settings.

Nigeria bears a substantial share of the global HIV burden, with an estimated 1.9 million people living with HIV and a national prevalence of approximately 1.4% among adults aged 15–49 years [11]. Within Nigeria, regional disparities exist, with Cross River State reporting a prevalence of about 1.8%, higher than the national average [12, 21]. Although ART coverage has expanded significantly, not all individuals receiving treatment achieve or sustain viral suppression.

Existing Solutions and Their Limitations

Antiretroviral therapy (ART) remains the most effective clinical intervention for achieving viral suppression. By suppressing viral replication, ART improves immune function and reduces HIV-related morbidity and mortality. Global expansion of ART has led to a significant decline in AIDS-related deaths, from approximately 2.1 million in 2004 to about 630,000 in 2024 [24]. However, ART effectiveness is highly dependent on consistent adherence and sustained engagement in care. Existing interventions such as: adherence counselling, routine viral load monitoring, and differentiated service delivery, have improved treatment outcomes. Nevertheless, these approaches often fail to fully address the socio-demographic and patient-related barriers that influence adherence behaviour. Factors such as

stigma, economic hardship, limited access to healthcare services, and inadequate knowledge about ART continue to hinder optimal treatment outcomes [16, 4].

Research Gap and Novelty

Despite extensive research on HIV treatment outcomes, significant gaps remain in understanding the determinants of viral suppression in specific contexts such as Cross River State. Much of the existing literature in Nigeria has focused on clinical or health-system factors, with limited attention to socio-demographic and patient-related determinants of adherence and viral suppression. Furthermore, few studies have employed mixed methods approaches to provide both quantitative and contextual insights into these factors.

This study addresses this gap by focusing specifically on how socio-demographic characteristics (e.g., age, sex, education, employment) and patient-related factors (e.g., adherence behaviour, knowledge, stigma, and clinic attendance) influence the achievement of undetectable viral load. The novelty of this work lies in its integration of quantitative and qualitative evidence to provide a comprehensive, context-specific understanding of behavioural and social determinants of viral suppression in Cross River State.

Achievements of the Study

This study provides empirical evidence on the proportion of ART clients achieving viral suppression and identifies key determinants associated with undetectable viral load. It highlights adherence as the strongest predictor of viral suppression and demonstrates how socio-demographic factors interact with patient behaviours to influence treatment outcomes. Additionally, qualitative insights offer deeper understanding of contextual barriers such as: stigma, economic constraints, and access to care.

Objective of the Study

The primary objective of this study is to examine the determinants of undetectable viral load among recipients of HIV care in Cross River State, Nigeria. Specifically, the study aims to:

1. Examine the relationship between socio-demographic factors of ART clients and undetectable viral load.
2. Determine the relationship between patient-related factors of ART clients and undetectable viral load.

Schematic Representation (Conceptual Framework)

The study is guided by a conceptual framework in which socio-demographic factors (age, sex, education, employment, residence) influence patient-related behaviours (ART adherence, clinic attendance, counselling participation, substance use), which in turn determine the likelihood of achieving undetectable viral load. This framework reflects the interaction between structural and behavioural determinants of HIV treatment outcomes.

In summary, this study responds to the need for context-specific, evidence-based understanding of viral suppression by focusing on key socio-demographic and patient-related determinants, thereby contributing to efforts aimed at achieving the UNAIDS 95-95-95 targets and improving HIV treatment outcomes in resource-limited settings.

Materials and Methods

Description of the Study Site

The study was conducted in selected health facilities providing HIV treatment and care services in Cross River State, located in the South-South geopolitical zone of Nigeria. Specifically, the study was carried out at the University of Calabar Teaching Hospital (UCTH) and the General Hospital, Calabar, both of which serve as major centers for HIV

treatment and care within the state. Cross River State shares boundaries with Benue, Ebonyi, and Akwa Ibom States and an international border with Cameroon. The state has an estimated population of approximately 3.5 million people and comprises both urban and rural communities.

HIV treatment services in the selected facilities include the provision of antiretroviral therapy (ART), adherence counselling, and routine viral load monitoring. These facilities serve a diverse population of people living with HIV and provide a suitable setting for examining determinants of undetectable viral load.

Description of the Experiments Done (Study Design and Data Collection Procedures)

This study adopted a mixed-methods research design integrating quantitative and qualitative approaches to examine determinants of undetectable viral load among ART clients. The quantitative component consisted of a facility-based cross-sectional survey of HIV-positive clients receiving antiretroviral therapy (ART). Eligible participants were individuals aged 15 years and above who had been on ART for at least six months and had documented viral load results. The sample size was determined using a one-proportion sample size estimation approach for viral load suppression, assuming a 50.0% expected proportion of viral suppression, a 95% confidence level, and a margin of error of 10.0%. This yielded an initial unadjusted sample size of 97 HIV-positive respondents. The sample size was subsequently adjusted to account for a design effect of 2.0 and a non-response rate of 5.0%, resulting in a final adjusted sample size of 203 participants. This adjusted sample size also corresponded to the total accessible population of eligible ART clients within the selected facilities during the study period. The final sample was proportionately distributed across the selected health facilities based on patient load:

University of Calabar Teaching Hospital (UCTH): 112 participants (55.2%), and General Hospital, Calabar: 91 participants (44.8%).

Structured interviewer-administered questionnaires were accordingly allocated and administered within each facility based on this proportional distribution. Eligible ART clients were identified from clinic registers, and stratified random sampling was used to select participants within each facility. The qualitative component involved in-depth interviews with a purposively selected subset of ART clients to explore experiences related to treatment adherence and engagement in HIV care. A total of 12 participants were recruited, with distribution across facilities as follows: University of Calabar Teaching Hospital (UCTH): 7 participants and General Hospital, Calabar: 5 participants.

Participants were selected to reflect diverse socio-demographic and adherence experiences. Interviews were conducted using a semi-structured guide and continued until thematic saturation was achieved.

Quantitative data were collected using a structured interviewer-administered questionnaire alongside review of patient medical records. The questionnaire captured information on socio-demographic characteristics (age, sex, marital status, education level, employment status, income level, and place of residence) and patient-related factors (ART adherence, substance use, clinic attendance, knowledge of ART, counselling participation, and perceived stigma). Viral load outcomes were obtained from clinical records.

Qualitative data were collected through face-to-face interviews conducted in private settings within the health facilities. Each interview lasted approximately 30–45 minutes and was audio-recorded with participants' consent.

Description of Laboratory Methods

Viral load measurements were obtained from routine clinical records maintained at the

selected health facilities: University of Calabar Teaching Hospital and General Hospital, Calabar. Viral load testing followed national guidelines, with measurements conducted at least six months after ART initiation and periodically thereafter. For this study, undetectable viral load was defined as a plasma viral load of less than 50 HIV RNA copies per millilitre, while viral suppression was defined as less than 1,000 copies per millilitre in accordance with national HIV treatment guidelines. These laboratory results were used as the primary outcome variable for assessing treatment success among ART clients.

Description of Statistical Methods Used

Quantitative data were analyzed using IBM SPSS Statistics version 28. Descriptive statistics were used to summarize study variables, with frequencies and percentages reported for categorical variables and means with standard deviations for continuous variables.

Bivariate analysis was conducted using Chi-square (χ^2) tests to examine associations between socio-demographic and patient-related factors and undetectable viral load. Variables that demonstrated statistical significance at $p < 0.05$ were included in a multivariate logistic regression model to identify independent predictors of undetectable viral load. Adjusted odds ratios (AORs) with 95% confidence intervals were reported.

Qualitative data were transcribed verbatim and analyzed using thematic analysis. The analytical process involved familiarization with transcripts, coding of relevant text segments, categorization of codes, and development of themes reflecting patient-related determinants of viral suppression.

Findings from the qualitative component were used to complement and provide contextual interpretation of the quantitative results, thereby enhancing the overall understanding of determinants of undetectable viral load.

Ethical Considerations

Ethical approval for this study was obtained from the Health Research Ethics Committee, Government of Cross River State, Ministry of Health, PMB 1049, Calabar (Approval No.:CRS/MH/HREC/023/Vol.V1/262). The ethical approval was granted for a duration of one year, within which the study was conducted in accordance with approved protocols.

Written informed consent was obtained from all participants prior to data collection. Participation was entirely voluntary, and respondents were informed of their right to withdraw from the study at any stage without any consequences to their access to healthcare services.

Confidentiality and anonymity were strictly maintained throughout the study. No personal identifiers were collected, and all data were coded to ensure participant privacy. Both

electronic and hard-copy data were securely stored in password-protected databases and locked cabinets accessible only to the research team. In line with standard research ethics guidelines, data will be retained for a minimum period of five (5) years after publication, after which they will be securely destroyed. All procedures were conducted in accordance with ethical principles for research involving human participants, including respect for persons, beneficence, and justice.

Results

Participant Characteristics

A total of 203 HIV-positive individuals receiving antiretroviral therapy (ART) were included in the quantitative component of the study. For data relating to socio-demographic and treatment-related characteristics of the participants see Table 1,

Table 1. Socio-Demographic Factors of ART Clients and Undetectable Viral Load (n = 203)

Variables	Frequency	Percentage
Age Distribution		
15–24	51	25.10%
25–34	61	21.70%
35–44	44	21.70%
45–54	31	15.30%
55 and above	16	7.90%
Total	203	100
Sex Distribution		
Male	91	44.80%
Female	112	55.20%
Total	203	100
Pregnancy Status		
Pregnant	17	15.20%
Not pregnant	95	84.80%
Total	112	100
Marital Status		
Single	71	35.00%
Married	102	50.20%
Divorced	11	5.40%
Widowed	10	4.90%
Separated	9	4.40%
Total	203	100

Highest Education Level		
No formal	9	4.40%
Primary	41	20.20%
Secondary	91	44.80%
Tertiary	62	30.50%
Total	203	100
Employment Status		
Full-time	51	25.10%
Part-time	20	9.90%
Self-employed	63	31.00%
Unemployed	41	20.20%
Student	20	9.90%
Retired	8	3.90%
Total	203	100
Monthly Income Level		
No Income	22	10.80%
< ₦10,000	52	25.60%
₦10,000–₦30,000	70	34.50%
₦30,000–₦50,000	41	20.20%
> ₦50,000/Above	18	8.90%
Total	203	100
Place of Residence		
Urban	121	59.60%
Rural	82	40.40%
Total	203	100
Duration on ART		
< 6 months	32	15.80%
6–12 months	41	20.20%
1–2 years	61	30.00%
2–5 years	50	24.60%
> 5 years	19	9.40%
Total	203	100

The study population was relatively young, with 55.1% of respondents aged 15–34 years. Females constituted a slightly higher proportion of participants (55.2%). Among female respondents, 15.2% were pregnant at the time of data collection. Half of the respondents were married (50.2%), and the majority had secondary (44.8%) or tertiary education (30.5%), indicating relatively high educational attainment. Regarding employment, self-employment (31.0%) was the most common

occupation. Most participants resided in urban areas (59.6%), and the largest proportion of respondents (30.0%) had been on ART for 1-2 years, reflecting relatively recent treatment initiation among many clients.

Proportion Achieving Viral Suppression

Viral load outcomes were obtained from clinical records and laboratory monitoring reports; (see Table 2).

Table 2. Distribution of Viral Load Outcomes Among ART Clients (n = 203)

Viral Load Category	Frequency	Percentage (%)
Undetectable (<50 copies/mL)	105	51.7
Suppressed (51–999 copies/mL)	56	27.6
Unsuppressed (≥ 1000 copies/mL)	32	15.8
Unknown	10	4.9
Total	203	100

Overall, 161 participants (79.3%) achieved viral suppression (<1000 copies/mL), while 105 participants (51.7%) achieved undetectable viral load (<50 copies/mL). However, 15.8% of clients remained virologically unsuppressed, indicating suboptimal treatment outcomes among a subset of ART clients. These findings suggest that while viral suppression rates among ART clients in the study setting are substantial, there remains a significant

proportion of patients who require intensified adherence support and clinical follow-up to achieve optimal virologic outcomes.

Bivariate Analysis: Patient-Related Factor

Chi-square (χ^2) tests examined associations between patient-related factors and undetectable viral load; see Table 3.

Table 3. Bivariate Associations (Patient-Related Factors)

Factor	χ^2	df	p-value	Significance
Recreational drug use	6.12	1	0.013	Yes
Ever counselled on substance use	7.41	1	0.006	Yes
Appointment attendance consistency	12.52	4	0.014	Yes
Missed appointment in last 6 months	10.79	1	0.001	Yes
Ease of accessing health facility	9.02	3	0.029	Yes
Belief that ART must be taken daily	8.54	2	0.014	Yes
Confidence (self-efficacy)	11.72	2	0.003	Yes
Adherence to ART schedule	22.61	3	0.000	Yes
Missed doses in past month	15.04	3	0.002	Yes
Use of reminders	6.57	1	0.010	Yes
Ever stopped ART >2 days	9.84	1	0.002	Yes
Difficulty accessing ART	5.92	1	0.015	Yes
Running out of medication	4.66	1	0.031	Yes
Ever considered stopping ART	7.98	1	0.005	Yes
Attendance at counselling	8.76	2	0.013	Yes
Missed counselling sessions	7.23	1	0.007	Yes

Key findings: the above analysis revealed several patient-related factors that were significantly associated with the achievement of undetectable viral load among clients receiving antiretroviral therapy (ART). Adherence-related behaviours demonstrated the strongest relationships with viral

suppression outcomes. Participants who consistently adhered to their prescribed ART regimen were significantly more likely to achieve undetectable viral load compared with those who reported irregular medication use ($\chi^2 = 22.61$, $p < 0.001$). Similarly, treatment interruption was significantly associated with

viral load status. Clients who reported ever stopping ART for more than two days were less likely to achieve viral suppression ($\chi^2 = 9.84$, $p = 0.002$), while those who reported running out of medication were also more likely to have detectable viral load ($\chi^2 = 4.66$, $p = 0.031$). The use of medication reminder strategies further demonstrated a statistically significant association with viral suppression ($\chi^2 = 6.57$, $p = 0.010$).

Engagement with HIV care services also emerged as an important factor. Regular attendance at clinic appointments was significantly associated with undetectable viral load ($\chi^2 = 12.52$, $p = 0.014$). In contrast, respondents who reported missing clinic appointments within the previous six months were significantly less likely to achieve viral suppression ($\chi^2 = 10.79$, $p = 0.001$). Difficulty accessing health facilities was also associated with poorer viral load outcomes ($\chi^2 = 9.02$, $p = 0.029$), suggesting that structural barriers may influence continuity of care.

Medication-taking behaviour further reinforced these findings. Participants who reported missing ART doses within the previous month were significantly less likely to achieve undetectable viral load compared with those who maintained consistent medication intake ($\chi^2 = 15.04$, $p = 0.002$). Substance use behaviours were also associated with viral

suppression outcomes. Recreational drug use showed a statistically significant relationship with viral load status ($\chi^2 = 6.12$, $p = 0.013$), with drug users being less likely to achieve viral suppression compared with non-users. However, tobacco use and alcohol consumption did not demonstrate statistically significant associations with viral load status.

Participation in counselling services was another factor significantly associated with viral suppression. Clients who reported attending counselling sessions were more likely to achieve undetectable viral load ($\chi^2 = 8.76$, $p = 0.013$), while those who missed counselling sessions were more likely to have detectable viral load ($\chi^2 = 7.23$, $p = 0.007$). In addition, receipt of counselling related to substance use was significantly associated with viral suppression outcomes ($\chi^2 = 7.41$, $p = 0.006$).

Overall, the findings indicate that patient-related factors particularly ART adherence, clinic appointment adherence, missed doses of medication, recreational drug use, and participation in counselling, were significantly associated with the likelihood of achieving undetectable viral load among ART clients.

Multivariate Logistic Regression

Independent predictors of undetectable viral load were identified using multivariate logistic regression; see Table 4.

Table 4. Predictors of Undetectable Viral Load

Variable	AOR	95% CI	p-value
Good ART adherence	4.82	2.10–11.04	<0.001
Regular clinic attendance	2.91	1.34–6.31	0.007
Counselling attendance	2.44	1.18–5.03	0.016
Recreational drug use	0.42	0.19–0.91	0.028
Missed doses	0.36	0.17–0.76	0.008

Interpretation: The multivariate analysis above indicates that good ART adherence was the strongest independent predictor of achieving undetectable viral load among ART clients (AOR = 4.82, $p < 0.001$), suggesting that individuals who consistently adhered to

treatment were nearly five times more likely to attain viral suppression. Regular clinic attendance (AOR = 2.91, $p = 0.007$) and participation in counselling sessions (AOR = 2.44, $p = 0.016$) were also positively associated with viral suppression, highlighting the

importance of continuous engagement in HIV care services. Conversely, recreational drug use (AOR = 0.42, $p = 0.028$) and missed ART doses within the past month (AOR = 0.36, $p = 0.008$) significantly reduced the likelihood of achieving undetectable viral load, indicating that behavioural factors that disrupt adherence can adversely affect treatment outcomes.

Qualitative Findings

To complement the quantitative findings, qualitative interviews were conducted with 12 key informants involved in HIV care and ART service delivery in the selected health facilities. Participants included nurses, physicians, counsellors, pharmacists, and other healthcare personnel directly engaged in HIV treatment programmes. The interviews explored provider perspectives on patient-related factors influencing adherence to antiretroviral therapy and the achievement of undetectable viral load among ART clients. Thematic analysis of the interview transcripts generated several themes that reflect behavioural and contextual factors affecting treatment outcomes.

Stigma and Disclosure Barriers

Healthcare providers consistently identified HIV-related stigma and fear of disclosure as persistent barriers affecting adherence to ART. According to participants, some clients remain reluctant to disclose their HIV status to family members or partners due to fear of discrimination or social rejection. This reluctance often influences treatment behaviours, including hesitation to take medication in the presence of others or reluctance to attend clinic appointments regularly. Providers noted that such concerns may lead to delayed medication intake, missed doses, or irregular clinic attendance. These observations reinforce the quantitative findings showing that adherence-related behaviours play a central role in determining viral suppression outcomes.

Economic Hardship and Treatment Challenges

Economic vulnerability emerged as another factor influencing clients' ability to maintain consistent engagement with HIV treatment services. Participants reported that transportation costs, unemployment, and unstable income frequently affect the ability of clients to attend clinic appointments or obtain medication refills on schedule. In addition, food insecurity was described as a challenge for some clients who prefer not to take ART on an empty stomach due to perceived side effects. Providers noted that these economic pressures may contribute to missed appointments or irregular medication intake, thereby affecting treatment continuity. These accounts complement the quantitative results that identified clinic attendance and consistent medication use as significant predictors of viral suppression.

Counselling and Adherence Support

Counselling services were widely described as a critical intervention for strengthening adherence and improving treatment outcomes among ART clients. Healthcare providers emphasized that adherence counselling is routinely provided to reinforce knowledge of HIV treatment, address misconceptions about ART, and identify barriers that may interfere with consistent medication use. Enhanced adherence counselling was particularly highlighted for clients with detectable viral load, where counselling sessions are used to assess adherence challenges and provide targeted support. Participants also noted that counselling helps improve patient motivation and self-management behaviours, which are essential for achieving sustained viral suppression.

Patient Self-Management and Reminder Strategies

Another theme that emerged from the interviews relates to self-management practices

adopted by ART clients to support medication adherence. According to healthcare providers, many clients adopt practical reminder strategies such as mobile phone alarms, assistance from family members, or personal routines to ensure that medication is taken consistently. These strategies were viewed as helpful mechanisms for minimizing missed doses and reinforcing daily treatment adherence. Providers indicated that such behavioural practices contribute positively to sustained engagement in treatment and improved viral load outcomes.

Overall, the qualitative findings highlight how stigma, economic challenges, counselling support, and patient self-management behaviours shape adherence to ART and engagement in HIV care services. These insights complement the quantitative results by providing contextual explanations for the observed associations between patient-related factors, particularly adherence behaviour, clinic attendance, counselling participation, and missed doses and the likelihood of achieving undetectable viral load among ART clients.

Discussion

Principal Findings

This study examined the influence of socio-demographic characteristics and patient-related behavioural factors on the achievement of undetectable viral load among clients receiving antiretroviral therapy (ART) in selected health facilities in Cross River State, Nigeria. The findings demonstrate that both socio-demographic and behavioural factors significantly shape viral suppression outcomes among people living with HIV.

The socio-demographic profile of respondents indicates that most ART clients were young adults, with females slightly more represented than males. A substantial proportion of respondents were married, had at least secondary education, and were engaged in informal or self-employment activities. Despite relatively high educational attainment, many participants reported low-income levels,

reflecting persistent economic vulnerability among ART clients. The quantitative analysis revealed that socio-demographic characteristics such as age, sex, marital status, education, and employment status were significantly associated with undetectable viral load. These characteristics influence treatment outcomes by shaping individuals' health-seeking behaviours, access to healthcare services, and capacity to sustain long-term adherence to ART.

These findings are consistent with prior empirical studies. For instance, [8] reported that age significantly influences viral suppression outcomes among ART clients. This study supports the current findings by demonstrating that older individuals were more likely to achieve viral suppression, indicating that maturity and stability may enhance adherence and long-term treatment engagement. Similarly, [10] found that viral suppression improves progressively with age across multiple African settings. The observed age gradient in viral suppression aligns with this study's findings, suggesting that younger individuals may face behavioural and structural barriers that reduce adherence and compromise treatment outcomes.

Marital status was also significant in this study, consistent with findings by [7]. Their findings indicate that individuals in stable relationships had higher viral suppression, supporting this study's result that social support systems enhance adherence behaviours and improve treatment continuity among ART clients. Furthermore, [6] highlighted the role of education, employment, and financial stability. This aligns with the present findings, suggesting that higher education and employment improve health literacy, access to care, and financial capacity, thereby promoting adherence and increasing the likelihood of viral suppression.

However, contrasting evidence from [27] reported no association between socio-economic factors and viral suppression. This

contradiction highlights contextual differences, suggesting that socio-demographic influences on viral suppression may vary across settings depending on healthcare accessibility, social support systems, and programmatic interventions.

Patient-related behavioural factors were also strongly associated with viral suppression. Clients who consistently attended clinic appointments, adhered to their medication schedules, and participated in counselling sessions were more likely to achieve undetectable viral load. Conversely, missed medication doses, treatment interruptions, and recreational drug use were associated with a reduced likelihood of viral suppression. These behavioural determinants highlight the central role of treatment engagement and adherence practices in achieving optimal HIV treatment outcomes.

Overall, the study provides evidence that viral suppression among ART clients is shaped by the combined influence of socio-demographic characteristics and patient-related adherence behaviours, thereby addressing the research gap concerning context-specific determinants of treatment outcomes in Cross River State.

The qualitative findings further illuminate the contextual factors underlying these patterns. Healthcare providers and ART clients described how stigma, economic hardship, and treatment-related knowledge influence adherence behaviour. Fear of HIV disclosure was frequently cited as a barrier to consistent medication use and clinic attendance, while financial constraints particularly transportation costs and food insecurity, affected clients' ability to attend clinic appointments or maintain regular medication schedules. These insights provide important contextual explanations for the quantitative findings and demonstrate how socio-demographic conditions interact with behavioural factors to influence viral suppression. Overall, the study provides evidence that viral suppression among ART

clients is shaped by the combined influence of socio-demographic characteristics and patient-related adherence behaviours, thereby addressing the research gap concerning context-specific determinants of treatment outcomes in Cross River State.

Adherence as the Strongest Predictor

Adherence to ART emerged as the most significant independent predictor of viral suppression in this study. The multivariate analysis demonstrated that clients who maintained good ART adherence were substantially more likely to achieve undetectable viral load compared with those who reported missed doses or inconsistent medication use. Similarly, regular clinic attendance and participation in counselling sessions significantly increased the likelihood of viral suppression.

These findings are strongly supported by existing literature. For example, [5] identified adherence as a key determinant of viral suppression.

This supports the present findings, demonstrating that poor adherence significantly increases the likelihood of viral non-suppression, emphasizing adherence as the most critical factor influencing ART treatment success. Similarly, [19] linked behavioural practices to viral suppression outcomes. This aligns with the study findings by showing that risky behaviours reduce viral suppression, reinforcing the importance of behavioural modification in improving adherence and achieving optimal treatment outcomes.

Substance use was also significant, consistent with [28]. Their findings demonstrate that alcohol use significantly increases the likelihood of detectable viral load, supporting this study's observation that substance use disrupts adherence and negatively affects viral suppression. Counselling and psychosocial support findings align with [20]. This study supports the current findings by highlighting that patients who

engage in positive health behaviours and receive counselling are more likely to achieve viral suppression through improved adherence and treatment understanding.

Additionally, [18] examined behavioural correlates of viral suppression. Although no association with smoking was found, the study emphasizes the broader role of behavioural factors in treatment outcomes, supporting this study's conclusion that patient behaviours significantly influence viral suppression.

These findings underscore the importance of sustained engagement in HIV care. Consistent adherence ensures adequate drug levels in the body, preventing viral replication and promoting immune recovery. The results further indicate that behavioural support mechanisms such as counselling and adherence monitoring play a critical role in reinforcing treatment adherence and improving health outcomes among ART clients.

The qualitative findings further strengthen the observed relationship between adherence behaviours and viral suppression by illustrating the critical role of counselling in HIV care. Counselling services were shown to enhance patients' understanding of antiretroviral therapy (ART), correct misconceptions about treatment, and build self-efficacy necessary for long-term disease management. Participants emphasized that counselling facilitated the adoption of practical adherence strategies, including the use of medication reminders and the establishment of structured daily routines. These behavioural supports are particularly important in enabling clients to navigate contextual barriers such as stigma, fear of disclosure, and economic hardship, thereby promoting sustained medication adherence and improved treatment outcomes.

This position is strongly supported by existing empirical literature. [1, 2] demonstrate that improved knowledge of HIV treatment and patient-centred care approaches significantly enhance adherence behaviours. Similarly, [17], highlight the importance of adherence

counselling in addressing barriers to viral suppression, while [3] establish a strong link between medication adherence and virological outcomes. Furthermore, [15] provide evidence that behavioural factors, particularly substance use, significantly undermine sustained viral suppression among people living with HIV.

Conversely, behaviours that compromise adherence most notably recreational drug use and missed medication doses, were associated with a significantly reduced likelihood of achieving viral suppression in this study. These findings underscore the dual importance of strengthening adherence-promoting interventions while simultaneously addressing behavioural risk factors that disrupt treatment continuity. Collectively, the evidence highlights the need for integrated, patient-centred HIV care models that combine adherence counselling, behavioural support, and targeted risk-reduction strategies to optimize virological outcomes among ART clients.

Comparison with Other Studies

The findings of this study are consistent with existing literature on determinants of viral suppression among people living with HIV. Previous studies conducted in sub-Saharan Africa and other regions have similarly reported significant associations between socio-demographic characteristics and HIV treatment outcomes.

For instance, [9] reported that age and sex were important predictors of viral suppression among ART clients. Similarly, [13] found that demographic characteristics such as age, sex, and educational attainment influenced viral suppression outcomes across several African countries. Evidence from high-income settings also supports these findings, with [14] demonstrating that demographic factors such as age, sex, and employment status significantly influence viral suppression among people living with HIV.

The strong relationship between ART adherence and viral suppression observed in this study is also consistent with findings from other low- and middle-income settings. [5] reported that poor adherence to ART was strongly associated with viral non-suppression among patients receiving treatment in Uganda. Similar studies conducted in Kenya and other African countries have likewise emphasized adherence as the most important determinant of viral suppression.

Furthermore, behavioural risk factors such as substance use have been shown to negatively influence HIV treatment outcomes. [19] demonstrated that behavioural risk factors influence HIV transmission and treatment outcomes, while [18] reported that alcohol and substance use were associated with higher likelihood of viral non-suppression. Collectively, these studies support the findings of the present research, confirming that both socio-demographic conditions and behavioural adherence practices are critical determinants of viral suppression among ART clients.

Study Limitations

Several limitations should be considered when interpreting the findings of this study. First, the cross-sectional design limits the ability to establish causal relationships between socio-demographic characteristics, patient-related behaviours, and viral suppression outcomes. The associations observed therefore indicate relationships rather than direct causality.

Second, some behavioural variables such as missed doses of medication or substance use, were based on self-reported information, which may be subject to recall bias or social desirability bias. Participants may have underreported behaviours perceived as undesirable, which could influence the accuracy of the findings.

Third, the study was conducted in selected health facilities within Cross River State, which may limit the generalizability of the results to

other regions with different healthcare systems or socio-demographic contexts. Nevertheless, the mixed-methods design strengthened the study by integrating quantitative analysis with qualitative insights, thereby providing a more comprehensive understanding of the factors influencing viral suppression among ART clients.

Despite these limitations, the study provides valuable context-specific evidence on the socio-demographic and patient-related determinants of viral suppression in Cross River State.

Equations

Logistic regression model used in the study:

$$\log\left(\frac{p}{1-p}\right) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_n X_n$$

Where:

- p = probability of achieving undetectable viral load
- X_n = independent variables
- β_n = regression coefficients

Conclusion

This study demonstrates that the achievement of undetectable viral load among ART clients in Cross River State is influenced by both socio-demographic characteristics and patient-related behavioural factors. Socio-demographic variables including age, sex, marital status, education level, and employment status, shape treatment engagement and adherence behaviours among people living with HIV.

However, behavioural factors related to treatment adherence emerged as the most critical determinants of viral suppression. Consistent adherence to ART, regular clinic attendance, and participation in counselling services significantly increased the likelihood of achieving undetectable viral load, while missed medication doses and recreational drug use reduced the likelihood of viral suppression.

The integration of quantitative and qualitative findings demonstrates that viral suppression is influenced not only by clinical

treatment but also by broader social and behavioural contexts. Stigma, economic hardship, and limited access to healthcare services can undermine adherence behaviours, whereas counselling, adherence education, and patient self-management strategies strengthen treatment engagement.

By focusing on socio-demographic and patient-related determinants, this study addresses an important research gap concerning context-specific factors influencing viral suppression among ART clients in Cross River State. The findings highlight the need for patient-centered interventions that strengthen adherence support, enhance counselling services, and address socio-economic barriers to treatment engagement.

Such approaches are essential for improving viral suppression outcomes and advancing HIV treatment goals in resource-limited settings.

Conflict of Interest

The contributors to the study declare no conflict of interest.

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The authors acknowledge all participants and healthcare providers who contributed to this study.

Data Availability

The datasets underlying the findings of this study can be obtained from the corresponding

author upon reasonable request. Premised on ethical considerations and the need for total compliance with research ethics, the dataset is not publicly available. All data were obtained from structured questionnaires, clinical records, and qualitative interviews conducted within the selected health facilities in Cross River State, Nigeria.

Author Contributions

Ofere, I. M. conceptualized the study, developed the research design, secured funding and coordinated the overall field activities. Agada, P. supervised the overall research process and provided critical review of the manuscript. He ensured language consistency, methodological validity, and verification of results, and confirmed the integrity and reliability of the data presented in the study and Mbeh, O.A. designed the quantitative questionnaire using the KoboCollect mobile data collection platform, coordinated the field data collection process, and conducted data verification and statistical analysis. The author also proofread the data analysis section to ensure accuracy and clarity of the results. All authors contributed to the revisions and approved the final manuscript.

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Epidemiological Profile and Temporal Trends of Cancer Incidence and Mortality in Guyana, 2015-2024: A Ten-Year Registry-Based Analysis

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Abstract

Cancer constitutes a growing non-communicable disease burden across the Caribbean, yet population-level data from Guyana remain sparse. This study characterises the ten-year epidemiological profile of cancer in Guyana, describing temporal trends in cancer incidence and mortality using national registry data spanning 2015 to 2024. A retrospective descriptive analysis of 8,822 cancer registry records was conducted, examining year of diagnosis, sex, topography, cancer stage, vital status, ethnicity, and geographic region. Descriptive statistics, proportional distributions, and case fatality rates (CFR) were computed. A total of 8,822 cases were registered over the decade, rising nearly threefold from 525 cases in 2015 to 1,635 in 2024. Overall case fatality was 53.8%. Females accounted for 59.1% of cases ($n=5,215$), while males bore higher mortality (CFR 61.6% vs. 48.8%). Prostate cancer was the leading male malignancy ($n=939$) and breast cancer the leading female malignancy ($n=896$). Cervical cancer ranked second in females ($n=487$). Stage IV disease carried a CFR of 68.1%. East Indians represented the largest ethnic group (31.2%). Region 4 (Demerara-Mahaica) contributed 44.8% of all cases. COVID-19 disruptions in 2020 coincided with a CFR peak of 69.3%, with a gradual decline to 42.8% by 2024. Guyana faces a significant and escalating cancer burden characterised by late-stage presentation, high case fatality, and geographic concentration of services. Strengthening early detection, expanding registry completeness, and developing context-sensitive prediction tools are urgently needed to improve cancer outcomes in this low- and middle-income country (LMIC) setting.

Keywords: Cancer Epidemiology, Cancer Registry, Caribbean Oncology, Case Fatality, Cervical Cancer, Guyana, LMIC.

Introduction

Cancer is among the leading causes of morbidity and mortality globally, accounting for an estimated 19.3 million new cases and 10.0 million deaths in 2020 [1]. The burden is increasingly borne by low- and middle-income countries (LMICs), where health system constraints, late-stage presentation, and limited access to curative therapies converge to elevate case fatality beyond levels observed in high-income settings [2]. The Caribbean region is no exception; projections suggest that the absolute

number of new cancer cases in the region will increase substantially by 2030, driven by demographic ageing and shifting risk factor profiles [3].

Guyana, a lower-middle-income nation on the northeastern coast of South America with a population of approximately 800,000, occupies a transitional epidemiological position characterised by a double burden of communicable and non-communicable diseases [4]. Cancer control in Guyana faces structural challenges including limited oncology

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infrastructure, a single national referral hospital (Georgetown Public Hospital Corporation), heterogeneous registry data quality, incomplete staging documentation, and workforce shortages in oncology and pathology [5]. Despite these constraints, the National Cancer Registry (NCR) has maintained continuous case ascertainment since at least 2015, providing a valuable longitudinal data resource that remains inadequately exploited for epidemiological characterisation.

Published data on cancer trends in Guyana are limited. Existing studies have focused narrowly on specific cancer types in isolation, and none has presented a comprehensive ten-year population-level analysis covering multiple cancer sites, staging distributions, demographic patterns, and temporal mortality trends [6, 7]. This evidence gap impedes the prioritisation of cancer control resources, the design of early-detection programmes, and the formulation of evidence-informed national cancer policies.

This study addresses that gap by analysing a decade of national cancer registry data (2015-2024) to characterise the epidemiological profile of cancer in Guyana, describe temporal trends in incidence and case fatality, stratify findings by sex, cancer site, disease stage, ethnicity, and geography, and identify implications for cancer control planning. The analysis directly informs an ongoing doctoral programme of research aimed at developing validated cancer survival prediction models for the Guyanese health system context.

Materials and Methods

Study Design and Data Source

A retrospective descriptive analysis was performed using the Guyana National Cancer Registry dataset spanning 2015 to 2024. The dataset comprised 8,822 records with 35 variables including sociodemographic characteristics (sex, date of birth, ethnicity, region, union status, occupation), clinical parameters (topography, morphology,

behaviour, tumour grade, staging), treatment modalities (surgery, chemotherapy, radiotherapy, immunotherapy, hormonal therapy, palliative care), and outcome data (vital status, date of death, cause of death, date of last contact).

Data Cleaning and Harmonisation

Raw data required extensive normalisation due to inconsistent coding conventions across registry years. Sex was recorded in at least seven distinct formats (e.g., 'Female', 'F', 'female', '2'); these were harmonised into three categories: Female, Male, and Unknown. Vital status was similarly fragmented, with entries including free-text dates, coded numerals (1 = Died, 2 = Alive/Discharged), and inconsistent alphabetic variants. All entries were mapped to four categories: Died, Alive, Discharged, and Unknown. Topography labels were title-cased and consolidated to avoid counting synonymous site descriptors as distinct categories. Staging was normalised from a mixture of Roman numerals, Arabic numerals, and free-text values into five categories: Stage I, Stage II, Stage III, Stage IV, and Unknown. Ethnicity was mapped to standardised groups. Year of diagnosis was extracted from the 'Year' field; rows with missing or non-parseable years were excluded from temporal trend analyses. All data management was conducted in Python 3.12 using the pandas and openpyxl libraries [8, 9].

Variables and Statistical Analysis

The primary outcome was the case fatality rate (CFR), defined as the proportion of registered cases with a vital status of 'Died' among all cases with a non-missing vital status during the registry period. Secondary outcomes included annual cancer registration volume and site-specific case counts stratified by sex. Covariates included year of diagnosis, sex, topography (cancer site), stage at diagnosis, ethnicity, and administrative region of residence. Descriptive statistics were computed

as counts and percentages. Stratum-specific CFRs were computed for year, sex, stage, and topography subgroups. All analyses were descriptive; no inferential statistics were applied given the population-based, non-probabilistic nature of the registry [10].

Ethical Considerations

This study constitutes a secondary analysis of routinely collected, de-identified administrative registry data. No primary data collection involving human participants was conducted. Patient addresses were present in the dataset but were not extracted or used in any analysis. Ethics clearance was obtained through the Internal Review Board, Ministry of Health Guyana and Texila American University Research Ethics Committee, and the study was conducted in accordance with the Declaration

of Helsinki principles for research using anonymised health data.

Results

Annual Registration Trends

Between 2015 and 2024, a total of 8,822 cancer cases were registered in the Guyana National Cancer Registry. Annual registration volumes increased nearly threefold over the decade, from 525 cases in 2015 to 1,635 cases in 2024, with a notable acceleration after 2022 reflecting improved ascertainment and potentially genuine incidence increases (Table 1). The year 2020 showed a modest reduction in registrations (n=714) consistent with reduced healthcare utilisation during the COVID-19 pandemic [11].

Table 1. Annual Cancer Registrations and Case Fatality Rates, Guyana 2015-2024

Year	Total Cases	Male (n)	Female (n)	Deaths (n)	CFR (%)
2015	525	186	339	336	64.0%
2016	411	148	263	265	64.5%
2017	821	291	530	537	65.4%
2018	758	272	486	449	59.2%
2019	990	354	636	459	46.4%
2020	714	255	459	495	69.3%
2021	805	289	516	519	64.5%
2022	810	290	520	379	46.8%
2023	1,352	484	868	610	45.1%
2024	1,635	585	1,050	700	42.8%
Total	8,822	3,154	5,667	4,749	53.8%

CFR = Case Fatality Rate. Male (n) and Female (n) represent harmonised sex categories. Total row includes 34 cases of unknown sex.

Sex Distribution and Sex-Stratified Mortality

Females constituted the majority of registered cases (n=5,215; 59.1%), while males accounted for 40.5% (n=3,573) and 0.4% (n=34) were of undetermined sex. Despite higher absolute case numbers in females, males carried a substantially higher case fatality rate (61.6%) compared to females (48.8%), reflecting the predominantly advanced-stage presentation of male cancers, particularly

prostate cancer, and differing tumour biology across leading sites [12].

Leading Cancer Sites by Sex

Site-specific distributions differed markedly by sex (Table 2). Among males, prostate cancer was the dominant diagnosis (n=939, 26.3% of all male cases), followed distantly by colorectal cancer (n=144, 4.0%) and lung cancer (n=139, 3.9%). Among females, breast cancer led (n=896, 17.2% of all female cases), followed by

cervical cancer (n=487, 9.3%) and endometrial cancer (n=264, 5.1%). The co-dominance of breast and cervical cancer in females underscores the centrality of female

reproductive tract malignancies to Guyana's cancer burden and points to significant opportunities for screen-and-treat prevention strategies [13, 14].

Table 2. Top Ten Cancer Sites by Sex, Guyana 2015-2024

Male Site	n (% Male)	Female Site	n (% Female)
Prostate	939 (26.3%)	Breast	896 (17.2%)
Colon	144 (4.0%)	Cervix	487 (9.3%)
Lung	139 (3.9%)	Endometrium	264 (5.1%)
Liver	104 (2.9%)	Ovary	169 (3.2%)
Stomach	74 (2.1%)	Colon	136 (2.6%)
Pancreas	61 (1.7%)	Lung	96 (1.8%)
Rectum	46 (1.3%)	Uterus	75 (1.4%)
Brain	46 (1.3%)	Liver	69 (1.3%)
Lymphoma	43 (1.2%)	Thyroid	66 (1.3%)
Bladder	38 (1.1%)	Pancreas	71 (1.4%)

Stage at Diagnosis and Stage-Stratified Mortality

Staging completeness was poor, with 73.6% of cases (n=6,489) classified as unknown stage. Among cases with documented staging, Stage II was most frequently recorded (n=1,524; 17.3%), followed by Stage III (n=374; 4.2%), Stage I (n=291; 3.3%), and Stage IV (n=144; 1.6%). Case fatality rates demonstrated the

expected monotonic increase with advancing stage: 25.4% for Stage I, 35.4% for Stage II, 36.1% for Stage III, and 68.1% for Stage IV (Table 3). The disproportionately high CFR among cases with unknown stage (60.1%) likely reflects a mixture of late-presenting and poorly documented cases, reinforcing the urgent need for staging completeness improvement [15].

Table 3. Case Fatality Rate by Stage at Diagnosis, Guyana 2015-2024

Stage at Diagnosis	n (%)	Deaths (n)	Case Fatality Rate (%)
Stage I	291 (3.3%)	74	25.4%
Stage II	1,524 (17.3%)	540	35.4%
Stage III	374 (4.2%)	135	36.1%
Stage IV	144 (1.6%)	98	68.1%
Unknown	6,489 (73.6%)	3,902	60.1%
Total	8,822 (100%)	4,749	53.8%

Ethnic and Geographic Distribution

East Indians represented the largest ethnic group in the cancer registry (n=2,754; 31.2%), followed by Africans (n=1,918; 21.7%), Mixed ethnicity (n=512; 5.8%), and Amerindians (n=301; 3.4%). A substantial proportion of

records (37.8%) had unspecified or non-standard ethnicity entries, limiting ethnic-stratified mortality analysis (Table 4). Geographically, Region 4 (Demerara-Mahaica, which encompasses the capital Georgetown) accounted for 44.8% of all registrations

(n=3,955), consistent with its concentration of oncology diagnostic services. Region 0, an administrative code for incomplete or

unregionated records, accounted for 19.0% of entries (n=1,680), indicating significant geographic documentation gaps (Table 5) [16].

Table 4. Ethnic Group Distribution, Guyana Cancer Registry 2015-2024

Ethnic Group	n (%)	Ethnic Group	n (%)
East Indian	2,754 (31.2%)	African	1,918 (21.7%)
Mixed	512 (5.8%)	Amerindian	301 (3.4%)
Other/Unspecified	3,337 (37.8%)	—	—

Table 5. Geographic Distribution of Cancer Cases by Administrative Region, Guyana 2015-2024

Region	Name	Cases (n)	% of Total
4	Demerara-Mahaica (Georgetown)	3,955	44.8%
0	Unregionated/Missing	1,680	19.0%
3	Essequibo Islands-West Demerara	1,031	11.7%
6	East Berbice-Corentyne	852	9.7%
10	Upper Demerara-Berbice	397	4.5%
2	Pomeroon-Supenaam	347	3.9%
5	Mahaica-Berbice	237	2.7%
1	Barima-Waini	151	1.7%
7	Cuyuni-Mazaruni	91	1.0%
8	Potaro-Siparuni	31	0.4%

COVID-19 Impact on Cancer Case Fatality

The CFR in 2020 (69.3%) was the highest recorded across the decade and coincided with the COVID-19 pandemic, which disrupted routine healthcare services, delayed treatment initiation, and reduced follow-up visits [11, 17]. The subsequent gradual decline in CFR from 64.5% in 2021 to 42.8% in 2024 may reflect progressive restoration of oncology services, increased registry ascertainment of less severe cases as clinical services expanded, or genuine improvement in treatment pathways. Prospective surveillance is needed to determine which factors are driving this trend.

Discussion

This analysis represents the most comprehensive ten-year epidemiological characterisation of cancer in Guyana to date, drawing on nearly 9,000 registry records spanning a full decade. The findings reveal a

cancer burden that is simultaneously growing in scale, concentrated in a narrow set of preventable or screen-detectable tumours, and characterised by strikingly high case fatality driven by late presentation and incomplete staging documentation.

The dominance of prostate cancer in males and breast cancer in females mirrors Caribbean regional patterns, where PAHO data consistently identify these as leading malignancies [3, 18]. However, Guyana's CFRs for both conditions appear higher than those reported in comparable Caribbean nations, suggesting deficiencies in early detection uptake, access to definitive treatment, and continuity of care. The burden of cervical cancer (n=487; 9.3% of female cases) is particularly concerning, as cervical cancer is largely preventable through HPV vaccination and screen-and-treat programmes [13]. Its persistence as the second most common female malignancy reflects limited vaccine programme

maturity and inconsistent uptake of cervical screening among eligible women.

The low staging completeness (26.4% of cases with documented stage) is a critical registry quality limitation that impairs survival analysis, clinical benchmarking, and programme planning. The high CFR observed in the unknown stage stratum (60.1%) likely reflects a concentration of advanced or terminal cases for whom comprehensive diagnostic workup was not performed prior to death. This finding aligns with observations from other LMIC cancer registries, where staging documentation is often constrained by limited pathology services, imaging capacity, and multidisciplinary tumour board infrastructure [15, 19].

The COVID-19 pandemic's impact on cancer outcomes is evident in the 2020 CFR spike to 69.3%, consistent with published evidence from other LMICs demonstrating pandemic-related delays in cancer diagnosis and treatment [11, 17]. Post-pandemic recovery appears to be underway, with CFR declining to 42.8% by 2024, though the direction of this trend warrants cautious interpretation pending more complete vital status ascertainment for 2023-2024 cohorts.

The geographic concentration of cases in Region 4 (44.8%) reflects the centralisation of oncology services in Georgetown rather than true epidemiological concentration of disease, introducing registry ascertainment bias that may undercount cancer burden in interior and rural regions. Amerindians, who disproportionately inhabit inland hinterland regions, comprised only 3.4% of registry entries, a proportion likely well below their true cancer burden given geographic access barriers to diagnosis and registration [16]. Future registry strengthening should prioritise decentralised registration points and outreach to under-represented communities.

These findings have direct implications for the development of machine learning-based cancer survival prediction models for Guyana.

The marked data quality challenges, including sparse staging, inconsistent sex coding, heterogeneous vital status entries, and high missingness in treatment fields, must be addressed through rigorous data standardisation before prediction models can be trained and validated with appropriate calibration. They also underscore the necessity of including missingness mechanisms and data quality flags as explicit model predictors or analysis strata, as recommended in contemporary predictive modelling guidelines for LMIC health data [20-22].

Conclusion

Guyana's cancer burden over the past decade has been characterised by rising registration volumes, persistently high case fatality, poor staging documentation, geographic concentration of service access, and sex-specific patterns dominated by prostate and breast cancer. These findings highlight urgent priorities for cancer control investment: HPV and breast cancer screening scale-up, staging documentation quality improvement, geographic decentralisation of oncology services, and development of validated clinical decision support tools calibrated to the Guyanese context. The cancer registry dataset characterised here provides the foundational evidence base for a doctoral programme of research aimed at developing context-sensitive survival prediction models that can support clinician decision-making and health system planning in Guyana.

Conflict of Interest

The authors declare that there is no conflict of interest.

Ethical Approval

Ethics clearance was obtained from the Texila American University Research Ethics Committee. The study uses de-identified secondary registry data and was conducted in compliance with the Declaration of Helsinki.

Author Contributions

Diana Elizabeth Khan conceptualised the study, performed data cleaning and analysis, and drafted the manuscript. Paul Abiodun Olaiya contributed to the study design, supervised the analysis, critically reviewed and revised the manuscript, and approved the final version for submission. Both authors read and approved the final manuscript.

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Data Availability

The data used in this study are held by the Guyana National Cancer Registry and the Ministry of Health, Guyana. Requests for data access should be directed to the relevant national authorities. Analytical code is available from the corresponding author upon reasonable request.

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Health Workers's Perspective on Health System Barriers to Effective IMNCI Implementation among Health Workers in Chongwe and Lusaka Districts, Zambia

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Abstract

Since the introduction of the IMNCI strategy in 1995 in Zambia, the Country has achieved good progress in reducing under-five mortality. In spite of its introduction, implementation of IMNCI has not been at its best, the 2018 Zambia's health facility assessment found that only 45% of health facilities had at least 60% IMNCI trained health workers attending to sick children whereas only 32% of health facilities received at least one supervisory visit during the survey period. Despite IMNCI being a critical strategy for Zambia, very limited evidence exists on health workers' perspective on key health system barriers for effective implementation of IMNCI. Most of the available evidence has focused on application of IMNCI skills. The study explored health workers perspective on Key health system barriers for implementation of the IMNCI strategy in Chongwe and Lusaka districts. The study employed a descriptive exploratory mixed method design and sequentially collected quantitative and qualitative data. Data was collected from health workers, National and District IMNCI Coordinators and Health facility assessment. The study revealed key health systems factors such as inadequate support, Lack of Budgetary allocation for IMNCI, Poor documentation and recording and Poor leadership and governance as barriers to implementation of IMNCI. This study therefore proposes a focus all Health system building blocks rather than just focusing on service delivery and work force related efforts as an approach that will promote responsive and resilient health systems capable of promoting quality and equitable Universal child health care services and consequently improved wellbeing of children.

Keywords: Health Facility, IMNCI Assessment, Resources, Under-five Children, WHO's Health System Building Blocks

Introduction

Despite the remarkable that have been made in reducing child mortality globally by 52% since 2000. IGME 2024 reports that an estimated 4.8 million children died before the age of five, including 2.3 million newborns in 2023. These deaths are not inevitable. Most of the common condition responsible for these deaths are related to the first 28 days of life such

as preterm birth, complications at birth and congenital anomalies, and infectious diseases such as pneumonia, malaria and diarrhoea [1, 2].

Most under-five children that seek Primary health care services, especially in the low and middle-income countries, often present with multiple conditions, and requires diagnostics services such as laboratory and radiological services for them to effectively handle such

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cases. However, on the ground the situation is different as most primary health centres have limited or non-existent diagnostic services which places health care workers in a difficult situation for them to meaningfully examine and provide the required care to these sick children [3]. To mitigate this challenge, and improve the quality of care given to new-borns and children under five in Primary health care setting. In 1995, WHO and UNICEF designed the Integrated Management of Childhood Illnesses (IMCI) strategy. Which sought to improve health workers skills, health system, and family and community practices [3]. The strategy has since been adopted in over 100 countries primarily in Asia, Africa and Latin Africa, and the strategy has been implemented, either in part or all of its three components [3, 4]. According to available evidence IMCI if implemented fully contributes to a reduction in child mortality [5] found that the strategy was associated with a 15% reduction in child mortality when implemented at scale in Primary health care facilities and at community level [3].

In Zambia, IMNCI was introduced as one of the key child Survival strategies in 1995 to help reduce under-five morbidity and mortality and tackle five major conditions that were responsible for more than two third of childhood deaths namely, respiratory tract infections, malaria, diarrhoea, malnutrition and measles [6]. This was at the backdrop when illnesses were managed through vertical programmes that were inappropriate to manage sick children presenting with signs and symptoms of more than one condition [6]. Over the years, Zambia has continued to make steady progress in improving child health and in reducing under five mortality from 197 death per 1000 live births (1996) to 42 deaths per 1000 live births (2024). Despite this improvement, under five mortality rate continues to be very high [7] beyond the Sustainable Development Goal of reducing child mortality to at least 25 or less deaths per

1000 live birth by 2030. Despite widespread successes of IMCI over last 25 years and the fact that most countries including Zambia still considers IMCI a key Child survival strategy for delivering lifesaving interventions, only a handful of countries have achieved full saturation of IMCI implementation and coverage remains low [8, 9].

Statement of the Problem

In Zambia, under five mortality rate at 61 deaths per 1,000 live deaths continues to be unacceptably high despite the successes that have been achieved from the time the IMNCI was adopted. IMNCI as one of the key child survival strategies adopted to address this problem has not been optimally implemented despite the strategy having been rolled out to all the 116 districts of Zambia. Only 45% of health facilities had at least 60% IMNCI trained health workers attending to sick children and whereas only 32% of health facilities received at least one supervisory visit during the survey period [10]. Implementation of IMNCI has been hampered by shortage of health workers particularly at health facility level, and has also not been ideal in health facilities which a relatively good number of staffing levels. Several challenges persists that affects the effective implementation of neonatal and child health programmes including IMNCI and these include; Inadequate human resources; Inadequate equipment, child friendly drugs and other commodities; Inadequacies in infrastructure normally without dedicated space for implementation of child health related services and Health system challenges including inadequate transport for effective referral systems; outreach services [11]. Under-five mortality rate in Lusaka province, which includes Chongwe and Lusaka, has significantly decreased from 197 death per 1,000 live births (1996) to 64 death per 1,000 live births (2024), despite this improvement under five mortality rate is still unacceptably high in spite of this progress.

Rationale for the Study

Studies done globally and in Zambia have focused mainly on assessing the application of the IMNCI strategy among health workers, and health facilities through health workers and health facility assessment. Limited evidence exists on health system barriers for effective implementation of IMNCI especially from the perspective of IMNCI trained health workers. Therefore, it will be good to understand health systems barriers or factors that impedes frontline health workers from adhering to IMNCI guidelines during the assessment of children from their perspective. Understanding and resolving these barriers could significantly help Zambia's efforts in further reducing under five morbidity and mortality, and consequently help the Country in its quest of reaching the SDG's target of 25 deaths per 1,000 population by 2030, and the Ministry of Health's National Health Strategic 2022 to 2026 goals of reducing under five mortality rate from 61 to 25 deaths per 1,000 by the end of the strategy period in 2026.

Health workers' perspectives on health systems factors that hinders the implementation of the IMNCI strategy have not fully been investigated in Zambia. It is on this basis that this study will help address this gap in knowledge, and generate knowledge that will help Programme managers and policy makers to design context specific health system strengthening strategies that will fully support health facilities and health workers to implement the IMNCI strategy with fidelity.

Literature Review

In 2023 alone, 4.8 million children died before reaching their fifth birthday, mostly from preventable causes. This translates to 13,100 children under the age of 5 dying every day in 2023. That included 2.3 million deaths in the neonatal period (aged 0–27 days) and 2.5 million deaths among children aged 1–59 months. Globally, infectious diseases, including pneumonia, diarrhoea and malaria,

remain a leading cause of under-five deaths, along with preterm birth and intrapartum-related complications these deaths are not inevitable. They are the result of unequal access to health care, nutrition, and protection, especially in the most fragile and underserved settings [9].

Despite this high mortality, the world has made remarkable progress in reducing child mortality. Since 2000, the global under-five mortality rate has fallen by 52 per cent, reflecting decades of investment and collaboration by governments, communities and partners. Millions of children have survived and gone on to thrive thanks to proven, life-saving interventions [2].

While the overall decline in under-five mortality is encouraging, progress has not been uniform across all age groups. Since 2000, deaths among children aged 1–59 months have fallen by 58 per cent, compared to a 44 per cent decline in neonatal deaths. Nearly half of all under-five deaths in 2023 occurred within the first 28 days of life, underscoring the heightened vulnerability of newborns and the need for greater investment in targeted interventions during this critical period [2]. Even as global averages improve, the reality for many children is shaped by where they are born and the conditions into which they are born. A child born in sub-Saharan Africa is, on average, 18 times more likely to die before the age of 5 than one born in Australia and New Zealand. The risk of under-five death in the highest-mortality country is 80 times greater than in the lowest. Children living in rural areas, from the poorest households, or born to mothers with the least education face significantly higher mortality risks [2].

Childhood Morbidity and Mortality in Zambia

Zambia's situation also conforms to the global picture; notable progress has been recorded in reduction of under-five mortality from 197 death per 1,000 live births (1996) to

42 death per 1,000 live births (2024)) [7]. However, notwithstanding this improvement, Under-five mortality rates still remain disturbingly high far beyond the Sustainable Development Goal target of at least 25 or less deaths per 1000 live birth by 2030.

Zambia adopted the IMNCI strategy in 1995 as a key child survival strategy for addressing high morbidity and mortality among under-five children as a result of preventative illness such as respiratory tract infections, malaria, diarrhoea, malnutrition and measles, and notable improvements have been achievement. Even with its introduction, IMNCI has not been implemented optimally as was shown from the 2018 Zambia's health facility survey. In order to fully understand health system factors that are responsible for non-adherence to IMNCI

protocols by health workers, factors were analysed at according to Key Health systems building blocks in relation to IMNCI namely; Health Information, financing and Leadership and Governance

Conceptual framework on Key Health system factors influencing IMNCI implementation

As show below, the independent variable for this study is effective IMNCI implementation which is influenced by the dependent variables namely Budget allocation, documentation and record keeping, and Leadership and Governance see figure 1 below. The dependent variables have a direct effect on independent variables-effective Implementation of IMNCI.

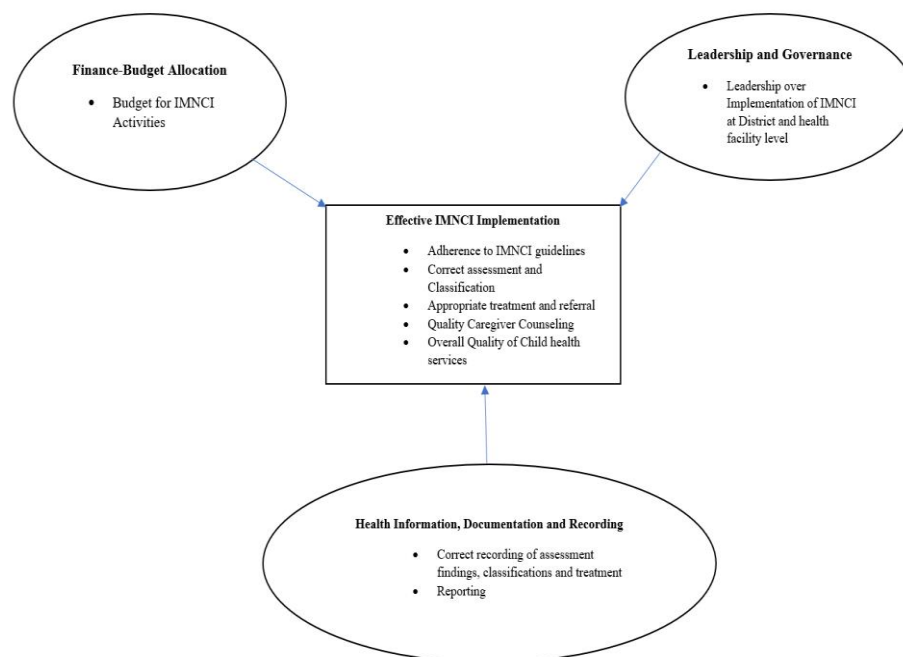


Figure 1. Conceptual framework on Key Health system factors that influence effective IMNCI Implementation

Source: Author 2025

1. Leadership and Governance

i. Lack of intergration and Poor Coordination of IMNCI Programme:

Integration of IMCI into existing health programs has emerged as a barrier to implementation of IMNCI as it has caused fragmentation of governance structures that

influence the IMCI program and other child health programs. Other vertical programs such as Expanded Program on Immunization (EPI) and nutrition were often prioritized and not synchronized to the IMCI program. Moreover, the coordinators managing these vertical programs were not trained in IMCI,

creating a lack of awareness of the IMCI aspects and also prompting them to focus on their specific programmes [12-14]. Poor coordination of IMNCI at district level and not having someone fully dedicated and accountable for the IMNCI Programme at affected the implementation of IMNCI at health facility level. There are also ambiguities in roles on IMNCI among District management cadres which resulted in poor coordination and communication [8]. Supervisors who were meant to do IMCI supervision were not able to, because of lack of time, lack of training on how to conduct supervision, and lack of tools for IMCI-specific supervision [15].

ii. **Lack of ownership and planning at provincial and district health levels:**

Despite the fact that many countries had decentralized the administration of health care services to the district level, district authorities weren't always given the skills and power they needed to efficiently organize, plan, carry out, and monitor services [12]. This was particularly true for IMCI, which more often lacked the management and governance structures of vertical programs [16].

2. **Inadequate Budgetary allocation for IMNCI**

Lack of budgetary allocation to support routine follow-ups and on-site mentorship among IMNCI trained primary health workers, this situation had prompted District health management teams to combine routine follow up visits with other follow-ups. This practice has great potential to reduce the quality of follow up on IMNCI as their scope are broaden to include other thematic areas, and the situation may become worse if people involved in the provision of supervision have are not been trained in IMNCI [13, 17].

3. **Documentation and Record Keeping**

Poor documentation and recording are major barriers to the effective implementation of Integrated Management of Neonatal and

Childhood Illness (IMNCI) guidelines among healthcare workers. Some of the common documentation and recording issues affecting IMNCI implementation that have been cited from various studies include: Missing or Incomplete Records: Health workers frequently fail to record essential assessment data, such as general danger signs, nutritional status, and immunization history, and Inaccurate Case Classification: Poor recording often leads to incorrect classification of illnesses, which in turn results in incorrect treatment [12, 15, 17]

Research Objective

To explore health workers' perspectives on health systems barriers to effective implementation of the IMNCI strategy at health facility level in Chongwe and Lusaka.

Specific Objectives

1. To explore health workers' experiences on Key health system barriers to implementation of IMNCI guidelines at health facility level.
2. To assess whether leadership and governance systems are in place and in use at District Health office and Health facility level that fosters fidelity implementation of IMNCI protocols at health facility level

Methodology and Design

A descriptive exploratory mixed methods design was employed. The study successively collected both quantitative and qualitative data on health facilities' s capacity to support IMNCI, and health workers perspective on barriers to effective implementation of IMNCI at health facility level respectively. A mixed method combined elements of qualitative and qualitative research in order to answer the study's research question in a single study or a program of inquiry. Mixed methods helped to gain a more complete picture of key health systems barriers to effective implementation of IMNCI at health facility level than a standalone method.

The study population were IMNCI trained health workers working in outpatient departments of selected health facilities of where referral to the next level was done for further management who were present on the day of data collection, the Chief IMNCI Officer and Maternal New born and Child health (MNCH) Coordinators in Lusaka and Chongwe districts. The two districts were purposively selected based on key characteristics such as population density and under-five attendance, and provided the researcher with both an urban and rural perspectives on Key Health systems barriers that hinder the full implementation of IMNCI strategy among health workers at health facility level.

The study was conducted in 15 IMNCI implementing health facilities in Lusaka and Chongwe districts. Convenience sampling was done to choose 5 IMNCI implementing facilities out of the 40 Primary health facilities in Chongwe and 10 IMNCI implementing facilities out of the 93 health facilities in Lusaka.

For qualitative (IDI), 10 health workers were purposively selected from the 10 health facilities (7 in Lusaka and 3 in Chongwe) out of 15 health facilities, and three Health managers were interviewed one at National level and 1 from each from the two District health offices while health assessment was done in all the 15 health facilities.

For Qualitative data, an in-depth interview guide was used to probe participants on key health systems barriers to implementation of

IMNCI from their perspective at health facility level, to Managers at District health office and National level. The IDI was administered to 10 purposively sampled health workers from 10 health facilities and 2 MNCH Coordinators and 1 Chief IMNCI Officer. Quantitative data was collected Health facility assessment.

Qualitative data analysis was done through Thematic analysis of transcribed data, this involved familiarizing with data, creating initial codes, looking for themes, reviewing recurrent themes and defining and labeling theme. The recurring themes related to experiences of health workers on barriers to implementation of IMNCI were identified through this process. Quantitative data was analyzed using Stata version 17.0. Microsoft excel was used to generate tables and graphs and percentages for easy data interpretation.

Results

Socio-demographic Characteristics of the Study Population

A total of 10 health workers were interviewed during the study. Among the study population, males constituted the majority of respondents (60%). The research results showed that the majority of health workers (50%) were young professionals aged 20-34, with a higher proportion aged 45 years old (30%) or older. In terms of experience, results showed an almost equal distribution between those with fewer than 5 years (40%) and those with over 10 years (40%). (Table 1)

Table 1. Distribution (n, %) of Participants based on Selected Demographic Information

Background characteristics	Frequency (n)	Percent (%)
Age		
20-34	5	50%
35-44	2	20%
45 and above	3	30%
Sex		
Male	6	60%
Female	4	40%

Years of Practice		
Less than 5 years	4	40%
5-9 years	4	40%
10 Years and Above	2	20%
Total	10	100.0

The main themes and sub themes that emerged from analysis of In-depth interviews of health care workers, District Maternal New

Born and Child health and Chief IMCI Officer are captured in Table 2 below.

Table.2. Themes and Sub Themes

Theme	Sub theme	
Theme 1. Health System barriers for effective implementation of IMNCI	Support for IMCI from DHO	Inadequate Support for IMNCI
	Budgetary Support for IMNCI	Lack of budgetary support
	Documentation and Recording	Poor documentation and Record keeping
Theme 2. Leadership and governance for IMNCI	Leadership and governance for IMNCI at health facility and District level	Leadership and Governance

Theme 1: Health System barriers for effective implementation of IMNCI

1.1 Support for IMCI from DHO

1.1.1 Inadequate support from District Health Offices: Participants felt that support from District Health Offices (DHOs) was inadequate and was responsible for limited application of the IMNCI skills, but on the other hand some felt that their health facility Centre in-charges tried their best to support them by ensuring that all drugs, equipment and supplies were available.

“Yes, in terms of supplies such as medicines and ORS and a few equipment, our Health facility in-charge tries to support us by all means, but the challenge has been with the District health office, who have been unable to provide us with the necessary Job aids for our screening rooms such as Chart booklets and wall charts to enable us refer to them as we assess children despite intense lobbying” (Participant no.3)

“Yes, the health facility in charge tries to support us, for example at one point they

designated one room at this facility specifically for seeing sick children, but the room was later given to Voluntary Medical Male Circumcision (VMMC) because of limited rooms” (Participant no.5)

“For the District Health Office, it is tricky and it is very difficult to tell what kind of support they provide, like you have observed, we do not have IMCI chart booklets, timers and wall charts to help us as we assess sick children. When it comes to Technical supportive supervision specifically for IMCI, it has been a while since it took place, it is usually integrated in quarterly Performance Assessment, and usually during Performance Assessment, it merely ends at asking questions concerning assessment of sick children” (Participant no.10)

“We have not been helped much by the District in terms of IMCI, we have time and again highlighted some of the challenges that we face as health workers in the assessment of sick children during Quarterly Performance Assessments, but nothing much has changed”. (Participant no.3)

Other participated felt supported to practice IMNCI

“Yes, we feel very much supported and encouraged to practice IMNCI because the health facility provides us an environment that supports management of children, for example, children we find dehydrated. There is an ORT corner where these children are managed. In addition, the health facility provides equipment such as thermometers, height boards and weighing scale which helps us to take all vitals such as weight, temperature and height” (Participant no.7)

The National IMNCI focal person on the other hand indicated that Districts and Health facilities were partially supported through provision of guidelines as well as conducting of technical support, supportive supervision and mentorship in selected provinces and districts.

“Districts, Health facilities and Health workers are partially supported in that the Ministry has providing guidelines for IMNCI as well as conducting technical support, supportive supervision and mentorship in selected provinces / districts”. **Chief IMNCI Officer.**

1.2 Budgetary Support for IMNCI

1.2.1 Lack of Budgetary allocation for IMNCI: The study revealed that there was no budget allocation specifically for IMNCI at both District and Health facility level. Budgets were available to support integrated programmes based on the needs of the District and health facilities, and not specifically to support standalone programmes like IMNCI.

“there is no budget specifically to support IMNCI at the health facility as the health facility allocation is not adequate”

Participant no.15

“there is no allocation specifically for IMCI, may be this could due to IMCI being overlooked” **Participant no.01**

“Yes, there is no budgetary allocation specifically for IMNCI and the funding that

is received is shared among all Programme”

Maternal New Born and Child Health Coordinator no.2

Lack of budgetary allocation for IMNCI at District and health facility level has significantly hindered the effective implementation of IMNCI and impacted various aspects of IMNCI, including training, supervision and provision of essential supplies.

1.3 Documentation and Record Keeping

1.3.1 Poor documentation and Record keeping: As shown in figure 2 below, a review of children's records for correctness of signs and symptoms, classifications and treatment during health facility assessment showed gaps in documentation of assessment of signs and symptoms, classifications and treatment as none of the health facility was able to score at least 95% on children's records sampled. This clearly shows gaps in skills and knowledge among health workers in IMNCI. According to participants this gap could be attributed to the non-configuration of the SMART CARE system according to IMNCI algorithm. This made it difficult for health workers to assess under five children according the IMNCI algorithm.

“One of the obstacles is that the SMART care system we use for screening of all patients including children is not set up in conformity with IMNCI which makes it difficult for us to apply IMNCI guidelines during assessment of children” (Participant no.10).

“Our health facility has completely gone digital through the SMART care system, but one major problem that we have noticed is that the SMART care system has not been organised according to IMNCI assessment steps, which presents a challenge for us when it comes to assessing sick under-five children” (Participant no.4).

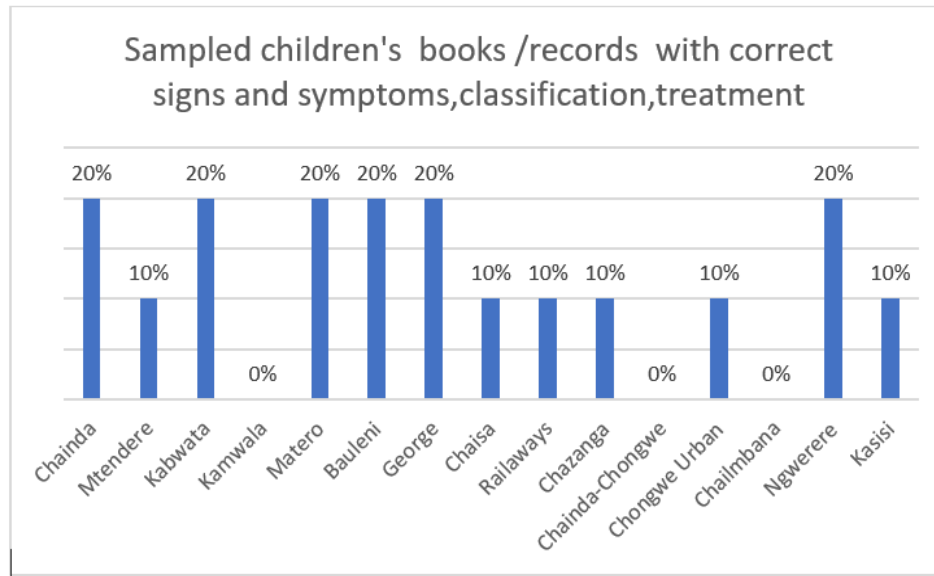


Figure 2. Percentage Distribution of Sampled Children’s Books /Records with Correct Signs and Symptoms, Classification, Treatment

Theme 2: Leadership and governance for IMNCI

Leadership and governance for IMNCI at health facility and District level

Leadership over the implementation of IMNCI at health facility and District Level- Findings from IDI revealed that all 15 health facilities and the 2 District Health offices visited had no specifically designated IMNCI Champion at Health facility and District level to provide day to day support to fellow health workers on IMNCI and to health facilities respectively. Lack of a Champion at health facility and District level resulted in lack of Programme oversight and ownership of the IMNCI Programme at health facility and District level.

“No, the health facility has no one to provide oversight over the IMNCI programme thus it presents a challenge when it comes to coordination and programme oversight” **Participant no .1**

No, we do not have a Health facility Lead for IMNCI at this facility to supervise IMNCI activities and ensure guidelines are adhered to.” **Participant no .7**

“There is no IMNCI Health facility focal point person or Champion to oversee the IMNCI Programme at our facility”

Participant no .5

“We do not have a designated IMNCI focal person for the district but I am able to cover this role since I coordinate Maternal Newborn and Child health in the district”.

Maternal New Born and Child health Coordinator no. 2.

At District level, in one districts IMNCI fell under the Maternal Newborn and Child Health (MNCH) Coordinator while in other District it fell under the Clinical Care Officer, but even then, these officers were charged with other responsibilities which often took precedence over IMNCI especially programmes that were well funded and easy to monitor such as Expanded Programme for Immunisation, HIV and TB. The supposedly IMNCI Champions were in some cases are not even trained and if trained, they were trained a long time ago such that it became difficult for them to successfully provide technical support to health facilities.

“Yes, I am trained in IMNCI but I was trained a long time ago in 2013 and I am not attended any refresher training from the time I was trained this it is difficult to provide

mentorship to recently trained staff”

Maternal New Born and Child health Coordinator no.1

This presents a very difficult situation; how do District focal point person provide Technical support to those trained in recent new IMNCI guidelines.

In terms of coordination, results from the study indicated that there were no specific coordination platforms for IMNCI as IMNCI was integrated in other platforms such as District Integrated management meeting where it was discussed and reviewed together with other programmes. At national level, the situation was different as there was a coordination team that provided leadership over the implementation of IMNCI, this was done through Child Health and IMNCI Technical working groups meetings, and this coordination platform has helped in terms of ensuring coordination and support for IMNCI among various partners across the country.

“At National level, we have a coordination team through Child Health and IMNCI Technical working groups which meet on a quarterly basis and this has helped in terms of ensuring coordination of various partners at national level in supporting IMNCI, However, inadequate funds continue to hamper efforts to improve the implementation of IMNCI”. **Chief IMNCI Officer**

Discussion

This study aimed to Identify Health systems barriers to implementation of the IMNCI strategy at health facility level from the perspectives of health workers and Health managers under specific objectives and emerging themes.

Theme 1: Health System barriers for effective implementation of IMNCI

Inadequate support from District Health Offices-Participants felt that health Centre in-charges tried their best to ensure all drugs,

equipment and supplies were available, but the major challenge was with the District health offices who were unable to provide them with the necessary support such as technical support, on-going on mentorship including materials for use during the assessment process. In contrast, some participants felt supported and encouraged to practice IMNCI as health facilities provided them with an environment that supports management of children, for example, having functional ORT corners for management of children with diarrhoea, and also provision of equipment such as thermometers, height boards and weighing scale. This is consistent with findings from other studies [18, 16].

Poor documentation and record keeping:

It is evident from this study that there are a lot of gaps in terms of documentation of assessment signs and symptoms, classifications and treatment as none of the health facility recorded a score of at least 95% of the records sampled. This situation could be attributed to health systems such as inadequate training of health workers in IMNCI, shortage of health workers thus making the few available health workers always rushing through the assessment process and not capturing the required information in their children's record books/cards. This presents a very difficult situation for assessment of quality of care provided to sick under five children as it is practically impossible to derive anything pertaining to IMNCI from Children's record books. The study also revealed the Non-configuration of the SMART care system with the IMNCI assessment algorithm as one of the barriers to practicing of IMNCI by health workers as the SMART care system was not configured according to the IMNCI algorithm, and this was compounded by the fact that most health facilities particularly in Lusaka had completely gone digital. This meant that health workers had to assess children according to the algorithm in the Smart care system and missed out important IMNCI assessment steps. Our

findings are similar to [19] which found Poor alignment between recording requirements of eIMCI and other clinic programmes increased participant's administrative workload, and also acted as a disincentive to eIMCI uptake, frequently leading participants to revert to paper IMCI which was quicker and where they felt more confident. In another study in Ethiopia, [20] found that the EMR was not comprehensive enough in that medical terminologies, diagnostic names and drug names were not found in the system, according to EMRs international standards.

Lack of Budgetary allocation for IMNCI-

The study found that there were no budget allocations specifically for IMNCI at both District and Health facility level. Funding when available supported integrated District health programmes. When it came to funding, usually other programmes such as Maternal, New Born and Child health particularly immunizations and also essential operational were prioritized at the expense of IMNCI. At National level, funds were inadequate to enable MoH conduct trainings and orientation to health workers, conduct technical supportive supervision and mentorship. Lack of budgetary allocation for IMNCI at District level has significantly hindered the effective implementation of IMNCI and has impacted various aspects of IMNCI, including training, supervision and provision of essential supplies. Our findings are line with other similar studies done globally which found inadequate budget allocation as a barrier to successful implementation of IMNCI [12, 15, 21].

Theme 2. Leadership and governance for IMNCI

Leadership and Governance-There were no specifically designated IMNCI Champion at Health facility and District level to provide support on IMNCI. Lack of a designated IMNCI Champion resulted in lack of Programme oversight and ownership on IMNCI at health facility and District level. At District

level, there were also disparities under which office IMNCI coordination fell, but even then, those assigned to manage IMNCI were charged with other responsibilities which often took precedence over IMNCI. In some cases, these officers were not even trained and if trained, they were trained a long time ago such that it became difficult for them to successfully provide technical support to health facilities. In terms of coordination, IMNCI was integrated in other platforms such as District Integrated management meeting while at national level, IMNCI was coordinated through the Child health and IMNCI Technical working groups, which helped in terms of ensuring coordination and support for IMNCI among various partners across the country. Our findings are supported by various studies which highlighted the problem of intergrating IMNCI into existing programmes, fragmentation of governance structures and donor shifts from IMNCI to ICCM [2, 13, 15, 21].

Limitations

This study employed a mixed methodology enabling the researcher to have a more detailed understanding of the research topic. However, the study, was limited to two districts namely Chongwe and Lusaka, and 15 facilities across the two districts and thus findings from this study could not be extrapolated to other districts of Zambia or beyond since the context could be different in the way health care services including IMNCI are provided. However, findings from this study could help Chongwe and Lusaka districts and Zambia as a whole to better understand key health systems barriers that impedes primary health care workers from adhering to the Integrated Management of New-Born and Child hood illnesses during the assessment of sick under five children.

The study has highlighted Health workers' perspectives on key Health system factors that impedes the implementation of IMNCI that could be common beyond the two districts. Furthermore, the study focused solely on health

system barriers to implementation of IMNCI and did not look at what motivates health workers to adopt and use IMNCI guidelines during the assessment of sick under five in Zambia, and also how community support and systems influences the use of IMNCI. There will be need to explore further the motivation for adoption and practice of IMNCI and community support and system required for effective implementation of IMNCI, it may be possible that the use of Key Informant Interviews might have influenced health workers to exaggerated their responses. However, this limitation may have been addressed by health facility assessment particularly the review of children's record books or cards to determine the application of IMNCI skills and Knowledge.

Conclusion and Recommendations

The purpose of this study was to explore key health system barriers from the perspective health workers to implementation of the IMNCI strategy for addressing under-five morbidity and mortality among at health facility level in Chongwe and Lusaka districts. From the study, it has been concluded that that non-adherence of health workers to IMNCI guidelines during assessment of Children under five in Lusaka and Chongwe, Zambia could be attributed to key health systems factors such as inadequate support and funding, Poor documentation and record Keeping, Poor leadership and Governance structures for IMNCI. In Zambia, currently there is limited evidence on health system barriers to adoption of IMNCI guidelines during assessment of under five children at Outpatient departments from the perspective of Health workers and managers, therefore this study provides insights and recommendations that this will enhance provision of health care for under five children in Zambia

This study proposes a focus on all Health system building blocks namely; Workforce, finance, Service delivery, Health Information

system, access to medicines and Leadership and governance rather than just focusing on service delivery as this will promote responsive and resilient health systems capable of promoting quality and equitable Universal child health care services and consequently improved wellbeing of children. This quite important as past efforts have focused mainly on ensuring availability of trained staff, capacity building and improving access to medical supplies and equipment, but this has not helped much. Strengthening of leadership and governance structures especially at District and Health facility levels will be key as this is where the gap is greatest as this will help in providing oversight and support towards implementation of all components of the IMNCI strategy at health facility level. Making funding available to support implementation and strengthening documentation and reporting alongside other building blocks will surely help the country attain its target of reducing under-five mortality rate from 61/1000 live births to 25/1000 live births by 2030.

Data Availability

Data supporting the conclusions of this article are available on request to Baleke Ngambi. The raw data that support the findings of this study will be made available to researchers upon request from corresponding Author.

Conflict of Interest

The authors declare that they have no conflict of interest.

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Authors's Contribution

Baleke Ngambi wrote the research proposal, developed the questionnaire, collected data, analysed the data and wrote the paper and interpreting of the findings as well as

participating on the preparation of the manuscript. Pamela Mwansa reviewed and provided input towards the research proposal, supervised the data collection, contributed to the interpretation of the findings, reviewed the paper and participated on the preparation of the manuscript. All authors read and approved the final manuscript.

Ethical Approval

Ethical clearance was obtained from University of Zambia Biomedical Research Ethics Committee (UNZABREC) ethical approval no. 5794-2024. The study was also cleared by Lusaka and Chongwe District Health

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Gestational Diabetes Mellitus in Guyana: Clinical Profiles, Obstetric Outcomes, and Predictors of Adverse Events — A Retrospective Cohort Analysis

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Abstract

Gestational diabetes mellitus (GDM) is a growing metabolic complication of pregnancy with significant public health implications in low- and middle-income countries. This retrospective cohort study characterises the clinical and obstetric profiles of 33 GDM-confirmed mothers who delivered at the Georgetown Public Hospital Corporation (GPHC), Guyana, in January to June 2017, and identifies predictors of adverse maternal and neonatal outcomes. Data were extracted from hospital charts using a standardised abstraction form covering sociodemographic, anthropometric, obstetric, glycaemic, and neonatal variables. The cohort had a mean age of 29.9 ± 6.6 years and was predominantly Afro-Guyanese (60.6%) and urban-dwelling (75.8%). Mean pre-pregnancy body mass index (BMI) was 32.1 ± 10.4 kg/m², with 57.6% classified as overweight or obese. Family history of diabetes was present in 21.2% of participants. Insulin monotherapy or combination regimens were used in 97.0% of cases. Caesarean section rate was 45.5%, and gestational hypertension was the most frequent complication, affecting 36.4% of the cohort. Macrosomia occurred in 15.2% of births (mean birth weight $3,392 \pm 676$ g). Breastfeeding was initiated by 84.8% of participants. Postpartum metabolic follow-up data were absent across all time points, representing a critical systemic gap. Findings underscore the need for preconception BMI screening, structured postpartum surveillance registries, and culturally tailored non-communicable disease prevention strategies for women with a history of GDM in Guyana.

Keywords: Caesarean Section, Caribbean Maternal Health, Gestational Diabetes Mellitus, Gestational Hypertension, Macrosomia, Postpartum Follow-Up.

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance with onset or first recognition during pregnancy, representing one of the most prevalent metabolic complications of gestation globally [1]. Prevalence estimates range from 5% to 20%, varying by diagnostic criteria, population characteristics, and regional epidemiological context [2]. Beyond immediate perinatal consequences—including macrosomia, birth

trauma, neonatal hypoglycaemia, and increased rates of operative delivery—GDM confers durable long-term risks for both mothers and offspring, including type 2 diabetes mellitus (T2DM), cardiovascular disease (CVD), and metabolic syndrome [3, 4].

In Guyana, as across the broader Caribbean, non-communicable diseases (NCDs) account for a substantial and growing proportion of the disease burden, against a background of socioeconomic constraints and variable

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healthcare access. The intersection of ethnic diversity—Indo-Guyanese, Afro-Guyanese, Amerindian, and Mixed populations—with dietary transitions, physical inactivity, and uneven healthcare access creates a complex risk environment for metabolic disorders during pregnancy [5]. Despite global recognition of GDM's implications, population-specific data on its burden, clinical management, and perinatal outcomes in Guyana remain extremely limited.

This study was conducted as the baseline analytical component of a broader 10-year retrospective investigation examining the long-term maternal and child health consequences of GDM in Guyana. The immediate objective is to characterise the clinical and obstetric profiles of GDM-affected mothers who delivered at the Georgetown Public Hospital Corporation (GPHC)—the country's principal tertiary referral centre—to identify predictors of adverse pregnancy outcomes, and to document gaps in the postpartum follow-up data infrastructure critical for long-term outcome assessment. Findings are expected to inform strengthened GDM screening protocols, postnatal surveillance frameworks, and evidence-based policy for maternal and child health in Guyana.

Materials and Methods

Study Design and Setting

A retrospective cohort study design was employed, drawing on chart-extracted data from the obstetrics and gynaecology records of the Georgetown Public Hospital Corporation (GPHC), Georgetown, Guyana. GPHC is the country's largest public tertiary hospital and the principal referral centre for high-risk obstetric cases nationally. The study focuses on the index delivery year of 2017, representing the earliest cohort within the planned 10-year retrospective window.

Study Population and Sampling

The source population comprised all women who delivered at GPHC between 1 January 2017 and 30 June 2017. Eligible participants were mothers with a confirmed GDM diagnosis documented in hospital records during the index pregnancy. Complete case-extraction was undertaken for 33 GDM-positive mothers identified from available chart records of a total of 42 GDM-positive mothers (78.57% of the total GDM pregnancies for the specified cohort) who comply with the inclusion criteria of the study. The GPHC Guidelines for diagnosis and treatment of diabetes in pregnancy, updates November 2013 include a FBS ≥ 92 mg/dl or following 2hr GTT with any of the following values FPG ≥ 92 1hr ≥ 180 2hr ≥ 155 .

Inclusion and Exclusion Criteria

Inclusion criteria: Women with a chart-confirmed GDM diagnosis during the index pregnancy who delivered at GPHC in January to June 2017.

Exclusion criteria: Records with no GDM status documentation; pre-gestational diabetes mellitus (Type 1 or Type 2 diabetes diagnosed prior to pregnancy); and records lacking both obstetric and neonatal outcome data.

Data Collection and Variables

Data were extracted from paper-based hospital charts using a standardised data abstraction form. Variables collected spanned five domains: (i) sociodemographic characteristics (age, ethnicity, education, occupation, residence); (ii) anthropometric and metabolic indices (pre-pregnancy weight, height, body mass index, fasting glucose, oral glucose tolerance test [OGTT] values); (iii) obstetric history (gravidity, parity, prior GDM, family history of diabetes and CVD); (iv) index pregnancy outcomes (GDM diagnosis date and method, treatment modality, gestational age at delivery, mode of delivery, birth weight, APGAR score, pregnancy complications, and breastfeeding initiation); and (v) postpartum

follow-up data (weight, fasting glucose, HbA1c at year-1, year-5, and year-10 time points; long-term diagnoses of T2DM, hypertension, CVD, and metabolic syndrome).

Variable Definitions

1. **Macrosomia:** Birth weight $\geq 4,000$ g.
2. **Preterm birth:** Delivery before 37 completed weeks of gestation.
3. **Gestational hypertension:** New-onset hypertension after 20 weeks of gestation without proteinuria, as documented in clinical records (defined as systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg, without significant proteinuria or other severe features of pre-eclampsia) [21, 24]. Lower Segment Caesarean Section (LSCS): surgical delivery via an incision through the lower uterine segment, preferred over classical caesarean section owing to reduced intraoperative blood loss and a lower risk of uterine rupture in subsequent pregnancies [22, 23].
4. **BMI classification:** Based on WHO criteria.

Statistical Analysis

Data were entered into a structured spreadsheet (Microsoft Excel 2019) with standardised variable coding. Continuous variables were summarised using means and standard deviations (SD). Categorical variables were described as frequencies and proportions. BMI was classified per World Health Organization (WHO) criteria: underweight (<18.5 kg/m²), normal (18.5–24.9), overweight (25.0–29.9), obese (30.0–34.9), and severely obese (≥ 35.0 kg/m²) [6]. Mixed coding

inconsistencies in raw chart data were standardised prior to analysis. Pregnancy complications were coded from free-text fields using pre-defined category definitions. All analyses were performed in Python (version 3.11) using the pandas and numpy libraries.

Ethical Approval

This study was conducted as part of a PhD research programme approved by the Ministry of Health Guyana Institutional Review Board, GPHC Research Committee and governed by Texila American University institutional research oversight. All data were de-identified; study IDs replaced hospital medical record numbers in all analytical datasets. No participant intervention or contact was involved in this retrospective record review.

Results

Sociodemographic Characteristics

Thirty-three women with confirmed GDM diagnoses were included in this analysis. Sociodemographic and baseline characteristics are presented in Table 1. The mean age at delivery was 29.9 years (SD 6.6; range 16–40). The cohort was predominantly Afro-Guyanese ($n=20$, 60.6%), followed by East Indian ($n=7$, 21.2%), other ethnicities ($n=4$, 12.1%), mixed ($n=1$, 3.0%), and Amerindian ($n=1$, 3.0%). Most participants resided in urban areas ($n=25$, 75.8%). Educational attainment was poorly documented (45.5% recorded as not stated); among those with documented education, secondary-level completion was most common ($n=7$, 21.2%). Family history of diabetes was present in seven participants (21.2%), and five (15.2%) reported a prior GDM pregnancy.

Table 1. Sociodemographic and Baseline Characteristics of GDM Mothers ($n=33$)

Characteristic	n (%)
Mean age (SD), years	29.9 (6.6)
Ethnicity: Afro-Guyanese	20 (60.6%)
Ethnicity: East Indian	7 (21.2%)
Ethnicity: Other / Mixed / Amerindian	6 (18.2%)
Urban residence	25 (75.8%)

Education: Secondary	7 (21.2%)
Education: Primary	6 (18.2%)
Education: University	4 (12.1%)
Family history of diabetes	7 (21.2%)
Family history of CVD	3 (9.1%)
Previous GDM	5 (15.2%)

Anthropometric and Metabolic Profile

Pre-pregnancy anthropometric data are summarised in Table 2. Mean pre-pregnancy BMI was 32.1 kg/m² (SD 10.4; range 14.9–51.8). Overweight and obesity (including severe obesity) were predominant, affecting 57.6% of participants with documented BMI. Three participants were underweight at pre-

pregnancy assessment. Ten records lacked sufficient data for BMI classification. Among the 10 participants with documented fasting glucose values, the mean was 124.4 mg/dL (SD 45.0)—substantially above the diagnostic threshold of 92 mg/dL recommended by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) [7]. OGTT data were available in a limited subset only.

Table 2. Anthropometric and Metabolic Characteristics

Parameter	Value	n with Data
Mean pre-pregnancy weight (SD), kg	74.0 (25.1)	26
Mean pre-pregnancy BMI (SD), kg/m ²	32.1 (10.4)	23
BMI: Underweight (<18.5)	3 (9.1%)	23
BMI: Normal (18.5–24.9)	2 (6.1%)	23
BMI: Overweight (25.0–29.9)	6 (18.2%)	23
BMI: Obese (30.0–34.9)	6 (18.2%)	23
BMI: Severely obese (≥35.0)	6 (18.2%)	23
BMI: Not documented	10 (30.3%)	—
Mean fasting glucose (SD), mg/dL	124.4 (45.0)	10
OGTT 1-hr documented	4 records (12.12%)	4
OGTT 2-hr documented	3 records (9.09%)	3

Obstetric History and GDM Management

Gravidity ranged from primigravida to grand multipara (gravidity 6). Five participants (15.2%) had a documented previous GDM pregnancy. Insulin monotherapy was the most

frequently employed treatment modality (n=20, 60.6%), followed by diet plus insulin combination (n=5, 15.2%) and insulin-metformin combinations (n=5, 15.2%). Table 3 summarises treatment distribution across the cohort [8, 9].

Table 3. GDM Treatment Modalities (n=33)

Treatment Modality	n	%
Insulin (monotherapy)	20	60.6%
Diet + Insulin	5	15.2%
Insulin + Metformin	5	15.2%
Metformin (monotherapy)	1	3.0%

Insulin + Exercise	1	3.0%
Exercise + Insulin	1	3.0%

Delivery and Neonatal Outcomes

Mean gestational age at delivery was 37.8 weeks (SD 2.2). Mode of delivery was split between spontaneous vaginal delivery (SVD; n=18, 54.5%), lower segment caesarean section (LSCS; n=15, 45.5%), and vaginal delivery (n=2, 6.1%), yielding an overall operative delivery rate of 45.5%. Mean birth weight was

3,392 grams (SD 676 g; range 2,200–4,800 g). Macrosomia (birth weight $\geq 4,000$ g) was recorded in five cases (15.2%), with one extreme case of 4,800 grams. APGAR scores were optimal (9 or 10 at 5 minutes) for the majority of neonates. Breastfeeding was initiated in 28 participants (84.8%). Delivery and neonatal outcomes are detailed in Table 4 [10, 11].

Table 4. Delivery and Neonatal Outcomes (n=33)

Outcome	Value
Mean gestational age at delivery (SD), weeks	37.8 (2.2)
Delivery mode: SVD (Spontaneous Vaginal Delivery)	18 (54.5%)
Delivery mode: LSCS (Lower Segment Caesarean Section)	15 (45.5%)
Mean birth weight (SD), grams	3,392 (676)
Macrosomia ($\geq 4,000$ g)	5 (15.2%)
Minimum birth weight, grams	2,200
Maximum birth weight, grams	4,800
Breastfeeding initiated	28 (84.8%)

Pregnancy Complications

Pregnancy complications were recorded from free-text chart entries. Gestational hypertension (GHTN) was the most prevalent complication, affecting 12 participants (36.4%). Macrosomia was present in five cases

(15.2%), preterm birth in three (9.1%), intrauterine growth restriction (IUGR) in one (3.0%), postpartum haemorrhage (PPH) in one (3.0%), and severe anaemia in one (3.0%). Several participants had concurrent complications. Table 5 presents complication frequencies [12, 13].

Table 5. Frequency of Pregnancy Complications (n=33)

Complication	n	%
Gestational hypertension (GHTN)	12	36.4%
Macrosomia	5	15.2%
Preterm birth	3	9.1%
Perineal lacerations (2nd/4th degree)	2	6.1%
Intrauterine growth restriction (IUGR)	1	3.0%
Postpartum haemorrhage (PPH)	1	3.0%
Severe anaemia (Hb 5.3 g/dL)	1	3.0%
Shoulder dystocia	1	3.0%
Failed induction/augmentation	1	3.0%

Postpartum Follow-Up Data

Postpartum surveillance data were critically limited across all follow-up time points. At the 1-year postpartum visit, most records contained only a date notation (e.g., '6 weeks', '2 weeks') or the entry 'NS' (not stated), with no metabolic values recorded. At year-5 and year-10 follow-up windows, all fasting glucose, HbA1c, and diagnostic outcome fields (T2DM, hypertension, CVD events, metabolic syndrome) were entirely empty across the cohort. Postpartum contraception was documented in only five participants: three bilateral tubal ligation (BTL) and two intrauterine device (IUD) insertions. This represents a fundamental gap in the longitudinal data infrastructure.

Discussion

This retrospective cohort analysis of 33 GDM-confirmed mothers at GPHC reveals several clinically significant patterns. The cohort was characterised by high pre-pregnancy overweight and obesity prevalence (57.6% combined), a mean BMI substantially above healthy range (32.1 kg/m²), a family history of diabetes in over one-fifth of participants, a caesarean delivery rate exceeding 45%, and gestational hypertension in over one-third. Macrosomia was recorded in 15.2% of births. These findings are broadly consistent with—and in several parameters exceed—published rates from comparable low- and middle-income Caribbean settings [14, 15].

When considered collectively, the data across all five tables point to a pattern that extends beyond individual clinical findings. A pharmacologically managed, high-risk population was identified and actively treated during pregnancy, yet the absence of any postpartum metabolic follow-up data suggests that structured long-term care was not provided after delivery. The sections that follow examine what these findings indicate about GDM care delivery, postpartum surveillance, and NCD prevention within the Guyanese health system.

The baseline and clinical data shown in Tables 1-3 characterize a cohort whose individual risk variables significantly increase the trajectory toward postpartum type 2 diabetes mellitus (T2DM) because they are mutually reinforcing rather than acting independently.

Over 80% of participants belong to groups—Afro-Guyanese and East Indian—for whom GDM-to-T2DM progression rates are documented to be two to four times higher than those of White counterparts [25, 26]. Yet these groups are not homogeneous in mechanism: Afro-Guyanese women face compounded structural vulnerability through differential access to preventive care and higher baseline hypertension prevalence [27], while East Indian women carry a physiologically distinct susceptibility [28].

Elevated pre-pregnancy BMI and associated insulin resistance are established contributors to GDM severity. In this cohort, 54.4% of women with documented BMI were obese or severely obese, and the mean fasting glucose at diagnosis of 124.4 mg/dL substantially exceeded the IADPSG threshold of 92 mg/dL, indicating that glucose dysregulation was marked at the point of diagnosis [29]. The high proportion of women requiring insulin (97% of pharmacologically treated cases) is consistent with this degree of hyperglycaemia and with published evidence that insulin requirement during a GDM pregnancy is associated with greater underlying metabolic impairment and a higher risk of postpartum T2DM [6]. Gestational hypertension (36.4%) and macrosomia (15.2%) add further dimensions to the postpartum risk profile of this cohort, both being associated with adverse long-term cardiovascular and metabolic outcomes in women with prior GDM [27, 28, 31].

GHTN was documented in 36.4% of this GDM cohort, substantially higher than general obstetric population estimates of 6–10% in the Caribbean region [12]. The co-occurrence of GDM and hypertensive disorders of pregnancy

reflects shared pathophysiological pathways involving placental dysfunction, endothelial injury, and oxidative stress [16]. This co-occurrence amplifies maternal cardiovascular risk trajectories postpartum, with direct implications for the long-term follow-up component of this research programme. The absence of documented long-term hypertension outcomes in this dataset underscores an urgent need to establish structured postpartum cardiovascular surveillance.

Lower Segment Caesarean Section (LSCS) was performed in 45.5% of cases [22, 23]. The 45.5% caesarean section rate substantially exceeds the WHO's recommended population-level caesarean rate of 10–15% [17] and is consistent with rates reported from high-risk GDM populations in the Caribbean and Latin America [18]. Macrosomia—present in 15.2% of this cohort—directly increases the likelihood of cephalopelvic disproportion and operative delivery. The downstream public health cost of elevated caesarean rates warrants targeted clinical guideline development at GPHC.

Insulin dominated the treatment landscape, used in 97.0% of the cohort in some form. This reflects GPHC's role as a tertiary facility managing complex obstetric cases. The limited use of metformin as monotherapy (one case) is notable, given accumulating evidence of comparable glycaemic efficacy for metformin in GDM with a more favourable cost and administration profile [19]. As Guyana's clinical guidelines evolve, expanded metformin uptake in appropriate patient subgroups may enhance treatment accessibility in resource-constrained settings.

Breastfeeding was initiated in 84.8% of participants—a rate that exceeds global averages and is a positive finding in this cohort. Breastfeeding is associated with reduced maternal T2DM risk following GDM and with reduced offspring adiposity and metabolic risk, making it a potentially protective modifiable factor of direct relevance to long-term outcome

analyses planned for subsequent study phases [20].

Structured postpartum follow-up is a recognised component of GDM management, spanning postnatal metabolic review, primary care handover, and longer-term NCD surveillance. Chen and Zhu (2024) note that adherence to postpartum metabolic screening remains poor across settings, with neither obstetric nor primary care services consistently taking responsibility for this follow-up phase [27]. The findings of this study are consistent with that observation. Women who used insulin during pregnancy, delivered macrosomic infants, experienced gestational hypertension, or had a prior GDM history — characteristics associated with heightened risk of postpartum T2DM — had no recorded metabolic outcomes at any follow-up time point. Chen and Zhu (2024) identify the first three to six postpartum years as the period during which T2DM risk is highest and preventive intervention is most likely to be effective [27]. Kramer et al. (2021), in a systematic review and meta-analysis of postpartum intervention studies, found that structured lifestyle programmes and pharmacological approaches including metformin are associated with meaningful reductions in T2DM progression in women with prior GDM [6, 30]. The absence of any postpartum follow-up documentation in this dataset indicates that this preventive window was not utilised, and that the infrastructure to support it was not in place at the time of the study.

The extent of missing data across this cohort reflects practical limitations of the paper-based recording system in use at GPHC during the study period. Educational attainment was unrecorded in 45.5% of participants; BMI was undocumented in 30.3%; fasting glucose values were absent in 70% of records; and OGTT results were recorded for fewer than 12% of the cohort. These gaps affect variables directly relevant to risk stratification and postpartum care planning. In the absence of an integrated

electronic health record or a minimum dataset standard for GDM, it is not possible to reliably link a woman's obstetric history to her subsequent primary care encounters, limiting the ability of community-level providers to identify women who may benefit from postpartum metabolic screening. Establishing a structured GDM register and standardising data capture for key metabolic and sociodemographic variables would support more effective longitudinal follow-up and enable generation of local burden estimates to guide health system planning.

GDM represents a well-defined period of elevated NCD risk during which women are in active contact with the health system, creating a practical opportunity for preventive intervention. Lavery et al. (2017) have noted that the antenatal and immediate postpartum period is associated with heightened health awareness and behavioural engagement [32]. The women in this cohort were identified, diagnosed, and treated during pregnancy, establishing a clinical record that documented risk factors for postpartum T2DM. Progression from gestational hyperglycaemia to overt T2DM is associated with serious long-term complications including cardiovascular disease, retinopathy, nephropathy, and recurrent GDM in subsequent pregnancies [28, 29]. In a health system with limited specialist endocrinology and nephrology capacity, primary prevention through postpartum screening and early lifestyle intervention is particularly relevant. Practical steps such as a standardised GDM discharge plan, a postpartum OGTT as a routine quality indicator, and linkage of obstetric and primary care records could support more systematic follow-up of women with a GDM history, without requiring substantial additional infrastructure investment.

The ethnic distribution of this cohort reflects the composition of the GPHC obstetric population, with Afro-Guyanese women comprising the majority of GDM cases

(60.6%). This is relevant to postpartum risk assessment, as published data indicate that Black and Afro-Caribbean women have higher rates of T2DM progression following GDM than White women, a difference attributed to a combination of physiological factors including adiposity patterns and inflammatory profiles, as well as sociostructural determinants such as healthcare access and dietary environment [33, 34]. Krieger's ecosocial framework offers a useful theoretical lens for understanding how social and structural conditions become embedded in health outcomes over time [37]. Within this context, GDM management focused solely on glycaemic control during pregnancy may be insufficient to address the longer-term metabolic risk trajectory of Afro-Guyanese women, for whom postpartum follow-up and lifestyle support may be particularly important.

East Indian women, comprising 21.2% of this cohort, represent a population for whom standard BMI-based risk thresholds may underestimate metabolic risk. Research on South Asian populations has identified a tendency toward greater visceral adiposity relative to total body mass, which is associated with insulin resistance and impaired glucose metabolism at BMI values below conventional obesity thresholds [35]. Rayanagoudar et al. (2016), in a meta-analysis of 95,750 women, found that non-white ethnicity was associated with a higher risk of T2DM following GDM [31]. These findings suggest that ethnicity-informed risk stratification, rather than BMI-based criteria alone, would be more appropriate for prioritising postpartum follow-up in this population.

The near-complete absence of socioeconomic data in this cohort is a methodological limitation with practical implications for postpartum risk management. Variables such as household income, educational attainment, food security, and proximity to health services are recognised determinants of postpartum OGTT uptake, adherence to lifestyle modification, and access

to pharmacological prevention [36]. McCarthy et al. (2023) found that clinical and social characteristics at delivery partially accounted for racial differences in post-GDM T2DM incidence and noted that more granular socioeconomic measurement would be needed to understand these disparities more fully [26]. Janevic et al. (2023) similarly documented significant ethnic variation in T2DM development after GDM [25]. Routine collection of standardised sociodemographic and social determinants data within the GDM antenatal record would enable more targeted postpartum follow-up and improve identification of women most at risk of being lost to follow-up after delivery.

Improving the collection of socioeconomic data within the GDM care pathway would require the systematic inclusion of a standardised minimum dataset within the antenatal record — capturing variables such as income quintile, educational attainment, household food security, housing stability, and proximity to health services — and carrying this information forward into postpartum follow-up documentation. Without such data, it is not possible to identify which women face the greatest structural barriers to attending postpartum screening, sustaining lifestyle changes, or accessing preventive medications. Ethnicity and socioeconomic position do not merely modify an individual's biological risk; they also shape whether the health system's response to that risk is accessible in practice. Targeted postpartum follow-up, informed by these determinants, would be a more equitable and effective approach than universal protocols applied without regard to the structural differences in how women experience care after GDM.

Limitations

Several limitations require acknowledgement. First, the retrospective chart-based design is constrained by documentation practices at the time of care; a

substantial proportion of records had key variables entered as 'not stated', particularly metabolic parameters and sociodemographic data. Second, the absence of a contemporaneous non-GDM control group precludes formal comparative analysis of complication rates. Third, the relatively small sample size ($n=33$) limits statistical power for multivariable modelling. Fourth, the study is restricted to GPHC and may not represent GDM management across private facilities or rural settings in Guyana. These limitations will be systematically addressed in the broader 10-year retrospective study design.

Conclusion

This baseline cohort analysis establishes the clinical and obstetric profile of GDM-affected mothers at GPHC, Guyana, and lays the empirical foundation for a 10-year retrospective investigation of long-term maternal and child outcomes. Key findings—including high pre-pregnancy obesity rates, elevated gestational hypertension and caesarean section rates, macrosomia in one in six births, and predominantly insulin-based management—have direct implications for clinical guidelines and preventive programming in Guyana's public health system.

Critically, the complete absence of postpartum metabolic follow-up underscores a systemic gap in the GDM care continuum requiring structural health system strengthening. Recommendations arising from this analysis include: (i) implementation of standardised pre-pregnancy BMI screening and counselling within antenatal care platforms; (ii) establishment of a dedicated GDM postpartum follow-up registry at GPHC; (iii) integration of annual fasting glucose and HbA1c monitoring into routine maternal health services for women with prior GDM; and (iv) development of culturally and ethnically tailored lifestyle modification programmes to interrupt the pathway from GDM to T2DM and cardiovascular disease. Future phases of this

research will incorporate prospective participant follow-up surveys and linkage with national health registries to generate the first comprehensive long-term GDM outcome data for Guyana.

Conflict of Interest

The authors declare that there is no conflict of interest.

Ethical Approval

This study was approved by the Institutional Review Board, Ministry of Health, Guyana, the Georgetown Public Hospital Corporation Research Committee and conducted under Texila American University PhD programme governance. All data were de-identified prior to analysis in accordance with institutional ethical standards for retrospective record review.

Author Contributions

Samantha N.A. Kennedy: conceptualisation, data curation, formal analysis, writing—original draft. Michael Tomori: supervision, co-author. Abiodun Olaiya Paul: methodology, writing—review and editing.

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Data Availability

The de-identified dataset supporting the findings of this study is available from the corresponding author upon reasonable request, subject to institutional data governance requirements.

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Telemedicine, Access, and Referral Burden in Guyana's Hinterland Regions: A Retrospective Study, 2022–2026

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Abstract

Healthcare access in Guyana's hinterland regions is constrained by geographic isolation, long travel distances, high transport costs, and limited specialist availability at peripheral facilities. Telemedicine has emerged as a strategy to bridge these gaps by enabling remote consultation, supporting local clinical decision-making, and reducing unnecessary patient referrals. This retrospective descriptive study analyzed annual program data and site-level operational records from the national telemedicine program across Guyana's hinterland from 2022 to 2026. Key indicators included communities served, telemedicine calls, patient visits, serious cases, critical care encounters, remote ultrasound examinations, medical evacuations, and hospital referrals eliminated. The program expanded from 4 communities in 2022 to 130 in 2026. Telemedicine calls increased from 55 to approximately 2,500, and patient visits from 84 to approximately 25,000. Patient visits per community rose from 21.0 in 2022 to 192.3 in 2026, indicating deepening service intensity beyond geographic expansion. Serious cases increased from 11 to approximately 850, critical care encounters reached approximately 200, and remote ultrasound use grew from 106 in 2024 to approximately 800 in 2026. Hospital referrals eliminated increased from 423 in 2024 to approximately 1,900 in 2026. Medical evacuations remained stable despite growing clinical volumes. These findings indicate that Guyana's hinterland telemedicine program achieved meaningful improvements in access, supported local management of complex clinical presentations, and contributed to referral burden reduction. Implementation quality and local integration appear to mediate utilization beyond geography alone. Future research should evaluate patient-level outcomes, referral appropriateness, and household cost savings.

Keywords: *Access to Healthcare, Guyana, Hinterland, Referral Burden, Telemedicine.*

Introduction

Healthcare Access in Guyana's Hinterland

Healthcare access in Guyana's hinterland regions is shaped by a geography that makes routine clinical contact extraordinarily difficult. The hinterland encompasses Regions 1, 7, 8, 9, and parts of Regions 5, and 10, covering vast forested and riverine territories with dispersed indigenous Amerindian communities connected by limited road networks, seasonal

river routes, and occasional airstrips. Travel to the nearest hospital from many hinterland communities [15, 17] requires between 4 and 14 working days of combined travel, imposes costs of GY\$6,000 to GY\$200,000 per round trip, and compels patients to lose multiple workdays [1, 2]. These structural barriers translate directly into avoidable delays in diagnosis and treatment, disrupted continuity of care for chronic conditions, and preventable deterioration in cases requiring timely specialist input.

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Prior to scaling telemedicine, peripheral health posts in the hinterland were staffed predominantly by community health workers and medexes operating without specialist support, reliable diagnostic equipment, or functional referral communications. The default clinical response to any case exceeding local capacity was physical referral to Georgetown or district hospitals, a pathway that was costly, slow, and frequently declined by patients unable to bear the associated burden [3]. The result was a two-tier system in which the de facto quality of care available to hinterland communities was substantially lower than that in the coastal urban zone.

Telemedicine as an Access Strategy

Telemedicine is the use of information and communications technology to deliver clinical services across geographic distance. It has been increasingly deployed in low-resource and remote settings to extend specialist reach, support local health workers, enable remote diagnostic assistance, and reduce unnecessary referrals [4, 5]. In Latin American and Caribbean contexts, telemedicine programs have demonstrated capacity to improve maternal and neonatal outcomes, increase management of chronic non-communicable diseases at primary level, and reduce emergency evacuation rates in geographically isolated settings [6, 7].

Guyana's national hinterland telemedicine program deployed digital health kits that include Basic, Advanced, and Connectivity Only configurations at health posts, health centers, and district hospitals across the hinterland. These kits enabled synchronous video consultation between peripheral health workers and Georgetown-based specialists, facilitated remote ultrasound examination using point-of-care devices, and provided platforms for case documentation and referral tracking. The program expanded from a pilot of 4 communities in October 2022 to a network of 130 communities by 2026 [1].

Study Objectives

Despite the program's rapid scale-up, peer-reviewed descriptive analysis of its utilization patterns, service intensity trends, and system-level effects on referral burden remained limited. This study analyzed annual program data and site-level records from 2022 to 2026 to:

1. Characterize the scale and intensity of telemedicine service delivery;
2. Assess trends in clinical acuity and diagnostic reach; and;
3. Examine system-level indicators including hospital referrals eliminated and medical evacuations.

The primary research hypothesis was:

1. H₁: Expansion of telemedicine in Guyana's hinterland between 2022 and 2026 was associated with increased healthcare access and measurable reduction in hospital referral burden, as evidenced by growth in patient visits per community, serious case management, and referrals eliminated per call.

Methods

Study Design

This was a retrospective descriptive study analyzing annual program summary data and site-level operational records covering program inception in October 2022 through December 2026. Full annual data were available for 2022 through 2025; 2026 figures are projections based on January 2026 actuals. Because the analysis used programmatic administrative data without a concurrent comparison group, findings are interpreted as descriptive program evidence rather than causal impact estimates.

Data Sources

Data were extracted from the National Telemedicine Program Dashboard containing:

1. An Overview sheet with annual program-level indicators;

2. A Detailed Overview sheet providing site-level data including region, location, coordinates, installation date, population, kit type, facility level, annual call and visit counts, estimated travel cost to hospital, average travel time, and working days lost to travel;
3. Year-specific Usage sheets (2022–2026) with device-level performance data including sessions, calls, encounters, and sensor utilization; and;
4. A Calls to Date sheet with individual call-level records. Site-level 2025 data were used for facility-level analysis given data completeness.

Variables and Derived Indicators

Primary indicators extracted from the Overview sheet included: total communities served, new communities installed, telemedicine calls, patient visits, critical care encounters, medical evacuations, serious cases, remote ultrasound patients, and hospital referrals eliminated. Derived service intensity indicators computed for each year included: calls per community, visits per community, visits per call, serious cases per call, evacuations per call, and referrals eliminated per call where data were available. Travel time to hospital (hours) and travel cost (GYD) were used as contextual variables in site-level interpretation.

Data Analysis

All analyses were descriptive. Annual indicator trends were examined across five years and presented in tabular and ratio form. Derived intensity ratios assessed whether utilization deepened within communities as the network expanded. Site-level 2025 data were reviewed to characterize utilization

heterogeneity across facilities and explore the relationship between utilization volume and travel burden. Where 2026 values were projections, this was noted explicitly. Indicators reported as ‘no data’ were treated as missing rather than zero. No inferential statistics were applied, as this was a complete census of program administrative records.

Ethical Considerations

This study analyzed de-identified aggregate administrative program data maintained by the National Telemedicine Program. No individual patient identifiers were accessed or reported. Secondary analysis of operational records for quality improvement and research was conducted in accordance with Texila American University research ethics guidelines. No direct patient contact or primary data collection was conducted.

Results

Program Expansion and Network Growth

The telemedicine program expanded from 4 communities at inception in October 2022 to 26 in 2023, 63 in 2024, 85 in 2025, and 130 in 2026. A 32-fold increase in network coverage over four years (Table 1). New site installations were highest in 2024 (37 new sites) and 2026 (45 new sites). By 2026, the network spanned Regions 1, 4, 5, 6, 7, 8, 9, and 10, with deepest coverage in Regions 1, 7, 8, and which are the most geographically remote hinterland areas. Estimated hospital travel costs at installed sites ranged from GY\$6,000 to GY\$200,000, and average travel times ranged from 2 to 336 hours, confirming that the program reached communities with extreme geographic isolation.

Table 1. Annual Telemedicine Program Indicators, Guyana Hinterland, 2022–2026

Year	Communities	New Sites	Calls	Visits	Critical Care	Evacuations	Serious Cases	Ultrasound	Referrals Elim.
2022	4	4	55	84	No data	No data	11	No data	No data

2023	26	22	443	2,572	No data	65	226	No data	No data
2024	63	37	658	8,993	56	37	273	106	423
2025	85	22	1,293	~15,000*	82	38	501	383	445
2026	130	45	~2,500†	~25,000†	~200†	~67†	~850†	~800†	~1,900†
Total	130	130	~4,949	~51,649	—	~207	~1,861	—	—

**Estimate due to data capture interruption during technology transition in early 2025. †Projected from January 2026 figures.*

Service Volume and Utilization Trends

Total telemedicine calls increased 45-fold over the study period: from 55 in 2022 to 443 in 2023, 658 in 2024, 1,293 in 2025, and approximately 2,500 in 2026. Patient visits grew even more sharply 298 fold from 84 in 2022 to approximately 25,000 in 2026. The ratio of visits to calls increased from 1.53 in

2022 to 13.67 in 2024 (Table 2), indicating that each telemedicine contact supported a substantially larger number of patient encounters as the program matured. Patient visits per community rose from 21.0 in 2022 to 192.3 in 2026, demonstrating deepening service intensity beyond mere geographic expansion. Calls per community increased from 13.75 to 19.23 over the same period.

Table 2. Derived Service Intensity Indicators, Guyana Hinterland Telemedicine Program, 2022–2026

Year	Calls per Community	Visits per Community	Visits per Call	Serious Cases per Call	Evacuations per Call	Referrals Elim. per Call
2022	13.75	21.00	1.53	0.20	No data	No data
2023	17.04	98.92	5.81	0.51	0.15	No data
2024	10.44	142.75	13.67	0.41	0.06	0.64
2025	15.21	176.47	11.60	0.39	0.03	0.34
2026	19.23	192.31	10.00	0.34	0.03	0.76

Clinical Acuity and Diagnostic Reach

The program’s clinical profile became more complex over time. Serious cases managed through telemedicine increased from 11 in 2022 to 226 in 2023, 273 in 2024, 501 in 2025, and approximately 850 in 2026. The serious cases per call ratio declined from 0.51 in 2023 to 0.34 in 2026, reflecting that volume growth increasingly incorporated lower-acuity contacts alongside complex case management consistent with a maturing primary care function rather than exclusive emergency use. Critical care encounters numbered 56 in 2024, 82 in 2025, and approximately 200 in 2026, indicating progressive use of the platform for the most clinically urgent presentations. Remote ultrasound grew from 106 examinations in 2024

to 383 in 2025 and approximately 800 in 2026, representing a qualitative expansion in diagnostic scope at the community level with particular significance for maternal and obstetric care.

System-Level Effects: Referrals Eliminated and Evacuations

Hospital referrals eliminated totaled 423 in 2024, 445 in 2025, and approximately 1,900 in 2026. The referrals eliminated per call ratio was 0.64 in 2024 and recovered to 0.76 in 2026, suggesting that approximately three in four telemedicine calls in 2026 were associated with a hospital visit avoided. Medical evacuations remained comparatively low and stable: 65 in 2023, 37 in 2024, 38 in 2025, and approximately 67 in 2026. Evacuations per call

decreased from 0.15 in 2023 to 0.03 in both 2025 and 2026, indicating that the proportion of telemedicine contacts requiring emergency physical transfer decreased as the program matured.

Site-Level Heterogeneity

Site-level analysis of 2025 data revealed substantial variation across communities (Table 3). The highest-volume facilities included R7 Paruima (906 patient visits, 73 calls), R7 Phillipai (669 visits, 57 calls), R7 Arau (644 visits, 70 calls), and R1 Santa Cruz (459 visits,

140 calls). Notably, travel time to hospital did not show a straightforward linear relationship with utilization [15-17]: R10 Hururu, with a 24-hour travel time, recorded 775 visits, while several sites with similar or longer travel times recorded minimal activity. This suggests that local implementation factors, including health worker engagement, training quality, community trust, kit functionality, and connectivity reliability—were significant mediators of utilization beyond geography alone.

Table 3. Top Facilities by Patient Visits, Guyana Hinterland Telemedicine Program, 2025

Facility	Region	Visits 2025	Calls 2025	Travel Time (h)	Travel Cost (GYD)	Kit Type
R7 Paruima	7	906	73	24	110,000	Advanced
R10 Hururu	10	775	29	24	15,000	Basic
R7 Phillipai	7	669	57	30	81,000	Advanced
R7 Arau	7	644	47	N/A	N/A	Advanced
R1 Santa Cruz	1	459	140	N/A	N/A	Advanced
R8 Paramakatoi	8	380	45	N/A	N/A	Advanced
R5 Moraikobai	5	198	18	4	N/A	Basic
R9 Fairview	9	189	87	48	16,000	Basic
R7 Waramadong	7	197	54	N/A	N/A	Advanced
R9 Shulinab	9	317	74	N/A	N/A	Advanced

Discussion

Telemedicine as a Bridge to Care

The findings demonstrate that Guyana's hinterland telemedicine program achieved meaningful expansion in both geographic coverage and actual service use between 2022 and 2026. The dramatic increase in visits per community from 21.0 to 192.3 confirms that the program became progressively embedded in routine clinical practice rather than remaining episodic or emergency only [4, 5]. For communities where hospital access requires days of travel at costs representing a significant share of household income, this embedding into routine care represents a qualitative

transformation in locally available health services. This finding is consistent with telemedicine effectiveness evidence from Brazil's Rede Universitária de Telemedicina, which demonstrated reduced emergency transfers in the Amazon region, and from Canada's northern telehealth networks showing sustained chronic disease care continuity for indigenous communities [11, 12].

Clinical Scope and Referral Burden

Growth in serious cases, critical care encounters, and remote ultrasound indicates that the program extended its clinical scope beyond low-acuity consultations [6]. The declining serious case per call ratio from 0.51

in 2023 to 0.34 in 2026 correctly reflects program maturation. A larger proportion of contacts represented routine primary care (antenatal follow-up, chronic disease monitoring) alongside complex case management, which is the expected pattern of a maturing service [8]. The approximately 1,900 hospital referrals eliminated in 2026, with a referrals-eliminated-per-call ratio of 0.76, indicates that telemedicine was associated with a hospital visit avoided in approximately three of four clinical contacts. A finding consistent with the telemedicine effectiveness literature from comparable remote settings [6, 7]. Stable evacuation rates despite tenfold volume growth further support the interpretation that telemedicine enabled earlier recognition and local stabilization, reducing the proportion of cases progressing to emergency transfer [4, 5].

Implementation Quality and Site-Level Variation

Substantial site-level heterogeneity confirms that geography creates the need for telemedicine but does not determine utilization [10]. Local implementation factors such as health worker engagement and confidence, connectivity reliability, equipment uptime, community trust, and integration into daily clinical workflows appear to be proximal determinants of uptake. This finding aligns with implementation science literature emphasizing that fidelity to implementation protocols, local adaptation, and staff training quality are stronger predictors of service uptake than structural availability alone [10]. High-utilization sites provide a natural model for identifying and systematically supporting implementation practices across the network.

Limitations

This study has six limitations. First, it is a retrospective descriptive analysis without a concurrent control group, limiting causal attribution. Second, 2026 data are projections from January figures. Third, 2025 patient visit

data are estimates due to a technology transition data capture gap. Fourth, operational definitions of ‘serious cases’ and ‘hospital referrals eliminated’ are not formally specified and may vary across sites and time. Fifth, no patient-level clinical outcomes or diagnoses are available, preventing assessment of clinical effectiveness. Sixth, site-level travel-burden correlations were exploratory without confounding adjustment. These limitations mean findings should be read as strong descriptive program evidence rather than definitive proof of causal impact.

Public Health and Policy Implications

The data support sustained investment in Guyana’s hinterland telemedicine program. With 130 communities served by 2026 and evidence of deepening clinical utility and referral burden reduction, the program has demonstrated proof of concept at national scale. The next phase should focus not only on further network expansion but on improving quality, reliability, and clinical depth at existing sites: investing in connectivity uptime through satellite and solar-powered backup systems, ensuring equipment maintenance contracts with service-level agreements, and providing ongoing health worker training in telemedicine-supported clinical protocols [2, 9].

The finding that implementation quality mediates utilization beyond geography creates both a challenge and an opportunity. A structured implementation support program including site visits, peer learning between high and low performing communities, health worker coaching, and community engagement could improve utilization at underperforming sites without additional capital investment [10]. The program’s utilization records provide the foundation for a monitoring dashboard enabling the Ministry of Health to identify priority support sites on an ongoing basis.

Telemedicine must be understood as a component of not a substitute for the broader Universal Health Coverage strategy. It

addresses the distance barrier to specialist consultation and diagnostic support but does not resolve deficits in physical infrastructure readiness, essential medicine supply, health worker distribution, or referral transport [3, 13]. Effective integration within the UHC agenda requires linkage with primary health care strengthening, reliable supply chain, culturally safe care practices for indigenous communities, and a functional referral and transport system that can act on the clinical decisions telemedicine enables [13, 14].

Conclusion

Guyana's hinterland telemedicine program achieved substantial growth in geographic coverage and clinical service delivery between 2022 and 2026. Growth in visits per community, serious case management, remote ultrasound use, and hospital referrals eliminated alongside stable medical evacuation rates despite rapidly expanding clinical volume is consistent with improved healthcare access, local management of complex clinical presentations, and referral burden reduction for some of the most geographically isolated communities in the region [18]. These findings suggest that access in remote settings depends not only on geography and transport barriers, but also on service delivery capacity and the availability of appropriately skilled personnel [19]. Site-level heterogeneity confirms that implementation quality and local integration are key determinants of actual utilization beyond geography alone [20]. Future research should evaluate patient level outcomes, referral appropriateness, timeliness, household cost savings, and health worker experience. Investment in implementation quality, connectivity reliability, and integration with the UHC agenda will be essential to ensure geographic reach translates into equitable, effective care for all hinterland communities.

Conflict of Interest

The authors declare no conflict of interest.

Ethical Approval

This study analyzed de-identified aggregate administrative program data maintained by the Ministry of Health of Guyana's national telemedicine program. No individual patient identifiers were accessed. Secondary analysis of operational records for research and quality improvement was conducted in accordance with Texila American University research ethics guidelines. No direct patient contact or primary data collection was involved.

Author Contributions

Aruna Faria: Conceptualization, data curation, formal analysis, writing original draft, writing review and editing.

Abiodun Olaiya Paul: Supervision, methodology, writing review and editing.

Data Availability

The data supporting this study are derived from the national telemedicine program operational dashboard maintained by the Ministry of Health of Guyana. Aggregate de-identified program data are available from the corresponding author upon reasonable request and subject to Ministry of Health approval.

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Epidemiological Trends of Dengue Fever Across Administrative Regions of Guyana, 2020–2022: A Cross-Sectional Analysis of Confirmed Case Data

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Abstract

Dengue fever remains a significant public health burden in Guyana, a low to middle-income country in the Caribbean South American region with a climate highly conducive to *Aedes aegypti* transmission. This study analyzed confirmed dengue fever case records from Guyana's ten administrative regions for 2020, 2021, and 2022, derived from the Ministry of Health national disease notification system. A total of 9,772 dengue fever cases were recorded over the three-year study period: 1,719 in 2020, 4,384 in 2021, and 3,669 in 2022. The sharpest burden was concentrated in regions 1, 6, and 2, which together accounted for more than 60% of cumulative cases. Adults aged 25–44 years constituted the largest affected age group across all years, accounting for 30.2%–34.1% of annual cases. A marginal female predominance was observed in 2021 and 2022, with females comprising 52.8% and 53.3% of cases, respectively. Region 1 recorded the highest single-year count (1,372 in 2021), while Regions 3 and 5 reported no cases across all years. These findings underscore persistent geographic heterogeneity in dengue transmission, the disproportionate burden in economically active age groups, and the urgent need to strengthen region-specific surveillance and implement integrated vector management strategies in Guyana.

Keywords: Age Distribution, Dengue Fever, Epidemiology, Guyana, Regional Surveillance, Vector-Borne Disease.

Introduction

Dengue fever is one of the fastest spreading mosquito-borne viral diseases worldwide, with an estimated 100–400 million infections annually across more than 100 endemic countries [1]. The disease, caused by any of four serotypes of dengue virus (DENV 1–4) and transmitted primarily by *Aedes aegypti* mosquitoes, poses a particularly severe threat in tropical and subtropical regions where warm temperatures and high rainfall create optimal conditions for vector breeding and virus replication [2]. The Pan American Health

Organization (PAHO) has reported a rising dengue burden across the Americas, with the Caribbean subregion consistently recording surges linked to seasonal rainfall patterns and the El Niño Southern Oscillation (ENSO) [3].

Guyana, a low to middle-income country situated on the northeastern Atlantic coast of South America with a population of approximately 786,000, occupies a unique epidemiological position. The country shares its tropical climate and vector ecology with the wider Caribbean and South American dengue belt, yet its national surveillance infrastructure

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and region-disaggregated disease data remain understudied in the peer-reviewed literature [4]. Guyana is divided into ten administrative regions, each with distinct ecological, demographic, and healthcare delivery characteristics that influence disease patterns. Understanding how the dengue case burden is distributed across these regions is critical for targeted resource allocation and public health response planning.

Existing evidence from the Caribbean indicates pronounced intranational heterogeneity in dengue transmission, driven by urban density, water storage practices, vector control capacity, and proximity to international travel corridors [5]. In Guyana, the coastal belt, particularly Regions 1, 2, and 6, hosts most of the population in dense urban and peri-urban settlements, while the interior regions (3, 7, 8, and 9) are sparsely populated and predominantly forested. This ecological gradient is expected to produce differential dengue risk, yet no peer-reviewed analysis has characterized this distribution using confirmed case data across multiple years.

The COVID-19 pandemic (2020–2022) further complicated dengue surveillance, as health system resources were diverted, clinical consultations declined, and testing rates were affected [6]. This context makes interpretation of dengue case counts during the study period particularly nuanced. A recent analysis by Baksh et al. [7] demonstrated significant lagged associations between temperature, rainfall, and dengue incidence in Guyana, yet the study was limited in its regional disaggregation and multi-year scope. The present study addresses this gap by providing a systematic, region-stratified epidemiological analysis of confirmed dengue fever cases across all 10 Guyanese administrative regions over 3 consecutive years (2020–2022).

Objectives

The primary objective of this study was to characterize the epidemiological trends of

confirmed dengue fever cases in Guyana between 2020 and 2022, stratified by administrative region, year, sex, and age group. Secondary objectives included identifying regions of disproportionate burden, describing demographic risk profiles, and generating evidence to inform targeted public health interventions.

Materials and Methods

Study Design

This study employed a retrospective cross-sectional design using routinely collected, secondary national disease notification data from the Guyana Ministry of Health (MoH). Data spanned three calendar years: 2020, 2021, and 2022.

Data Sources

Confirmed dengue fever case data were obtained from the national communicable disease notification system maintained by the MoH Epidemiology Unit. Data were structured at the regional level (Regions 1–10) and included information on disease type (dengue fever versus dengue haemorrhagic fever/shock syndrome), sex (male, female), and age group (<1, 1–4, 5–14, 15–24, 25–44, 45–64, and 65+ years). Hydrometeorology data covering monthly rainfall (mm), daytime temperature (°C), and night-time temperature (°C) for regions 5, 6, and 9 were obtained from the Guyana Hydrometeorological Service for 2020–2022 to provide climatic context for case trends.

Case Definition

Dengue fever cases included in this analysis were confirmed cases only, as classified by the MoH Epidemiology Unit using WHO diagnostic criteria, including clinical presentation consistent with dengue fever alongside positive laboratory results (NS1 antigen, IgM, IgG, or RT-PCR) [8]. Dengue hemorrhagic fever and dengue shock syndrome

were recorded separately and are reported as supplementary findings.

Data Management and Analysis

Regional case counts were extracted from the MoH structured datasets for each year and aggregated by age-sex stratum and region. Total case counts by year were computed by summing male and female counts across all age strata at the national level. Regional proportional contributions were calculated as a percentage of the national annual total. Age-sex distribution was expressed as absolute counts and percentages. Descriptive statistics, including means and ranges, were computed for meteorological variables. All analyses were performed using Python (version 3.11) with the pandas, numpy, and openpyxl libraries, as well as Microsoft Excel. Ethical approval was not required as the study used anonymized aggregate secondary data from the national surveillance system.

Ethical Considerations

The study used anonymized, de-identified aggregate data from the national communicable disease surveillance system. No individual patient identifiers were accessed or reported. An institutional review board exemption was obtained from Texila American University due to the data's retrospective, secondary, and aggregate nature.

Results

National Case Counts and Annual Trends

A total of 9,772 confirmed dengue fever cases were reported across Guyana's ten administrative regions over the three-year study period (Table 1). Annual case counts were 1,719 in 2020, 4,384 in 2021, and 3,669 in 2022, representing a 155% increase from 2020 to 2021 and a subsequent 16.3% decline in 2022 relative to the 2021 peak. The year 2021 thus constituted the peak transmission year within the observation window.

Table 1. National Annual Confirmed Dengue Fever Case Counts, Guyana, 2020–2022

Year	Total Cases	Male (%)	Female (%)
2020	1,719	875 (50.9%)	844 (49.1%)
2021	4,384	2,070 (47.2%)	2,314 (52.8%)
2022	3,669	1,713 (46.7%)	1,956 (53.3%)
Total	9,772	4,658 (47.7%)	5,114 (52.3%)

Source: Guyana Ministry of Health, National Communicable Disease Notification System, 2020–2022.

Sex Distribution

Male cases slightly exceeded female cases in 2020 (50.9% vs 49.1%). However, females comprised the majority in 2021 (52.8%) and 2022 (53.3%), consistent with patterns observed in other tropical settings where females may face higher household vector exposure [9]. Over the three-year period, females accounted for 52.3% of all national cases (Table 1) [see Table 1].

Age Group Distribution

Adults aged 25–44 years consistently represented the largest affected group, comprising 34.1% of cases in 2020, 30.2% in 2021, and 31.2% in 2022 (Table 2). The 45–64 year old group was the second largest across all three years, accounting for approximately 20–21% of cases each year. Children under 5 years (groups <1 and 1–4 combined) accounted for 4.8%–9.5% of annual cases, with the highest proportion in 2021. The elderly (65+) made up 6.5–8.7% of cases across years. The 15–24-year-old group remained the third largest

annually, ranging from 18.1% to 21.2% [see Table 2].

Table 2. Confirmed Dengue Fever Cases by Age Group, Guyana, 2020–2022

Age Group	2020 (n)	2020 (%)	2021 (n)	2021 (%)	2022 (n)
<1	19	1.1%	95	2.2%	75
1–4	64	3.7%	318	7.3%	275
5–14	221	12.9%	463	10.6%	455
15–24	365	21.2%	875	20.0%	663
25–44	587	34.1%	1,324	30.2%	1,144
45–64	352	20.5%	926	21.1%	769
65+	111	6.5%	383	8.7%	288
Total	1,719	100%	4,384	100%	3,669

Source: Guyana Ministry of Health, National Communicable Disease Notification System, 2020–2022.

Regional Distribution of Cases

Pronounced geographic heterogeneity was observed across all three years (Table 3). Region 1 (Barima-Waini) was the highest-burden region in 2020 (477 cases; 27.8% of national total) and 2021 (1,372 cases; 31.3%), though it declined to 749 cases (20.4%) in 2022. Region 6 (East Berbice-Corentyne) recorded the second-highest cumulative burden: 214 cases (12.4%) in 2020, rising sharply to 979 (22.3%) in 2021, and remaining elevated at 884 (24.1%) in 2022. Region 2 (Pomeroon-Supenaam) consistently ranked third, with 272 (2020), 565 (2021), and 518 (2022) cases, respectively. Collectively, Regions 1, 2, and 6 accounted for 56.1% of cases in 2020, 67.4% in 2021, and 58.7% in 2022 [see Table 3].

Region 8 (Potaro-Siparuni) displayed a striking upward trajectory from 86 cases (5.0%)

in 2020 to 570 cases (15.5%) in 2022, representing a 563% increase over the study period. Similarly, Region 9 (Upper Takutu-Upper Essequibo) increased from 56 cases (3.3%) in 2020 to 498 cases (13.6%) in 2022, a nearly nine-fold increase. By contrast, Region 10 (Upper Demerara-Berbice) declined markedly from 566 cases in 2021 to 149 in 2022 [see Table 3].

Regions 3 (Essequibo Islands-West Demerara) and 5 (Mahaica-Berbice) recorded the lowest case burdens. Region 3 reported only 7, 16, and 6 cases in 2020, 2021, and 2022, respectively. Region 5 recorded zero confirmed dengue cases over the entire three-year period, though this likely reflects limitations of the surveillance system rather than the true absence of disease [see Table 3].

Table 3. Confirmed Dengue Fever Cases by Administrative Region, Guyana, 2020–2022

Region	2020 (n)	2020 (%)	2021 (n)	2021 (%)	2022 (n)	2022 (%)
Region 1	477	27.8	1,372	31.3	749	20.4
Region 2	272	15.8	565	12.9	518	14.1
Region 3	7	0.4	16	0.4	6	0.2
Region 4	145	8.4	68	1.6	151	4.1
Region 5	0	0.0	0	0.0	0	0.0
Region 6	214	12.4	979	22.3	884	24.1
Region 7	215	12.5	282	6.4	144	3.9
Region 8	86	5.0	248	5.7	570	15.5
Region 9	56	3.3	288	6.6	498	13.6

Region 10	247	14.4	566	12.9	149	4.1
National	1,719	100	4,384	100	3,669	100

Source: Guyana Ministry of Health, National Communicable Disease Notification System, 2020–2022.

Dengue Hemorrhagic Fever

Dengue hemorrhagic fever/shock syndrome (DHF/DSS) was reported in small numbers: 2 cases in 2020, 4 cases in 2021, and 42 cases in 2022 (Table 5). The 2022 surge in DHF/DSS (predominantly in regions 6, 8, and 9) warrants further clinical and serological investigation, as it may signal secondary heterotypic infection or cocirculation of multiple serotypes [10].

Climatic Context

Available hydrometeorological data from regions 5, 6, and 9 provided contextual insight

into rainfall and temperature patterns during the study period (Table 4). Annual cumulative rainfall was substantially higher in 2021 (Region 5: 3,055.7 mm; Region 6: 3,348.6 mm; Region 9: 2,747.9 mm) compared to 2020 (Region 5: 2,045.1 mm; Region 6: 2,068.4 mm; Region 9: 1,881.4 mm), temporally coinciding with the sharp case increase in 2021. Mean daytime temperatures remained relatively stable across the three years (30.6–31.9°C), while Region 9 recorded consistently higher daytime temperatures despite comparatively lower rainfall [see Table 4].

Table 4. Annual Hydrometeorological Parameters for Regions 5, 6, and 9, Guyana, 2020–2022

Region/ Variable	2020 Rain (mm)	2020 Day T (°C)	2020 Night T (°C)	2021 Rain (mm)	2021 Day T (°C)	2021 Night T (°C)	2022 Rain (mm)	2022 Day T (°C)
Region 5	2,045.1	31.9	23.1	3,055.7	30.9	23.3	2,786.7	30.6
Region 6	2,068.4	31.3	22.8	3,348.6	31.1	22.7	3,134.5	31.1
Region 9	1,881.4	31.9	23.3	2,747.9	31.9	23.2	2,813.6	31.9

Source: Guyana Hydrometeorological Service, 2020–2022. Rain = Annual cumulative rainfall; Day T = Mean annual daytime temperature; Night T = Mean annual night-time temperature.

Table 5. Confirmed Dengue Fever Cases by Age Group and Year, with Sex Disaggregation, Guyana, 2020–2022

Age Group	2020 M	2020 F	2020 T	2020 %	2021 M	2021 F	2021 T	2021 %	2022 M	2022 F	2022 T	2022 %
<1	10	9	19	1.1	54	41	95	2.2	37	38	75	2.0
1–4	31	33	64	3.7	175	143	318	7.3	111	164	275	7.5
5–14	123	98	221	12.9	231	232	463	10.6	239	216	455	12.4
15–24	170	195	365	21.2	403	472	875	20.0	294	369	663	18.1
25–44	310	277	587	34.1	587	737	1,324	30.2	521	623	1,144	31.2
45–64	177	175	352	20.5	438	488	926	21.1	382	387	769	21.0
65+	54	57	111	6.5	182	201	383	8.7	129	159	288	7.8
Total	875	844	1,719	100	2,070	2,314	4,384	100	1,713	1,956	3,669	100

M = Male; F = Female; T = Total. Source: Guyana Ministry of Health, National Communicable Disease Notification System, 2020–2022.

Discussion

This investigation constitutes the first systematic, multi-year, region-stratified characterization of confirmed dengue fever burden across all ten administrative regions of

Guyana for the period 2020 to 2022. Cumulatively, 9,772 cases were documented over the three-year window, with a peak annual burden of 4,384 cases in 2021, positioning Guyana among Caribbean and South American

nations that have experienced notable dengue escalation, consistent with PAHO regional surveillance trends [3]. The 155% interannual rise from 2020 to 2021 is consistent with hemisphere-wide amplification patterns attributable to the resumption of post-pandemic health-seeking behavior, altered vector population dynamics, and elevated hydrometeorological drivers that support *Aedes aegypti* proliferation. Boston and Kurup [16] previously estimated that climate variables, including temperature and rainfall, exert a measurable influence on dengue transmission in Georgetown, Guyana, providing foundational support for the climatic drivers documented in the present multi-regional analysis.

The spatial concentration of cases within the coastal corridor, particularly Regions 1, 2, and 6, is attributable to the confluence of ecological conditions and demographic density that define Guyana's Atlantic littoral zone. Region 1 (Barima-Waini), though comparatively sparse in population, persistently ranked as the highest-burden region, an observation that may reflect both heightened forest-edge transmission dynamics and structural limitations in remote health facility reporting capacity. Analogous coastal-interior risk gradients have been characterized across Amazonian South America and Caribbean Island systems [11]. The influence of ambient temperature and precipitation on dengue incidence is well established in other tropical settings; Colón-González et al. [17] demonstrated in Mexico that seasonal shifts in temperature and humidity significantly modulate dengue transmission risk, a mechanism directly applicable to Guyana's comparable climate profile. Distributed lag modeling approaches, as formalized by Gasparrini et al. [18], offer robust methodological frameworks that future Guyanese dengue surveillance analyses could adopt to quantify delayed hydrometeorological

effects on case counts with greater statistical precision.

The rapid ascent of interior regions 8 and 9 to high-burden status by 2022 represents a significant epidemiological transition warranting dedicated prospective monitoring. Plausible contributing mechanisms include intensified population mobility associated with artisanal gold mining operations, the inadvertent creation of stagnant water reservoirs in excavated terrain that serve as larval breeding habitats, and incremental expansion of diagnostic capacity and passive case detection following pandemic-related service disruptions. Hii et al. [19] demonstrated that integrating temperature and rainfall data into forecasting models substantially improves the predictive accuracy of dengue incidence projections—a method that could be operationalized for these emerging interior burden zones in Guyana. Tun-Lin et al. [20] further established that *Aedes aegypti* larval development rates and survival are directly temperature-dependent, implying that the consistently high daytime temperatures recorded in region 9 (31.9°C across all study years) may confer particular entomological suitability for accelerated vector population turnover. The World Meteorological Organization [24] has documented increasing global mean temperatures and intensified precipitation variability as characteristic features of the current climate trajectory, further contextualizing the hydrometeorological drivers observed in this dataset. Baksh et al. [7] confirmed significant lagged relationships between rainfall and dengue incidence within Guyana's coastal belt, and the substantially elevated 2021 rainfall totals across all three monitored regions corroborate the case surge pattern documented in this analysis.

The demographic structure of dengue cases observed in Guyana is consistent with patterns reported in other tropical nations. The disproportionate case burden in the 25–44-year

age stratum is mirrored in findings from Brazil [12] and Colombia [13], where occupationally active adults sustain elevated exposure risk through outdoor work environments and bear primary household responsibilities for vector source reduction. Lee et al. [21] demonstrated in Colombia that early warning systems incorporating climate and non-climate predictors can successfully identify high-risk populations and geographic clusters prior to outbreak peaks, an approach that Guyana's Ministry of Health could feasibly adapt given the consistent age and regional risk profiles identified here. Ramachandran et al. [22] further showed in a 19-year retrospective analysis from India that empirical models combining temperature, rainfall, and relative humidity can reliably predict dengue incidence, underscoring the potential utility of integrating Guyana's available hydrometeorological data into operational predictive frameworks. The marginal female predominance documented in 2021 and 2022 aligns with evidence from multiple endemic settings and plausibly reflects differential domestic exposure patterns or disparities in healthcare-seeking behavior [9]. The sustained representation of the 15–24-year cohort at approximately 20% of annual cases across all three years highlights school-age and young adult populations as priority targets for community-based health education and vector source reduction initiatives.

The consistent reporting of zero confirmed dengue cases from region 5 (Mahaica-Berbice) over a three-year period is epidemiologically inconsistent with the region's ecological setting and its geographic proximity to high-burden neighboring regions. This pattern most plausibly reflects structural surveillance deficiencies, inadequate diagnostic laboratory infrastructure, fragmented case notification pathways, or suboptimal clinician compliance with mandatory disease reporting rather than an authentic absence of dengue transmission [14]. Walker et al. [23] documented the re-emergence of dengue in a regional Australian

setting where routine surveillance had previously underestimated viral circulation, reinforcing the principle that reporting gaps can substantially obscure the true epidemiological footprint of dengue in areas with limited diagnostic coverage. Urgently addressing the underlying surveillance infrastructure deficits in region 5 is therefore a prerequisite for generating reliable national incidence estimates and ensuring equitable resource allocation across all administrative regions.

The marked escalation in DHF/DSS cases during 2022 (42 cases versus 2–4 in the two preceding years) constitutes a clinically consequential shift in disease severity that merits systematic virological investigation. The immunological mechanism of antibody-dependent enhancement, by which prior exposure to one dengue serotype amplifies disease severity upon heterotypic secondary infection, underlies the elevated DHF/DSS risk in populations with documented multi-serotype circulation [15]. The geographic clustering of severe cases in regions 6, 8, and 9 in 2022 may reflect serotype heterogeneity across Guyana's interior regions, where communities may lack pre-existing cross-reactive immunity to newly introduced serotypes. Spatial Bayesian modeling approaches, such as those formalized by Besag et al. [25], could provide rigorous analytical frameworks for future studies aiming to map serotype-specific dengue risk at the sub-regional level and to disentangle the relative contributions of population immunity gradients and environmental drivers to observe patterns of severe disease.

Several limitations are acknowledged. The dataset covers only confirmed cases, likely representing a fraction of the true dengue incidence given known under-reporting and under-testing in low-resource surveillance systems. Testing rates, case definitions, and reporting completeness may have varied across regions and over time, particularly during the COVID-19 pandemic period. Hydrometeorology data were available for only

three regions (5, 6, and 9), limiting the scope of climatic contextualization. Population denominators for incidence rate computation were not available at the regional level with sufficient precision to enable reliable incidence rate calculations. Despite these limitations, this analysis provides the most comprehensive multi-year regional description of dengue cases in Guyana to date.

Conclusion

Dengue fever poses a growing, geographically heterogeneous public health burden across Guyana's 10 administrative regions. The 2021 case peaked, geographic concentration in coastal regions, emergence of interior regions as new high-burden areas in 2022, and pronounced adult demographic risk collectively demand a regionalized, evidence-driven response strategy. Priority actions should include strengthening diagnostic and reporting capacity in low-reporting regions, deploying targeted integrated vector management in high-burden and emergent regions, initiating prospective serotype surveillance, and developing early warning systems that integrate hydrometeorological data for timely dengue outbreak prediction and response. The data generated by this study establishes a baseline epidemiological profile essential for designing and evaluating dengue prevention programs in Guyana.

Conflict of Interest

The author declares no conflict of interest in the conduct and reporting of this research.

Ethical Approval

This study used anonymized, de-identified aggregate secondary data from Guyana's national communicable disease notification

system. No individual patient data or identifiers were accessed. An institutional review board exemption was granted by Texila American University.

Author Contributions

Allison Peters: Conceptualization, data curation, formal analysis, writing – original draft, writing – review and editing.

Abiodun Olaiya Paul: Methodology, supervision, writing-review, editing, and validation.

Nayan Persaud: Resources, investigation, validation.

Dr. Keisha A. Nelson: Resources, data curation, investigation.

Komalchand Dhiram: Resources, hydrometeorological data curation.

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Data Availability

The aggregate data supporting the findings of this study were obtained from the Guyana Ministry of Health National Communicable Disease Notification System and the Guyana Hydrometeorological Service. Data may be made available upon reasonable request to the corresponding author, subject to MoH data governance policies.

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Knowledge, Attitudes, and Practices Related to Cervical Cancer Screening and Traditional Medicine Use among Indigenous Women in Guyana's Region 9: A Baseline Cross-Sectional Assessment

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Abstract

Cervical cancer is a serious health threat for Indigenous women in Guyana's remote Region 9 (Upper Takutu-Upper Essequibo). To understand why, we spoke with 101 Amerindian women (Makushi and Wapishana), ages 21 to 65, at health centers and community events across the region between November and December 2025. We asked them about their knowledge, attitudes, and practices around cervical cancer screening, HPV, and the use of traditional medicine. Our survey found that the average age of participants was 32.6. While over 60% had an HPV test (with 27.7% testing positive), less than half (44.6%) had ever had a Pap smear. At the same time, traditional medicine plays a major role in their lives. Over 40% of the women consult traditional healers, mostly for women's health issues, and many use both traditional and modern treatments. The biggest hurdles to getting medical care were distance (67.3%), cost (47.5%), and long waits at clinics (41.6%). Our findings point to a critical gap in cervical cancer screening and highlight how central traditional medicine is to healthcare for these communities. This shows an urgent need for health programs that are culturally aware and blend modern and traditional approaches to improve women's health in Region 9.

Keywords: Cervical Cancer, Guyana, Health Disparities, HPV, Indigenous Health, Knowledge Attitudes Practices, Traditional Medicine, Screening.

Introduction

Cervical cancer is the fourth most common malignancy among women worldwide, accounting for approximately 604,000 new cases and 342,000 deaths in 2020 [1]. The disease disproportionately affects women in low- and middle-income countries (LMICs), where limited access to screening, early diagnosis, and treatment drives persistently high mortality [2, 3]. In Guyana, the age-standardised incidence rate of cervical cancer is approximately 44.7 per 100,000 women, among the highest in the Americas [4, 5]. This burden is particularly severe among Indigenous populations in remote administrative regions.

Region 9 (Upper Takutu-Upper Essequibo) encompasses some of the most geographically

isolated communities in Guyana, predominantly inhabited by the Makushi and Wapishana peoples [6]. These communities face compounding disadvantages including geographic isolation, inadequate health infrastructure, shortages of trained healthcare personnel, linguistic barriers, and deep-rooted reliance on traditional medicine [7, 8]. The interplay between traditional medicine (TM) systems and biomedical healthcare remains poorly understood in this context, yet it critically shapes health-seeking behaviour for reproductive health conditions including cervical cancer [9].

The World Health Organization (WHO) recognized traditional medicine as a key healthcare resource in regions with limited

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access to conventional medical services [10]. Studies across sub-Saharan Africa and South America have documented the widespread integration of plant-based remedies, spiritual healing, and indigenous health practices in the management of gynecological conditions [11, 12]. However, systematic evaluation of TM use alongside formal cervical cancer screening programmes among Indigenous Guyanese women remains absent from the published literature.

Knowledge, attitudes, and practices (KAP) surveys are well-established epidemiological tools for characterizing health behaviour and informing targeted public health interventions [13]. Understanding the KAP of Indigenous women regarding HPV, cervical cancer screening, and traditional medicine is essential for designing culturally acceptable and effective prevention strategies. This study was conducted as part of the baseline assessment of a larger 12-month mixed-methods comparative effectiveness research initiative titled 'Navigating Health: Assessing Knowledge, Attitudes, and Practices among Indigenous Women in Guyana's Regions 1 and 9.' The present paper focuses specifically on Region 9 findings from baseline data collected in November–December 2025.

The objectives of this study were: (i) to describe the sociodemographic and reproductive health profile of Indigenous women in Region 9; (ii) to assess cervical cancer screening uptake and HPV test positivity; (iii) to characterize traditional medicine use and attitudes toward integrated care; and (iv) to identify the principal barriers to accessing reproductive health services.

Materials and Methods

Study Design and Setting. A cross-sectional baseline survey was conducted between November and December 2025 among women attending health centres and community outreach sites in Region 9, Guyana. Region 9 spans the Upper Takutu-Upper Essequibo

territory and is characterized by vast geographical distances between communities, limited road access, and reliance on boat or aircraft travel [7].

Participants. Eligible participants were female, aged 21–65 years, self-identified as Indigenous (Makushi or Wapishana), and residing in Region 9 at the time of data collection. Women who were unable to provide informed consent were excluded. A total of 101 women were enrolled using purposive and convenience sampling at health centres in Quatata, Parishara, Fly Hill, Massara, Hiowa, Aranaputa, Wowetta, Annai, Rupertee, Moco Moco, Kumu, Toka, St. Ignatius, Quarrie, and Lethem as well as community outreach sessions.

Data Collection. Trained interviewers administered a structured questionnaire adapted from six standardized data collection instruments (Forms 8.1–8.6), covering: baseline demographic and socioeconomic characteristics; clinical assessment including gynecological examination and cervical cancer screening (Pap smear, HPV testing, VIA); traditional medicine practice documentation; follow-up assessment; economic evaluation; and adverse events reporting. Where required, interpreters facilitated data collection in Makushi and Wapishana languages.

Clinical Screening. Cervical cancer screening included visual inspection with acetic acid (VIA), HPV testing using cervical swab specimens, and Pap smear collection where feasible. Trained health professionals at designated health centres conducted clinical assessments. Gynecological examination findings were recorded systematically, including cervical appearance, size, mobility, and previous procedures.

Statistical Analysis. Descriptive statistics were computed for all variables. Continuous variables are reported as means with standard deviations. Categorical variables are presented as frequencies and percentages. Chi-square tests were used to assess associations between

categorical variables. A binary logistic regression was also conducted to identify independent predictors of cervical cancer screening uptake. All analyses were conducted using SPSS version 26.0. A p-value of <0.05 was considered statistically significant.

Ethical Considerations. Ethical approval was obtained from the relevant institutional review board of the Ministry of Health, reference no. 113/2025 before study commencement. Informed written consent was obtained from all participants. Community-based participatory research principles guided all engagement activities, with community advisory boards established in each participating community. Indigenous data sovereignty principles (CARE framework) were applied throughout data collection and management.

Results

Sociodemographic Characteristics. A total of 101 women participated in the baseline survey. Table 1 presents the sociodemographic profile. The mean participant age was 32.6 years (SD ± 8.4), with the majority (51.5%) aged 21–30 years. Most participants identified as Makushi (81.2%), with 18.8% Wapishana. Common-law unions were the most prevalent marital status (44.6%), followed by marriage (33.7%). Secondary education was the most common educational attainment (42.6%). Monthly household income fell predominantly in the GYD 40,000–80,000 range (56.4%). English and an Amerindian language were spoken by 76.2% of participants.

Table 1. Sociodemographic Characteristics of Study Participants – Region 9 (N=101).

Characteristic	n	%
Age Group (years)		
21–30	52	51.5
31–45	33	32.7
46–65	16	15.8
Mean Age (SD)	32.6 (± 8.4)	
Ethnicity		
Makushi	82	81.2
Wapishana	19	18.8
Marital Status		
Common-law	45	44.6
Married	34	33.7
Single	22	21.8
Education Level		
Primary complete or less	38	37.6
Secondary complete	43	42.6
Tertiary	20	19.8
Monthly Household Income (GYD)		
<40,000	22	21.8
40,000–80,000	57	56.4
>80,000	22	21.8
Other Characteristics		
Ever had Pap smear	45	44.6
Use of Traditional Healers	42	41.6

Combines Traditional and Biomedical Treatments	35	34.7
Main Barrier to Care		
Distance/Transportation	68	67.3
Cost	48	47.5
Long waiting times	42	41.6
Primary Language		
English only	24	23.8
English and Amerindian Language	77	76.2

Cervical Cancer Screening Uptake. Table 2 summarizes clinical screening outcomes. Only 44.6% of participants had ever undergone a Pap smear. HPV testing was performed in 61.4% of participants; of these, 27.7% tested positive. VIA was conducted in 46.5% of participants, with 17.8% yielding a positive

result. Previous cervical procedures were documented in 7.9% (LEEP), 4.0% (biopsy), and 2.0% (cryotherapy) of participants. Overall, 23.8% of participants reported symptoms at baseline, including abnormal vaginal bleeding, pelvic pain, back pain, vaginal discharge, and weight loss.

Table 2. Clinical Screening Outcomes among Participants – Region 9 (N=101).

Screening Outcome	n	%
HPV Test Collected	62	61.4
HPV Positive	28	27.7
HPV Negative	34	33.7
HPV Not Performed	39	38.6
VIA Performed	47	46.5
VIA Positive	18	17.8
VIA Negative	29	28.7
Pap Smear Collected	45	44.6
Abnormal Pap Result	12	11.9
Previous LEEP	8	7.9
Previous Cryotherapy	2	2.0
Previous Biopsy	4	4.0
Symptomatic at Baseline	24	23.8

Traditional Medicine Use. Table 3 presents traditional medicine use patterns. Traditional healers were consulted by 41.6% of participants. Community healers were the most common healer type (21.8%), followed by family members (17.8%). Women's health and womb care were the most frequent conditions for which traditional medicine was sought

(27.7%). Equal trust in traditional and modern medicine was reported by 37.6% of participants. Among traditional medicine users, 34.7% concurrently used biomedical treatments, though only 15.8% disclosed this dual use to their healthcare provider. Barter and exchange were common payment methods for traditional healers (17.8%).

Table 3. Traditional Medicine Use and Attitudes toward Treatment – Region 9 (N=101).

Variable	n	%
Uses Traditional Healers	42	41.6
Healer Type		
Community Healer	22	21.8
Family Member	18	17.8
Multiple Healers	2	2.0
Conditions Treated Traditionally		
Womb Care/Women's Health	28	27.7
General Illness	14	13.9
Attitudes and Practices		
Trust in Traditional Medicine Equal to or Greater than Modern	38	37.6
Combines Traditional and Biomedical Treatment	35	34.7
Discloses Traditional Use to Doctor	16	15.8
Traditional Treatment for Cervical/Reproductive Concerns	28	27.7
Payment Method		
Barter/Exchange	18	17.8
Free	20	19.8
Cash	4	4.0

Barriers to Care. As shown in Table 4, the most commonly reported barriers to accessing healthcare were distance and transportation (67.3%), cost (47.5%), and long waiting times (41.6%). The mean distance to the nearest

health facility was 11.2 miles, with a mean travel time of 94 minutes and mean transport cost of GYD 4,032 per visit. Fear was identified as a barrier by 11.9% of participants, while 7.9% cited lack of professional personnel.

Table 4. Healthcare Access Barriers by Participant Frequency – Region 9 (N=101).

Barrier	n	%
Distance to facility	68	67.3
Transportation cost	48	47.5
Long waiting times	42	41.6
Fear	12	11.9
Lack of professional personnel	8	7.9
No barrier identified	11	10.9
Mean distance to facility (miles)	11.2	-
Mean travel time to facility	94 mins	-
Mean transport cost (GYD)	4,032	-

Reproductive Health and Contraceptive Characteristics. Table 5 details reproductive health characteristics. Over half of participants (55.4%) currently used contraception, with hormonal injection being most prevalent (31.7%), followed by implants (13.9%). The

mean age at first pregnancy was 17.8 years, mean parity was 2.9, and mean age at sexual debut was 16.4 years. Comorbidities were present in 41.6% of participants, with hypertension (23.8%) and diabetes (13.9%) being most common.

Table 5. Reproductive Health and Contraceptive Characteristics – Region 9 (N=101).

Characteristic	n	%
Currently uses contraception	56	55.4
Contraceptive Type		
Injection	32	31.7
Implant	14	13.9
Condoms	3	3.0
Other	7	6.9
Reproductive History		
Mean age at first pregnancy (years)	17.8	-
Mean parity	2.9	-
Mean age at first sexual intercourse (years)	16.4	-
Nulliparous	10	9.9
Other Health Characteristics		
History of tobacco use	4	4.0
Alcohol use (occasional or more)	24	23.8
Comorbidities (any)	42	41.6
Hypertension	24	23.8
Diabetes	14	13.9
Other comorbidities	8	7.9

Screening Uptake by Age Group. Table 6 presents the sample characteristics for screening analysis. Of the 101 participants, 46 (45.5%) had ever undergone cervical cancer

screening. The mean age of the study sample was 32.7 years. The distribution of screening uptake across age groups is illustrated in Figure 1.

Table 6. Sample Characteristics for Screening Analysis – Region 9 (N=101).

Total Participants	Screening Uptake	Ever Screened	Mean Age (yrs)
101	45.5%	46	32.7

SCREENING UPTAKE BY AGE GROUP

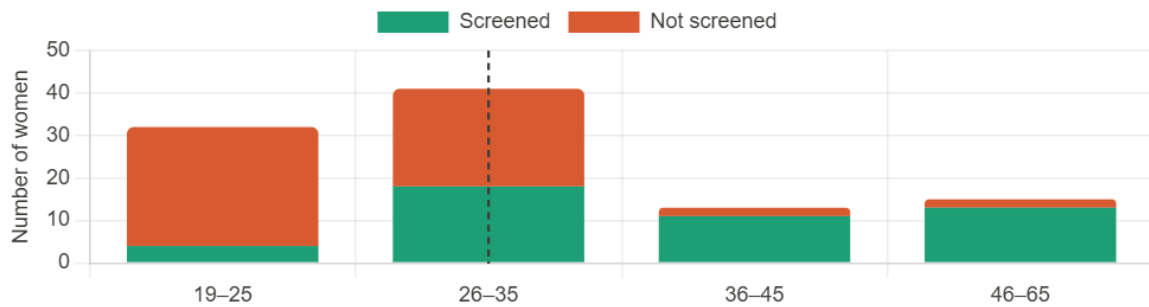


Figure 1. Screening Uptake by Age Group – Region 9 (N=101).

Logistic Regression Analysis. Table 7 presents the univariate logistic regression results. Age (OR = 1.186; 95% CI: 1.107–1.270; $p < 0.001$), education level (OR = 0.492; 95% CI: 0.289–0.838; $p = 0.008$), and total pregnancies (OR = 1.386; 95% CI: 1.127–1.705; $p = 0.002$) were statistically significant

predictors of screening uptake at univariate level. Household size met the $p < 0.25$ criterion ($p = 0.164$) and was also advanced to multivariate analysis. Literacy and electricity access were excluded due to near-perfect separation.

Table 7. Univariate Logistic Regression (All Candidates) – Region 9 (n=101).

Variable	n	OR	95% CI	p-value	Selected
Age (years)	101	1.186	1.107–1.270	<0.001	Yes ***
Education level	101	0.492	0.289–0.838	0.008	Yes **
Total pregnancies	100	1.386	1.127–1.705	0.002	Yes **
Household size	101	1.178	0.940–1.476	0.164	Yes ($p < 0.25$)
Marital status	101	1.859	0.635–5.420	0.256	No
Contraception use	100	0.631	0.282–1.413	0.261	No
Smoking	101	3.766	0.380–37.49	0.258	No
Motorized transport	101	0.686	0.307–1.535	0.359	No
Monthly HH income	73	0.781	0.476–1.281	0.324	No
Self healthcare decision	101	0.704	0.316–1.565	0.389	No
Traditional healer use	90	1.354	0.566–3.240	0.496	No
Electricity access	101	0.005	0.00–493,422	0.568	No*
Literacy	101	0.001	-	0.834	No*

*Note: Literacy and electricity were dropped due to near-perfect separation — all literate women shared the same outcome category in this sample, making OR estimates unstable. Variables with $p < 0.25$ advanced to multivariate analysis: age, education, total pregnancies, household size.

Multivariate Binary Logistic Regression. Table 8 presents the multivariate model results. After mutual adjustment, age was the only statistically significant independent predictor of cervical cancer screening uptake (OR = 1.210;

95% CI: 1.10–1.33; $p < 0.001$). Education level, household size, and total pregnancies did not retain statistical significance in the multivariate model, suggesting their univariate associations were confounded by age.

Table 8. Multivariate Binary Logistic Regression – Region 9 (n=101).

Variable	β	SE	Wald z	OR	95% CI	p-value	Sig
Age (years)	0.190	0.049	3.884	1.210	1.10–1.33	<0.001	***
Education level	0.025	0.364	0.069	1.025	0.50–2.09	0.945	ns
Household size	0.236	0.207	1.139	1.266	0.84–1.90	0.255	ns
Total pregnancies	–0.188	0.203	–0.927	0.829	0.56–1.23	0.354	ns

Model Fit Statistics. Table 9 presents the model fit statistics. The overall model was statistically significant ($\chi^2(4) = 42.96$; $p < 0.001$). The Nagelkerke R^2 of 0.467 indicates the model explains approximately 47% of

variance in screening uptake. The AUC of 0.854 indicates excellent discriminative ability. Overall accuracy was 81.0%, with sensitivity of 69.6% and specificity of 90.7%.

Table 9. Model Fit Statistics – Region 9 (n=101).

Statistic	Value	Interpretation
LR Chi-square test	$\chi^2(4) = 42.96$; $p < 0.001$	Model significant
Nagelkerke R^2	0.467	~47% variance explained
AUC (C-statistic)	0.854	Excellent discrimination
Overall accuracy	81.0%	Sensitivity 69.6% / Specificity 90.7%
–2 Log-likelihood (null)	137.99	Intercept-only model
–2 Log-likelihood (model)	95.03	Reduction of 42.96 points
AIC	105.03	Lower = better fit
Cox & Snell R^2	0.349	Pseudo R-squared

Univariate vs. Multivariate Comparison. Table 10 presents a comparison of univariate and multivariate odds ratios. Age remained an independent predictor in the multivariate model (OR = 1.21; 95% CI: 1.10–1.33; $p < 0.001$).

Education, household size, and total pregnancies lost significance after mutual adjustment, suggesting their univariate associations were confounded by age.

Table 10. Odds Ratios – Univariate vs. Multivariate Comparison – Region 9 (n=101).

Variable	Univariate OR (95% CI)	p	Multivariate OR (95% CI)	p	Change
Age	1.19 (1.11–1.27)	<0.001	1.21 (1.10–1.33)	<0.001	Independent
Education	0.49 (0.29–0.84)	0.008	1.03 (0.50–2.09)	0.945	Confounded

Pregnancies	1.39 (1.13–1.71)	0.002	0.83 (0.56–1.23)	0.354	Confounded
Household size	1.18 (0.94–1.48)	0.164	1.27 (0.84–1.90)	0.255	Not sig.

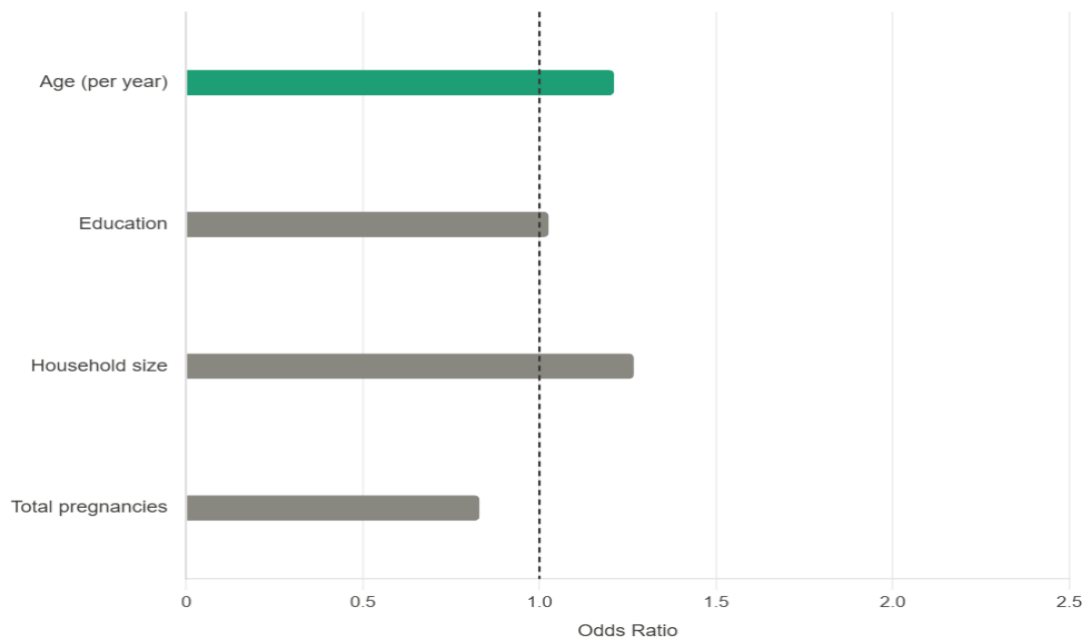


Figure 2. Forest Plot – Multivariate Odds Ratios (with 95% CI) for Region 9 (n=101).

Discussion

This study is the first to really map out how Indigenous women in Guyana’s Region 9 approach cervical cancer prevention, revealing a complex picture shaped by geography, culture, and a strained healthcare system. The HPV positivity rate of 27.7% is alarmingly high, well above the global average of about 11.7% [14] and reflects the heavy burden of cervical cancer in Guyana [4]. At the same time, Pap smear uptake is very low (44.6%), a pattern seen in other Indigenous and remote communities in Latin America where similar barriers prevent women from getting screened [15, 16]. What’s particularly striking is the widespread use of traditional medicine. That over 40% of women consult traditional healers—and that many use both traditional and modern treatments without telling their doctor—raises a serious concern for patient safety, as some herbal remedies can interfere with prescribed medications [17, 18]. This finding highlights a disconnect between the two

systems of care. It’s not surprising that distance, cost, and long wait times were the biggest barriers to care. A 94-minute journey and a significant transportation cost are major hurdles for women in households earning as little as GYD 40,000 a month. These are well-known factors that lead to women being diagnosed with late-stage cancer [19, 20]. Our findings also show that women are starting families young, with an average age of sexual debut at 16.4 and first pregnancy at 17.8. These are known risk factors for HPV and cervical cancer [21, 22], and they point to the need for health education that combines cervical cancer prevention with sexual and reproductive health. The findings are consistent with published data from Indigenous communities in the Guyana Shield region [6, 23]. In our analysis, age was the only independent factor predicting who gets screened. Simply put, older women were more likely to have had a Pap smear. This suggests that outreach efforts need to be intensified for younger women, regardless of their education level or how many children they have. The fact

that nearly 40% of women trust traditional and modern medicine equally isn't a problem to be solved, but an opportunity. It points toward a path for creating integrated, culturally safe health programs that respect Indigenous knowledge while ensuring access to life-saving modern medicine [24, 25]. The multivariate odds ratios for predictors of cervical cancer screening uptake are presented in Figure 2. Our study has some limitations. Because it's a snapshot in time, we can't draw conclusions about cause and effect. Our sampling method might also mean that the women we spoke to at health centers are different from those who don't seek care at all. We are still collecting follow-up data, which will give us a more complete picture over time. Finally, this study was focused on one region, so the findings may not apply to other Indigenous communities.

Conclusion

Our research shows that preventing cervical cancer in Guyana's Region 9 is a complex challenge, caught at the intersection of a high HPV burden, low screening rates, a deep reliance on traditional medicine, and major structural barriers to care. These factors create serious gaps in early detection and consistent care for Indigenous women.

To make a real difference, we need culturally sensitive health programs that are easy to access, are offered in local languages, and respect local healing practices. Building trust and open communication between communities and healthcare providers by integrating traditional and modern care will be key to getting more women screened and improving their health.

Future research should focus on tracking the long-term effectiveness of such integrated models. We need to better understand how culturally grounded programs can create lasting change in cervical cancer prevention for remote and Indigenous peoples. These efforts are essential if we are to achieve equitable health

outcomes and reduce preventable deaths among Indigenous women in Guyana.

Conflict of Interest

The author declares no conflict of interest.

Ethical Approval

Ethical approval for the study was obtained from the Texila American University Institutional Review Board and the Ministry of Health, Guyana (reference no. 113/2025). All participants provided informed written consent prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki and the CARE principles of Indigenous data sovereignty.

Author Contributions

Seraiah Arliana Dimple Validum: Conceptualization, Methodology, Investigation, Formal Analysis, Writing – Original Draft.

Michael Olabode Tomori: Supervision, Project Administration, Writing – Review & Editing.

Data Availability

The dataset supporting the findings of this study is available from the corresponding author upon reasonable request and subject to ethical approval and institutional data governance agreements.

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Awareness, Implementation of Climate Change Mitigation Measures, Adaptative Practices and Challenges Faced by Rural Farmers of Lebialem Division in The South West Region of Cameroon

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Abstract

Climate change is severely affecting agriculture worldwide, and rural farmers in Lebialem Division are particularly vulnerable. Most of them rely on rain-fed farming, making them highly susceptible to unpredictable weather patterns like irregular rainfall, prolonged dry seasons, and extreme heat. To develop an effective and sustainable solutions, it is essential to understand how these farmers perceive climate change, what actions they are taking, and the challenges they encounter. A descriptive cross-sectional approach was used. Data were collected from eight villages across the three subdivisions using a multistage sampling technique. Data were analyzed using SPSS. Key statistical indicators used included Adjusted Odds Ratios (AORs), 95% Confidence Intervals (CI), and p-values. Farmers in Lebialem were highly aware (92,3%) of climate change with age group 41–50 (AOR = 7.50 (95% CI: 1.52–37.10; p = 0.014) more likely to be aware through daily experiences, even if they lack formal scientific understanding. They were actively involved in mitigation practices (87.1%) like planting trees, using mulch, organic manure, and avoiding bush burning, efforts which are often rooted in traditional knowledge. Adaptation strategies included crop diversification, irrigation, and planting crop varieties (84.1%). However, these efforts faced serious challenges such as poor tree survival rates, financial constraints, limited water access and unpredictable weather. Traditional leaders and NGOs offer support, but broader assistance remains limited. Rural farmers in Lebialem are committed to addressing climate change by combining indigenous practices with modern techniques. However, challenges limit their success. Strengthening institutional support, improving technical training, and providing financial resources are key to building resilience and ensuring food security in the region.

Keywords: Adaptation, Challenges, Awareness, Climate Change, Mitigation, Rural Farmers.

Introduction

Climate change has gradually moved from being a distant environmental concern to a lived reality that farmers across the world now face on a daily basis. Agriculture, more than many other sectors, feels the impact directly. Unpredictable rainfall, prolonged dry seasons, floods, rising temperatures, and increasing pest

outbreaks are disrupting farming systems and threatening food production, rural livelihoods, and even public health [1–3]. For regions that depend heavily on agriculture, especially Sub-Saharan Africa, these changes are particularly damaging. In Cameroon, where more than two-thirds of the population relies on farming for survival, climate-related shocks place

enormous pressure on food security and household incomes [4–6].

At the same time, agriculture occupies a complex position in the climate change debate. Farming activities contribute to greenhouse gas emissions through deforestation, livestock production, and land-use change, yet the sector also holds great potential for reducing emissions and building resilience. Whether farmers are able to play this positive role depends largely on their level of awareness, access to information, financial capacity, education, and the support systems around them [7, 8]. In wealthier countries, farmers are supported by strong institutions, modern technologies, climate data, insurance schemes, and extension services. These supports make it easier for them to anticipate climate risks and adopt practices that protect both productivity and the environment [9–11]. In contrast, most farmers in Sub-Saharan Africa, including those in Cameroon, rely on rain-fed agriculture and traditional practices such as mulching, composting, crop rotation, and intercropping. While these methods are often environmentally friendly, they are usually adopted as survival strategies rather than deliberate climate mitigation actions and receive little formal recognition or support [12–14].

Awareness plays a key role in shaping how farmers respond to climate change. In many developed countries, farmers increasingly recognize climate change as a serious threat and are more willing to participate in mitigation and adaptation efforts, largely because they have access to education, digital information, and organized farmer networks [15]. In Sub-Saharan Africa, however, awareness is mostly shaped by personal experience. Farmers clearly observe changes such as delayed rains, shorter growing seasons, declining yields, and rising pest pressure, yet many do not fully understand the broader scientific causes of these changes [16, 17]. Studies in Cameroon show that although many rural farmers can describe shifts in weather patterns, only a small proportion

have received formal training or reliable climate information. Most depend on informal sources such as local radio, community leaders, or NGOs, which limits the depth of understanding needed for long-term planning [18].

Beyond knowledge gaps, rural farmers face structural challenges that make effective climate action difficult. Poor road networks, limited access to electricity and internet services, inadequate irrigation systems, financial exclusion, and weak agricultural extension services all constrain the adoption of mitigation and adaptation measures [19, 20]. In areas like the Lebialem Division of the South West Region of Cameroon, these difficulties are intensified by socio-political instability, which further restricts access to markets, technical support, and external assistance. As a result, many farmers' responses to climate change remain small-scale, reactive, and insufficient to ensure long-term resilience [21].

Despite these limitations, rural farmers continue to show determination and creativity in responding to climate stress. They adjust planting dates, experiment with different crop varieties, and adopt soil conservation practices using the limited resources available to them. However, without stronger institutional backing and targeted support, these efforts are unlikely to achieve lasting impact. There is therefore a clear need for evidence that goes beyond general observations and systematically examines farmers' levels of awareness, the mitigation measures they implement, the adaptive practices they use, and the challenges they face [22]. Such data are essential for identifying patterns, understanding relationships, and informing policies that are grounded in the realities of rural farming communities.

This study responds to that need by examining climate change awareness, mitigation measures, adaptive practices, and implementation challenges among rural farmers in the Lebialem Division of Cameroon.

By focusing on a localized and vulnerable rural setting, the study provides context-specific evidence that is often missing from broader national or regional analyses. Its integrated approach helps bridge the gap between what farmers know, what they do, and what prevents them from doing more. Ultimately, the findings aim to support the design of practical, inclusive, and sustainable strategies that strengthen agricultural resilience, improve food security, and enhance the capacity of rural farmers in Cameroon to cope with a changing climate [23].

Materials and Methods

This study was conducted in the Lebialem Division of the South West Region of Cameroon, a predominantly rural area comprising three subdivisions; Alou, Fontem, and Wabane. The division is characterized by hilly terrain, fertile soils, and a high dependence on subsistence farming, with major crops including maize, cassava, Irish potatoes, beans, plantains, and vegetables. Farming activities rely heavily on rainfall and traditional methods. In recent years, farmers in the area have experienced delayed rainfall, prolonged dry seasons, and increased pest outbreaks, which have negatively affected agricultural productivity. The area also faces infrastructural challenges such as poor road networks, limited access to electricity, internet services, and agricultural extension support, compounded by ongoing socio-political instability. Lebialem Division was therefore selected because it represents a typical rural farming context in Cameroon that is highly vulnerable to climate change impacts.

A descriptive cross-sectional study design was employed to assess climate change awareness, implementation of mitigation measures, adaptive practices, and challenges faced by rural farmers. The study population consisted of rural farmers aged 18 years and above who had resided in the division for at least three years and were actively engaged in

farming activities. The sample size was determined using Cochran's formula at a 95% confidence level and 5% margin of error, yielding a minimum of 384 participants, which was increased to 403 to account for non-response. A multistage sampling technique was used: Lebialem Division was purposively selected, communities were randomly chosen from each subdivision, and households were systematically sampled by selecting every second household. One eligible farmer was recruited from each selected household.

Data were collected using a structured questionnaire developed in line with the study objectives. The instrument assessed socio-demographic characteristics, climate change awareness, mitigation measures, adaptive practices, and challenges to implementation. Awareness-related questions were multiple-choice, while mitigation, adaptation, and challenge variables were measured using a three-point Likert scale (disagreed, indifferent, agreed). The questionnaire was administered through face-to-face by trained research assistants. Literate respondents completed the questionnaire independently, while non-literate participants were assisted to ensure accurate responses. To ensure validity and reliability, the questionnaire was pretested among farmers in Fongutengong village, a community with similar characteristics to the study area, and necessary revisions were made to improve clarity and relevance.

Completed questionnaires were entered into Kobo tool, cleaned in Microsoft Excel, and analyzed using SPSS version 27. Descriptive statistics were used to summarize key variables, while Chi-square tests examined associations between categorical variables. Multivariate logistic regression analysis was conducted to identify socio-demographic factors associated with climate change awareness, with results presented as adjusted odds ratios, 95% confidence intervals, and p-values. Findings were summarized using tables and charts. Ethical approval was obtained from the Ethical

Review Board of the Faculty of Health Sciences, University of Buea. Administrative authorization was secured from relevant health authorities and village heads. Written or verbal informed consent was obtained from all participants, and confidentiality was strictly maintained throughout the study.

An approval for the study was obtained from the faculty of health science, University of Buea, Cameroon and an administrative authorization gotten from the South West Regional Delegation of Public Health and from the various heads of the communities.

Results

Lebialem Division is made up of three subdivisions: Alou, Fontem, and Wabane. The sociodemographic characteristics of the 403 respondents are presented in Tables 1. Respondents were fairly evenly distributed across the subdivisions, with 36.5% coming from Wabane, 36.0% from Alou, and 27.5% from Fontem. Participants were drawn from eight communities, with M'muock Fossimondi recording the highest number of respondents (23.1%), followed by Bechati (13.4%) and M'muock Mbie (13.2%), while Ntesseh had the least representation (6.9%). Males constituted the majority of respondents (61%), while

females accounted for 39%. Most respondents were within the productive age groups of 31–40 years (32.3%) and 41–50 years (26.1%), followed by those aged 21–30 years (17.9%). Respondents aged above 60 years were the least represented (6.9%). A greater proportion of respondents were married (60.5%). Household sizes were predominantly moderate, with nearly half of the respondents (49.4%) having 4–6 household members. Smaller households of 1–3 members accounted for 25.1%, while households with 7–9 members represented 18.4%. The smallest proportion of respondents came from households with more than 10 members (7.2%).

Most respondents had primary education (30.8%), followed by secondary education (28.0%) and high school education (21.8%). Only 13.6% had attained university education, while 5.7% had no formal education. Income levels were generally low, with 92.8% earning less than 100,000 FCFA per month. Farm sizes were mostly small to medium, with nearly half of the respondents (49.6%) cultivating 3–5 hectares and 33.5% farming less than 3 hectares. Farming experience varied, though most respondents reported 6–10 years (37.2%) or 1–5 years (28.3%) of experience.

Table 1. Demographic data of study participants in the Lebialem Division

Variable	Categories	Frequency	Percent (%)
Community	Bechati	54	13.4
	Bellah	40	9.9
	Besali	44	10.9
	M'muock Fossimondi	93	23.1
	M'muock Letch	49	12.2
	M'muock Mbie	53	13.2
	Menji	42	10.4
	Ntesseh	28	6.9
	Total	403	100
Subdivision	Alou	145	36.0
	Fontem	111	27.5
	Wabane	147	36.5
	Total	403	100
Gender	Female	157	39.0

	Male	246	61.0
	Total	403	100
Age group	>60	28	6.9
	21–30	72	17.9
	31–40	130	32.3
	41–50	105	26.1
	51–60	68	16.9
	Total	403	100
Marital status	Married	244	60.5
	Single	159	39.5
	Total	403	100
Household size	>10	29	7.2
	1–3	101	25.1
	4–6	199	49.4
	7–9	74	18.4
	Total	403	100
Educational level	No formal education	23	5.7
	Primary	124	30.8
	Secondary	113	28.0
	High school	88	21.8
	University	55	13.6
	Total	403	100
Monthly income	<100,000 FCFA	374	92.8
	>100,000 FCFA	29	7.2
	Total	403	100
Farm size	<3 hectares	135	33.5
	3–5 hectares	200	49.6
	6–10 hectares	61	15.1
	>10 hectares	7	1.7
	Total	403	100
Farming years	1–5	114	28.3
	6–10	150	37.2
	11–15	47	11.7
	>15	92	22.8
	Total	403	100

The age distribution of respondents ranged from 21 to 86 years, with a mean age of 43.13 years (SD = 11.98), as presented in Table 2.

Table 2. Age distribution of respondents

N	Minimum	Maximum	Mean	Std. Deviation
403	21	86	43.13	11.982

Awareness of climate change among respondents is presented in Table 3. A large majority (92.3%) reported being aware of climate change. Climate change was commonly defined as changes in rainfall patterns (64.0%) and shifting seasonal changes (57.1%), followed by increased ambient temperature (34.7%). Respondents identified deforestation, loss of biodiversity, and improper fertilizer use

as major causes. Floods, drought, food insecurity, and the emergence of pests and diseases were widely perceived as environmental effects. Nearly all respondents (96.0%) reported a decrease in crop yield due to climate change. Information on climate change was mainly obtained from other farmers and friends, with less reliance on mass media and formal sources.

Table 3. Awareness of climate change by rural farmers of the Lebialem Division

Variable	Categories	Frequency	Percent %
Awareness of climate change	No	31	7.7
	Yes	372	92.3
	Total	403	100
Definition of climate change	Increase ambient temperature	140	34.7
	Change in rainfall pattern	258	64
	Shifting seasonal change	230	57.1
	Occurrence of drought	94	23.3
	Unpredictable rainfall	113	28
	Occurrence of flood	130	32.3
	Total	965	239.5
Causes of climate change	Burning of fossil fuel	120	34
	Careless use of fertilizer	134	38
	Over tilling of land	90	25.5
	Burning crop residue	115	32.6
	Cutting down of trees	175	49.6
	Loss of biodiversity	146	41.4
	Total	780	221
Effect of climate change	Food insecurity	167	43.5
	Appearance of new pest and disease	185	48.2
	Storm	153	39.8
	Drought	167	43.5
	Flood	212	55.2
	Water scarcity	123	32
	Total	1007	262.2
Effect of climate change on crop yield	Increase crop production	44	11.1
	Decrease crop production	382	96
	Increase adaptation cost	1	0.3
	Total	427	107.3
Source of information	Key informants	93	23.4
	Other farmers	288	72.4

	/Radio/television/social media	90	22.6
	Friends	235	59
	Opinion leaders	102	25.6
	NGO's	164	41.2
	Total	972	244.2

Mitigation measures adopted by farmers are illustrated in Figure 1. Organic manure use, tree planting, improved soil cover, mulching,

irrigation, and minimum tillage were widely supported as effective strategies to reduce climate change impacts on farming activities.

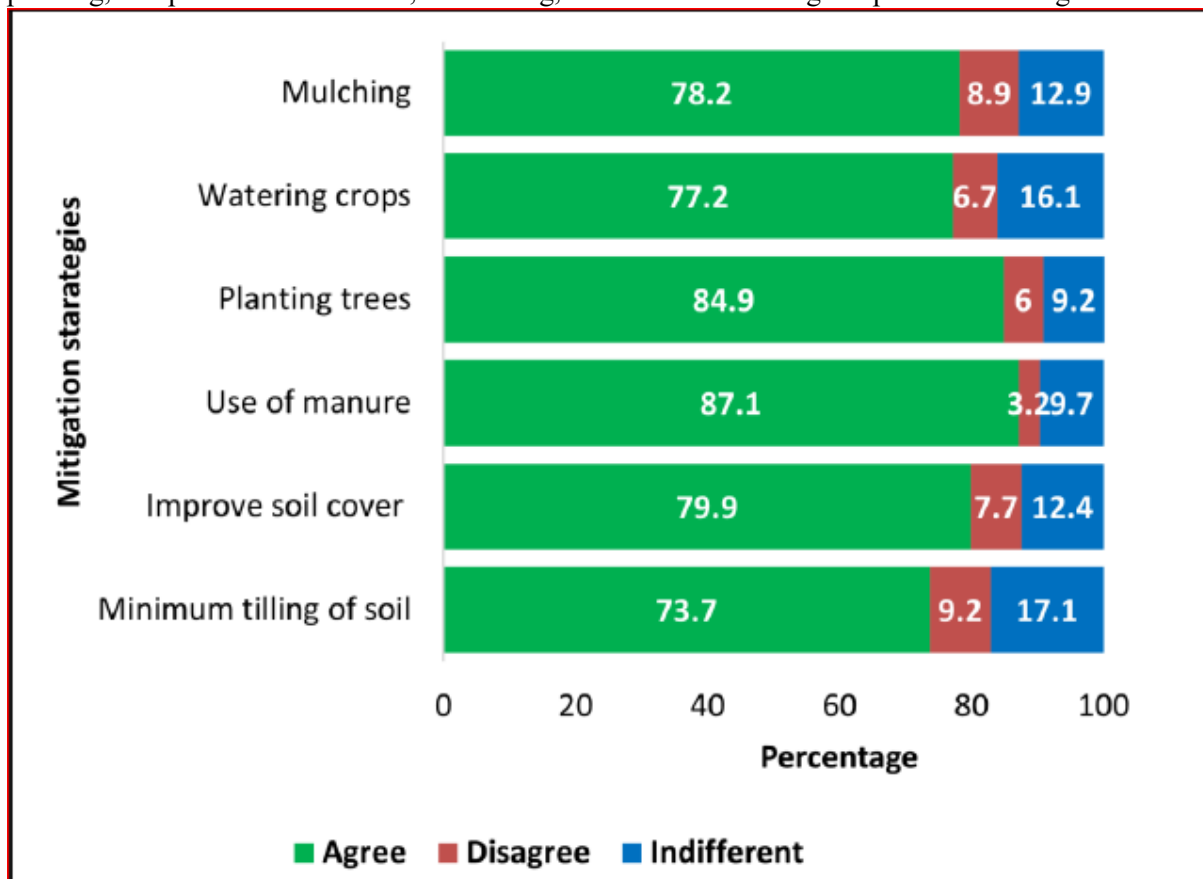


Figure 1: Mitigation measures put in place to fight against climate change by rural farmers of the Lebiale Division

Factors independently associated with climate change awareness are shown in Table 4. Married respondents and those aged 31–50 years were significantly more likely to be aware

of climate change. Higher income was inversely associated with awareness, while farmers with smaller farm sizes (<3 hectares) were significantly more aware.

Table 4. Factors independently associated with awareness of climate change

Variable	Categories	AOR	95% CI		Sig.
			Lower	Upper	
Marital status	Married	2.99	1.15	7.78	0.025*
	Single	1			
Age group	>60	3.73	0.59	23.76	0.164

	31-40	4.45	1.25	15.84	0.021*
	41-50	7.50	1.52	37.10	0.014*
	51-60	1.59	0.53	4.77	0.406
	21-30	1			
Monthly income	Above 100 000	0.09	0.03	0.24	<0.001*
	Less than 100 000	1			
Farm size	<3 hectares	5.26	1.41	19.67	0.014*
	>10 hectares	1.60	0.12	21.26	0.720
	3_5 hectares	1.25	0.46	3.39	0.666
	6_10 hectares	1			

Adaptive practices used by rural farmers are presented in Table 5. Practices such as planting resistant crop varieties, sharing information, adjusting farming calendars, crop rotation,

drainage, and pesticide use were widely supported. Early harvesting and blocking water canals received the lowest levels of support.

Table 5. Adaptive practices put in place to fight against climate change by rural farmers

Variable	Agree (%)	Disagree (%)	Indifferent (%)
Any available policy	321 (79.7)	25 (6.2)	57 (14.1)
Adjust farming timing according to rainfall	325 (80.6)	35 (8.7)	43 (10.7)
Plant crop varieties to resist scarcity	339 (84.1)	22 (5.5)	42 (10.4)
Planting more leguminous plant	311 (77.2)	43 (10.7)	49 (12.2)
Follow up weather forecasts	305 (75.7)	33 (8.2)	65 (16.1)
Change to other plant types	293 (72.7)	54 (13.4)	56 (13.9)
Use of pesticides	313 (77.7)	32 (7.9)	58 (14.4)
Crop rotation	311 (77.2)	30 (7.4)	62 (15.4)
Drainage	311 (77.2)	35 (8.7)	57 (14.1)
Cleaning canals	301 (74.7)	31 (7.7)	71 (17.6)
Blocking water canal	232 (57.6)	106 (26.3)	65 (16.1)
Early harvest	160 (39.7)	188 (46.7)	55 (13.6)
Farm inspection	315 (78.2)	39 (9.7)	49 (12.2)
Share information	326 (80.9)	33 (8.2)	44 (10.9)
Late sowing	254 (63)	77 (19.1)	72 (17.9)
Decrease in use of fertilizer	224 (55.6)	147 (36.5)	32 (7.9)

Finally, challenges faced in implementing mitigation measures are illustrated in Figure 2. Major barriers included lack of clear policies, poor implementation of existing policies, inadequate knowledge and skills, high cost and

limited availability of organic inputs and irrigation systems, pest and disease pressure, unpredictable weather, poor market access, and widespread deforestation, sustainable agriculture.

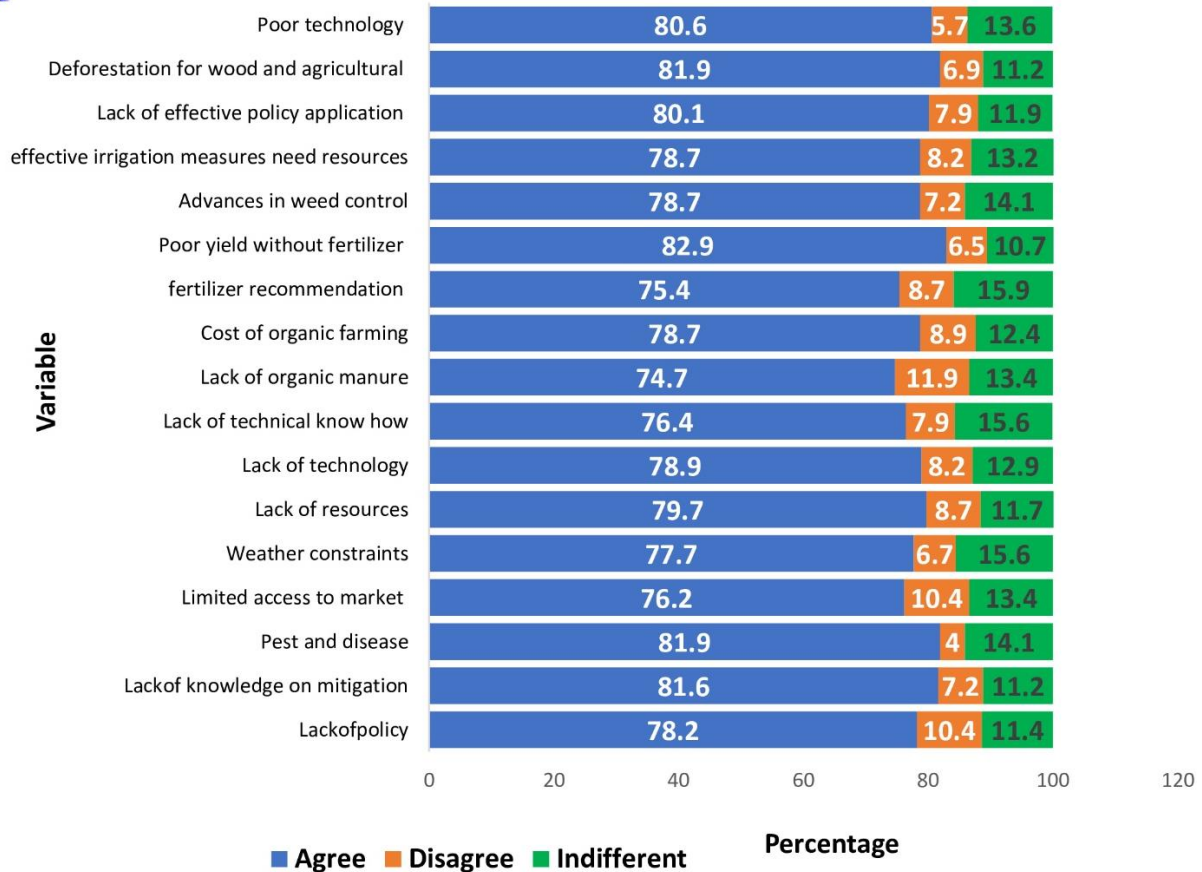


Figure 2: Challenges faced in the implementation of these measures by the rural farmers in the Lebialem Division

Discussion

The demographic profile of respondents provides important context for understanding awareness, mitigation, adaptation, and challenges related to climate change among rural farmers in the Lebialem Division. The relatively balanced distribution of respondents across Wabane, Alou, and Fontem subdivisions enhances the representativeness of the findings and suggests that the results reasonably reflect climate-related experiences across the division. However, variations in community participation, with higher representation from more accessible areas such as M'muock Fossimondi and lower participation from less

accessible communities like Ntesseh, highlight the persistent influence of geographical accessibility on research participation and service delivery in rural Cameroon. Similar patterns have been reported in other rural studies where infrastructure and road conditions significantly affect farmer engagement [24].

The predominance of male respondents reflects existing gender dynamics in rural agricultural systems, where men are more likely to be recognized as household heads and primary landholders. This finding is consistent with national and regional studies indicating that women, despite contributing substantially to agricultural labor, remain underrepresented

in formal agricultural surveys and decision-making structures [25, 26]. Such gender disparities have implications for climate change mitigation and adaptation, as women often have limited access to land, finance, and extension services, which may constrain their ability to implement climate-smart practices.

The age distribution shows that farming activities in Lebialem are largely undertaken by middle-aged adults, particularly those between 31 and 50 years. This age group is generally considered economically active and physically capable of engaging in labor-intensive farming practices. However, the relatively low participation of younger farmers suggests potential long-term sustainability concerns, especially in the context of youth migration and declining interest in agriculture. Similar trends have been observed across Sub-Saharan Africa, where rural youth increasingly migrate to urban centers due to limited economic opportunities and climate-related uncertainties [27].

Educational attainment among respondents was generally low, with most farmers having only primary or secondary education. This limited educational background may restrict farmers' ability to fully understand complex climate processes or access written and digital climate information. Several studies have shown that education plays a crucial role in enhancing climate change awareness, technology adoption, and adaptive capacity [28, 29]. Therefore, low educational levels may partly explain gaps observed between awareness of climate change and the effective implementation of mitigation strategies.

The economic profile of respondents reveals widespread income vulnerability, with the vast majority earning less than 100,000 FCFA per month. Low income significantly limits farmers' capacity to invest in climate-resilient technologies such as irrigation systems, improved seeds, and soil conservation infrastructure. This finding supports earlier research in Cameroon and other African countries, which indicates that financial

constraints are a major barrier to climate change mitigation and adaptation among smallholder farmers [30, 31]. The predominance of small to medium farm sizes further underscores the subsistence nature of agriculture in the study area, where farmers operate with minimal buffers against climate shocks.

Despite these socio-economic constraints, awareness of climate change among respondents was remarkably high. Over 90% of farmers reported being aware of climate change, largely through observable environmental changes such as irregular rainfall, shifting seasons, and rising temperatures. This suggests that experiential knowledge plays a critical role in shaping climate awareness in rural settings. Similar findings have been reported across Sub-Saharan Africa, where farmers often recognize climate change through lived experiences rather than formal climate education [32, 33]. However, awareness alone does not necessarily translate into comprehensive understanding, as knowledge of less visible drivers such as biodiversity loss and soil degradation was comparatively limited.

The regression analysis provides further insight into the socio-economic factors influencing climate change awareness. Married farmers were significantly more likely to be aware of climate change than unmarried farmers, possibly due to greater household responsibilities and stronger engagement in community networks. Age also played a significant role, with farmers aged 31–50 showing higher awareness compared to younger farmers. This aligns with findings from other studies which suggest that accumulated farming experience enhances sensitivity to environmental change [34]. Interestingly, higher income was negatively associated with climate awareness, a finding that may reflect reduced direct engagement in day-to-day farming activities among wealthier farmers. Similarly, farmers with smaller landholdings were more likely to be aware of climate change,

likely because limited land increases vulnerability to climate shocks and heightens sensitivity to environmental change [35].

In terms of mitigation measures, the findings indicate widespread adoption of low-cost, locally accessible strategies such as tree planting, use of organic manure, mulching, and reduced tillage. These practices are consistent with climate-smart agriculture principles and have been widely promoted across Africa due to their affordability and environmental benefits [36]. However, more capital-intensive strategies such as irrigation, while widely recognized as important, remain difficult to implement due to water scarcity and high costs. This gap between perceived usefulness and actual implementation reflects structural constraints rather than lack of willingness among farmers.

Adaptive practices followed a similar pattern, with high uptake of crop diversification, adjustment of farming calendars, and reliance on informal information-sharing networks. These strategies demonstrate farmers' capacity for autonomous adaptation based on experience and social learning. However, practices requiring technical knowledge or external inputs, such as advanced water management and optimized fertilizer use, showed lower levels of adoption. This finding supports existing evidence that adaptation among smallholder farmers is often incremental and constrained by access to resources and institutional support [37].

The challenges identified were multifaceted and interrelated. A large proportion of respondents reported limited technical knowledge, inadequate policy support, high costs of inputs, water scarcity, pest and disease pressure, and poor market access. These constraints collectively undermine the effectiveness and sustainability of mitigation and adaptation efforts. The findings align with broader regional studies indicating that weak extension services, limited financial support,

and poor infrastructure remain major barriers to climate resilience in rural Africa [38, 39].

Overall, the findings suggest that while rural farmers in the Lebialem Division possess high awareness of climate change and are actively engaging in mitigation and adaptation practices, their efforts are significantly constrained by socio-economic, institutional, and environmental barriers. Strengthening extension services, improving access to affordable inputs, investing in water infrastructure, and developing inclusive climate policies tailored to smallholder realities are essential for translating awareness into sustained climate resilience.

Conclusion

This study examined the level of awareness of climate change, the mitigation and adaptive practices employed, and the challenges faced by rural farmers in the Lebialem Division of the South West Region of Cameroon. The findings demonstrate that rural farmers in the study area possess a high level of awareness of climate change, largely driven by observable changes in rainfall patterns, temperature increases, soil fertility decline, and increased pest and disease incidence. Although most farmers may lack formal scientific knowledge of climate change, their awareness is strongly grounded in long-term farming experience and direct environmental observation.

The results further reveal that rural farmers are actively implementing various climate change mitigation and adaptation measures. Commonly adopted mitigation practices include tree planting, mulching, composting with organic manure, crop rotation, and reduced bush burning. Adaptive practices such as adjusting planting calendars, cultivating drought-tolerant crop varieties, diversifying crops, and engaging in small-scale irrigation and livestock farming were also widely reported. These findings indicate that farmers are not passive victims of climate change but

are proactively responding within the limits of their available resources and knowledge.

Despite this willingness to act, the study identified significant challenges that hinder the effective implementation and sustainability of climate change mitigation measures. Major constraints include limited access to water resources, poor survival rates of planted trees, inadequate financial capacity, insufficient technical knowledge, and weak access to agricultural extension services. Inadequate infrastructure and limited institutional and policy support further constrain farmers' ability to scale up climate-smart practices. These barriers reduce the overall effectiveness of mitigation and adaptation strategies and expose farmers to continued climate-related risks.

The findings also highlight the importance of local and traditional governance structures in supporting climate-related actions. Community leadership and local organizations play a complementary role in mobilizing farmers and encouraging collective responses to climate change, particularly in areas where formal government support is limited. However, reliance on local initiatives alone is insufficient to ensure long-term climate resilience.

Overall, the evidence suggests that while rural farmers in the Lebialem Division are aware of climate change and are making efforts to mitigate and adapt to its impacts, their capacity to do so effectively remains constrained by socio-economic, institutional, and infrastructural challenges. Strengthening institutional support systems, improving access

to extension services, enhancing climate education, and providing affordable climate-smart inputs are essential for transforming existing farmer-led efforts into sustainable and scalable climate resilience strategies. Addressing these gaps will not only improve agricultural productivity and food security but also contribute to broader climate change mitigation efforts in Cameroon.

Conflict of Interest

The authors report no conflict of interest in this study.

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Data Availability

The datasets used in this study are available from the corresponding author and can be gotten on reasonable request.

Author Contributions

Dr Fietsop Ernestine Nkemtah conceived the study, collected the data, conducted the analysis, and drafted the manuscript. The other authors supervised the research, contributed to the interpretation of results, and critically reviewed the manuscript. All authors read and approved the final manuscript.

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Strategies to Reduce the Increasing Risk Factors and Rate of Terminal Diseases Among Youths in Oji River, Udi and Environs in Enugu State, Nigeria

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Abstract

Terminal diseases including advanced cancers, chronic kidney disease, severe cardiovascular diseases, liver failure, and chronic respiratory illnesses are increasingly observed among young populations in developing regions. In Oji River, Udi and surrounding communities of Enugu State, Nigeria, youth exposure to unhealthy lifestyles, substance abuse, environmental pollution, poor healthcare access, and weak preventive services may accelerate progression into irreversible disease states. This study assessed major risk factors driving terminal diseases among youths in Oji River, Udi and environs, and proposed evidence-based strategies for reducing future terminal disease burden. Data were analyzed using SPSS version 25. Chi-square tests were applied to determine associations between risk exposures and self-reported chronic symptoms ($p < 0.05$). Out of 400 questionnaires distributed, 378 were correctly completed (response rate: 94.5%). Risk factors identified included frequent alcohol consumption (47.6%), cigarette smoking (18.5%), illicit drug use (13.2%), low physical activity (56.4%), unhealthy dietary practices (61.1%), and high reliance on self-medication (68.2%). Environmental exposure to smoke, fumes and waste-burning pollution was reported by 41.5%. Screening practices were poor: blood pressure checks (22.8%), blood glucose checks (14.0%), and hepatitis screening (11.6%). Chi-square analysis showed significant associations between smoking/pollution exposure and persistent cough/breathlessness ($p < 0.05$). Terminal disease risks among youths in Oji River and Udi are increasing due to modifiable behavioral and environmental exposures coupled with poor preventive health utilization. Interventions such as routine screening programs, youth-targeted health education, improved primary healthcare access, environmental pollution regulation, and stronger control of alcohol and tobacco use are urgently needed.

Keywords: Behavioral Risk Reduction, Disease Prevention Strategies, Health Promotion, Non-Communicable Diseases, Oji-River, Public Health Interventions, Risk Factors, Terminal Diseases, Udi Local Government, Youth Health.

Introduction

Terminal diseases are chronic progressive health conditions that may advance to

irreversible stages, leading to death, severe disability, or prolonged dependency. They include advanced malignancies, end-stage

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renal disease, chronic liver failure, severe cardiovascular disease, chronic obstructive pulmonary disease, and complications of poorly managed infectious diseases such as hepatitis and HIV exactly [1].

Globally, non-communicable diseases (NCDs) account for the majority of deaths and disability, with increasing prevalence in low- and middle-income countries. This growing burden is linked to rapid urbanization, dietary transitions, sedentary lifestyles, increased tobacco and alcohol consumption, and limited access to preventive healthcare services [2]. In Nigeria, these determinants are further worsened by weak health infrastructure, poverty, poor public health financing, and low screening uptake [3]. In Enugu State, particularly in Oji River and Udi LGAs, youths are increasingly exposed to environmental pollutants from waste burning, mechanic workshops, and industrial activities. The region also experiences rising consumption of alcohol, tobacco, and drug substances among young adults, partly driven by unemployment, peer pressure, stress, and inadequate youth-focused mental health services [4].

The burden of terminal diseases among youths is particularly concerning because the youth population represents the productive workforce of society. Early onset of chronic illness reduces productivity, increases household poverty, and imposes catastrophic healthcare costs on families. Additionally, late presentation to hospitals remains common due to reliance on self-medication, herbal treatment, and poor awareness of early warning signs [5].

This study examines the prevalence of major modifiable risk factors associated with terminal diseases among youths in Oji River, Udi and environs, and proposes comprehensive prevention strategies tailored to the socio-cultural realities of the area.

Methods/Methodology

Study Design

This study employed a descriptive cross-sectional survey design.

Study Area

The study was conducted in selected communities within Oji River and Udi Local Government Areas of Enugu State, Southeastern Nigeria. These areas comprise rural and semi-urban settlements characterized by small-scale businesses, agriculture, artisan work, and increasing youth migration.

Study Population

The population included youths aged 15-35 years who had lived in the study communities for at least 6 months.

Sample Size

A total of 400 respondents were targeted to ensure statistical reliability and account for incomplete responses.

Sampling Technique

A multistage sampling technique was adopted:

Stage 1: purposive selection of Oji River and Udi LGAs.

Stage 2: random selection of communities within each LGA.

Stage 3: systematic selection of households.

Stage 4: random selection of eligible youths per household.

Data Collection Tool

Data were collected using a structured questionnaire adapted from WHO STEP wise approach to NCD risk factor surveillance. Sections included:

1. Socio-demographic information.
2. Lifestyle behaviors (diet, smoking, alcohol, exercise).
3. Substance use.
4. Environmental exposure.

5. Health-seeking behavior and screening history.
6. Awareness of chronic and terminal diseases.

Validity and Reliability

Content validity was ensured through expert review by public health specialists. A pilot study was conducted in a nearby community outside the study area. Cronbach alpha reliability coefficient was 0.82, indicating strong internal consistency.

Data Collection Procedure

Trained assistants administered questionnaires in English and Igbo. Participants provided written or verbal informed consent.

Data Analysis

Data were analyzed using SPSS version 25. Results were summarized with descriptive statistics. Chi-square test was used to determine associations between selected risk factors and chronic symptom reports. Significance level was set at $p < 0.05$.

Results

Response Rate

Out of 400 questionnaires distributed, 378 were completed and analyzed, giving a response rate of 94.5%.

Socio-Demographic Characteristics of Respondents (Table 1)

Table 1. Socio-Demographic Characteristics of Respondents (n = 378)

Variable	Category	Frequency (n)	Percentage (%)
Age	15-19	64	16.9
	20-24	108	28.6
	25-29	122	32.3
	30-35	84	22.2
Sex	Male	199	52.6
	Female	179	47.4rc
Education	Primary	38	10.1
	Secondary	144	38.1
	Tertiary	197	51.9
Employment	Student	123	32.5
	Artisan	96	25.4
	Trader	71	18.8
	Unemployed	88	23.3

Field Survey Data, 2024; adapted from WHO STEP wise NCD Risk Assessment Framework.

Prevalence of Risk Behaviors (Table 2)

Table 2. Prevalence of Lifestyle and Behavioral Risk Factors (n = 378)

Risk Factor	Frequency (n)	Percentage (%)
Cigarette smoking	70	18.5
Alcohol consumption (any)	180	47.6
Frequent alcohol intake (≥ 3 times/week) so s cllsc	81	21.4
Illicit drug use	50	13.2

Poor dietary habit (high fried/sugary foods)	231	61.1
Low physical activity	213	56.4
Self-medication	258	68.2
Use of herbal remedies as first treatment	240	63.5

Field Survey Data, 2024; adapted from WHO STEP wise NCD Risk Assessment Framework [1].

Environmental Exposure (Table 3)

Table 3. Environmental Exposure Patterns (n = 378)

Exposure	Frequency (n)	Percentage (%)
Regular exposure to smoke/fumes	157	41.5
Exposure to wastomze burning sites	146	38.6
Exposure to mechanic workshop pollutants	104	27.5
Exposure to industrial emissions	72	19.0

Field Survey Data, 2024; adapted from WHO STEP wise NCD Risk Assessment Framework.

Screening and Preventive Health Practices (Table 4)

Table 4. Screening Practices among Respondents (n = 378)

Screen Practice	Frequency (n)	Percentage (%)
BP check within last 6 months	86	22.8
Blood sugar check within last 12 months	53	14.0
Hepatitis B/C screening ever	44	11.6
HIV screening ever	97	25.7
Routine medical check-up ever	61	16.1

Field Survey Data, 2024; guided by preventive screening indicators [11].

Chi-Square Association between Risk Factors and Chronic Symptoms (Table 5)

Table 5. Association between Smoking, Pollution Exposure and Chronic Respiratory Symptoms (n = 378)

Variable	Persistent cough/breathlessness	No symptoms	χ^2	p-value
Smoking (Yes)	41	29	9.71	0.002
Smoking (No)	79	229		
Pollution exposure (Yes)	72	85	8.23	0.004
Pollution exposure (No)	48	173		

Field Survey Data, 2024. Chi-square analysis computed using SPSS version 25.

Significant association at $p < 0.05$

Discussion

This study revealed a high prevalence of modifiable risk factors for terminal diseases among youths in Oji River, Udi and environs. Poor dietary habits (61.1%) and low physical activity (56.4%) were the most common risk

factors, indicating an ongoing nutrition and lifestyle transition consistent with patterns reported in other Nigerian communities [6]. Such behaviors predispose young individuals to obesity, diabetes mellitus, hypertension, and cardiovascular diseases, which may progress to terminal stages if unmanaged.

Alcohol consumption was high (47.6%), with 21.4% reporting frequent intake. Alcohol abuse is associated with liver disease, hypertension, stroke, mental illness, and increased risk of injury-related mortality. Early initiation of alcohol use among youths is often influenced by peer pressure, unemployment, and lack of structured youth engagement programs [7].

Cigarette smoking prevalence (18.5%) is concerning because tobacco is a well-established risk factor for lung cancer, chronic obstructive pulmonary disease, cardiovascular diseases, and stroke. The significant association between smoking and chronic respiratory symptoms in this study further supports the role of tobacco as a contributor to long-term morbidity [8].

Self-medication was highly prevalent (68.2%), suggesting poor health-seeking behavior and limited healthcare trust. The widespread use of antibiotics without prescription contributes to antimicrobial resistance and increases the risk of kidney and liver damage due to drug toxicity. Similarly, prolonged use of analgesics may predispose individuals to chronic kidney disease, which may progress to end-stage renal failure [9].

Environmental exposure to smoke, fumes, and waste-burning pollution was reported by 41.5% of respondents. Exposure to particulate matter and toxic chemicals is associated with chronic respiratory disease and cancer. Youths working as artisans, welders, and mechanics face heightened risk due to occupational hazards. The significant association between pollution exposure and chronic respiratory symptoms confirms the health risks posed by environmental conditions in the study area [10].

Preventive screening was poor. Only 22.8% had checked blood pressure recently, and hepatitis screening was extremely low (11.6%). This indicates that many youths may unknowingly live with chronic infections such as hepatitis B or early hypertension until

complications occur. Late presentation remains a major contributor to terminal disease outcomes in Nigeria [11].

The findings highlight the urgent need for preventive health interventions targeting youths. Without immediate action, the current prevalence of risk factors may translate into rising cases of advanced cancers, end-stage kidney disease, liver cirrhosis, stroke, and chronic respiratory failure in the coming decades.

Recommended Strategies to Reduce Terminal Disease Risk Among Youths

Community-Based Screening and Early Detection Programs

Quarterly mobile outreach screening should be implemented across communities in Oji River and Udi. Screening should include:

1. Blood pressure checks.
2. Random blood sugar testing.
3. Hepatitis B and C screening.
4. BMI and obesity assessment.
5. Kidney function tests (where feasible).
6. Early detection reduces progression to irreversible disease stages [12].

Strengthening Primary Healthcare Services

Primary healthcare centers should be strengthened through:

1. Improved staffing and training.
2. Availability of essential drugs.
3. Provision of diagnostic tools (glucometers, sphygmomanometers).
4. Youth-friendly consultation services.
5. Subsidized services for low-income youths.
6. Health insurance enrollment should be expanded to reduce financial barriers [13].

School-Based and Community Health Education

Health education should be integrated into secondary schools and community youth programs. Topics should include:

1. Dangers of tobacco and alcohol.
2. Nutrition education.
3. Dangers of self-medication.
4. Benefits of early hospital consultation.
5. Reproductive health and infectious disease prevention.
6. Peer educators and youth health ambassadors should be trained to deliver consistent messaging [14].

Regulation and Control of Alcohol and Tobacco Sales

Local government authorities should enforce restrictions on:

1. Sale of alcohol to minors.
2. Unregulated street alcohol production.
3. Tobacco advertisement and accessibility.
4. Community bylaws should include penalties for illegal sale of controlled substances [15].

Drug Abuse Prevention and Rehabilitation Programs

Drug prevention campaigns should involve:

1. NDLEA collaborations.
2. Counseling units in communities.
3. Youth rehabilitation referral systems.
4. Faith-based and traditional leader engagement.
5. Drug abuse is linked to mental illness, risky behaviors, and chronic organ damage [16].

Environmental Pollution and Occupational Safety Control

Policies should address:

1. Waste burning regulations.
2. Provision of waste disposal facilities.
3. Workplace safety enforcement in mechanic and welding areas.

4. Distribution of protective equipment such as face masks.
5. Environmental health officers should routinely inspect high-risk zones [17].

Promotion of Healthy Diet and Food Security

Community programs should encourage:

1. Reduced intake of processed foods.
2. Increased consumption of fruits and vegetables.
3. Reduction in sugary drinks.
4. Promotion of home gardening and local agriculture.
5. This can reduce obesity, diabetes, and cardiovascular risks [18].

Youth Physical Activity and Fitness Programs

Community sporting programs should be supported through:

1. Football tournaments.
2. Fitness clubs.
3. Weekly community walks.
4. School sports infrastructure.
5. Physical activity improves cardiovascular health and reduces metabolic disease risk [19].

Mental Health and Stress Reduction Programs

Mental health interventions should include:

1. Stress management education
2. Youth mentorship programs
3. Counseling centers
4. Community dialogue sessions on depression and anxiety
5. Mental health stability reduces substance dependency and unhealthy coping mechanisms [20].

Limitations of the Study

This study relied on self-reported data which may introduce reporting bias. The cross-sectional design limits causal interpretation. Also, clinical laboratory confirmation of diseases was not performed

due to resource constraints. Despite these limitations, the study provides useful baseline evidence on major risk factors affecting youths in Oji River and Udi.

Conclusion

The study demonstrates that youths in Oji River, Udi and environs are significantly exposed to modifiable behavioral and environmental risk factors that may predispose them to terminal diseases. Poor diet, low physical activity, alcohol abuse, tobacco use, self-medication, drug misuse, and exposure to pollution were prominent. Screening practices were poor, and preventive healthcare culture remains weak.

Reducing the future burden of terminal diseases requires multi-sectoral strategies involving routine screening, youth-focused health education, stronger primary healthcare delivery, strict substance control, environmental protection, improved occupational safety, and mental health interventions. If implemented, these strategies can reduce disease progression and improve youth health outcomes in Enugu State.

Conflict of Interest

The authors declare no conflict of interest.

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Ethical Approval

Ethical approval was obtained from an appropriate institutional ethics committee in Enugu State. Informed consent was obtained from all respondents. Confidentiality and anonymity were ensured throughout the research process.

Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors Contributions

Ikeonwueme Peace: Conceptualization, study design, supervision of data collection, manuscript drafting.

Abudullah Mohammad Sabo: Literature review, methodology development, data analysis, interpretation of results.

Chukwu Moses: Instrument development, field data collection, discussion writing, manuscript editing.

All authors reviewed and approved the final manuscript.

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Prevalence of Non -Adherence to Tuberculosis Therapy and Associated Factors among Patients with Pulmonary Tuberculosis at Mwananyamala Regional Referral Hospital, Dar- es- salaam

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Abstract

This study aimed to assess the prevalence of non- adherence to Tuberculosis therapy and associated factors among patients with pulmonary Tuberculosis at Mwananyamala Regional Referral Hospital, Dar es Salaam. It was a cross-sectional study involving Tuberculosis (TB) patients who attended the outpatient clinic at Mwananyamala Regional Referral Hospital. The sample size of this study consisted of 422 participants who were selected through systematic random sampling. Data collection was done by using structured questionnaires incorporated in Open Data Kit (ODK); in addition, the TB treatment card and the Morisky Medical Adherence scale (MMS) were also used. Data analysis was done by Statistical Package for the Social Sciences (SPSS) version 16.0 to find the proportion of respondents choosing different responses. The study findings indicated that most patients adhere to TB treatment by 98%, and only 2% did not adhere to TB treatment. Factors associated with adherence, such as TB drugs' side effects and non-compliance, did not influence non-adherence. The study recommends the same modality of treatment to continue to maintain the adherence level of TB patients. This study has implications for all stakeholders involved in TB patients' management. The practical and theoretical implications provide the benefits of the study to the government, non-governmental organizations, and research organizations.

Keywords: Non-Adherence, Non-Compliance, Patients, Side Effects, Tuberculosis.

Introduction

Background of the Study

In 1993 the World Health Organization(WHO) declared Tuberculosis(TB) a global emergency disease with 2 billion people affected by the disease [1]. Nevertheless, it is still a disease of public health importance, as in 20 century, TB has become a threat. It is one of the oldest communicable diseases which creates a global problem with significant mortality and morbidity despite of effort of implementing direct observed therapy (DOT) treatment strategies in many countries since 1995 to enhance TB drug adherence[2].

Global estimates show that in every three people, one is infected with Mycobacteria tuberculosis (MTB) and at risk of developing the disease [3]. TB is among the top ten killer infectious diseases worldwide [4]. One of the factors that contributes to the high burden of the disease is non-adherence to prescribed ant- TB drugs by patients, which results in treatment failure and prevent to achieve TB control program goals [5].

Adherence is the degree to which an individual follows a set of agreed actions. In the medical field, it involves: practice of taking prescribed medication, seeking help if symptoms change, attending a consultation, and

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making lifestyle changes. It assumes an equal relationship between two people and its voluntary process [5, 6], It involves three phases, which are: initiation, implementation, and discontinuation phase [7].

There are many factors which results to non-adherence, such as non-compliance and TB drugs' side effects. Non-compliance is an autocratic relationship in which someone follows instructions (compliant) or does not follow instructions (non-compliant) [6]. It can also be defined as a patient behavior aligned with medical advice on how to take drugs [8], and the side effect of TB drugs is defined by WHO as a medical occurrence temporally associated with medicine but not necessarily causally related. It can be any unfavorable or unintended sign, including laboratory findings or symptoms that are temporally associated with the use of a medicinal product [9].

In 2015 more than 9.6 million new cases with TB and mortality of 1.5 million observed globally and in 2018 WHO emphasized on global strategy to end TB by 2030, [2] Significant TB cases about 80% occur in high burden TB countries and sub-Sahara Africa contain 70% of the world TB burden with estimated TB active case of more than 4 million which results to 650,000 death every year, [2].

Tanzania is one of the countries with a high burden of TB, with a prevalence of 275/100000 population and an incidence of 164,000 cases [2]. The highest of TB cases in Tanzania are found in Dar es Salaam by 21.9%, followed by Mwanza with 9.3%, then Shinyanga 6.4%, and Mbeya 6.6% [2].

Given the high burden of TB and MDR-TB in Tanzania, this study seeks to understand the level of non-adherence to TB treatment and factors associated with patients with Tuberculosis. The overall goal of the study is to produce scientific evidence that will guide health providers on how to enhance adherence to TB therapy among individuals on treatment. This will as a consequence reduce cost of treatment to the patients, TB relapse, reduce

side effects of injectable anti-TB drugs caused by non –compliance of treatment, in addition, enhanced adherence will reduce duration of treatment and hospital admission if they develop drug resistance TB, reduce physcosocial impact, low cure rate, reduce mortality rate of TB patients and prevent transmission of resistant strain of Tuberculosis disease.

This study aims to determine the level of non-adherence to TB therapy, which can reveal what proportional of patients who do not adhere to treatment, and the association between treatment non-compliance, TB drug side effects, and TB treatment non-adherence. Many studies have shown a clear link between non-adherence with treatment failure, social, economic, and treatment factors contribute to non-adherence to TB therapy. In Tanzania, the level of non-adherence is 20%, still high [10], which is above the WHO recommendation [11]. This is a reason why this study is chosen to quantify non-adherence to patients and understand reasons for non-adherence, which will contribute to the implementation of targeted interventions as well as ensure optimal adherence in order to control Tuberculosis [12].

Tuberculosis is one of the main communicable diseases with higher mortality and morbidity worldwide, contributing 10.4 million cases in 2017 globally, with mortality of 1.7 million patients [13]. TB treatment, which has a duration of 6 months, is a foundation of Tuberculosis control and prevention, but non- treatment adherence is the main factor that results in treatment failure or Mult- drug resistance tuberculosis (MDR-TB), and in 2017, there were 558,000 MDR-TB patients worldwide [10]. The current TB treatment faces a lot of challenges due to TB drug side effects and long-term treatment resultong in MDR-TB, and the main cause is treatment non-adherence and loss to follow-up [3]. A mix of different ant- TB drugs and a longer duration of 6 months result in risk of treatment interruption, which may result in

persistence of TB infection, TB relapse, drug resistance, and death. Challenges faced by patients to follow long-term treatment and the number of pills taken daily make adherence a complex behavioral phenomenon [14].

Globally, there is implementation of Direct Observed therapy (DOT) with the intention to reduce treatment failure, drug resistance, and TB relapse, but its influence to reduce TB new cases has been affected by non-compliance to DOT supervisors as well as patients. There is a significant magnitude of non-adherence to chronic disease, including TB disease, globally [15].

In developing countries, there are many factors which affect non adherence to TB treatment which include; drug side effects, age, distance to the health facility, traditional belief leading to self-treatment, pill burden, lack of family support, lack of food, lack of adequate communication from health care professionals and low income, long duration of treatment [11, 15].

Tanzania is one of the countries with a high burden of Tuberculosis, there were 75,845 patients in 2018, with the increase of 6,205 (9%) new cases, compared to 2017. New and relapsed cases were 74,692, of which 48% were bacteriologically confirmed, pulmonary TB patients were 79%, and 14% were children. Dar es Salaam remains a major city with tuberculosis patients in Tanzania. It contributes 20% of all TB cases in Tanzania. There is a variation of TB patients across the country, from which, in previous years, 50% of patients were contributed by seven regions, which are, Mwanza, Arusha, Dar-es-Salaam, Geita, Mbeya, Manyara, and Dodoma [16].

Most of the TB complications are due to non-adherence to TB medications. Non-adherence has been considered as a major obstacle which hinder eradication of TB globally, and the WHO defines non-adherence as patients who do not complete treatment and recommends that non-adherence should not exceed 5% [11, 17]. In Tanzania, adherence is defined as taking all

TB drugs for a period of six months, and missing more than 6 doses in four weeks is regarded as non-adherence [18]. It is difficult to assess non-adherence to TB therapy, but up to one fourth of patients do not complete six-month treatment [19]. Treatment adherence behavior (TAB) can be explained as the extent to which a person practices taking medication, following a diet, and change life style as recommended by Health care provider, conversely, it is non-adherence [5].

Failure to adhere to TB therapy may result in treatment failure as well as Multidrug-resistance pulmonary Tuberculosis, morbidity, mortality, low treatment success rate, long treatment regimen, transmission of TB resistance strain to the community, economic burden as a result of increased admission rate and hospital stay, and acquisition of chronic TB manifestation [20]. Understanding adherence behavior is important for effective and efficient treatment planning, improving understanding of fluctuation in treatment outcome in disease monitoring programs, knowledge of adherence patterns is important in TB program decisions, and consideration of patient experience influences patient-centric management, which will promote treatment adherence [5].

Several efforts have been put in place to manage adherence challenges. The World Health Organization has set targets in its 2017 End TB strategy for reducing deaths by 95% and new cases by 90% in 2035, along with the implementation of the DOT strategy (10). DOT strategy needs every patient to have a treatment partner that observe patient daily while taking medication [11].

WHO also introduced digital adherence technology, funding, and technical support to combat the challenges of non-adherence to achieve its mortality and morbidity reduction [4, 10]. A defaulter tracing system was also created to ensure that patients adhere to treatment to reduce the TB burden across the globe [20]. Fee exemption has been introduced in developing countries, and Fixed-dose

combination of anti-TB drugs has been put in place since 1980 to enhance adherence to TB therapy [20]. TB awareness programs and increased access to health facilities have been put in place to enhance adherence to TB therapy [11].

In 2006, Tanzania, through the National Tuberculosis and Leprosy Control Program (NTLP), introduced Patient-centered TB Treatment (PCT). This approach gave opportunity patient to choose either home-based direct observed treatment (HB-DOT) supervised by supporters of their own choice or Health facility-based direct observed treatment (HF-DOT) supervised by medical staff. The purpose of introducing this was to enhance TB therapy adherence, and currently more than $\frac{3}{4}$ of all TB patients prefer home-based direct observed therapy [4]. Because of its impact on global health, TB has been considered in the United Nations (UN) goals for reducing incidence cases of MDR-TB and mortality rate, as well as disease risk [21].

Despite the effort taken, including the DOT strategy, adherence to TB therapy remains a major challenge. Digital adherence technology, its impact on adherence is still limited [10]. Introduction of Patient- Centered treatment (PCT), which also failed to enhance adherence. This study considered patient and drug factors that were suspected to be major factors of non-adherence.

TB remains an infectious disease worldwide and results in many deaths in poor countries. Increase in TB drug resistance has worsened the situation, and this is due to non-adherence to TB treatment [15, 22]. WHO estimates that TB death is 54million between 2000 and 2017, and new cases are 10 million yearly, and patients have not recovered after several treatments due to non-adherence to TB therapy. Tanzania is among the top 20 countries with a high TB burden worldwide, ranked as number 15 [23]. It is the WHO designed a high- burden tuberculosis country [24].

One of the agenda items in Sustainable Development Goals (SDGs) is to end the global TB pandemic by the year 2030, in line with this WHO goal of reducing TB deaths by 90% and incidence rate by 80% in 2030 by ensuring adherence to TB treatment is implemented [25]. Treatment of tuberculosis in Tanzania is six months. It is expected that patients take their drugs daily. However, some patients in Tanzania do not take their TB drugs daily, hence they don't complete the six-month treatment [23].

There are limited data on non-adherence in Tanzania[22]. Studies done have limitations on small sample size and data collected from these studies are not informative on provision of prevalence and other factors related to non-adherence and drug resistance at a national level, as samples were not representative, and most of the studies were not done according to the current international recommended methodology [26]. The study determined the proportional of patients who do not adhere to treatment. This enables health workers in TB clinics to provide an effective way on how drugs should be taken to prevent TB relapse, death, and transmission of resistance strain. This study was conducted to determine the prevalence of non-adherence to TB therapy and associated factors among patients with pulmonary Tuberculosis.

Health Believe Model (HBM) was adopted in this study. This model was developed by a social scientist in the United states of America (USA) in 1950 to understand why people fail to adopt prevention strategies of different diseases or screening of various tests to detect diseases. Later, this theory was used for patients' response to compliance and symptoms with medical treatment. The theory suggests that personal belief in the threat of disease, as well as belief in recommended health behaviour will predict whether a person can adopt the behaviour or not.

The concept of HBM comes from behaviour and psychological theory with two components

of health behaviour which include: belief that specific health action will prevent, or cure disease or desire to avoid disease or get well once the disease is already acquired, an individual's course of action is determined by the perception of barriers or benefits aligned with the behaviour. The HBM has six constructs out of which the first four were from when the theory was developed, but the last two were added later.

The constructs are as follows: Perceived susceptibility: This can be explained as the subjectivity of a person's perception of the risk of acquiring a certain disease. Different people have different feelings about the vulnerability of the disease. Perceived severity: This can be explained as individual feelings on the seriousness of acquiring a disease or sometimes leaving a disease untreated. There is a variation in feelings on the severity of the diseases among different groups of people. Normally, they are considered as social consequences (social relationships or family life) or medical impacts such as death or disability) Perceived benefit: This can be explained as individual's perception of effectiveness of actions available to reduce the impact of the disease (or cure the disease). The course of action is taken after considering perceived susceptibility and perceived benefit, in which an individual will accept a recommended health action if it is thought to be beneficial [27].

Perceived barrier: This can be explained as individual feelings about obstacles, implementing a recommended health action. Different people have different feelings about barriers, which can weigh the effectiveness of proposed action against cost implications such as expensive, dangerous (including side effects), time consuming or unpleasant, such as painful. **Cue to action:** This refers to a stimulus needed to initiate decision making process to agree with recommended health action, it can be external such as a newspaper or an article, or receive advice from others, or an illness of a family member, but it can also be internal, such

as a wheeze or chest pain. **Self-efficacy:** This can be explained as the level of individual confidence in the ability to perform recommended health behaviour. It considers whether the person performs the desired behavior [27].

Two variables are obtained from this theory: Perceived benefit (reflects compliance part of patients to take anti-TB drugs), which means patients will comply with treatment if they thought that the treatment is beneficial and will not comply (non-compliance) if they thought that the treatment is not beneficial. Perceived barrier (reflected as TB drugs side effects) which may hinder patients from taking anti-TB drugs) All these can lead to non-adherence to the drug, which is the dependent variable.

Many studies show that adherence to Tuberculosis therapy does not reach the required level in Sub-Saharan Africa. In Tanzania, one study done in Kilimanjaro shows 79% of TB patients were adherent, and a study done in Mwanza shows only 83% of TB patients adherent [10]. Tanzania is one of the countries with the highest burden of TB, with an incidence rate of 269 (127-464) per 100,000 population in 2017. The mortality rate of TB is 47 (21-83) per 100,000 population in 2017, with MDR-TB patients of 0.9%. The success of treatment of TB is not 90% adherence as required in 2017 [10].

The main objective of this study was to determine the prevalence of non-adherence to Tuberculosis therapy and associated factors among patients with pulmonary tuberculosis at Mwananyamala Regional Referral Hospital. The specific objectives were: To determine the proportion of non-adherence to TB therapy among patients with pulmonary TB at Mwananyamala Regional Referral Hospital, to ascertain the association between TB treatment non-compliance and non-adherence among patients with pulmonary TB at Mwananyamala Regional Referral Hospital, and to establish the association between TB drugs' side effects and non-adherence among patients with pulmonary

TB at Mwananyamala Regional Referral Hospital.

The novelty of this study includes demonstrating an exceptionally high TB treatment adherence rate (98%) in a regional hospital setting in Tanzania. It also challenges known assumptions by showing that commonly factors, such as drug side effects, did not significantly influence non-adherence in this population.

Materials and Methods

This was a quantitative study with a cross-sectional design. A total of 422 TB patients were involved; The sample was drawn from a sample frame of 900 TB patients from Mwananyamala TB clinic. Assessment of the participants was done on adherence to TB drugs.

The sample size was calculated using a formula used in cross-sectional studies with 95% confidence interval.

$$S = Z^2 p \frac{1-p}{d^2} + 10\% \text{ non-respondents}$$

Where S=sample size.

Z=standard normal variate.

P=prevalence of outcome.

d=absolute error.

Z= 1.96.

P=0.2.

d = 0.04 .

Therefore.

$S = 1.96 \times 1.96 \times 0.2 (1-0.2) / (0.04)^2 + 10\%$
non-respondents.

$S = 384 + 38 = 422.$

The sample size of this study was 422 patients.

The sample size was completed within one month, because the number of follow-up patients per day was over 50 and only 14 patients were needed per day, and systematic sampling was used. The study was conducted in 2021, Dar es Salaam Tanzania, at Mwananyamala Regional Referral Hospital.

Positivism was used in this study because this is a quantitative study, and assumptions are prevalence of non-adherence would be

quantified; there is a possibility of determining what factors can influence non-adherence to anti-TB drugs. The factors that can results in non-adherence to ant-TB are: non-compliance with anti-TB drugs, side effects of ant-TB drugs, and other factors that might cause adherence to ant-TB drugs are: proper education of the patients, a good health system structure, and a good patient- to- health care relationship.

Different tools were used to collect data, which include: a structured questionnaire, a TB treatment card, and the MMS-8 scale. The structured Questionnaire was used as it contained specific questions that guided participants to respond to questions related to non-adherence. It was used as an instrument for data collection and was distributed randomly. The researcher used five attributes when developing standardized research questionnaires, and these were: strongly disagree, disagree, neutral, agree, and strongly agree. This enabled easy and timely responses to questionnaires by respondents. Responses from a structured questionnaire were received from the patients, and the questions were structured based on the common causes of non-adherence to TB therapy, non-compliance, and TB drug side effects. TB treatment cards were also used to collect data on adherence. These cards indicated how many doses had been taken by patients for a certain period. Each TB patients had a treatment card, and these cards were obtained from them. MMS-8 scale was also used to collect data related to adherence; questions related to non-adherence were asked, and responses were obtained from patients. ODK software was used as an instrument tool for collecting data, and then the data was sent to the SPSS program for further processing.

In Tanzania, according to the National Tuberculosis and Leprosy program (NTLP) guidelines of 2017, non-adherence is regarded if a patient misses more than 6 doses in four weeks. This study used NTLP 2017 guidelines to assess non-adherence. The TB treatment card

was used to assist the process, and patients who missed more than 6 doses within any of the four weeks of the treatment period were regarded as non-adherent.

Morisky medical adherence scale (MMS-8) was also used to assess non-adherence, in which there were 8 questions asked. For the first seven questions, each question has one mark for yes and 0 for no. Question no 8 Likert scale was used with a score ranging from 0 to 4. Overall score for this scale ranges from 0 to 11, and <2 was considered as adherence, and > 2 was considered as non-adherence. The higher the score, the lower the adherence. The questions were applicable over the entire treatment period, from 1 month to six months.

Compliance was assessed by using a summated rating scale (Likert scale). This scale has been used to assess compliance in most medical conditions and has recently been used by [28] to assess compliance with COVID-19 precaution measures. 5 points Likert scale was used in this study, in which four compliance questions were asked with responses of strongly agree, agree, neutral, disagree, and strongly disagree. Patients who responded to disagree and strongly disagree were regarded as non-compliant to specific questions as well as to the overall score.

Data analysis for this study was done with the help of SPSS statistical software. Categorical variables were summarized by calculating proportions from frequencies, and means and standard deviations were used to summarize continuous variables. Study population characteristics were compared between TB patients on therapy who are adherent and non-adherent using the chi-square test for categorical variables and the student t-test for continuous variables. Variables with $p < 0.2$ in this analysis were included in the multivariable logistic regression model to assess the independent association between non-adherence and the risk factors. All analyses were two-tailed at a significance level of 0.05.

Ethical Considerations

Permission to conduct this research was obtained from the Director of Research Post Graduate Studies, School of Public Health, University of Dar es Salaam and consent was requested from all participants. Name of participants was not recorded to maintain confidentiality.

Results

Characteristics of Study Participants

Among the patients who did not adhere to treatment, 75% were male and 25% female. In a group of non-adherent patients, 87.5% were between the aged of 25 and 45 years, while 12.5% between 68 and 85 years, and none of the patients were between 46 and 65 years. 75% of non-adherent patients were not married, while 25% were married. This study shows that there was an association between marital status and non-adherence, as the p-value was 0.038.

Among patients who fail to adhere to treatment, 75% were not employed, and only 25% were employed. 50% of the patients who did not adhere to treatment had primary education, 37.5% had secondary education, 12.5% had never gone to school, and none of the patient had university education.

Other factors associated with non-adherence, such as following healthcare instructions, knowledge of TB disease, alcohol use, family support, and distance to the health facility, have been assessed in this study. 25% of the patients who did not adhere to treatment had no knowledge of TB disease, while 75% had knowledge on Tuberculosis disease. 80% who failed to adhere to treatment did not take alcohol, while 20% took alcohol. In a group of non-adherent patients, 62.5% receive family support while taking anti-TB drugs however; 37.5% did not receive family support while taking anti-TB drugs. 62.5% of patients who did not adhere to treatment, distance to the health facility was not a challenge, while 37.5% had a challenge with distance to the health facility

affecting their ability to adhere to treatment. All these factors except Alcohol intake have an association with non-adherence, as their p-

value is less than 0.01. These results are illustrated in Table 1.

Table 1. Characteristics of Study Participants by MMS-8 Score

	Total	Adherence (414, 98%)	Non-Adherence (8, 2%)	P-Value
Gender				
Male	288(68.25%)	282(68.12%)	6(75%)	0.625
Female	134(31.75%)	132(31.88%)	2(25%)	
Age				
25-45	270(63.98%)	263(63.53%)	7(87.5%)	0.326
46-65	128(30.33%)	128(30.92%)	0(0%)	
66-85	24(5.69%)	23(5.55%)	1(12.5%)	
Married				
Yes	275(65.16%)	150(36.23%)	2(25%)	0.038
No	147(34.84%)	141(34.06%)	6(75%)	
Employed				
Yes	152(36.02%)	150(36.23%)	2(25%)	0.562
No	270(63.98%)	264(63.77%)	6(75%)	
Education				
Never	24(5.69%)	23(5.56%)	1(12.5%)	0.173
Primary school	208(49.29%)	204(49.28%)	4(50%)	
Secondary school	153(36.26%)	150(36.23%)	3(37.5%)	
University	37(8.76%)	37(8.93%)	0(0%)	
Follow instructions				
Yes	421(99.76%)	414(100%)	7(87.5%)	0.00
No	1(0.24%)	0(0%)	1(12.5%)	
TB knowledge				
Yes	413(97.86%)	407(98.31%)	6(75%)	0.562
No	9(2.14%)	7(1.69%)	2(25%)	
Alcohol intake				
Yes	81(19.19%)	79(19.08%)	2(20%)	0.535
No	335(80.81%)	335(80.38%)	8(80%)	
Family support				
Yes	389(92.18%)	384(92.75%)	5(62.5%)	0.00
No	33(7.82%)	30(7.25%)	3(37.5%)	
Distance effect				
Yes	8(1.89%)	5(1.21%)	3(37.5%)	0.00
No	414(98.11%)	409(98.79%)	5(62.5%)	

Non-Adherence by MMS-8 Scale

Eight questions of MMS-8 were used to assess the level of adherence. For the first seven

questions: each question has 1 mark for a Yes response and 0 mark for a No response, and question number 8 a Likert scale was used with a score ranging from 0 to 4. The overall score

for this scale ranges from 0 to 11; the questions were asked considering the overall treatment period, i.e., from the first month to six months.

Out of 422 patients, 98% of the patients adhered to treatment while 2% did not adhere to treatment as indicated in Figure 1.

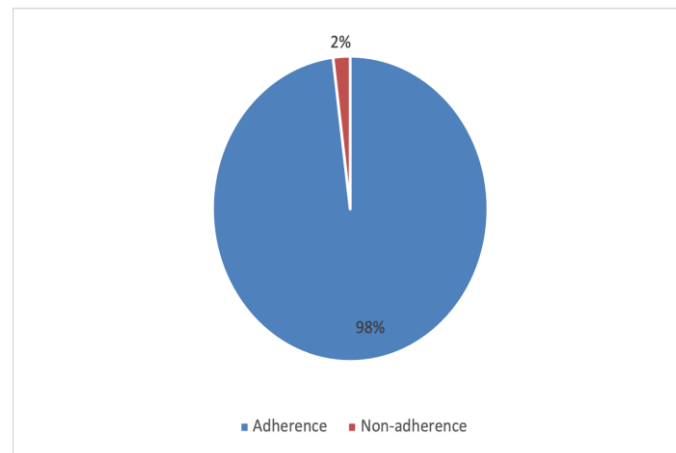


Figure 1. Non-Adherence by MMS-8

Non- Adherence by Treatment card

TB treatment cards were also used to assess non-adherence; all treatment cards (100%) of patients have been completed as per the NTLP guideline recommendation, which means adherence is 100%.

Associations between Tb Drugs Side Effects and Non-Adherence

Out of 8 patients who did not adhere to treatment, 50% had TB drug side effects, while the other 50% did not experience any side effects. Among patients who adhered to TB treatment, (30.68.0%) had TB drug side effects, while 69.32% did not have side effects. This study shows that there is no association between TB drug side effects and non-adherence, as the p-value was 0.261, as shown in Table 2.

Table 2. Association between Overall TB Drugs Side Effects and Non-Adherence

Side effects	Non-Adherence (n, %)	Adherence (n, %)	P-Value
	(8, 2%)	(414, 98%)	
Yes	4(50%)	127(30.68%)	0.261
No	4(50%)	287(69.32%)	
Total	8(100)	414(100)	

Association between Specific TB Drugs Side Effects and Non-Adherence

Common TB drugs' side effects have been evaluated in this study, such as discomfort, feeling more sicker, interference with work activities, Numbness, headache, dizziness, and skin rash. Among patients who did not adhere

to treatment, 62.5% did not experience discomfort, 37.5% had discomfort; none of the patients felt more sicker or had work interference while taking ant-TB drugs. 25% of the patients experienced numbness, headache, dizziness, and skin rash, while 75% did not have these side effects. In this study, all TB drug side effects evaluated have no association

with non-adherence, as they have a p-value of greater than 0.05, except discomfort, which has

a p-value of less than 0.01, as illustrated in Table 3.

Table 3. Association between Specific TB Drugs Side Effects and Non-Adherence

Side effects	Total	Adherence (414, 98%)	Non-adherence (8, 2%)	P-Value
Discomfort				
Yes	9(2.13%)	6(1.45%)	3(37.5%)	0.00
No	413(97.87%)	408(98.55%)	5(62.5%)	
Feel Sicker				
Yes	3(0.71%)	3(0.72)	0(0%)	0.971
No	413(97.87%)	408(98.55%)	5(62.5%)	
Work interference				
No	422(100%)	414(100%)	8(100%)	-
Numbness				
Yes	100(23.7%)	98(23.67%)	2(25%)	0.628
No	322(76.3%)	316(76.33%)	6(75%)	
Headache, dizziness or skin rash				
Yes	50(11.85%)	48(11.4%)	2(25%)	0.628
No	372(88.15%)	366(86.73%)	6(75%)	

Association between Specific Non-Compliance Factors and Non-Adherence

On assessing compliance-specific factors, among patients who did not adhere to treatment, 75% agreed, and 25% strongly agreed that they take drugs before a meal, and none of the patients were neutral on the same question. 87.5% of the patients agreed, and 12.5% were neutral on taking food within 30minutes to 1 hour after taking ant-TB drugs, and none strongly agreed on the same question. 71.43% of

non-adherent patients agreed, and 28.57% were neutral on taking 3-5 liters of water per day, and none strongly agreed, strongly disagreed, or disagreed on the same question. 50% of the patients were neutral, and the other 50% agreed that they take a diet rich in vegetables and fruits; none of the patient strong agreed or disagreed on the same question. All compliance factors assessed in this study have no association with non-adherence except taking water 3-5 liters per day, which has a p-value of less than 0.01, as illustrated in Table 4.

Table 4. Association between Specific Non- Compliance Factors and Non-Adherence

Compliance Taking drugs before meal	Total	Adherence (414,98%)	Non-adherence (8,2%)	P-value
Strong agree	214(50.71%)	213(46.14%)	1(25%)	0.233
Agree	198(46.92%)	191(47.83%)	7(75%)	
Neutral	10(2.37%)	414(0.72%)	0(0%)	
Taking food after 30min-1 hour				
Strong agree	191(45.26%)	191(45.26%)	0(0%)	
Agree	207(49.05%)	200(48.31%)	7(87.5%)	
Neutral	24(5.69%)	23(6.43%)	1(12.5%)	
3-5 liters of water per day				

Strong agree	108(25.59%)	108(26.09%)	0(0%)	0.000
Agree	153(36.26%)	148(35.75%)	5(71.43%)	
Neutral	152(36.02%)	150(36.23%)	2(28.57%)	
Disagree	8(1.89%)	7(1.69%)	0(0%)	
Strong disagree	1(0.24%)	1(0.24%)	0(0%)	
Taking diet rich in vegetables				
Strong agree	127(30.09%)	127(30.09)	0(0%)	0.000
Agree	184(43.6%)	180(43.48%)	4(50%)	
Neutral	107(25.360)	103(24.88%)	4(50%)	
Disagree	4(0.96%)	4(0.96%)	0(0%)	
Overall P-Value				0.382

Multivariable logistic Regression

From the data analysis plan, any variable that predict the outcome and has a p-value of less than 0.2 was considered in the multivariable logistic regression to determine the independent association between non-adherence, non-compliance, and risk factors. These variables were: marital status, follow instruction, knowledge on TB, family support, distance to the health facility, discomfort, and taking 3 to 5 liters of water per day, as shown in Table 1.

Married patients were more likely to adhere to treatment (OR 5.809, CI 95%,1.157-29.151) than non- married patients, and the results were statistically significant as the p value was less than 0.05. Patients who follow healthcare instructions were more likely to adhere to treatment (OR 9.193, CI 95%,9.193-9.193) than those who do not follow instructions, and the results were statistically significant as the p-value was less than 0.05. Patients who had TB knowledge were 19.381 times more likely to adhere to treatment (CI 95%,3.314-113.342) than those who did not have TB knowledge, and

the results were statistically significant as the p-value was less than 0.05. Patients who receive family support while taking ant- TB drugs were 7.68 times more likely to adhere to treatment (CI95%,1.75-33.697), but the results are not statistically significant as the p-value was greater than 0.05.

Patients who had no challenge with the distance factor to the health facility were less likely to adhere to treatment (OR 0.02, CI 95%,0.04-0.109) than those who had a challenge, and the results are statistically significant as the p- value was less than 0.05. Patients who had no discomfort symptom were less likely to adhere to treatment (OR 0.25, CI 95%,0.05-0.127) than those who had discomfort symptoms and the results were statistically significant as the p-value was less than 0.05. Patients who take 3-5 liters of water per day while taking ant- TB drugs were 2.6 times more likely to comply with treatment (CI 95%,0.05-0.127) than those who do not take the same amount of water, and the results are statistically significant as the p- value was less than 0.05, as illustrated in Table 5.

Table 5. Multivariable Logistic Regression

	Multivariable models	
	Odds ratio (95% CI)	p-value
Marital status - Yes	5.809 (1.157-29.151)	0.03
Follow instructions -Yes	9.193(9.193-9.193)	0.00
TB knowledge-Yes	19.381(3.314-113.342)	0.01
Family support -Yes	7.680(1.750-33.697)	0.07

Distance effect-No	0.02(0.04-0.109)	0.00
Discomfort-No	0.25(0.05-0.127)	0.00
Taking 3-5 liters of water-Yes	2.6(2.110-3.241)	0.00

Hypothesis Testing

The first null hypothesis stated that; non-compliance does not influence Tuberculosis therapy non-adherence. The results indicated that a significant level of variable non-compliance is 0.382, which was above 0.05, so we failed to reject the null hypothesis, and the conclusion was that non-compliance did not influence on Tuberculosis therapy non-adherence. In assessing specific non-compliance factors, only one factor (discomfort) had a p-value of less than 0.05, as shown in Table 4.

The second null hypothesis stated that TB drug side effects do not influence Tuberculosis therapy non-adherence. Results indicated that the significance level of the variable TB drug side effect was 0.261 higher 0.05 then we failed to reject the null hypothesis, and Therefore the conclusion was that TB drug side effects did not influence on Tuberculosis therapy non-adherence.

Discussion

From the results, assessing non-adherence by using MMS-8 score majority of patients had adherence of 98.% and non-adherence was 2%, these findings are similar to the study done in Tanzania by Mkopi et al.[29], from which majority of patients 95.7% adhered to treatment and non-adherence was only 4.3%, most of patients follow health care instructions and actions which results to higher level of adherence, these findings support two major components of Health belief Model (HBM) which are belief of specific health actions to prevent or cure disease and desire to avoid disease or to get well once the disease is acquired.

Assessment of non-adherence using treatment card shows that all treatment cards of

the patients (100%) have been completed as per NTLP recommendation, which means patients have been taking drugs as required, adherence was 100%. All patients accepted all health recommendations and took drugs as planned; these findings support one construct of HBM, which is perceived benefit (perception of effectiveness of the actions available to cure disease), and is similar to a study done by Oshi et al. [30] , which highlighted that proper documentation and monitoring of the treatment card improve adherence.

Specific side effect factors were also assessed, and only one factor (discomfort) was associated with non-adherence, with a p-value of less than 0.05. These results are similar to those of Neves et al.[31], which suggests that discomfort is related to non-adherence. It shows that there is an obstacle for a patient to implement the recommended health action. This supports one construct of HBM, which is perceived barrier. However, overall side effects had no association with non-adherence, as the p-value was 0.261, which was greater than 0.05. These results contradict those of Noor Haslinda and Muhamad Hanafiah Juni [32], which showed that there was an association between TB drug side effects and non-adherence.

Association between specific non-compliance factors and non-adherence was tested, and only one factor (taking water 3-5 liters per day) had an association with non-adherence, as the p-value was below 0.05. These results support a study done by Popkin et al.[33] which indicates that drinking plenty of water reduces gastrointestinal irritation, supports continued use of drugs by reducing side effects, and supports compliance. It shows that the seriousness of the disease and treatment were highly considered by the patients, this

support one construct of HBM, which is perceived severity.

Multivariable logistic regression was done on the variables that predict the outcome with a p-value of less than 0.2. Married patients adhere to treatment more than non-married patients; these results are similar to those of Kidenya et al.[34], which shows marital status influences adherence. This can be explained as advice received from family members, including a spouse, may influence treatment adherence, it supports one construct of HBM, which is cue to action, and this is the external part of this construct external stimulus can influence a certain behavior such as spouse advice.

Logistic regression was also done between following health care instructions and non-adherence, from which most patients who followed instructions adhere to treatment more, as compared to those who did not follow instructions. These results are similar to those of Ndwiga et al. [35] which shows that following healthcare instructions influences adherence. The findings also support the construct of HBM, which is perceived benefit. Patients perceived that taking medication as advised is an effective way to reduce the impact of the disease or cure it which why they were able to follow instructions as recommended.

Similarly, logistic regression was done between TB knowledge and non-adherence; the results showed that patients with TB knowledge adhere to treatment more, as compared to those who do not have TB knowledge. These results are similar to those of Sani et al.[11] which show TB knowledge influences adherence. Knowledge received by patients from health care staff may act as an external stimulus to adhere to treatment. This supports one construct of HBM, which is the cue to action especially, the external part of the construct. This study recognized that there is adequate knowledge given to the patients as well as to the close relatives of the patients on TB disease, adherence to treatment, and side effects of the

drugs, which overall influence adherence to medication.

Logistic regression between family support and non-adherence was also done, and results show that patients who received family support while taking ant- TB drugs are more likely to adhere to treatment as compared to those who do not receive family support, but these results were not statistically significant. These findings are similar to those of Urnilla Afrilian et al. [36] from which family support influences adherence. Family support can act as an external stimulus that influences adherence to treatment, this support one of the constructs of HBM, which is the cue to action. This study recognized that family members have been highly involved in recent years as part of the management of the patients. It is now a requirement that each patient should have a treatment supporter, all these influences adherence to treatment.

Again, logistic regression between the distance factor to the health facility and non-adherence was done, and the results show that patients who had no challenge with the distance factor to the health facility were less likely to adhere to treatment. These results contradict those of Aziz et al.[4]. from which patients with no distance factor challenges were more likely to adhere to treatment; also, these results contradict the HBM construct, which is perceived as a barrier. This can be explained as there might be other factors that affect the ability of the patients to adhere to treatment, which have not been explained in this study.

Logistic regression between discomfort and non-adherence was done, and results show that patients who had no discomfort symptom were less likely to adhere to treatment. These results contradict those of Neves et al. [31], which suggest that patients with no discomfort symptoms were more likely to adhere to treatment. The results also contradict one of the HBM constructs which is the perceived barrier. This can also be explained that there are other

factors that affect treatment adherence, which have not been explained in this study.

Lastly, logistic regression was done between taking 3-5 liters of water and non-compliance, and the results show that patients who take 3-5 liters of water per day are more likely to comply with treatment. These results are similar to those of Popkin et al[33] which indicates drinking plenty of water to facilitate drug compliance by reducing organ damage. These results also support one of the constructs of HBM, which is perceived severity. Patients believed that taking enough water would reduce the side effects of the drug, which in the long run would reduce liver damage thus why they were able to follow instructions as recommended by healthcare professionals.

Conclusion

This study was done to determine the prevalence of non-adherence, and associated factors (non-compliance and TB drug side effects) in patients with Pulmonary Tuberculosis. Data analysis shows that the majority of patients adhere to treatment; common factors that cause non-adherence, such as non-compliance and TB drug side effects, do not influence non-adherence in this study.

In this study, TB therapy non-adherence was thought to depend on non-compliance and TB drugs, side effects. It was observed in this study that non-compliance and TB drug side effects

do not influence non-adherence, therefore results are not a true reflection of the proposed conceptual framework. However, the HBM explained very well all of the variables used in this study.

Conflict of Interest

There is no conflict of interest.

Funding

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Ethical Approval

Ethical approval was obtained from the Director of Research Postgraduate Studies, School of Public Health, at the University of Dar es Salaam.

Data Availability

Data from this study is available on request.

Author Contribution

Beno Mbeya: Conceptualization, Methodology, Writing original draft, data curation, formal analysis.

Theresia Ambrose: Writing review, editing and supervision.

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Artemisinin Partial Resistance in Sub-Saharan Africa: Epidemiological Patterns, Molecular Markers, and Implications for Malaria Control

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Abstract

Artemisinin partial resistance (ART-R) represents a growing concern for malaria control in Sub-Saharan Africa. This narrative review synthesizes current evidence on the epidemiology, molecular markers, therapeutic efficacy, transmission dynamics, and surveillance of ART-R. Structured searches of peer-reviewed literature and grey sources published between 2020 and 2025 were conducted, focusing on clinical studies of artemisinin-based combination therapy (ACT) efficacy, PfKelch13 (PfK13) mutations, and surveillance reports. Data were extracted descriptively and synthesized thematically across four domains: emergence patterns, molecular markers and phenotypic expression, treatment efficacy and partner drug susceptibility, and transmission and surveillance capacity. Validated PfK13 mutations associated with ART-R, including R561H, C469Y, A675V, and R622I, have emerged independently across Sub-Saharan African countries. While delayed parasite clearance is observed with these mutations, first-line ACTs continue to show high cure rates in many settings, reflecting the combined activity of artemisinin derivatives and partner drugs. Candidate PfK13 mutations and markers of altered partner drug susceptibility have also been reported, highlighting potential emerging vulnerabilities in the ACT framework. Prolonged parasite clearance may increase the window of transmission, particularly in low to moderate transmission settings. Surveillance capacity is expanding but remains uneven, with gaps in genomic monitoring, timely reporting, and integration into policy processes. Overall, ART-R in Sub-Saharan Africa remains focal and of low prevalence, with limited evidence of widespread clinical impact. Strengthening integrated molecular and therapeutic surveillance, improving data-to-policy translation, and implementing targeted interventions in high-risk areas are critical to prevent wider dissemination and sustain ACT effectiveness, thereby supporting malaria control gains across the region.

Keywords: ACT Efficacy, Artemisinin Partial Resistance, Malaria, Molecular Surveillance, PfK13 Mutations, Sub-Saharan Africa.

Introduction

Malaria remains among the most important global public health concerns, with an estimated 282 million cases and over 600,000 deaths annually, primarily occurring in low- and middle-income countries. Sub-Saharan Africa bears the greatest burden, accounting for more than 90% of global malaria cases and

deaths [1]. *Plasmodium falciparum* is the predominant species in this region and is responsible for most severe disease outcomes, including hospitalizations and mortality [1]. Malaria transmission across Sub-Saharan Africa is highly heterogeneous, ranging from perennial high-transmission settings to seasonal or low-transmission areas [2]. This variability influences acquired immunity, clinical

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manifestations, and the effectiveness of control interventions [3]. In addition, socioeconomic conditions, environmental factors, and health system capacity contribute to substantial variation in malaria burden [4]. These differences create diverse epidemiological contexts that shape both transmission dynamics and intervention effectiveness.

In this context, artemisinin-based combination therapies (ACTs) remain the cornerstone of treatment for uncomplicated *P. falciparum* malaria. These therapies combine a fast-acting artemisinin derivative with a longer-acting partner drug, enabling rapid parasite clearance and sustained therapeutic effect [5]. Together with vector control strategies such as insecticide-treated nets and indoor residual spraying, ACTs have contributed to significant reductions in malaria morbidity and mortality across the region [6]. However, the durability of these gains depends on the continued effectiveness of antimalarial drugs. Artemisinin partial resistance, first identified in Southeast Asia, is characterized by delayed parasite clearance and has been linked to mutations in the *Pfkelch13* (PfK13) gene [5]. This form of resistance is not typically characterized by immediate treatment failure, but rather by changes in parasite clearance dynamics, making early detection dependent on clinical and molecular indicators. Although ACTs largely remain effective, the presence of molecular markers associated with reduced artemisinin susceptibility raises concern about potential future declines in treatment efficacy [7].

In Sub-Saharan Africa, the detection of PfK13 polymorphisms has been increasingly reported, but their epidemiological and clinical significance remains incompletely understood [8, 9]. Current evidence is fragmented across molecular surveillance, therapeutic efficacy studies, and transmission assessments, limiting integrated interpretation. In addition, the presence of both validated and novel PfK13 mutations presents challenges for classification

and risk assessment, particularly where phenotypic evidence is limited [10, 11].

Given the heterogeneity of malaria transmission, drug pressure, and health system capacity across Sub-Saharan Africa, a comprehensive understanding of the emergence and spread of artemisinin partial resistance is essential. This review aims to synthesize current evidence on epidemiological patterns, molecular markers, therapeutic efficacy, transmission dynamics, and surveillance capacity to inform timely and adaptive malaria control strategies.

Methods

This is a structured narrative review that synthesizes evidence on the emergence of artemisinin partial resistance (ART-R) in Sub-Saharan Africa from 2020 to 2025. The review was conducted between January and March 2025.

Strategy

Structured searches were performed in PubMed, Google Scholar, and grey literature sources covering the period 2020 - 2025. Keywords and Medical Subject Headings (MeSH) included “artemisinin partial resistance,” “kelch13 mutations,” “PfK13,” “ACT failure,” “therapeutic efficacy,” “malaria treatment,” and “Sub-Saharan Africa,” combined with Boolean operators (“AND” “OR”). Backward citation searching of reference lists from included studies was conducted to identify further eligible publications.

Eligibility Criteria

Included studies comprised original clinical investigations assessing ACT efficacy, parasite clearance dynamics, or therapeutic outcomes in Sub-Saharan African populations; molecular studies reporting PfK13 polymorphisms associated with ART-R; and surveillance or programmatic reports documenting emerging resistance trends. Review articles were included

to provide context and to identify additional primary sources. Only studies conducted in Sub-Saharan Africa reporting data on artemisinin susceptibility were considered. Studies unrelated to artemisinin resistance, PfK13 mutations, or ACT outcomes were excluded unless providing relevant contextual information.

Data Extraction and Synthesis

Data were extracted descriptively, including country, ACT regimens, therapeutic outcomes, parasite clearance patterns, and reported PfK13 mutations (validated or candidate). Relevant surveillance findings and policy updates were also included to contextualize emerging trends. Quantitative synthesis or meta-analysis was not performed due to variability in study designs and outcome definitions. Findings were organized thematically into four key domains: epidemiologic patterns of emergence, molecular markers and phenotypic expression, therapeutic efficacy and partner drug susceptibility, and transmission dynamics with surveillance capacity.

Results

This section synthesizes evidence from 39 sources (2020-2025) on artemisinin partial resistance in sub-Saharan Africa. The included evidence comprised different study designs, including modelling and genomic surveillance approaches, molecular surveillance of PfK13 mutations, therapeutic efficacy studies, systematic reviews, and World Health Organization reports. Findings were organized into key domains including epidemiologic patterns of emergence, molecular markers and phenotypic expression, therapeutic efficacy and partner drug susceptibility, and transmission dynamics with surveillance capacity.

Epidemiologic Patterns of Emergence

The reviewed studies reported increasing detection of PfK13 mutations associated with artemisinin partial resistance across several

Sub-Saharan African countries. In Rwanda, nonsynonymous PfK13 mutations increased over successive survey years [12].

In Uganda, PfK13 variants including A675V, C469Y, 469F, and 561H were detected across multiple districts, with frequencies in some locations ranging from approximately 10% to over 50% depending on district and survey period [8]. In Western Kenya, PfK13 mutations associated with artemisinin resistance were detected across serial cross-sectional school-based surveys conducted in 2019, 2022, and 2023, showing temporal variation in detection and prevalence of key variants across study years [13].

Spatial heterogeneity was observed across countries. In Uganda, mutations were unevenly distributed across districts, with higher concentrations in northern regions [8]. In Kenya, mutations were distributed across multiple counties, with variation in detection across survey years (Osoti et al., 2025). In Tanzania, Rwanda, and Uganda, R561H has been reported, while A675V and C469Y were mainly reported in northern Uganda, and R622I in Ethiopia and Eritrea [8, 14–16].

Genomic analyses indicate that several African PfK13 variants emerged independently within local parasite populations rather than through importation from Southeast Asia [9]. In Western Kenya, serial surveys showed temporal variation in mutation detection, including absence of A675V and R561H in 2019, detection of multiple variants in 2022, and emergence and fluctuation of key mutations in 2023 [13].

In West Africa, studies from Ghana and Nigeria report a high proportion of PfK13 wild-type parasites alongside multiple novel non-synonymous polymorphisms, many of which are geographically or ecologically restricted and not yet classified as validated artemisinin resistance markers [10, 11]. In Central Africa, molecular surveillance of *Plasmodium falciparum* isolates between 2016 and 2021 showed limited PfK13 diversity, with a small

number of nonsynonymous mutations reported and a predominance of wild-type alleles [17].

Molecular Markers and Phenotypic Expression

Mutations in the PfK13 propeller domain are associated with delayed parasite clearance, the clinical phenotype defining artemisinin partial resistance [7]. A total of 13 PfK13 propeller-domain mutations have been recognized as molecular markers associated with artemisinin partial resist A total of 13 PfK13 propeller-domain mutations have been consistently reported as validated molecular markers of artemisinin partial resistance in global surveillance datasets, including: F446I, N458Y, C469Y, M476I, Y493H, R539T, I543T, P553L, R561H, P574L, C580Y, R622I, and A675V. This list is periodically updated based on emerging evidence and WHO-supported global surveillance data [5].

In addition to validated markers, several PfK13 propeller-domain mutations are classified as candidate or associated markers of artemisinin partial resistance. These include P441L, G449A, C469F, A481V, R515K, P527H, N537I/D, G538V, and V568G [5]. These variants have been reported in surveillance studies, and a subset has shown in vitro or field signals of reduced artemisinin susceptibility, although they have not met validation thresholds for confirmed resistance status [7]. Experimental studies report that PfK13 mutations are associated with altered parasite biology, including reduced hemoglobin endocytosis and impaired activation of artemisinin during early ring stages [18].

Higher day 3 parasitemia is reported among infections carrying validated mutations compared with wild-type parasites [19]. Where assessed, parasite clearance half-life was prolonged relative to historical baselines [20]. PfK13 polymorphisms beyond the validated and candidate markers have also been reported in surveillance datasets, although their phenotypic relevance remains unconfirmed due

to insufficient clinical and in vivo evidence [21].

Quantitative measures of parasite clearance, including parasite clearance half-life and proportion of patients with detectable parasitemia on day 3, were reported in multiple therapeutic efficacy studies [19, 20]. In several studies, infections carrying validated PfK13 mutations were associated with higher proportions of day 3 positivity compared with infections with wild-type alleles [19]. There is also documented evidence on the presence of multiple PfK13 polymorphisms within single study populations, with varying frequencies across sites [21].

Therapeutic Efficacy and Partner Drug Susceptibility

Across the reviewed studies, PCR-corrected efficacy of first-line artemisinin-based combination therapies (ACTs) remains within policy-recommended thresholds, with most studies reporting day 28 or day 42 cure rates above 90%, while a few studies reported values below lower values [22, 23]. Variation in reported efficacy was observed across transmission settings and follow-up durations, with differences in 28-day and 42-day endpoints across studies [22, 24–26]. Validated PfK13 mutations associated with artemisinin partial resistance were reported, with studies documenting prolonged parasite clearance half-life in infections carrying these mutations [8]. Higher day 3 parasite positivity was also reported in infections with validated PfK13 mutations compared with wild-type infections [19].

Markers associated with reduced susceptibility to ACT partner drugs, including lumefantrine, amodiaquine, and piperaquine, were reported in selected surveillance settings [27]. However, simultaneous high-level resistance to both artemisinin and partner drugs leading to widespread treatment failure was not documented in the reviewed studies [5, 8, 25]. Geographical variation in the frequency of

partner drug resistance markers was observed across both regional and within-country surveillance settings, with heterogeneity reported between ecological zones and transmission sites [27, 28].

Recurrent parasitemia in high-transmission settings was frequently attributed to reinfection rather than recrudescence following PCR genotyping, which distinguishes new infections from true treatment failure in therapeutic efficacy studies [24–26]. Evidence from therapeutic efficacy studies indicates that PCR-corrected analyses reduce estimated treatment failure compared with uncorrected outcomes, particularly in settings with high reinfection pressure [24].

Dynamics and Surveillance Capacity

Delayed parasite clearance associated with validated PfK13 mutations has been reported to prolong the duration of asexual parasitemia, extending the period during which infected individuals may contribute to transmission [29]. Some studies report that artemisinin partial resistance mutations are associated with altered parasite fitness and changes in gametocyte production dynamics, including increased gametocyte carriage during infection [30, 31]. In low-to-moderate transmission settings, prolonged parasite clearance times have been reported to coincide with extended infectious periods [32].

At the population level, reduced ACT efficacy has been associated with sustained parasite circulation in settings approaching elimination, where residual transmission foci may persist despite control efforts [33]. Integration of therapeutic efficacy studies (TES) with molecular surveillance has been reported as a recommended strategy for monitoring artemisinin resistance signals [34].

Genomic sequencing capacity in Africa has expanded in recent years; however, it is concentrated in a limited number of research hubs, with many samples requiring external processing [35]. Dependence on externally

funded collaborations and variable reporting timelines have been reported to affect surveillance turnaround times [36]. Linkages between molecular surveillance data, therapeutic efficacy monitoring, and national policy review processes have been reported as inconsistently implemented across settings [37].

Discussion

The evidence synthesized in this review highlights a critical stage in the emergence of artemisinin partial resistance (ART-R) in Sub-Saharan Africa, where molecular signals are evident but widespread clinical failure has not yet materialized in therapeutic efficacy studies [8]. Across settings, PfK13 mutations associated with delayed parasite clearance demonstrate a focal and heterogeneous distribution, supporting the interpretation that selection is occurring locally [9, 14]. These spatial patterns are consistent with the uneven distribution of mutations reported across countries and within surveillance sites in the reviewed studies [8, 14–16, 38].

At the molecular and clinical interface, PfK13 propeller-domain mutations are associated in multiple studies with delayed parasite clearance and increased day 3 parasitemia; however, these associations are not uniform across all settings or study populations [22, 23]. Despite these molecular signals, therapeutic efficacy studies consistently report that first-line artemisinin-based combination therapies (ACTs) largely maintain high PCR-corrected cure rates within recommended thresholds, typically exceeding 90% in most sites, although variation across transmission settings and follow-up durations is evident [22, 23]. This reflects heterogeneity in ACT performance rather than uniform efficacy across all endemic settings.

This divergence between molecular detection of resistance markers and clinical outcomes is partly explained by the continued efficacy of partner drugs and the modifying

effect of host immunity in endemic settings, which together mitigate the clinical impact of delayed parasite clearance phenotypes [27]. In addition, PCR-corrected analyses consistently show lower treatment failure rates compared with uncorrected estimates, as recurrent parasitemia is frequently attributable to reinfection rather than recrudescence in high-transmission environments [24–26]. This distinction is critical for interpreting variability in reported ACT efficacy across studies and transmission settings.

The presence of molecular markers associated with reduced susceptibility to partner drugs, including lumefantrine, amodiaquine, and piperazine, further suggests emerging pharmacological pressure within ACT combinations [27]. However, available evidence does not demonstrate confirmed widespread dual resistance to both artemisinin and partner drugs, and clinically significant treatment failure attributable to combined resistance remains unreported in the included studies [5, 8, 25]. Notably, substantial geographical variation in the frequency of partner drug resistance markers has been reported across ecological zones and within-country surveillance sites, indicating heterogeneous selection pressures [25, 27].

From a transmission perspective, delayed parasite clearance may extend the duration of asexual parasitemia and, in some cases, increase gametocyte carriage, potentially prolonging infectiousness in treated [30, 31]. These effects are likely more pronounced in low-to-moderate transmission or pre-elimination settings, where residual parasite reservoirs contribute disproportionately to ongoing transmission and may sustain local transmission foci even under high treatment coverage [32]. In such contexts, even modest reductions in drug efficacy may translate into disproportionate epidemiological consequences.

Operationally, surveillance systems across Sub-Saharan Africa demonstrate improving but

uneven capacity for detecting and responding to emerging resistance signals. Although molecular surveillance and therapeutic efficacy studies are increasingly integrated in some settings, delays in sequencing, data reporting, and translation into policy continue to limit real-time responsiveness [35, 39]. Furthermore, inconsistent linkage between molecular findings, therapeutic efficacy data, and national treatment guideline review processes represents a persistent structural limitation [37]. These system-level gaps reduce the speed at which emerging resistance signals can inform national policy decisions.

Overall, the findings support a scenario of early-stage ART-R in Africa, where focal emergence of PfK13 mutations and partner drug susceptibility markers occurs alongside sustained ACT efficacy, but with increasing epidemiological complexity requiring intensified and better-integrated surveillance systems. This highlights the need for strengthened molecular–clinical integration to detect early transitions toward clinically significant resistance.

Conclusion

Artemisinin partial resistance in sub-Saharan Africa is currently focal and of low to moderate prevalence, but evidence indicates ongoing emergence and local detection of PfK13 mutations, along with markers of reduced partner drug susceptibility, which may pose a potential threat to the long-term effectiveness of ACTs. While first-line therapies remain largely efficacious, with most therapeutic efficacy studies reporting PCR-corrected cure rates above recommended thresholds, proactive measures are essential. Strengthening integrated surveillance systems, expanding molecular monitoring of PfK13 and partner drug markers, and ensuring timely translation of surveillance findings into adaptive treatment policies are recommended. Targeted interventions in high-transmission and identified hotspot areas, combined with

continued therapeutic efficacy studies, will be important to limit further spread and sustain malaria control gains across the region.

Limitations

This narrative review relied on descriptive synthesis rather than systematic analysis and therefore does not provide quantitative pooled estimates of effect. The included studies varied in methodology, outcome definitions, and reporting standards, which may contribute to heterogeneity in reported findings. Geographic coverage was also incomplete, with some regions underrepresented, potentially limiting the generalizability of the findings. Additionally, the review was based on published articles and grey literature, which may introduce publication and reporting bias and exclude relevant unpublished data.

Author Contributions

HN conceived the study, conducted the literature review, performed data synthesis, and drafted the manuscript. ALR contributed to the review of the manuscript. All authors reviewed and approved the final version.

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Conflict of Interest

The authors declare that there are no conflicts of interest.

Ethical Approval

This study is based on a narrative review of published literature and publicly available reports. Ethical approval was not required as it did not involve primary data collection.

Data Availability

All data supporting the findings of this study are derived from published articles and publicly available sources cited within the manuscript. No new datasets were generated or analyzed.

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Exploration of Mothers and Caregivers' Perspectives on Vaccination Dropout among Children Aged 12-23 Months in The Gambia: Using Thematic Analytical Approach

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Abstract

In recent years, full childhood routine immunisation coverage has fallen by 5% to levels not seen since 2008; between 2019 and 2021, 67 million children were under-vaccinated. We aimed to identify and describe the determinants of vaccination drop-out from the perspectives of mothers and caregivers. In The Gambia, vaccination coverage has improved from 76% in 2015 to 85% in 2020-21. However, this coverage is still behind the target set by the Global Vaccine Action Plan (GVAP) of 90% and 80% coverages for all antigens at the national and district levels respectively by 2020. These disparities highlight systemic barriers and the need to identify determinants of dropout to guide targeted interventions. The study was conducted in Upper River Region (rural) and West Coast Health Region 2 (semi-urban), selected for their historically high dropout rates (6.1% and 7.5% respectively). We conducted focus group discussions with community stakeholders, including mothers' clubs and traditional communicators, to gain deeper insights into social and structural influences on vaccination dropout. Findings of the study revealed that caregivers generally possessed adequate awareness of the purpose and benefits of childhood vaccination and widely associated vaccination with disease prevention, child survival and development. Health workers emerged as the most credible and influential source of vaccination information, seconded by community-based actors such as village health workers and local leaders. Interventions should therefore be tailored to address drivers of dropout in communities. Service quality, timeliness and reliability need to be improved, and tailored messaging and awareness creation are needed.

Keywords: Drop Out, Gambia, Immunization, Pentavalent, Vaccination.

Introduction

Vaccination is considered the most successful and cost-effective public health intervention against infectious diseases [1, 2]. Each year, about 3 million deaths among children are prevented from vaccine-preventable diseases (VPDs) such as

diphtheria, tetanus, pertussis, influenza, and measles [3]. However, during the COVID-19 pandemic from 2019 to 2021, an estimated 67 million children did not complete the routine childhood vaccination schedules to protect them from life-threatening diseases [4]. By 2021, global immunisation coverage for infants had fallen to 81%, the lowest rate in over a

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decade, largely due to the COVID-19 pandemic's crippling impact on global vaccine supply chains and disruptions to routine health services [5].

The Gambia's National Immunisation Programme recommended that all children receive 16 doses of vaccines before age 2, including 1 dose of BCG, 3 of pentavalent vaccine (DPT-HepB-Hib), 4 of oral polio vaccine (OPV), 1 of inactivated polio vaccine, 3 of pneumococcal conjugate vaccine (PCV), 2 of rotavirus vaccine and 2 of measles containing vaccines and a dose of Yellow Fever [6]. The country is in the process of introducing the four doses of the malaria vaccine into the routine schedule [6]. Immunization services are delivered both in public health facilities, including at static and outreach sessions in communities, as well as through private facilities. The government purchases and freely provides vaccines to both public and private facilities, but caregivers who seek services from private facilities often pay fees for children to be weighed and other services prior to vaccination.

In The Gambia, despite significant progress in immunization coverage—from 76% in 2013 to 85% in 2020—vaccination dropout remains a major challenge to achieving full protection [7]. In this study, vaccination dropout is defined as receipt of Penta1 but failure to receive Penta3 by 12-23 months of age. The 2020 Demographic and Health Survey (DHS) reported high initial uptake of multi-dose vaccines such as DPT-HepB-Hib, pneumococcal conjugate vaccine (PCV), and rotavirus vaccine (98–99%), yet completion rates declined to 92–95% for the final doses [6]. A 2024 vaccination coverage survey further revealed marked regional disparities, with dropout rates reaching 6.1% in Upper River Region and 7.5% in Western Region 2. These patterns suggest the presence of systemic and structural barriers that warrant further investigation.

The dropout rate is one of the determinants of immunization coverage and program performance, program continuity, and follow-up. Immunization dropout signifies that the child has received the first recommended dose of the vaccine yet has missed the next recommended dose. It is the rate difference between the first and final dosage or the rate difference between the first vaccination and the last vaccine dropout, so it denotes that the first recommended dose of the vaccine was received, but the subsequent recommended doses are not received. For instance, if children miss the three doses of pentavalent vaccine, it shows to the fact that there an access problem while a high dropout rate between Penta1 and the measles immunization suggests a service utilizations problem [19]. In addition, the measles vaccination dropout rate indicates whether the national immunization program is able to reach children beyond the first year of life with vaccination services [18]. The World Health Organization (WHO) recommended that Penta 1 to Penta3, BCG to Measle-Containing Virus (MCV1), and MCV1 to MCV2 should be used as the indicators of immunization dropout [18]. Furthermore, WHO stresses that if the dropout rate is more than 10%, then it implies that many children are not using the services [20, 21].

Addressing barriers to full vaccination is especially important in The Gambia. Strengthening routine immunization services, mass vaccination campaigns, Periodic Intensification of Routine Immunization (PIRI) especially in difficult to reach and underserved communities will help reduce vaccination dropout. Policy makers therefore need to address the barriers to vaccination services including the disproportionate concentration of vaccination dropout in remote and underserved communities by strengthening women's accessibility to health facilities in rural communities [11, 12]. Vaccination coverage rates can be improved through the use of postcards, automated telephone reminders and

short message services (SMSs) through mobile phones.

Previous research in low-income and middle-income countries has identified barriers at the individual, interpersonal and health systems levels that can lead to vaccination drop-out, including poor access to facilities, unreliable and poorly perceived service quality, fear of side effects, lack of family support, gender dynamics, health worker availability, missed opportunities, childcare challenges for siblings, lack of motivation, poor attitudes and behaviour by health workers, loss of vaccination cards and displacement or migration of caregivers [8-10, 13, 17]. Studies conducted in The Gambia and Malawi, for instance, highlighted additional barriers such as poor understandings of vaccination schedules, rumours or misconceptions fueled by religious beliefs, insufficient communication between health workers and communities, and unreliable outreach services [14-16].

Research Methodology

This study employed a concurrent mixed methods design to investigate factors associated with vaccination dropout in The Gambia. The study will be conducted in two distinct health regions: Upper River Region (URR) and West Coast Region 2 (WCR2), selected for their historically high dropout rates (6.1% and 7.5% respectively). The mixed methods design allows for simultaneous collection of both quantitative and qualitative data, providing complementary insights into the complex factors influencing vaccination dropout.

Research Design

The study adopts a case-control design for the quantitative component, complemented by a qualitative investigation. Focus Group Discussions (FGDs) were held with special groups such as Mothers' clubs, traditional communicators, who were expected to be closed to these health facilities to explore deeper knowledge into the research topic.

Study Setting

The research was conducted in selected health facilities within URR and WCR2. These regions represent diverse geographical and socioeconomic contexts, with URR being predominantly rural and WCR2 primarily urban/peri urban. Health facilities from these regions were selected based on dropout rates identified through DHIS2 data analysis.

Qualitative Strand Sample Size and Selection

The qualitative component employed purposive sampling with maximum variation to ensure diverse perspectives. The sample size was guided by the principle of information power and theoretical saturation, with initial targets as follows:

- *Key Informant Interviews (KIIs):*
 1. 10 healthcare providers (5 per region)
 2. Selection criteria: minimum 2 years' experience in immunization services, representation of different cadres (nurses, public health officers, supervisors)
- *Focus Group Discussions (FGDs):*
 1. 4 FGDs (2 per region) to ensure homogeneity and to encourage open discussion.
 2. 8-10 participants per group
 3. Special groups such as Mothers' clubs, traditional communicators etc would be identified and interviewed.

Inclusion and Exclusion Criteria

For Focus Group Discussions and in-depth interviews, the study included mothers/caregivers from special groups (Traditional Communicators, MSGs etc) that demonstrated willingness to share detailed experiences about vaccination services. Priority was given to participants who could communicate effectively in local languages (Mandinka, Fula, or Wolof) and have been primary caregivers throughout their children's vaccination schedules. For the focus group discussions, participants must be comfortable

sharing experiences in a group setting and available for the full duration of the discussion. Those with hearing or speech impairments that might hinder group interaction were offered individual interviews instead.

Qualitative Data Collection and Analysis

The qualitative component employed systematic data collection and analysis procedures designed to ensure methodological rigor and comprehensive understanding of vaccination dropout determinants. Individual in-depth interviews were conducted with mothers of children who dropped out of vaccination (n=12) and healthcare workers from study facilities (n=12), using semi-structured interview guides with an expected duration of 60-90 minutes per interview. Focus group discussions were conducted with mothers of both dropout and complete vaccination children (n=4 groups) and community leaders including traditional healers, religious leaders, and community health volunteers (n=4 groups). Each focus group comprised 6-8 participants with homogeneous composition to encourage open discussion, lasting 90-120 minutes including introduction, main discussion, and closing activities.

Data Collection Procedures and Recording

All qualitative data collection sessions were digitally audio-recorded using high-quality recording devices with participant consent, supplemented by backup recording equipment to prevent data loss. Detailed field notes were maintained by facilitators and co-facilitators, documenting non-verbal observations, contextual factors, group dynamics, and immediate reflections on key themes. Multiple strategies were employed to ensure comprehensive participation including round-robin questioning techniques, direct invitations for quiet participants, small group breakout activities within focus groups, and anonymous

written input opportunities for sensitive topics. Culturally appropriate facilitation techniques recognized local communication styles and social hierarchies that might influence participation patterns.

Data Saturation Strategy

Data saturation was assessed systematically using constant comparative analysis conducted after every third interview or focus group discussion. The saturation assessment process began after completing minimum thresholds of 15 individual interviews and 6 focus group discussions to ensure adequate preliminary data for meaningful comparison. Saturation was defined as the point where no new themes, patterns, or insights emerge in three consecutive data collection events, with existing themes becoming increasingly redundant and predictable. The assessment was conducted by the primary qualitative analyst in consultation with the research team, using a structured saturation grid documenting new themes, sub-themes, and insights from each data collection event. If saturation was not achieved after the planned sample size, additional interviews or focus groups were conducted up to a maximum of 30 interviews and 12 focus groups.

Transcription and Translation Procedures

All audio recordings were transcribed verbatim within 48 hours of data collection by professional transcribers with native fluency in study languages and extensive experience with health research terminology. Transcribers were selected based on language competency, previous research experience, and successful completion of confidentiality training and data protection certification. For interviews conducted in local languages (Mandinka, Fula, or Wolof), a two-step process was employed: first, direct transcription in the original language, followed by translation to English by certified translators. Quality control measures

included research team review of 20% of transcripts against original recordings for accuracy verification, with systematic error patterns documented and addressed through additional transcriber training. Back-translation of a random 20% sample will be conducted to ensure translation accuracy and maintain conceptual equivalence, with local terms and culturally specific concepts documented with explanatory notes to preserve meaning during analysis.

Analysis Team and Inter-Coder Reliability

The qualitative analysis team comprised of the researchers with support from the local supervisor and data expert: the researcher with extensive mixed-methods health research experience, the local supervisor (a qualitative research specialist) with doctoral-level training in qualitative methods, and a data expert with master-level training and cultural knowledge. All team members received training in framework analysis methodology, coding procedures, and NVivo 12 software use before beginning analysis. Inter-coder reliability was rigorously assessed with all three team members independently coding the same subset of transcripts (minimum 20% of total data) using the preliminary coding framework. Cohen's kappa coefficients were calculated to assess pairwise agreement between coders, with target kappa values of ≥ 0.80 indicating substantial agreement. Krippendorff's alpha was used for assessing reliability across all three coders simultaneously. Discrepancies in coding were systematically documented and resolved through structured discussion sessions, with consensus coding achieved through negotiation and discussion.

Quality Assurance and Validation

Throughout the analysis process, regular team meetings will be held to discuss emerging findings and ensure analytical rigor. The analysis will pay particular attention to deviant

cases that don't fit emerging patterns, using them to refine and validate the developing theoretical understanding. Member checking will be conducted with a subset of participants to validate interpretations and enhance credibility. Team members will maintain reflexive journals documenting analytical decisions, potential biases, and evolving interpretations throughout the process. The findings will be presented using thick description, incorporating verbatim quotes to support themes while maintaining participant confidentiality through pseudonyms.

Triangulation and Bias Mitigation

Potential limitations including recall bias and social desirability bias will be addressed through multiple strategies. Mothers might misremember reasons for dropout, especially regarding logistical barriers like clinic stockouts, while social desirability bias may lead participants to under-report forgetfulness or negligence as reasons for dropout. To minimize these biases, responses will be triangulated with clinic records and healthcare worker interviews to verify reasons for dropout. If mothers report inability to access vaccines due to stockouts, this will be compared with facility stock records to confirm if stockouts actually occurred at the reported times. Healthcare worker perspectives will be triangulated with facility assessments and service delivery data to validate reported system barriers. The integration of quantitative and qualitative findings will provide additional validation through methodological triangulation, with convergent, complementary, and discordant findings systematically examined and interpreted.

Data Collection Tools and Descriptions

For qualitative data collection, semi-structured interview guides were developed for questions related to vaccination dropout and completion of vaccination schedules. These guides were structured around key domains

identified from the literature review and conceptual framework, while allowing flexibility to explore emerging themes. Focus group discussion guides were designed to facilitate group dynamics and encourage interactive dialogue about community perceptions and experiences with vaccination services. All qualitative tools included probing questions to elicit rich, detailed responses about barriers and facilitators to vaccination completion.

Language and Cultural Adaptation

The questionnaires were administered in participants' preferred language among English, Mandinka, Wolof, and Fula, covering over 95% of the target population. Translation followed rigorous forward-backward translation procedures using certified translators, with independent back-translation verification and expert committee review. Data collectors were matched to participants based on language preference, and standardized prompts and probes were developed in all target languages. Regular team discussions addressed translation challenges, with documentation of translation decisions and cultural adaptations maintained throughout the study period.

Ethical Considerations

Ethical clearance was obtained from The University of The Gambia (UTG) Research & Ethics Committee. In addition, letters of permission to conduct the study were also obtained from the MoH's Director of Health Services and Regional Directors of Health in the selected health regions. Written informed consent was provided to participants before data collection. For those participants who cannot read and write, there were interpreters who interpreted the whole consent form in their local languages. Once consent was given, these participants were expected to thump print on the consent form, indicating their willingness to participate in the study. All the participants participating in the study were informed that

participation was totally voluntary. The right to withdraw from the study at any moment during the interview was assured. No personal identifiers were used on data collection forms. The recorded data will not be accessed by a third person except the researcher and will be kept confidentially and anonymously. The purpose of the research was to gather information about children's vaccination status and no blood sample was collected from participants. In addition, participants (both health workers and mothers) were not paid or given any financial incentives. Participation was voluntary.

Permission to use data

Having obtained ethical approval the UTG Research & Ethics Committee. permission to use data, project reports and activity plans will be sought in writing from the Ministry of Health of The Gambia.

Confidentiality

All through the process of review and extraction of information needed to complete this research, all raw data (reports, plans, project documents) with identifying information will only be kept by the researcher in a password protected computer and any hard copies will be kept under key and lock to restrict access to only the researcher. All information identifying health facilities and organizations from which information is extracted will be replaced with codes during analysis so that all information is anonymous. The dissertation will then be written as a whole with no identifying information.

Data protection

Data was highly anonymized. All study data will be stored for a minimum of five years following the dissemination of results. Study data was collected both electronically and paper based.

Digital data will be kept on a password-protected computer owned by the researcher himself. Access to this data will be limited to

the researcher or any authorized members of the core research team only.

Data will be destroyed after the minimum five-year retention period. The data will be safely destroyed, in line with the national guidelines and policies, and in accordance with ethical principles of confidentiality, data protection, and legal compliance. The destruction process will be designed to: protect participant confidentiality, prevent unauthorized access or data breaches, Comply with ethical approvals, informed consent agreements, and applicable data protection laws

The researcher will employ the following methods of data destruction:

1. Digital or Electronic Data: Files stored on computers or cloud systems will be permanently deleted and securely erased using certified file-erasing software (e.g., file eraser).
2. Email-based data or information backed up on drives will be securely and permanently overwritten or removed from storage systems.
3. Data stored on external devices (USBs, external hard drives) will either be physically destroyed or wiped using professional data-wiping tools.
4. Paper-Based Records (if any): Any physical documents, such as questionnaires or consent forms, will be shredded using a cross-cut shredder or destroyed in accordance with institutional procedures.

The researcher will conduct all procedures in line with national guidelines and policies. The researcher will also align the data storage and destruction processes of this study to Gambia's data protection guidelines and best practices in research ethics.

To ensure the principles of privacy and confidentiality during interviews and focus group discussions (FGDs), the following measures will be implemented:

1. Training of Data Collectors: All data collectors had training on ethical research practices, with a strong focus on data

confidentiality, privacy protection, and respectful engagement with participants.

2. Confidentiality Agreements: Prior to data collection, all data collectors signed a confidentiality and privacy agreement, committing to protecting participants' information and handling all data responsibly.
3. Interviews and FGDs were conducted in private, quiet, and secure locations that ensure participants could speak freely without fear of being overheard or identified.
4. For Focus Group Discussions (FGDs), the following additional measures were employed: All FGD participants were asked to sign a group confidentiality agreement in their own local languages before the session began. This agreement emphasized the importance of not disclosing any personal information or discussions outside of the group setting.

While this study presents minimal physical risk, it was recognized that some questions may cause emotional discomfort—particularly for mothers reflecting on their child's missed vaccinations or for healthcare workers discussing systemic challenges in service delivery. To address this, all data collectors were trained to conduct interviews in a sensitive, respectful, and non-judgmental manner, with the ability to recognize signs of participant distress. Participants were informed that their involvement was voluntary, that they may skip any question, and that they may withdraw at any point without penalty. If a participant became visibly distressed, the interview was paused, and the participant was given the option to continue, reschedule, or stop the interview. Where necessary, participants were referred to appropriate psychosocial support services, including the Mental Health Unit under the Ministry of Health. Contact details for these services were shared with participants as part of the consent process. This distress protocol ensured that emotional well-

being as respected and protected throughout the research.

Results of the Focus Group Discussions

Understanding and Perceived Benefits of Childhood Vaccination

Participants across all FGDs demonstrated a generally strong understanding of childhood vaccination. Vaccination was commonly described as a preventive health measure that protects children from illnesses and strengthens immunity. Caregivers frequently associated vaccination with child survival, healthy growth, and protection from diseases that were perceived as severe or life-threatening.

Several participants referenced specific vaccine-preventable diseases such as polio, measles, meningitis, and COVID-19, indicating awareness of both routine immunization and campaign-based vaccines. This understanding often motivated continued attendance at vaccination sessions even when children were no longer receiving injections but only supplements or monitoring services.

However, a small number of participants noted that while vaccination was generally understood, not all caregivers fully appreciated the importance of completing the entire vaccination schedule, which contributed to partial or incomplete vaccination among some children.

Illustrative quotations:

"Childhood vaccination is all about giving children vaccines that will protect them from sicknesses and ensure their overall health."

"If a child is vaccinated, they grow healthy and are protected from diseases that used to affect many children before."

Sources of Information and Communication on Vaccination

Health workers emerged as the most trusted and influential source of information on childhood vaccination. Participants consistently reported receiving vaccination

information during RCH sessions through health talks, counseling, and direct interactions with nurses and public health officers.

Community-based structures such as village health workers, community birth companions, and local leaders played a critical role in disseminating information and reminding caregivers about upcoming vaccination sessions. These actors were especially important in mobilizing women and addressing forgetfulness regarding appointment dates.

In addition to formal sources, participants acknowledged exposure to information from radio, social media platforms, WhatsApp audios, and community discussions. While these channels sometimes supported vaccination campaigns, they were also identified as major pathways for misinformation and rumors.

Illustrative quotations:

"Normally, vaccination schedules are communicated to us through our village health worker and community birth companions."

"Sometimes we hear information on the radio or see videos on social media about vaccination campaigns."

Attitudes Toward Childhood Vaccination

Overall, attitudes toward childhood vaccination were overwhelmingly positive. Most caregivers expressed strong support for vaccinating their children and viewed vaccination as an essential and beneficial service, particularly because it is provided free of charge.

Vaccination was also described by some participants as a social norm or tradition that has been practiced across generations, reinforcing acceptance within communities. Positive attitudes were often strengthened by visible benefits, such as healthier children and reduced incidence of serious illnesses.

Despite these positive attitudes, participants acknowledged that a minority of caregivers

remained hesitant or inconsistent in attendance due to fears, misconceptions, or competing responsibilities.

Illustrative quotations:

"We are happy about immunization because it helps our children grow healthy."

Fears, Concerns, and Misconceptions Related to Vaccination

Fear of side effects was one of the most commonly reported concerns. Caregivers frequently mentioned pain, fever, swelling, persistent crying, and abscesses following injections. These experiences sometimes caused anxiety and emotional distress, particularly among first-time mothers.

Misinformation and conspiracy beliefs were also discussed, especially information circulating through WhatsApp audios and social media. Some participants reported hearing claims that vaccines were unsafe, intended to harm specific populations, or could cause death or infertility.

Despite exposure to misinformation, many caregivers indicated that trust in health workers and personal observation of vaccinated children helped counter these fears and encouraged continued participation in vaccination services.

Illustrative quotations:

"We hear audios saying the vaccines are meant to eliminate us, but when health workers explained, we understood it was not true."

"The child may cry or get fever, but we still come back because we know it is for their protection."

Barriers to Vaccination Completion and Dropout

Participants identified multiple interconnected barriers that contribute to vaccination dropout. Distance to health facilities and the physical burden of trekking, particularly for caregivers with multiple young children, were frequently cited challenges.

Long waiting times at clinics were another

major barrier. Caregivers reported arriving early but remaining at facilities until afternoon, which conflicted with household chores, farming activities, and food preparation responsibilities.

Pregnancy and birth-spacing stigma also emerged as an important factor. Some women reported feeling ashamed to bring an older child for vaccination when they were pregnant again or had recently delivered, leading to selective attendance for younger children only.

Additionally, caregivers described reduced motivation to attend sessions when children were no longer receiving injections or when weighing and other services were unavailable.

Illustrative quotations:

"Sometimes when a woman gets pregnant, she only brings the newborn and leaves the older child because she feels shy."

"You can come in the morning and stay until afternoon, and that makes it difficult to continue coming every month."

Decision-Making Dynamics and Gender Roles

Mothers were identified as the primary decision-makers regarding childhood vaccination in most households. They were responsible for taking children to clinics, keeping vaccination cards, and interacting with health workers.

Fathers and other family members also played influential roles, either by providing support such as transport fares and reminders or, in some cases, discouraging participation due to personal beliefs or social norms.

Gender norms were noted to influence male involvement, with some men perceiving vaccination clinics as female spaces, which limited their direct participation in child health services.

Illustrative quotations:

"In our community, mothers are the ones who mostly take children for vaccination."

Experience with Health Workers and Service Delivery

Most participants described positive experiences with health workers, emphasizing respectful treatment, patience, and clear communication during vaccination sessions. Positive interactions increased trust and motivated caregivers to continue attending clinics.

However, a few concerns were raised regarding injection techniques and occasional operational challenges such as card mix-ups or overcrowding during clinic days. These issues, although not widespread, contributed to anxiety among some caregivers.

Overall, the quality of interpersonal communication between health workers and caregivers was viewed as a critical factor influencing vaccination uptake and completion.

Illustrative quotations:

"They are polite and explain everything well, that is why we trust them."

Community Support and Suggested Solutions

Participants highlighted strong peer and community support systems, particularly among women who attend clinics together and encourage one another. Community health volunteers and leaders were seen as instrumental in sustaining vaccination activities.

Suggested solutions focused on improving service accessibility and convenience. These included expanding mobile and outreach clinics, opening more vaccination sites in remote communities, reducing waiting times, and improving reminder systems.

Participants also emphasized the need for continuous sensitization, home visits, and increased male involvement to address persistent barriers and misconceptions.

Illustrative quotations:

"If health workers come earlier and reduce waiting time, more mothers will

complete the vaccination."

Summary of Key Findings

The study examined the determinants of childhood vaccination dropout in The Gambia through qualitative methods involving caregivers, community stakeholders, and health workers. Findings indicate that vaccination dropout is multifactorial, arising from the interaction of cognitive, socio-cultural, and health-system-related factors rather than outright refusal of immunization.

Caregivers generally possessed adequate awareness of the purpose and benefits of childhood vaccination and widely associated immunization with disease prevention, child survival, and healthy development. Nonetheless, a persistent knowledge gap was observed regarding the importance of completing the full vaccination schedule, with some caregivers perceiving early doses as sufficient protection. Health workers emerged as the most credible and influential source of vaccination information, supported by community-based actors such as village health workers and local leaders. However, mass and social media simultaneously functioned as channels for misinformation, contributing to uncertainty and fear.

Attitudes toward vaccination were predominantly positive, with immunization viewed as socially normative and beneficial, particularly due to its free availability. Despite this overall acceptance, a minority of caregivers exhibited hesitancy or inconsistent attendance linked to misconceptions, fear of adverse effects, and competing livelihood responsibilities. Concerns about side effects—especially fever, swelling, and pain—were frequently cited and amplified by circulating rumors and conspiracy narratives, although trust in health professionals and personal observation of vaccinated children often mitigated these fears.

Structural and logistical barriers constituted significant contributors to dropout. Long

distances to health facilities, extended waiting times, conflicting domestic or agricultural duties, and reduced perceived value of clinic visits when injections or complementary services were unavailable collectively discouraged consistent attendance. Social factors such as pregnancy-related stigma and closely spaced births further influenced selective participation, with some caregivers prioritizing younger children over older ones.

Decision-making dynamics were largely maternal, with mothers bearing primary responsibility for clinic attendance and record keeping, while fathers and extended family members played supportive or, at times, discouraging roles. Gender norms that framed immunization spaces as predominantly female limited male engagement and indirectly affected household support. Experiences with health workers were mostly positive and characterized by respectful communication, which reinforced trust and continuity; however, occasional service delivery challenges, including overcrowding and administrative errors, generated anxiety and could weaken motivation.

Community support mechanisms—particularly peer encouragement among women and the involvement of community volunteers—served as important facilitators of vaccination completion. Participants consistently proposed practical improvements such as expanding outreach services, increasing the number of vaccination points, reducing waiting times, strengthening reminder systems, and enhancing male involvement. Overall, the results underscore that vaccination dropout is primarily a continuity and access challenge shaped by intersecting informational, social, and systemic determinants rather than a lack of general acceptance of immunization.

Conclusion

Vaccination dropout in The Gambia persists despite high initial uptake because completion is shaped by an interplay of behavioral, social,

and systemic factors rather than simple refusal or lack of awareness. Caregivers generally value vaccination and trust health workers, but incomplete knowledge about full schedules, fear of side effects, and exposure to misinformation undermine consistency. Structural barriers—distance, long clinic waiting times, and service inefficiencies—further erode motivation, particularly for women balancing heavy domestic and economic responsibilities. Gender norms limit shared responsibility, while pregnancy-related stigma and selective attendance contribute to missed later doses.

Tailored public health interventions towards the awareness creation for all mothers attending maternal and child health services on vaccination schedules and the importance of childhood vaccination completion are hereby recommended. Reduce waiting times and operational bottlenecks by staggering appointment times and improving client flow management, ensuring consistent availability of complementary child health services (e.g., weighing) to maintain perceived value of visits. Therefore, vaccination dropout is best understood as a continuity problem driven by convenience, confidence, and community context rather than acceptance alone. Sustainable improvement requires integrated strategies that address both demand-side perceptions and supply-side accessibility and efficiency.

Author's Contribution

The author, local supervisor and the data expert have all contributed significantly to the planning and design of the study. The researcher (BB) conceptualized the study, led the training and field data collection, and wrote the manuscript. The local supervisor (BC) provided guidance on the methodology and supported the preparation and supervision of the study processes and provided critical input on the manuscript. The data expert (Mr. Bubacarr Jallow) led the data analysis,

interpretation and validation of the findings. The author thoroughly reviewed and approved the final version of the manuscript prior to submission.

Conflict of Interest

The author hereby declares that there is no conflict of interest.

Financial Disclosure

The author hereby declares that no financial or commercial relationship influenced the conduct or outcomes of this study.

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Availability of Data and Materials

The datasets used and/or analyzed during the study can be obtained from the author upon request.

Ethics Approval and Consent to Participate

Ethical approval was obtained from the University of The Gambia Research and Ethics Committee. Permission to conduct the study was also granted by the Ministry of Health's Director of Health Services and the Regional Health Directors in Upper and Western Health Regions. In addition, written informed consent (in their own local languages) was obtained from all participants prior to data collection.

Consent for Publication

Not applicable.

Competing Interests

The author hereby declares that there are no competing interests.

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Vaccine Acceptance, Hesitancy, and Uptake Determinants in the African Mpox Response: A Systematic Review and Meta-Analysis

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Abstract

The 2024 Public Health Emergency of International Concern (PHEIC) declaration for mpox exposed a critical demand-side gap in Africa's vaccination response. Despite the Africa CDC and WHO-led Access and Allocation Mechanism (AAM) delivering over 1.9 million doses to African nations, uptake in several high-burden settings remained well below target coverage levels. A systematic review and meta-analysis following PRISMA 2020 guidelines pooled data from 18 studies (120-source evidence base, 2016–2026) using the DerSimonian–Laird random-effects model with Freeman–Tukey double arcsine transformation. Databases searched included PubMed/MEDLINE, Embase, Scopus, and grey literature from WHO, Africa CDC, and UNICEF. Subgroup analyses were conducted by subregion and outbreak phase; meta-regression examined determinants including trust in health authorities, prior vaccination history, education level, and misinformation exposure. Study findings showed pooled vaccine acceptance across 14 studies was 0.58 (95% CI: 0.52–0.64; $I^2 = 89\%$). Pooled hesitancy was 0.32 (95% CI: 0.27–0.38; $I^2 = 89\%$). East Africa had the highest subregional acceptance (64%; 95% CI: 57–71%) and Central Africa the lowest (49%; 95% CI: 41–57%). Trust in health authorities (OR 2.1), prior vaccination history (OR 1.8), higher education (OR 1.5), and misinformation exposure (OR 0.6) were the strongest determinants. Peak outbreak phase was associated with higher uptake (67%; 95% CI: 59–74%) versus early phase (49%; 95% CI: 42–56%). Conclusion: Vaccine acceptance in Africa averages below 60%, with one-third of populations expressing hesitancy. Demand generation must operate alongside supply-side scale-up through trust-based communication, community engagement, and targeted misinformation responses.

Keywords: Acceptance, Africa, Hesitancy, Mpox, Vaccine-Uptake, Vaccine-Utilization.

Introduction

Mpox (formerly monkeypox) is a zoonotic viral disease caused by the monkeypox virus (MPXV), an Orthopoxvirus closely related to variola. Although first identified in humans in 1970 in the Democratic Republic of the Congo (DRC), mpox remained largely confined to Central and West Africa for several decades.

The 2022 multi-country outbreak changed this epidemiological profile dramatically, and the emergence of clade Ib MPXV in 2024 prompted the WHO Director-General to declare mpox a Public Health Emergency of International Concern (PHEIC) for the second time in August 2024 [1].

By mid-2024, Africa had reported more than 45,000 suspected mpox cases and

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approximately 1,500 deaths across at least 12 countries, with the DRC accounting for over 38,000 suspected infections and more than 1,000 deaths [2, 3]. The geographic distribution of mpox across Africa is heterogeneous: while Central African countries bear the heaviest burden, West and East African countries have reported periodic outbreaks and imported cases, with surveillance capacity varying considerably across settings.

The global response mobilised third-generation smallpox vaccines primarily MVA-BN (Modified Vaccinia Ankara–Bavarian Nordic, marketed as JYNNEOS/Imvamune/Imvanex) for mpox prevention. By 2025, the Africa Centres for Disease Control (Africa CDC) and World Health Organization (WHO) led Access and Allocation Mechanism (AAM) through the Continental Incident Management Support Team (IMST) for Mpox had allocated and distributed approximately 1.9 million doses of MVA-BN mpox vaccines to African countries, with two successive allocation rounds covering 13 priority nations [4, 5]. However, Africa CDC data indicate that while allocations have improved, a significant proportion of received doses remained unadministered approximately 1,259,827 MVA-BN doses and 775,862 LC16m8 doses had been administered by end of 2025, reflecting utilization rates of approximately 63% and 25% respectively [6]. These figures embed a dual crisis: a supply challenge that the AAM is addressing, and a demand-side challenge rooted in hesitancy, misinformation, and structural access barriers.

Vaccine hesitancy defined by the SAGE Working Group as a delay in acceptance or refusal of vaccination despite availability has been well-documented across African immunisation programs. A survey in the DRC found that approximately 61% of respondents expressed willingness to receive an mpox vaccine, implying nearly four in ten were not affirmatively accepting [7]. A multicounty web-panel survey across Nigeria, Uganda,

Morocco, Egypt, Kenya, and South Africa found hesitancy rates approaching one-third of respondents in some settings [8]. These demand-side gaps coexist with the structural and logistical barriers that constrain the allocation–administration continuum.

Understanding the determinants of mpox vaccine acceptance and hesitancy in Africa and quantifying their magnitude through rigorous meta-analysis is an essential component of a comprehensive vaccination strategy. This paper therefore aims to: (1) pool available estimates of vaccine acceptance and hesitancy in African populations relevant to mpox vaccination; (2) conduct subgroup analysis by subregion and outbreak phase; (3) identify determinants of acceptance through meta-regression; and (4) derive evidence-based implications for demand generation strategies. This paper is derived from a comprehensive PhD dissertation, “Navigating the Continuum of Mpox Vaccination in Africa: A Systematic Review and Meta-Analysis of Allocation, Administration, and Uptake Gaps in the Regional Response,” which addresses the full vaccination continuum.

Materials and Methods

Study Design

This paper reports a systematic review and meta-analysis component of a larger study examining the mpox vaccination continuum in Africa. The methodology follows PRISMA 2020 guidelines. The study protocol was designed for registration with PROSPERO, with open-science archiving on OSF as a contingency.

Eligibility Criteria

Studies were included if they: (a) reported quantitative data on mpox vaccine acceptance, hesitancy prevalence, or uptake in African populations, or reported vaccine acceptance data from COVID-19 or HPV vaccination programs applicable as transferable determinants; (b) were published between 1

January 2016 and the final search date; (c) provided sufficient data for proportion extraction or odds ratio calculation; and (d) were peer-reviewed articles, high-quality preprints, or official reports. Studies focused exclusively on non-African populations, laboratory studies, or opinion pieces without empirical data were excluded.

Information Sources and Search Strategy

Databases searched included PubMed/MEDLINE, Embase, Scopus, Web of Science, Global Health (CABI), and African Index Medicus, supplemented by grey literature from WHO, WHO AFRO, Africa CDC, UNICEF, and Gavi. The PubMed search string combined: (“mpox” OR “monkeypox”) AND (“vaccine acceptance” OR “vaccine hesitancy” OR “vaccine uptake” OR “vaccination coverage”) AND (“Africa” OR “sub-Saharan Africa” OR [individual country terms]). Filters: 2016–present. Reference lists were hand-searched and forward citation tracking was applied.

Study Selection and Data Extraction

Two independent reviewers screened titles, abstracts, and full texts using Rayyan. Inter-rater agreement was assessed using Cohen’s kappa (κ). Disagreements were resolved by discussion with a third reviewer. Data extracted included: study design, country/region, population type, sample size, acceptance proportion, hesitancy prevalence, determinants (with effect sizes), and outbreak context. Risk of bias was assessed using the Joanna Briggs Institute (JBI) checklist for cross-sectional studies and AMSTAR-2 for included systematic reviews.

Statistical Analysis

For studies reporting uptake or acceptance proportions, the Freeman–Tukey double arcsine transformation was applied to stabilize variance:

$$y = \arcsin \sqrt{p} + \arcsin \sqrt{\left(p + \frac{1}{n}\right)}.$$

Pooled proportions were back-transformed for interpretation. A DerSimonian–Laird random-effects model was applied given anticipated substantial heterogeneity. Between-study heterogeneity was assessed using Cochran’s Q test and Higgins’ I^2 statistic ($I^2 \geq 75\%$ = considerable heterogeneity). Subgroup analyses were performed by geographic subregion (West, Central, East, Southern Africa) and outbreak phase (early, peak, post-peak). Meta-regression explored determinants reported as odds ratios using log-transformed pooled OR estimates. Publication bias was assessed using funnel plot inspection, Egger’s regression test, and trim-and-fill adjustment. All analyses were conducted in R (meta, metaphor packages).

Results

Study Selection

The systematic search identified 120 studies (2016–2026) included in the overall qualitative synthesis, of which 18 provided extractable quantitative data eligible for meta-analysis. For the acceptance and hesitancy component reported in this paper, 14 studies contributed uptake/acceptance proportions, and 5 studies contributed determinant effect sizes (meta-regression). The temporal distribution of included studies reflected the post-2022 acceleration in mpox research (39% published 2024–2026). No serious risk of publication bias was found: Egger’s test yielded $p < 0.10$, but trim-and-fill adjustment shifted pooled estimates by less than 3% in absolute terms.

Pooled Vaccine Acceptance and Hesitancy Estimates

Across 14 studies, pooled vaccine acceptance was (Table 1):

$$\begin{aligned} &\text{Pooled Acceptance } (\hat{p}) \\ &= 0.58 \text{ (95\% CI: } 0.52 \\ &\quad - 0.64\text{); } I^2 = 89\% \end{aligned}$$

Pooled vaccine hesitancy was:

Pooled Hesitancy ($\hat{p}$)
= **0.32 (95% CI: 0.27 – 0.38); $I^2 = 89\%$**

The high I^2 value indicates that the majority of observed variability reflects genuine cross-country and contextual differences rather than sampling error. Acceptance ranged from 38% in conflict-affected fragile settings to 82% in targeted urban vaccination campaigns, with most studies clustering between 50–70%. The

DRC-specific study by Nkamba et al. (2024) reported acceptance of 61.0% among 5,226 respondents, with higher acceptance among healthcare workers and respondents in historically endemic regions [7]. The six-country eClinicalMedicine (2024) study documented hesitancy levels approaching one-third across Nigeria, Uganda, Morocco, Egypt, Kenya, and South Africa [8].

Table 1. Subregional Pooled Vaccine Acceptance Estimates (Random-Effects Meta-Analysis)

Subregion	No. Studies	Pooled Acceptance (%)	95% CI (%)	I^2 (%)
East Africa	5	64	57–71	78
Southern Africa	3	61	54–68	72
West Africa	6	52	45–59	85
Central Africa	4	49	41–57	88

Source: Meta-analysis derived from 18-study quantitative subset. Random-effects model (DerSimonian–Laird). Freeman–Tukey transformation applied.

Acceptance by Outbreak Phase

Uptake varied significantly across outbreak phases (Table 2):

Table 2. Pooled Uptake by Outbreak Phase

Outbreak Phase	Pooled Uptake (%)	95% CI (%)	n Studies
Early phase	49	42–56	4
Peak transmission	67	59–74	5
Post-peak / containment	55	48–63	5

Source: Meta-analysis derived from 18-study quantitative subset. Random-effects model (DerSimonian–Laird). Freeman–Tukey transformation applied.

Uptake was highest during peak transmission, reflecting heightened risk perception, and declined post-peak as perceived urgency fell. Early-phase uptake was constrained by low-risk awareness and administrative preparation lag.

Determinants of Acceptance: Meta-Regression Findings

Meta-regression across five studies reporting adjusted odds ratios identified the following statistically significant determinants of vaccine acceptance (Table 3).

Table 3. Meta-Regression Determinants of Vaccine Acceptance

Determinant	Pooled OR	Interpretation
Trust in health authorities	2.1	Doubled likelihood of vaccine acceptance
Prior vaccination history	1.8	Positive spillover from prior vaccine experience
Higher education level	1.5	Moderate positive association
Misinformation exposure	0.6	Significantly reduced acceptance probability

Source: Random-Effects Meta-Analysis.

Regional Uptake Estimates

Regional subgroup meta-analysis of pooled uptake estimates is presented in Table 4. East Africa demonstrated the highest pooled uptake

and Central Africa the lowest, consistent with differences in routine immunisation infrastructure, regulatory harmonisation, and governance capacity.

Table 4. Regional Uptake Estimates

Region	Pooled Uptake (%)	95% CI (%)	I ² (%)
East Africa	64	57–71	78
Southern Africa	61	53–69	74
West Africa	53	45–60	86
Central Africa	48	40–56	89

Source: Random-Effects Meta-Analysis

Uptake by Regulatory Readiness

Countries were classified by regulatory readiness (participation in AVAREF, EAC-MRH, or ZaZiBoNa; rapid emergency use authorisation capacity). Table 5 presents pooled

uptake estimates stratified by readiness tier. High-readiness countries demonstrated substantially higher uptake, confirming that faster approval-to-rollout transitions and governance capacity are independent structural determinants of vaccination performance.

Table 5. Uptake by Regulatory Readiness Status

Regulatory Readiness	Pooled Uptake (%)	95% CI (%)
High readiness	66	59–73
Moderate readiness	58	50–65
Low readiness	46	39–53

Source: Random-Effects Meta-Analysis

Risk of Bias Assessment

Of 34 observational studies in the full evidence base, 53% were rated low risk, 35% moderate risk, and 12% high risk. Cross-sectional designs and self-reported vaccine intention were the most common limitations. Most systematic reviews (n=21) were of high or moderate quality under AMSTAR-2. Publication bias assessment via Egger's regression test indicated possible small-study effects ($p < 0.10$); however, trim-and-fill adjustment produced less than 3% absolute change in pooled estimates, indicating that conclusions are unlikely to be substantially distorted.

Discussion

The central finding of this meta-analysis pooled vaccine acceptance of 58% and hesitancy of 32% across African contexts

confirms that demand-side barriers constitute a significant and quantifiable component of the mpox vaccination gap. These estimates align with what was observed in early COVID-19 vaccine rollouts in sub-Saharan Africa, where acceptance ranged widely but central tendency analyses consistently found one-quarter to one-third of populations expressing hesitancy or refusal [9, 10].

The subregional gradient is revealing. East and Southern Africa demonstrated higher pooled acceptance (64% and 61% respectively), whereas Central and West Africa showed lower estimates (49% and 52%). This pattern correlates with routine immunisation baseline performance and regulatory harmonisation engagement: East African Community Medicines Regulatory Harmonisation (EAC-MRH) participants and Southern African Development Community

ZaZiBoNa initiative members show more streamlined regulatory-to-rollout transitions, which in turn may support public trust in the vaccination system [11]. Central Africa's lower acceptance is contextualised by conflict-affected settings in the DRC, where insecurity, community displacement, and institutional distrust compound hesitancy [7, 22]. Improving local vaccine manufacturing capacity and equitable access across subregions remains a structural priority for closing these gaps [24, 25].

The outbreak phase findings carry significant programmatic implications. The significant increase in acceptance during peak transmission (67% vs 49% in early phase) confirms that risk perception is a dynamic, phase-sensitive driver of vaccine demand [20, 21]. Campaigns that capitalise on heightened risk salience during peak outbreaks while maintaining structural readiness to rapidly deploy doses are likely to achieve higher utilisation. Conversely, the post-peak decline to 55% underscores the need for sustained communication even after outbreak intensity subsides particularly for second-dose completion in the two-dose MVA-BN schedule.

Trust in health authorities (pooled OR 2.1) was the single strongest determinant of acceptance, confirming a finding consistent across all analogous vaccination contexts in Africa, including Ebola, COVID-19, and routine childhood immunisation [12, 13]. This underscores that demand generation is fundamentally a trust-building exercise, not merely an information campaign. Trusted messengers including community health workers, religious leaders, local elders consistently outperform institutional media communications in fragile settings. Embedding community liaison networks into vaccination preparedness planning is therefore a structural requirement, not an optional addition.

Prior vaccination history (OR 1.8) reflects a positive spillover effect: populations with prior

positive vaccine experiences are more willing to accept new vaccines. This has bidirectional implications. The COVID-19 vaccine experience in Africa has been characterised by both supply delays and, in some settings, adverse communication creating negative spillover [23]. The evidence presented here suggests that the history of that experience directly influences mpox acceptance. Restoring and maintaining vaccine confidence therefore has benefits that extend across vaccine-preventable diseases [15].

Misinformation exposure (OR 0.6) halved the likelihood of acceptance, reinforcing the critical importance of social listening and rapid response communication infrastructure. Misinformation in the African mpox context has spread across social media platforms, targeting vaccine safety and conspiratorial narratives [16, 17]. Without sustained counter-messaging and transparent adverse event reporting, the structural gains achieved by the AAM in supply delivery are partially neutralised by demand suppression [29].

The high heterogeneity ($I^2 = 88\text{--}89\%$) across pooled estimates underscores that no single acceptance figure is generalisable across Africa. Country-specific and subnational contexts determine the actual demand landscape [18]. This has direct implications for vaccination program design: blanket national campaigns are likely to underperform compared to geographically and demographically targeted approaches, informed by behavioural analysis and community mapping [19].

The distinction between stated acceptance and actual uptake is critical. Implementation science evidence demonstrates that willingness to vaccinate does not automatically translate into vaccination [14]. Uptake requires vaccine availability, eligibility clarity, accessible service points, trusted communication, and follow-up for second doses. In the African mpox context which is characterised by phased and constrained supply rollouts even

populations with high stated acceptance may fail to receive doses due to logistical and access barriers. This administration–uptake gap, estimated at approximately 24% in the broader thesis, interacts with demand-side hesitancy to produce the observed uptake shortfalls.

This paper has limitations. The 18-study quantitative subset includes primarily COVID-19 and HPV vaccination analogues for determinant analysis, as mpox-specific acceptance studies remain sparse [26, 27]. While these analogues provide inferential strength given shared structural and socio-behavioural determinants, direct mpox-specific estimates are needed as vaccination programs mature [28]. The high heterogeneity limits precision of pooled estimates and requires cautious interpretation. Cross-sectional study designs prevent causal inference. Ethical considerations around equitable vaccine allocation also remain relevant for programmatic translation of these findings [30].

Conclusion

Mpox vaccine acceptance in Africa averages 58%, with approximately one-third of populations expressing hesitancy. This demand-side gap is patterned by subregion, outbreak phase, and individual-level determinants particularly trust in health authorities, prior vaccine experience, education, and misinformation exposure. Acceptance is not uniform and varies substantially across and within countries. East and Southern Africa show higher pooled acceptance, while Central and West Africa exhibit lower levels, consistent with structural and governance gradients.

Closing the administration–uptake gap requires deliberate, context-sensitive demand generation strategies operating in parallel with supply-side scale-up. Priority actions include: institutionalising community-centred risk communication infrastructure; deploying trusted messenger networks ahead of campaigns; establishing real-time

misinformation monitoring and response systems; capitalising on peak-phase risk perception to maximise vaccination rates; and using behavioural analytics to target hesitant subpopulations. Regulatory harmonisation and health-system strengthening, which reduce the time from allocation to community delivery, also indirectly support acceptance by building institutional credibility.

Conflict of Interest

The author declares no conflict of interest.

Ethical Approval

This manuscript synthesises publicly available published and official secondary data. No primary data collection involving human participants was undertaken; formal ethical approval was therefore not required.

Data Availability

This systematic review and meta-analysis is based entirely on publicly available published literature and official reports from WHO, Africa CDC, and UNICEF. No original datasets were generated. All source studies and reports are cited in the reference list and are accessible through the respective publishers and institutional repositories.

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Author Contributions

- Charles Ugochukwu Ibeneme: Conceptualisation, methodology, formal analysis, data curation, writing original draft, review and editing.
- Olaiya Paul Abiodun: Supervision, review of methodology, analysis, data curation and original draft.
- Glory Onyeugo: Review of original draft, data curation, analysis and editing

- Lilian Maliro: Review of original draft, data curation, analysis and editing
- Titilola Munkail: Review of original draft, data curation, analysis and editing
- Folake Abiola Abiodun: Review of original draft, data curation, analysis and editing
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Leveraging Artificial Intelligence (AI) to Improve Trade and Commerce Efficiency in Guyana

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Abstract

The "Digital Guyana" initiative centers on AskGov, an AI platform providing 24/7 consultancy to bridge the gap between remote entrepreneurs and central regulation. By simplifying complex filings like the Local Content Act via mobile devices, the government ensures small businesses can navigate legal frameworks previously accessible only to large firms. Once integrated, these businesses leverage predictive logistics to align production with global demand. Agencies like the GRDB and GuySuCo use AI-equipped drones and modeling to monitor crop health, reducing chemical waste by 15% and stabilizing supply chains against seasonal constraints. This precision is mirrored in the oil and gas sector. Digital Twins on vessels like the Liza Unity optimize maintenance through real-time virtual modeling, while AI-powered underwater vehicles provide high-resolution seabed mapping for low-impact resource extraction. Industrial efficiency further drives SME growth via modernized financial services. Institutions like Republic Bank now use AI credit scoring to analyze non-traditional data, unlocking capital for businesses without formal credit histories. This allows manufacturers like DDL to adopt dynamic pricing tools for international competition. Further, to ensure ethical growth, the EPA utilizes real-time AI monitoring to track offshore production and waste. By automating Local Content Act compliance, the government ensures expansion translates into fair employment for the Guyanese workforce. Finally, advancements are secured within Silica City, where 3D AI models of power grids and drainage systems predict koker/sludge failures, ensuring infrastructure remains resilient against climate change.

Keywords: AskGov, Digital Twins, Local Content, Predictive Logistics, Silica City.

Introduction

The Digital Guyana initiative represents a strategic shift toward an agentic, AI-driven economy designed to bridge the gap between complex regulatory frameworks and operational execution. This research explores how platforms like AskGov and Digital Twin technologies are transforming Guyana's primary sectors by automating administrative tasks and optimizing industrial performance. By analyzing the integration of machine learning in the oil, gas, and agricultural sectors, this study evaluates the synergy between

government-led digital consultancy and private-sector technological investment.

Central to this transformation is the empowerment of Small and Midsize Enterprises (SMEs) through modernized financial and logistical tools. The findings highlight how AI-driven credit scoring and predictive demand forecasting are dismantling traditional barriers to market entry, allowing local businesses to compete on an international scale. As Guyana navigates rapid economic expansion, this research sets the stage for assessing how these AI applications simultaneously drive industrial efficiency,

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ensure environmental stewardship, and reinforce the mandates of the Local Content Act.

Purpose of the Study

This study analyzes how AI-driven platforms like AskGov and Digital Twins bridge the gap between Guyana's regulatory frameworks and industrial execution. It evaluates the synergy between government digital initiatives and private-sector investment to optimize efficiency in the oil, gas, and agricultural sectors while ensuring compliance with the Local Content Act.

Furthermore, the research evaluates how AI-driven tools, including credit scoring for SMEs and Digital Twin modeling, optimize operational efficiency, foster inclusive innovation, and ensure strict adherence to the Local Content Act and environmental mandates to support Guyana's long-term economic and ecological sustainability

Research questions

1. How does the integration of agentic AI platforms like "AskGov" and digital twins affect operational efficiency and regulatory compliance in Guyana's primary economic sectors?
2. To what extent do AI-driven credit scoring and predictive logistics empower Guyanese SMEs to compete in international markets?

Material and Methods

The following approaches were utilized to synthesize secondary sources for understanding the impact on Trade and Commerce in Local Industries in Guyana:

Literature Review

A comprehensive review of scholarly articles, government reports, and industry publications was conducted to establish a theoretical framework for AI's role in trade and local content. This process synthesized global digital transformation trends with Guyana's

specific regulatory environment, focusing on how machine learning enhances compliance and supply chain resilience.

Data Collection

Primary and secondary data were integrated from policy documents, business reports, and industry experts. Primary insights were gathered through virtual interviews with oil and gas stakeholders and SME representatives, providing a firsthand perspective on AI adoption hurdles, credit access, and the practical utility of agentic platforms like AskGov.

Data Analysis

To contextualize Guyana's progress, the study utilized a Comparative Benchmarking approach, analyzing AI adoption in nations like Norway, the UAE, and Singapore. The analysis focused on Sectoral Maturity Mapping, comparing Guyana's use of Digital Twins on the Liza Unity and autonomous drilling to global standards in the North Sea. By benchmarking the AskGov initiative against digital government models in "AI-first" states like Estonia, the research identified how natural language processing can specifically bypass traditional infrastructure bottlenecks to provide 24/7 regulatory guidance.

The study further employed an SME Scalability Assessment, evaluating how AI-driven credit scoring models, similar to those used in other emerging markets can bridge the "finance gap" for local contractors.

Synthesis and Interpretation

The collected data were synthesized to identify critical trends, systemic challenges, and high-impact opportunities for AI within Guyana's trade and commerce sectors. By correlating qualitative interview insights with quantitative industry reports, the study mapped the direct impact of automation on market competitiveness and supply chain reliability.

The findings were interpreted through the lens of local economic policies, such as the

Local Content Act and the Low Carbon Development Strategy (LCDS). This ensured that the conclusions remained grounded in Guyana's specific industrial needs, focusing on how AI-driven tools like AskGov and Digital Twins align with national mandates for transparency, SME inclusivity, and sustainable resource management.

Discussion/Findings

As part of the broader "Digital Guyana" initiative, the government has developed AskGov, an agentic AI-powered platform designed to serve as a 24/7 digital consultant for citizens and businesses. Trained on local regulatory frameworks like the Local Content Act and national tax structures, the tool allows entrepreneurs to navigate complex administrative processes, such as registering for the oil and gas supply chain, using simple, natural language queries [34]. By providing remote accessibility via mobile devices [35]. Within this context, the following 'sub-headings were framed and discussed: -

Predictive Logistics (Demand Forecasting in Agriculture, Retail, and Fuel)

According to Abayomi and Thomas [3], Artificial Intelligence (AI) can predict market demand and supply fluctuations by analyzing historical sales data, weather trends, and consumer behaviour. In Guyana's agricultural sector, AI can analyze historical data on rice and sugar production along with weather patterns to predict future yields and demand. This can help farmers and exporters optimize storage, reduce waste, and meet market needs efficiently.

For example, the Ministry of Natural Resources in Guyana has launched a landmark AI-powered mineral mapping project covering the country's Shield [33]. By utilizing machine learning to analyze historical geological data alongside new hyperspectral aerial surveys, the project identifies high-potential deposits of gold and rare earth elements [33]. This reduces the environmental impact of traditional "prospecting" and ensures that the government can negotiate more favorable terms with international mining firms based on precise resource data [33].

Companies such as ¹*ExxonMobil* have employed AI in offshore drilling operations, demonstrating its potential in Guyana. These applications focus on improving operational efficiency, predictive maintenance, and real-time monitoring of oil production. For example, in collaboration with ²*Aize* and ³*SBM Offshore*, the company deployed digital twin software on the Liza Unity and Liza Destiny FPSO vessels. These virtual models integrate real-time data from multiple sources, improving predictive maintenance, turnaround activities (TAR), and operational planning, directly improving commerce efficiency in Guyana's primary economic driver [1].

Additionally, ExxonMobil partnered with ⁴*Ocean Infinity* to conduct high-resolution seabed mapping within the Stabroek Block using AI-powered autonomous underwater vehicles (AUVs). Covering approximately 3,100 square kilometres at depths of 70 to 2,150 meters, these surveys enhance geological and geotechnical understanding while minimizing risks and environmental impact [21].

To support these findings, we look at the work of LeewayHertz [18], who posits that AI-based demand forecasting models improve

¹ ExxonMobil is one of the largest integrated fuels, lubricants, and chemical companies in the world, managing a leading portfolio of resources. It also holds significant positions in high-growth commodity petrochemical and polymer products.

² Aize is an industrial software company that provides tools for users to visualize, navigate, collaborate, and work on digital representations of assets.

³ SBM Offshore is a global leader in offshore energy solutions, focusing on innovative floating production systems and services for the oil and gas industry.

⁴ Ocean Infinity is a technology company that develops innovative robotic technology aimed at transforming maritime operations to enhance sustainability for both people and the planet.

supply chain efficiency by analyzing real-time and historical data, helping businesses optimize inventory and reduce stockouts. This approach can apply to supermarkets, agricultural producers, and fuel distributors in the country. For example, AI-driven demand forecasting can predict which products will be in high demand based on trends, seasons, and consumer behaviour. This prevents stockouts (which lead to lost sales) and overstock (which leads to waste).

Further, Guyana's supply chain is affected by transportation constraints, including limited infrastructure in some regions. AI can predict demand and optimize inventory distribution, ensuring that goods are available where they are needed. Additionally, since Guyana imports many consumer goods, AI can help supermarkets adjust their orders based on currency fluctuations, import delays, and local production capacity. Already, the government is looking at expanding the GRDB drones and GuySuCo modeling to act as the "eyes" of the supply chain in all sectors.

To further improve oversight and regulatory compliance, ExxonMobil, in collaboration with the Guyanese ⁵Environmental Protection Agency (EPA), has deployed AI-powered measuring instruments on FPSO vessels. These devices provide real-time production monitoring by continuously tracking oil output and uploading data to a cloud-based system. This technology enables authorities to monitor every barrel produced and ensures proper disposal of produced water, reinforcing environmental responsibility in offshore operations [14].

Walmart, one of the largest retailers in the world, uses AI-based demand forecasting to optimize inventory and reduce stockouts. The company analyzes real-time sales data, weather patterns, and seasonal trends to ensure stores

are stocked with the right products. Walmart's AI-driven supply chain improvements have reduced overstock and improved product availability [6].

In India, AI-driven demand forecasting helps farmers plan crop production and distribution. Companies like ⁶*CropIn* use AI to analyze satellite data, weather conditions, and market demand, allowing farmers to grow the right crops at the right time. This reduces food waste, improves market prices, and enhances supply chain efficiency [23].

Recognizing the limitations of traditional methods, Amazon turned to AI as the solution to its supply chain challenges. By leveraging machine learning, predictive analytics, and automation, Amazon has transformed its supply chain into a highly responsive and efficient system. The company has revolutionized demand forecasting by using AI to analyze real-time data from sales, social media, economic trends, and weather patterns. Unlike traditional methods, AI-driven forecasting improves accuracy by predicting demand shifts and adjusting inventory accordingly. This approach reduces stockouts and excess inventory, enhancing efficiency and cost-effectiveness [25].

Further, a key application is regional demand forecasting. For example, if a storm is expected, Amazon's AI system increases the stock of essential items in nearby warehouses. This proactive inventory management ensures product availability and improves customer satisfaction while minimizing losses [11].

Additionally, the Shell company has also implemented AI-based demand forecasting for fuel distribution in multiple countries, including the Netherlands, Singapore, and the UK. By using machine learning algorithms, Shell predicts fuel demand based on traffic patterns, economic activity, and weather

⁵ EPA - An independent agency with responsibility to promote, facilitate and coordinate effective environmental management, protection, and sustenance of Guyana of Natural Resources.

⁶ Founded in 2010, CropIn is a global Agtech pioneer who has built the world's first purpose-built industry cloud for Agriculture.

conditions. This reduces shortages, optimizes fuel storage, and improves logistics planning [26].

These examples show how AI-based demand forecasting can improve supply chain efficiency in supermarkets, agriculture, and fuel distribution. Guyana can benefit by using AI to streamline inventory, align agricultural production with demand, and improve fuel distribution. As the country develops its oil and gas sector, AI can also help predict energy needs and optimize exports. Embracing AI-driven forecasting will create a more resilient, efficient, and competitive economy. Using AI to predict demand for rice, sugar, and fuel ensures inventory is positioned where needed, reducing waste.

SME Empowerment (*Digital consultants ("AskGov") and AI credit scoring*)

To bolster business competitiveness for SMEs, the government of Guyana launched "AskGov," a Generative AI platform trained on local regulatory frameworks. This tool allows local entrepreneurs to navigate the complexities of the Local Content Act and tax filings through a natural language interface, effectively acting as a 24/7 digital consultant for small businesses in remote regions [34]. Furthermore, local financial institutions like Republic Bank (Guyana) have implemented AI-driven credit scoring models that analyze non-traditional data (such as utility payments), enabling SMEs without extensive credit histories to access the capital needed for trade expansion [35].

Avakov [2] posits that Small Midsize Enterprises (SMEs) can leverage AI-driven market analysis tools to identify trends, adjust pricing strategies, and improve customer engagement. AI-powered chatbots and Customer Relationship Management (CRM) systems help businesses compete with international firms.

Avakov [2], argued that the integration of AI allows SMEs to personalize their customer interactions and deliver more tailored solutions,

leading to increased customer satisfaction and loyalty. AI-powered tools, such as machine learning, predictive analytics, and natural language processing, enable businesses to identify trends, predict customer behaviours, and optimize resources. By automating data collection and analysis, these tools reduce the reliance on manual processes and minimize human error. SMEs, which often have limited resources, can benefit significantly from such technologies, as they provide access to advanced analytics previously only available to larger corporations.

An example of Avakov method of AI integration can be seen at Hootsuite (a social media management platform in Canada). Hootsuite uses AI to analyze market trends and social media sentiment, providing SMEs with insights on how to tailor their marketing campaigns and engage effectively with customers. The platform also offers AI-powered tools for scheduling posts and analyzing performance metrics, allowing small businesses to optimize their social media presence [8].

Additionally, Loom is a video messaging platform in the USA that uses AI to enhance customer engagement by providing automated responses and personalized suggestions through its AI-powered chatbot. This chatbot helps users find solutions to common queries and streamlines customer support, making it easier for SMEs to interact with customers efficiently [17].

OmniLens is another example of an AI-powered analytics tool for SMEs in the retail sector, OmniLens helps businesses analyze sales patterns, customer preferences, and competitor behavior. By providing insights into market trends and adjusting inventory and pricing strategies, it enables retailers to make data-driven decisions that improve profitability and stay competitive [22].

In Guyana, SMEs can implement AI-driven tools, like the expansion of the AskGov tool to enhance market analysis, pricing strategies, and

customer engagement, similar to the examples from Hootsuite, Loom, and OmniLens. Local retail businesses could adopt AI tools for social media sentiment analysis and sales forecasting, enabling them to better understand market trends and customer behaviour, just like Hootsuite's AI-driven market analysis. Small hotels and restaurants could use AI-powered chatbots and CRM systems (similar to Loom's platform) to engage customers and provide 24/7 support, enhancing the overall customer experience.

Additionally, AskGov has the potential to have local retailers integrate AI-powered analytics tools like OmniLens to monitor sales data, adjust pricing strategies, and optimize inventory based on consumer preferences and competitor activities. By adopting these AI tools, SMEs in Guyana can enhance their operational efficiency, improve customer satisfaction, and better compete with international firms [27].

Guyanese agro-processors, such as Roy's Quality Spices and Sterling Products Limited, can leverage AI-driven market analysis to monitor demand trends for exports like rice, sugar, and spices, use AI-powered CRM tools to maintain relationships with international buyers and improve sales forecasting, and optimize pricing based on global demand and real-time market conditions, ensuring competitiveness in Caribbean and North American markets [9].

AI-driven market analysis and trend identification play a crucial role in helping businesses analyze large datasets to uncover patterns beyond human capabilities. By leveraging AI algorithms, companies can forecast market demand, optimize inventory, and streamline operations based on real-time data. This technology enhances decision-making, reduces risks, and ensures that businesses remain competitive in fast-changing industries [9]. This suggests that AI-powered analytics can be particularly beneficial for SMEs in emerging economies like Guyana,

where data-driven insights can support local businesses in adapting to consumer preferences and market shifts.

Additionally, AI-driven pricing strategies and customer engagement solutions enable businesses to compete effectively with international firms. AI-powered dynamic pricing models are revolutionizing industries such as food & beverage and hospitality by adjusting prices in real-time based on demand, competitor pricing, and external factors [7]. Similarly, Generative AI enhances marketing and customer engagement by creating personalized content, automating responses, and improving customer interactions [16]. These advancements allow businesses to optimize revenue generation while delivering tailored experiences to customers, fostering long-term loyalty and brand growth.

Regulatory Compliance and Policy Adherence

The AskGov AI-powered digital platform, by extension, provides 24/7 access to Guyana's regulatory frameworks, such as the Local Content Act and tax laws. By allowing users to navigate complex administrative tasks through natural language on mobile devices, it eliminates the need for hinterland residents to travel to Georgetown for basic inquiries. This automation streamlines government operations, reducing manual workloads and allowing agencies to prioritize high-level compliance and oversight.

To reinforce the AskGov initiative, we look at LeewayHertz [18], who argued that Artificial Intelligence (AI) can automate compliance monitoring, while automated auditing tools also ensure transparency in contract allocation and resource management. This suggests that AI will have the capability to reduce the risk of non-compliance with local content policies.

For example, the U.S. Securities and Exchange Commission (SEC), used AI to automate compliance monitoring in the financial sector. SEC uses machine learning

algorithms to analyze massive datasets and detect suspicious trading activities or potential violations of financial regulations. The SEC's AI-driven system helps identify insider trading, market manipulation, and other compliance breaches more efficiently than manual methods. The system analyzes transaction data, market trends, and social media sentiment, providing regulators with insights into potential risks and ensuring that firms adhere to legal standards. This approach helps reduce human error and allows for faster identification of non-compliance [4].

In Guyana, AI can improve compliance monitoring in industries like oil and gas by ensuring adherence to local content policies. For instance, the application of automated auditing tools to oversee contract allocation and resource management [12]. This suggests that AI can help identify discrepancies in the allocation of contracts to local companies, ensuring compliance with regulations that prioritize local businesses. Notably, the Local Content Act in Guyana mandates that a certain percentage of contracts and employment be allocated to local suppliers and workers in the oil and gas industry. AI-powered systems can automatically cross-check contract allocations and track performance against local content requirements, reducing the risk of non-compliance [5].

Additionally, AI-driven solutions can be used by government agencies or regulatory bodies in Guyana to conduct automated audits, ensuring that resource management practices meet regulatory standards. In sectors such as mining and construction, where transparency is crucial, AI can flag potential compliance violations or inefficiencies, allowing for proactive interventions. For instance, an AI system might analyze project data to verify that local contractors are given priority and that resources like materials and labor are being sourced according to the legal framework. These tools would streamline the audit process, minimize human error, and enhance

transparency in the management of natural resources and government contracts.

According to Jones [12], in the United Kingdom, the National Audit Office (NAO) has employed AI-based auditing tools to improve transparency and efficiency in the public sector. The NAO uses data analytics and machine learning algorithms to examine large volumes of government spending data, ensuring that funds are allocated according to legal requirements and policy guidelines. Jones argued that by automating the auditing process, the NAO can detect discrepancies, errors, or mismanagement in real-time, improving accountability and resource management. Additionally, AI tools also help identify trends and patterns that might indicate potential compliance failures, reducing the likelihood of fraud or inefficient use of public resources.

Based on these examples, AI-driven compliance monitoring can enhance transparency in sectors like oil and gas, agriculture, and public procurement in Guyana. For example, AI tools could automate the verification of local content compliance in the oil and gas industry by analyzing contract allocations, employment data, and resource distribution to ensure that a required percentage is awarded to local businesses, as mandated by the Local Content Act. This technology could reduce administrative errors and improve efficiency, ensuring that regulatory guidelines are met in real-time. Similarly, AI can be applied in public procurement to track contracting processes and identify potential discrepancies or corruption, enhancing accountability in government spending and resource management [28].

Additionally, AI-based auditing systems could streamline the management of public resources in Guyana. Agencies such as the Guyana Revenue Authority could use AI to detect tax evasion by cross-referencing business transaction data with tax filings, flagging discrepancies for further investigation. AI can also assist in the monitoring of natural

resource management, ensuring sustainable practices, and verifying compliance with environmental regulations in the mining and forestry sectors. By automating these processes, Guyana can foster better governance, transparency, and efficiency in managing its natural resources and public funds.

Environmental Stewardship (Predictive Maintenance and Real-time Monitoring)

As Guyana is applying Digital Twin technology to civil infrastructure. As part of the Silica City initiative, the government is developing a 3D AI-driven model of the national power grid and drainage systems [32]. This system uses real-time sensors to predict "koker" (sluice) failures and urban flooding risks, allowing the Ministry of Public Works to conduct proactive maintenance before seasonal rains begin, thereby protecting commercial logistics routes [32].

A review of environmental monitoring and sustainability was conducted by Kumar et al. [15], which revealed that Artificial Intelligence (AI)-driven environmental monitoring tools are increasingly being utilized to predict and mitigate ecological risks, thereby supporting eco-friendly business practices. These AI-powered solutions leverage machine learning algorithms, big data analytics, and remote sensing technologies to detect environmental changes, such as air and water pollution, deforestation, and climate anomalies, in real-time. This suggests that by enabling early detection and intervention, AI enhances the effectiveness of conservation efforts and regulatory compliance, reducing negative environmental impacts.

Jia et al. [13] conducted a comprehensive review on Cleaner Production, which shows that predictive maintenance in industrial operations powered by AI, significantly reduces waste and enhances resource efficiency. Jia et al. argued that by analyzing equipment performance data, AI can forecast potential failures and optimize maintenance

schedules, thereby minimizing downtime, extending asset lifespan, and reducing resource consumption. This not only improves operational efficiency but also reduces carbon footprints and industrial waste generation.

The application of AI in environmental monitoring and predictive maintenance directly contributes to the achievement of multiple Sustainable Development Goals (SDGs). For instance, AI-driven environmental monitoring supports SDG 13 (Climate Action) by improving climate resilience and response strategies. It also aids SDG 14 (Life Below Water) and SDG 15 (Life on Land) by preventing pollution and habitat destruction. Meanwhile, predictive maintenance aligns with SDG 9 (Industry, Innovation, and Infrastructure) by promoting sustainable industrialization and SDG 12 (Responsible Consumption and Production) by optimizing resource use and minimizing waste [23] and [13].

Guyana can leverage AI-driven environmental monitoring to protect its rich biodiversity and natural resources. AI-powered satellite imaging and remote sensing can track deforestation, illegal mining, and water pollution in key areas like the Amazon rainforest and the Essequibo River [15]. Real-time data can support conservation efforts and regulatory actions, aligning with the country's Low Carbon Development Strategy (LCDS) and SDG 13 (Climate Action). Additionally, AI-based air quality monitoring can help address pollution from urban and industrial growth, improving environmental sustainability and public health (SDG 15 - Life on Land) [13].

Additionally, in Guyana's oil and gas sector, AI-driven predictive maintenance can minimize equipment failures, reduce emissions, and enhance safety in offshore operations (SDG 12 - Responsible Consumption and Production) [13]. AI can also optimize agriculture by improving irrigation and fertilizer use, ensuring sustainable food production (SDG 9 - Industry,

Innovation, and Infrastructure) [15]. By integrating AI into these sectors, Guyana can balance economic growth with environmental protection, reinforcing its leadership in green technology adoption.

The review conducted by Jia et al. [13] and others [15] [23] examined the link between Sustainable Development Goals (SDGs) and environmental monitoring and predictive maintenance; this comprehensive review concludes that integrating AI technologies into environmental and industrial management, businesses and governments can transition towards more sustainable practices, fostering a balance between economic growth and environmental stewardship. The following are examples of how AI integration impacts Sustainable Development Goals (SDGs).

A review conducted by Numalis [20], demonstrate the scope of AI in the Oil and Gas industries. The findings shows the many areas where AI continues to improve efficiency in the oil and gas industry, such as equipment maintenance and reservoir modeling. For instance, AI-powered systems using machine learning and deep learning can help in upstream operators find optimal wells. Studies indicate that AI can help improve the recovery of hydrocarbons by 10%, corresponding to accessing about \$1 trillion worth of oil.

In Germany, ⁷Siemens [24] uses AI-driven predictive maintenance to enhance energy efficiency and reduce waste, supporting SDG 9 (Industry, Innovation, and Infrastructure) and SDG 12 (Responsible Consumption and Production). By predicting equipment failures, Siemens prevents breakdowns, minimizes resource wastage, and lowers carbon emissions, aligning with SDG 13 [24].

Additionally, IBM and Tesla also leverage AI for sustainable practices. IBM's AI monitors air and water quality, helping industries reduce pollution and comply with regulations, contributing to SDG 6 (Clean Water and

Sanitation) and SDG 14 (Life Below Water) [10]. Tesla optimizes resource use and predictive maintenance in its production processes, reducing waste and enhancing efficiency, aligning with SDG 12 and SDG 9 [29]. These AI applications ensure sustainability while improving industrial performance.

Further, given Guyana's burgeoning oil and gas sector, AI can be used for predictive maintenance in drilling operations and equipment management. By implementing AI tools to predict equipment failures and optimize energy usage, oil companies can minimize downtime and reduce waste, leading to more sustainable resource extraction. Additionally, AI-driven environmental monitoring tools could be used to monitor oil spills, air quality, and water contamination, helping to mitigate ecological risks and ensure compliance with environmental regulations.

Notably, ExxonMobil is one of the largest players in Guyana's oil and gas sector, and while the company is not explicitly using AI for environmental monitoring or predictive maintenance in public disclosures, it is known to leverage advanced technologies to optimize operations and reduce environmental impact. The company uses digital monitoring tools to assess offshore drilling operations, detect equipment malfunctions, and prevent spills. AI could be integrated into these systems to enhance predictive maintenance and further mitigate ecological risks, aligning with ExxonMobil's focus on sustainability [19].

Additionally, the Environmental Protection Agency (EPA) of Guyana has partnered with Maxar Technologies to employ AI-powered environmental monitoring tools. This collaboration enables the EPA to monitor offshore petroleum activities in real-time, utilizing services like the Crow's Nest Multi-Sensor Oil Detection to identify potential spills and ensure compliance with environmental

⁷ Siemens is a German multinational technology conglomerate that focuses on various sectors, including

industrial automation, infrastructure, transport, and healthcare.

regulations [19]. These initiatives demonstrate Guyana's commitment to integrating advanced AI technologies in its oil and gas industry to promote sustainable resource extraction and environmental stewardship.

Similarly, in the Agriculture sector, AI can help monitor environmental variables such as soil moisture, temperature, and weather patterns to predict crop health and optimize resource usage. Predictive maintenance systems can also be used on irrigation equipment and machinery, reducing waste, improving water usage efficiency, and ensuring that farming equipment operates at optimal levels. AI tools can aid in minimizing pesticide usage, optimizing fertilizer application, and managing irrigation schedules to reduce environmental impact. In the local agricultural sector, AI has moved beyond theory into field application.

Notably, the Guyana Rice Development Board (GRDB) now utilizes AI-equipped drones to conduct multispectral imaging of rice paddies [30]. By analyzing "heat maps" of crop health, farmers can implement variable-rate fertilization, reducing chemical waste by an estimated 15% while maximizing yields in regions like Mahaica-Berbice [30]. Similarly, GuySuCo has integrated AI-driven predictive modeling at the Albion Estate to automate the scheduling of mechanical harvesters based on real-time weather patterns and cane maturity data, addressing chronic labor shortages [31].

Likewise, SMEs in Guyana's manufacturing and industrial sectors can leverage predictive maintenance to reduce equipment downtime and waste. By employing AI to monitor machine performance and anticipate failures before they occur, companies can minimize the need for emergency repairs, which often result in wasted resources and higher energy consumption. AI-driven resource efficiency monitoring can also help businesses track material usage, optimize energy consumption, and reduce carbon emissions, supporting eco-friendly operations. Companies such as

Demerara Distillers Limited (DDL), which is one of the country's largest manufacturers, may use data analytics and predictive technologies to maintain equipment and reduce downtime.

While these companies are on the path to technological innovation, AI-driven environmental monitoring and predictive maintenance are still emerging fields in Guyana. There are significant expansion opportunities, particularly with the continued growth in the oil and gas sector, agriculture, and manufacturing industries. Local companies, along with government support and potential collaborations with international tech firms, could explore AI-based tools to improve resource management, reduce waste, and enhance sustainability.

Summary of Findings

SME Empowerment

The government's AskGov platform serves as a 24/7 digital consultant, enabling local entrepreneurs to navigate the complex Local Content Act and tax filings through natural language. This is complemented by local financial institutions like Republic Bank, which use AI credit scoring to analyze non-traditional data, such as utility payments, to unlock capital for businesses lacking formal credit histories. These tools collectively lower the barriers to entry, allowing small businesses to compete effectively with international firms.

Predictive Logistics

AI-driven demand forecasting is revolutionizing supply chain efficiency across Guyana's retail, agriculture, and fuel sectors. By analyzing historical sales, weather patterns, and consumer behavior, these systems prevent both stockouts and overstock waste. In the agricultural sector specifically, the GRDB and GuySuCo utilize AI-equipped drones and multispectral imaging to optimize fertilization and harvesting, which has already demonstrated a 15% reduction in chemical waste in regions like Mahaica-Berbice.

Regulatory Oversight

To ensure transparency in the booming oil and gas industry, the EPA has deployed AI-powered measuring instruments on FPSO vessels to track production and waste disposal in real-time. These automated auditing tools allow authorities to monitor every barrel produced, ensuring strict adherence to environmental regulations and the Local Content Act. This shifts oversight from manual, error-prone processes to a continuous, cloud-based verification system that guarantees fair contract allocations for Guyanese workers.

Environmental Stewardship

Guyana is leveraging AI to protect its natural resources through predictive maintenance and real-time ecological monitoring. As part of the Silica City initiative, 3D AI models of the national power grid and drainage systems use sensors to predict "koker" (sluice) failures and urban flooding risks. Furthermore, technologies like Digital Twins on vessels such as the Liza Unity allow for proactive equipment maintenance, minimizing the risk of oil spills and reducing the overall carbon footprint of industrial operations.

Conclusion

Guyana is rapidly transitioning from a traditional resource-based economy to a digitally-augmented one. The synergy between government-led AI initiatives, like AskGov, and private-sector technological investments, such as Digital Twin modeling, has created a robust framework for sustainable development. By automating regulatory compliance and optimizing supply chains in the agriculture and energy sectors, the country is effectively positioning itself as a regional leader in green technology and industrial innovation.

The findings revealed that AI-driven integration in Guyana enhances trade efficiency through a multi-sectoral approach: the AskGov platform and non-traditional credit scoring at Republic Bank democratize access to

regulatory guidance and capital for SMEs, while industrial precision tools like Digital Twins on the Liza Unity and GRDB drones stabilize supply chains and reduce agricultural chemical waste by 15%. Furthermore, real-time monitoring by the EPA ensures regulatory transparency and compliance with the Local Content Act, and the Silica City project's 3D AI models strengthen climate resilience by predicting infrastructure failures to protect vital commercial logistics routes.

However, the full realization of this potential faces critical hurdles. The current digital divide and a lack of long-term longitudinal data on pilot projects like Silica City mean that the benefits of AI are currently most visible in urban and industrial hubs rather than the deep hinterland. Addressing these limitations is essential to ensure that the "Digital Guyana" initiative results in equitable growth across all demographics.

To bridge these gaps, it is recommended that the government prioritize offline synchronization and multi-language support for its digital platforms. By establishing a National AI Data Warehouse, Guyana can democratize access to high-value data, empowering local SMEs to build homegrown solutions. This strategic evolution will ensure that the nation's digital infrastructure is as resilient and inclusive as the physical resources that currently drive its economy.

Limitations

Temporal Constraints and Pilot Data

A primary limitation of this research is the lack of long-term longitudinal data, as many of the featured AI deployments, including AskGov and the Silica City 3D modeling are currently in their early or pilot stages. Because these systems have only recently been integrated into Guyana's national infrastructure, it is difficult to measure their long-term socio-economic impact or their durability against shifting market cycles. Consequently, the findings represent a "snapshot" of potential

rather than a comprehensive analysis of sustained performance over several years.

Infrastructure and the Digital Divide

Furthermore, the "digital divide" remains a significant barrier to the universal efficacy of AI tools in Guyana, particularly concerning high-speed internet penetration in deep riverine and interior regions. While the government aims for remote accessibility via mobile devices, citizens in the hinterland may still face connectivity hurdles that prevent them from fully utilizing real-time platforms like AskGov. This geographical disparity suggests that the immediate benefits of AI integration may be more concentrated in urban coastal centers, potentially leaving rural agricultural and mining communities at a temporary disadvantage.

Recommendations

Strategic Expansion of Digital Governance

To maximize the inclusivity of the "Digital Guyana" initiative, it is recommended that the government expand the AskGov architecture to incorporate multi-language support and offline capabilities. Integrating Indigenous languages and Dutch or Portuguese translations would ensure that hinterland communities and border regions are not left behind by the digital transition. Furthermore, developing a lightweight, offline-synchronized version of the app would allow entrepreneurs in areas with intermittent connectivity to access critical regulatory and tax guidance without requiring a constant high-speed internet connection.

Data Democratization and Local Innovation

Additionally, establishing a centralized National AI Data Warehouse would serve as a powerful catalyst for local innovation. By providing SMEs with access to anonymized, high-quality datasets—including historical market trends, multispectral soil data, and real-

time weather patterns—the government can significantly lower the R&D costs for local tech startups. This "data democratization" would enable small-scale agro-processors and retailers to build their own predictive models, fostering a homegrown tech ecosystem that reduces reliance on expensive international software and aligns with national development goals.

Conflict of Interest

The authors declare no conflicts of interest in conducting this research. The study is conducted with an objective approach to analyzing the potential of AI in Guyana's trade and commerce sectors.

Ethical Approval

This study was conducted in accordance with the ethical standards of Texila American University. As the research primarily utilized a synthesis of secondary literature, publicly available government policy documents (such as the Local Content Act and LCDS), and anonymized professional interviews, it was deemed exempt from full Institutional Review Board (IRB) review. All virtual interviews were conducted with informed consent, ensuring participant confidentiality and the voluntary nature of data contribution. No sensitive personal data or classified government records were accessed during this study.

Author Contributions

Dr. Visham F. Budhoo is the sole author of this research. He was responsible for the conceptualization of the study, the design of the research methodology, data collection and synthesis, the comparative analysis of AI adoption in emerging markets, and the drafting and critical revision of the manuscript. The author has read and approved the final version of the article for publication.

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Data Availability

The data supporting the findings of this study are derived from a combination of public domain documents and synthesized industry reports. Primary data, including comparative benchmarking datasets for Guyana, are available from the corresponding author, Dr. Visham F. Budhoo, upon reasonable request. Publicly cited data regarding the Liza Unity and AskGov initiative can be accessed via the Ministry of Natural Resources and official Government of Guyana digital portals.

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Therapeutic Potential of Berberine in Lung Cancer: A Systematic Review and Meta- Analysis of Preclinical Studies

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Abstract

Berberine, a natural isoquinoline alkaloid, has demonstrated anticancer properties in various malignancies. This systematic review and meta-analysis evaluated the efficacy of berberine specifically in lung cancer preclinical models. We conducted a comprehensive literature search across PubMed, Web of Science, and Scopus. From 427 initially identified publications, three high-quality preclinical studies met inclusion criteria, providing data on 172 experimental animals for tumor volume analysis and 134 animals for tumor weight assessment. Berberine significantly inhibited tumor volume (SMD -1.5140, 95% CI: -2.0164 to -1.0116; $p < 0.0001$) and tumor weight (SMD -2.0546, 95% CI: -2.5484 to -1.5607; $p < 0.0001$) in experimental lung cancer models. Considerable heterogeneity was observed across studies ($I^2 = 92.1\%$ for tumor volume, $I^2 = 87.6\%$ for tumor weight). Mechanistically, berberine exhibited p53-dependent antitumor activity, demonstrated oral bioavailability through dietary administration, and functioned as a small-molecule immune checkpoint inhibitor by reducing PD-L1 expression on tumor cells. Berberine demonstrates significant antitumor activity in lung cancer models through multiple complementary mechanisms. Despite the robust preclinical evidence, the limited number of included studies necessitates further investigation through standardized protocols and carefully designed clinical trials to evaluate berberine's potential as an adjunctive or alternative therapy for lung cancer.

Keywords: Alkaloids, Cancer, Meta-Analysis, Preclinical Studies, Systematic Review.

Introduction

Cancer continues to pose a major mortality rates, resulting to millions of deaths each year [1, 2]. Among all cancer, lung cancer is the major cause of cancer-related death worldwide, estimating for appropriately 1.8 million deaths annually according to the World Health Organization [3]. Lung cancer is commonly categorized into two primary groups: Non-

Small Cell Lung Carcinoma (NSCLC) and Small Cell Lung Carcinoma (SCLC). NSCLC represents about 80% of all clinically diagnosed cases, the most frequent histological subtype is adenocarcinoma. In contrast, SCLC accounts for approximately 15% of cases and is characterized by its aggressive nature, rapid proliferation, and associated with diminished long-term outcomes [4]. The primary risk factor for lung cancer is tobacco smoking,

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contributing to approximately 90% of cases. Tobacco smoking remains the primary risk factor for lung cancer, accounting for nearly 90% of all cases. The other contributing factors such as exposure to second-hand smoke, asbestos, radon, many carcinogenic substances, and family history of the disease [5].

Even though, significant advancement has been made in the development of immunotherapies and targeted therapies, the survival (5 years) rate for lung cancer remains below 25%, highlights the need for crucial role in treatment strategies. The disease is commonly diagnosed at later stage due to is early-stage indicators and progressive deterioration. Traditional therapies include chemotherapy and radiotherapy, are restricted in efficacy, and problems such as tumor recurrence and drug resistance continues to exhibit a major clinical challenge, focusing the need for innovative therapeutic approaches [6]. Recently, many researchers have shown interest towards natural phytochemicals have attracted increasing interest a potential anticancer activity because of their diverse biological activities and preferably low side-effect profile. Among these, berberine is an isoquinoline alkaloid derived from plants, belongs to Berberidaceae family, has observed a significant role for cancer therapy [7].

Berberine has employed remarkably anti-tumor effects in both in vitro and in vivo studies, showing activity against various cancer types, with specifically strong effects in breast and lung cancers [8, 9]. Its anticancer actions are multifunctional, including the suppression of cell proliferation, stimulation of apoptosis, modulation of critical signaling pathways, and blocks tumor migration and metastasis [10]. Berberine exerts wide-ranging effects that targets the dysregulated cellular processes often associated with lung cancer. Previously, research has demonstrated that berberine can downregulates the cell proliferation of A549 cells by regulating pathways such as matrix metalloproteinase 2 (MMP-2)/ Bcl-2/Bax and

Janus kinase 2 (Jak2)/ vascular endothelial growth factor (VEGF)/ AP-1 [11].

In NSCLC, both *in vitro* and *in vivo* analysis, berberine inhibited cell growth by damaging DNA replication [12] and promoted cell apoptosis via the miR19a/ MAPK signalling pathway [13]. Gaining insight into its molecular pathways is essential for advancing the development of precise and effective cancer treatments. This systematic review and meta-analysis synthesize and assess the existing evidence on Berberine's therapeutic potential in NSCLC models, with a particular focus on its impact on tumor cell proliferation and tumor size reduction.

Materials and Methods

This systematic review and meta-analysis were performed in alignment with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure methodological clarity and transparency.

Eligibility Criteria

We included experimental studies that met the following criteria: (1) used rodent (mice or rat) models of lung cancer, (2) administered berberine as the primary intervention, (3) included a proper control group, (4) reported quantitative outcomes related to tumor growth, survival, or other relevant anticancer effects, and (5) were published in English. Studies with combined treatments were included only if they had a berberine-only arm. We excluded in vitro studies, studies using non-rodent animal models, conference abstracts, letters, case reports, reviews, and duplicate publications.

Information Sources and Search Strategy

We conducted a comprehensive literature search of PubMed, Embase, Web of Science, Scopus, and the Cochrane Library from inception through July 2024. The search strategy combined Medical Subject Heading (MeSH) terms and keywords related to

berberine, lung cancer, and animal models. In addition, reference lists of the included studies and pertinent review articles were manually screened to uncover any further eligible studies. The detailed PubMed search strategy is outlined as follows:

((("Berberine"[Mesh] OR berberin* OR umbellatine OR "berberine alkaloid" OR "berberine compounds") AND ("Lung Neoplasms"[Mesh] OR "lung cancer" OR "lung carcinoma" OR "pulmonary cancer" OR "pulmonary neoplasm" OR "lung tumor" OR "non-small cell lung cancer" OR "NSCLC" OR "small cell lung cancer" OR "SCLC") AND ("Disease Models, Animal"[Mesh] OR "Models, Animal"[Mesh] OR "Mice"[Mesh] OR "Rats"[Mesh] OR mice OR mouse OR murine OR rat OR rats OR rodent*))

Study Selection

Two investigators (MB and AG) independently screened titles and abstracts of all retrieved records for eligibility. Full-text articles of studies deemed potentially eligible were retrieved and independently evaluated by two investigators. Any discrepancies were addressed through consultation with a third reviewer (NP).

Data Collection Process

A standardized data extraction form was developed and piloted on a random sample of 5 included studies before implementation. Two investigators (MB and AG) independently extracted data from all included studies. Discrepancies were resolved through consensus or consultation with a third investigator (NP).

Data Items

From each study, we collected the following details: (1) study-related information including the first author, year of publication, and country; and (2) characteristics of the animal model such as species, strain, sex, age, weight, and the technique used to induce lung cancer; (3) intervention details like berberine source, purity, dose, route of administration, treatment

duration, frequency; (4) control group details; (5) sample size per group; (6) outcome measures such as tumor size, tumor weight; and (7) adverse events or toxicity data if reported.

Bias Assessment

The methodological quality of the included studies was evaluated using SYRCLE's risk of bias tool, which is specifically tailored for assessing bias in animal research [14]. This tool evaluates 10 domains: sequence generation, baseline characteristics, allocation concealment, random housing, blinding of investigators/caregivers, random outcome assessment, blinding of outcome assessor, incomplete outcome data, selective outcome reporting, and other sources of bias. Two investigators (MB and AG) independently evaluated the risk of bias in the studies, and any disagreements were resolved through consensus or by consulting a third investigator (NP).

Synthesis Methods

A random-effects meta-analysis was performed using Review Manager 5.4 (The Cochrane Collaboration) and R version 4.1.0 with the "meta" package [15]. For continuous outcomes (e.g., tumor volume, tumor weight), standardized mean differences (SMDs) with 95% confidence intervals (CIs) were calculated due to expected variations in measurement methods across studies. For time-to-event data (survival), hazard ratios (HRs) with 95% CIs were calculated. Statistical heterogeneity was assessed using the I^2 statistic, with values of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively. When substantial heterogeneity was detected ($I^2 > 50\%$), we conducted subgroup analyses to explore potential sources of heterogeneity, including animal species, lung cancer model type, berberine dose, and route of administration.

Results

The systematic literature search initially identified 427 potentially relevant publications across electronic databases including PubMed, EMBASE, Web of Science, and Scopus. After removing 86 duplicates, 341 studies underwent title and abstract screening (Figure 1). During this preliminary screening, 287 studies were excluded because they did not meet the basic inclusion criteria. The remaining 54 full-text articles were assessed for eligibility based on the predefined criteria. Of these, 51 were

excluded for the following reasons: 23 studies did not include appropriate control groups, 14 studies used berberine in combination with other treatments without a berberine-only arm, 9 studies did not report quantifiable data on tumor volume or weight, and 5 studies used cancer models other than NSCLC. Ultimately, only three studies [16-18] met all inclusion criteria and had sufficient data for quantitative synthesis. These studies collectively provided data on 172 experimental animals for tumor volume analysis and 134 animals for tumor weight analysis.

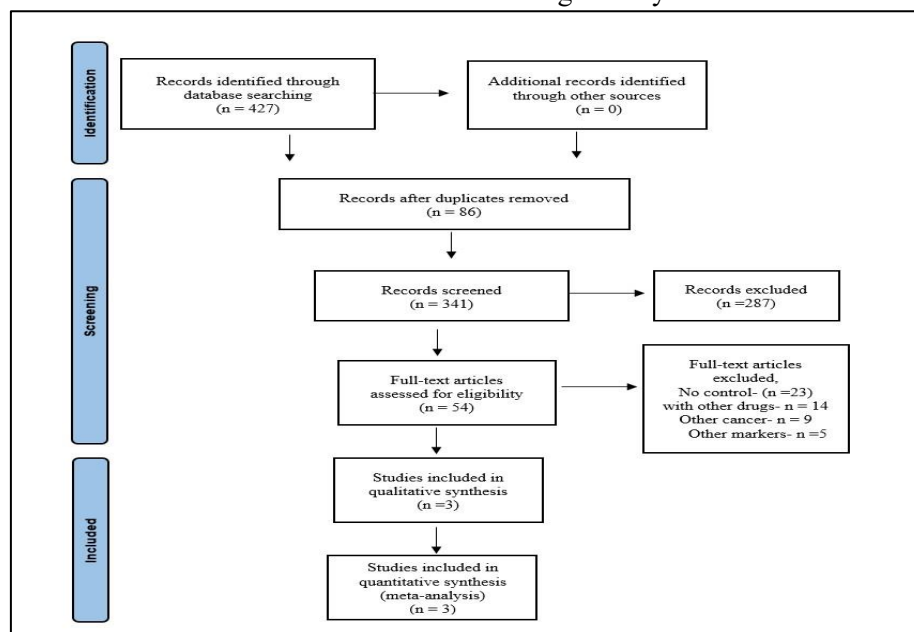


Figure 1. Schematic Representation of the Search Strategy and Screening Stages using PRISMA

Details of the Included Studies

Three preclinical studies investigating the antitumor effects of berberine in NSCLC models were included in this meta-analysis (Table 1). The first study by Katiyar et al. (2011) demonstrated that berberine inhibited tumor growth more effectively in p53-positive A549 cells compared to p53- deficient H1299 cells, indicating a p53-dependent mechanism in both in vitro and xenograft models [16]. The second study by James et al. (2010) provided evidence for dietary berberine and *Phellodendron amurense* extract reducing lung tumor xenograft growth in vivo through cell cycle arrest and inhibition of proliferative

kinase signaling, irrespective of p53 status, thereby supporting the oral bioavailability and chemopreventive potential of berberine [17]. Finally, discovered berberine to be a small-molecule immune checkpoint inhibitor. They found that berberine reduced PD L1 expression on tumor cells by inhibiting CSN5-mediated deubiquitination, which subsequently improved T-cell-mediated tumor cell destruction and boosted antitumor immunity in Lewis lung carcinoma models [18]. These studies collectively reveal various mechanisms through which berberine demonstrates strong anticancer effects in lung cancer models, such as promoting apoptosis, causing cell cycle arrest, and modulating immune checkpoints.

Table 1. Summary of Selected Studies

Author (Year, Country)	Species/Strain (Gender, Age)	Cell Line	Dosage	Frequency	Route	Duration	Control	Outcome	Mean ₀	SD ₀	n ₀	Mean ₁	SD ₁	n ₁	p-value
Michael A. James (2011, Missouri)	Mice, Balb/c (M, 4–6w)	A549	1800 ppm	Daily	Free intake	4 weeks	DMSO	TV	0.06	0.023	4	0.022	0.024	4	0.05
		A549	5400 ppm	Daily	Free intake	4 weeks	DMSO	TV	0.06	0.023	3	0.014	0.012	2	0.04
Santosh K. Katiyar (2009, Alabama)	Mice, Balb/c (F, 6–7w)	A549	50 mg/kg	qd	po	7 weeks	PBS	TV	1.4	0.17	9	0.9	0.4	10	<0.01
		A549						TW	2.32	0.27	10	2.0	0.3	10	0.03
		A549	100 mg/kg	qd	po	7 weeks	PBS	TV	1.4	0.17	6	0.6	0.4	10	<0.01
		A549						TW	2.32	0.27	6	1.1	0.2	10	<0.01
		A549	200 mg/kg	qd	po	7 weeks	PBS	TV	1.4	0.17	7	0.3	0.6	10	<0.01
		A549						TW	2.32	0.27	9	0.6	0.3	10	<0.01
		A549	100 mg/kg	qd	po	7 weeks	PBS	TW	2.71	0.31	10	2.3	0.29	10	0.02
		A549	100 mg/kg	qd	po	7 weeks	PBS	TV	1.59	0.11	10	1.0	0.5	10	<0.01
		A549						TW	2.71	0.31	10	1.8	0.22	10	<0.01
		A549	200 mg/kg	qd	po	7 weeks	PBS	TV	1.59	0.11	10	0.6	0.2	10	<0.01
		A549						TW	2.71	0.31	10	1.1	0.1	10	<0.01
Yang Liu et al. (2020)	Mice, C57BL/6 and BALB/c-nu/nu nude mice (8 week)	A549	4 mg/kg	Daily	Ip	18 days	PBS	TV (mm ³)	2.4	0.5	5	1.2	0.3	5	<0.001
		A549	8 mg/kg	Daily	Ip	18 days	PBS	TV (mm ³)	2.4	0.5	5	1.4	0.5	5	<0.001
		A549	4 mg/kg	Daily	Ip	18 days (Exp 2)	PBS	TV (mm ³)	2.5	0.5	6	2.5	0.6	5	ns
		A549	8 mg/kg	Daily	Ip	18 days (Exp 2)	PBS	TV (mm ³)	2.5	0.5	6	2.6	0.5	5	ns
		A549	4 mg/kg	Daily	Ip	18 days	PBS	BW	2.3	1.5	5	2.2	1.1	5	ns

Quality Assessment

In this meta-analysis, we evaluated three preclinical studies assessing berberine's antitumor effects in non-small cell lung cancer models. Quality assessment revealed moderate to high methodological quality across all studies. While all studies employed appropriate randomization techniques and included suitable control groups with complete outcome reporting, none explicitly described sample size calculations or allocation concealment methods. Only Liu et al. clearly mentioned blinding of outcome assessors [18]. Katiyar et al. demonstrated rigorous p53 status verification in cell lines and xenograft models, James et al. provided thorough analytical validation of berberine bioavailability using HPLC, and Liu et al. employed comprehensive immune profiling techniques [16, 17].

Meta Analysis

Tumor Volume

A meta-analysis of 3 studies (n = 172; 86 experimental, 86 control) evaluating berberine's effects on tumor volume in experimental lung cancer animal models demonstrated significant antitumor activity (Figure 2). The common effect model revealed a standardized mean difference (SMD) of -1.5140 (95% CI: -2.0164 to -1.0116; p < 0.0001), while the random effects model showed an SMD of -4.8677 (95% CI: -8.6113 to -1.1242; p = 0.0155). Considerable heterogeneity was observed between studies ($I^2 = 92.1\%$, 95% CI: 88.1% to 94.8%; Q = 139.74, p < 0.0001), which likely reflects variations in experimental protocols, berberine dosages, and animal models.

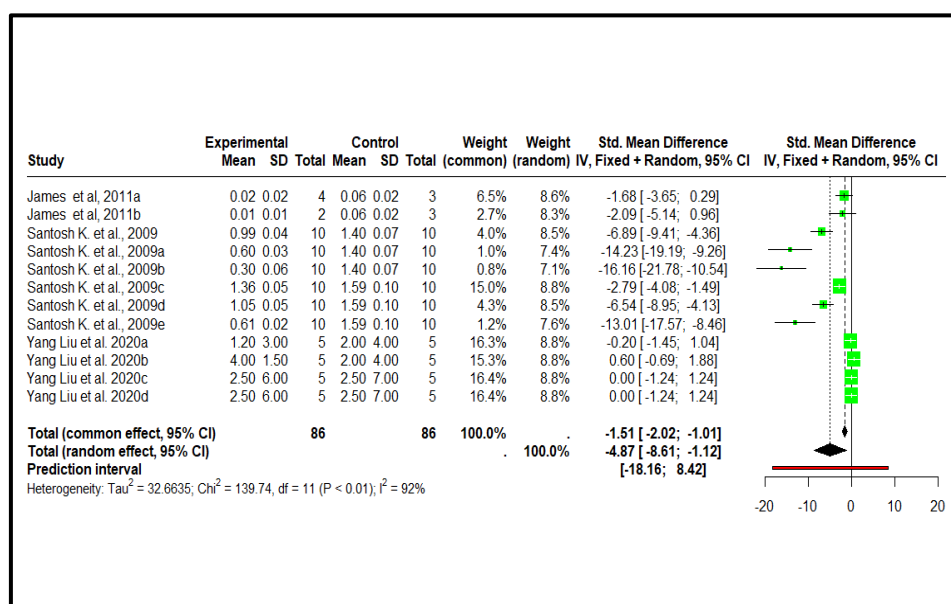


Figure 2. Forest plot for Tumor Volume

Tumor Size

A meta-analysis comprising 2 studies (n = 134; 67 experimental, 67 control) examining berberine's impact on tumor weight in experimental lung cancer animal models demonstrated potent antitumor effects (Figure 3). The common effect model yielded a standardized mean difference (SMD) of -

2.0546 (95% CI: -2.5484 to -1.5607; p < 0.0001), while the random effects model showed an SMD of -3.4176 (95% CI: -5.9576 to -0.8777; p = 0.0166). Significant heterogeneity was observed among studies ($I^2 = 87.6\%$, 95% CI: 76.8% to 93.4%; Q = 48.46, p < 0.0001), likely reflecting differences in methodology, dosing regimens, and animal models used.

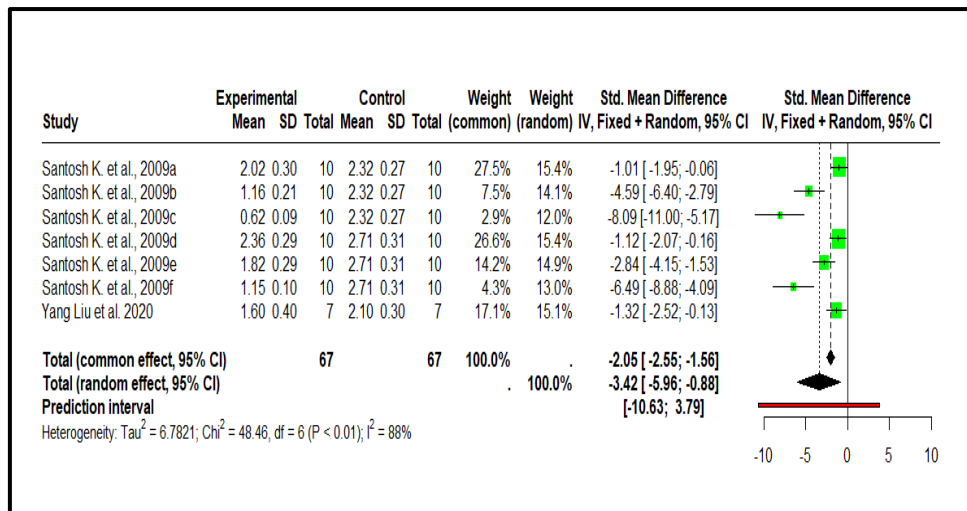


Figure 3. Forest Plot for Tumor Weight

Publication Bias

Funnel plot analysis for both tumor size (Figure 4) and tumor weight (Figure 5)

outcomes showed symmetrical distribution, indicating no significant publication bias. These results support the robustness and reliability of the pooled effect estimates in the meta-analysis.

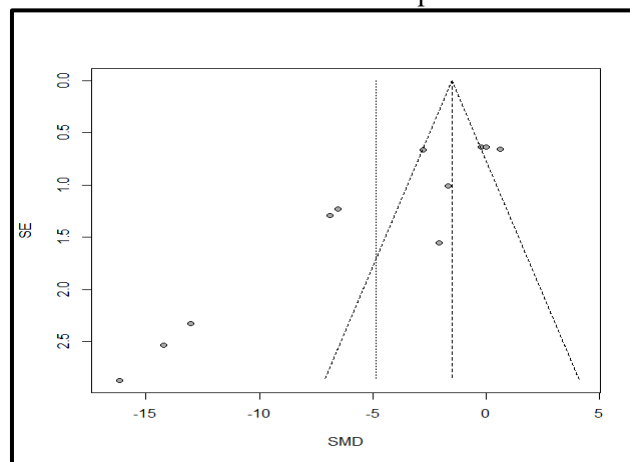


Figure 4. Funnel Plot for Tumor Volume

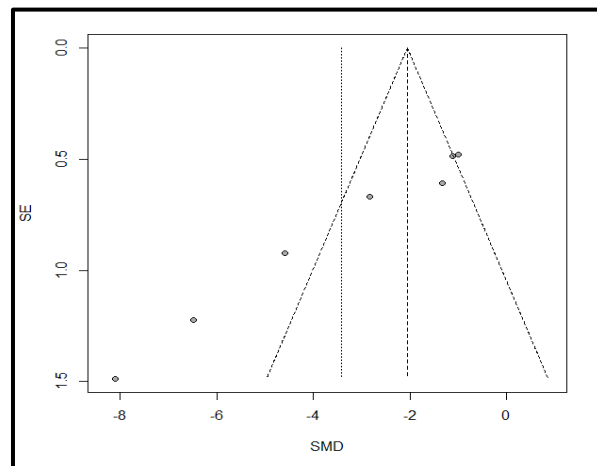


Figure 5. Funnel Plot for Tumor Weight

Discussion

In this systematic review and meta-analysis of berberine's antitumor effects in NSCLC models, we found robust evidence supporting its therapeutic potential. Our analysis of three high-quality preclinical studies demonstrated significant inhibition of tumor volume (SMD -1.5140, 95% CI: -2.0164 to -1.0116; $p < 0.0001$) and tumor weight (SMD -2.0546, 95% CI: -2.5484 to -1.5607; $p < 0.0001$) in experimental lung cancer animal models. The strength of berberine's antitumor activity appears to operate through multiple complementary mechanisms. Katiyar and colleagues demonstrated a p53-dependent pathway, where berberine showed greater efficacy in p53-positive tumor models compared to p53-deficient ones, suggesting potential for stratified therapeutic approaches based on tumor genetic profile [16]. James and colleagues established berberine's oral bioavailability and efficacy when administered through dietary routes, highlighting its potential as a chemopreventive agent [17]. This finding is particularly valuable as it supports a non-invasive administration route that could enhance patient compliance. Recently, Liu and his team uncovered a new role for berberine as a small-molecule immune checkpoint inhibitor. They demonstrated that berberine reduces PD-L1 expression on tumor cells, suggesting its potential as an alternative or complementary approach to antibody-based immunotherapies [18]. The significant heterogeneity observed across studies ($I^2=92.1\%$ for tumor volume, $I^2=87.6\%$ for tumor weight) likely reflects the diversity in experimental approaches, dosing regimens, and animal models. This heterogeneity, while complicating direct comparisons, underscores berberine's robust activity across different experimental conditions. Future studies should focus on standardizing protocols to better quantify dose-response relationships and optimum treatment regimens.

Our findings align with previous meta-analyses examining berberine's effects across multiple cancer types, which reported particularly strong effects in breast and lung cancers.

A previous meta-analysis reviewed 26 in vivo studies from 2000 to 2018 investigating the antitumor effects of berberine (BBR) across various cancer types. The findings revealed that BBR significantly reduced tumor volume and weight in animal models, with a clear dose-response relationship. It also inhibited angiogenesis in tumor tissues without affecting the animals' body weight. The strongest evidence supported BBR's efficacy in breast and lung cancers, while findings in colorectal and gastric cancers remained limited. No publication bias was detected, suggesting robust preclinical evidence for BBR's anti-tumor potential [19]. However, unlike previous broader analyses, our focused examination of lung cancer models provides more specific insights into berberine's potential application in this particular cancer type. Berberine, a natural plant-derived alkaloid, shows strong anti-cancer potential against lung cancer. Preclinical studies demonstrate its ability to inhibit lung cancer cell proliferation, invasion, and migration, while promoting apoptosis and reducing tumor growth in vivo. Berberine also influences key molecular pathways, including DNA repair, epigenetic regulation, and interactions with noncoding RNAs. Moreover, it enhances the effectiveness of chemotherapy and other drugs, making it a promising candidate for integrative lung cancer therapy. Further research is warranted to validate its clinical applicability [20].

Despite these promising results, several limitations must be acknowledged. The small number of included studies ($n=3$) reflects the stringent inclusion criteria but limits the generalizability of our findings. Additionally, all included studies were preclinical, necessitating caution when extrapolating to human applications. The absence of detailed

toxicity assessments beyond tumor metrics also represents a gap that future research should address.

Conclusion

In conclusion, berberine exhibits considerable antitumor effects in non-small cell lung cancer models through various mechanisms, including the induction of apoptosis, arresting the cell cycle, and modulating immune checkpoints. These findings warrant further investigation through rigorous preclinical studies with standardized protocols and, ultimately, carefully designed clinical trials to evaluate berberine's potential as an adjunctive or alternative therapy for lung cancer.

Use of Large Language Models, AI and Machine Learning Tools

The authors used Claude AI to assist with revising and formatting the final manuscript. All content was reviewed and validated by the authors.

Author Contributions

The present study is the result of the collaborative work of all authors. M.B. and N.P.D. contributed to conceptualization, methodology, review, and editing. M.B., A.G., S.M., and collected the samples. M.B., S.M.,

and N.P.D. drafted the manuscript. S.M., M.B., and N.P.D. performed statistical analysis. All authors interpreted the results and critically reviewed and revised the final manuscript.

Conflict of Interest

The authors have no potential conflicts of interests with respect to the research, authorship, and/or publication of this article.

Data Availability

The datasets from this study are available from the corresponding author upon reasonable request.

Ethical Approval

The local Institutional Review Board deemed the study exempt from review.

Declaration of Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

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Determinants of Vaccination Dropout among Children in the Gambia: A Mixed-Method Comparison of Urban and Rural Health Regions

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Abstract

The dropout rate is the proportion of vaccine recipients who have not completed their vaccination schedules. In The Gambia, vaccination dropout persists despite rising immunization coverage from 76% in 2013 to 85% in 2020. The 2020 DHS reports high initial uptake of multi-dose vaccines (98–99%), but final-dose completion drops to 92–95%. These disparities highlight systemic barriers and the need to identify determinants of dropout to guide targeted interventions. This study employed a mixed-methods approach, combining a quantitative unmatched case-control design with a qualitative component. In the quantitative phase, mothers of children who completed the routine immunization schedule (controls) compared with mothers of children who experienced vaccination dropout (cases). The qualitative component included in-depth interviews with mothers from both groups to explore contextual factors, perceptions, and lived experiences related to vaccination completion. The findings indicated that maternal education was consistently associated with vaccination dropout. Children from households in the poorest wealth quintile were more likely to drop out of routine immunization compared with those in the highest wealth quintile. Maternal age was also significantly associated with vaccination dropout. Geographic access played an important role: shorter distance to health facilities was associated with lower dropout rates, while limited access to nearby health services contributed to higher vaccination dropout. Identifying the factors associated with dropout is essential for designing targeted interventions. Strengthening community-based outreach, improving service accessibility, and promoting maternal health service use may help reduce dropout and enhance immunization outcomes.

Keywords: Drop Out, Vaccination, Immunization, Pentavalent, Measles-rubella, Gambia

Introduction

Immunization is one of the most successful and cost-effective public health interventions [1, 2], preventing an estimated 2–3 million deaths annually worldwide [3, 4]. It plays a central role in achieving the Sustainable Development Goals (SDGs), particularly SDG 3, which aims to ensure healthy lives and

promote well-being for all. Childhood vaccination remains a core strategy for reducing under-five mortality to fewer than 25 deaths per 1,000 live births by 2030 [5].

The Expanded Programme on Immunization (EPI) was introduced in The Gambia in May 1979 following the 1978 yellow fever epidemic in the Upper River Region. Initially implemented as a vertical programme, EPI was

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later integrated into broader maternal and child health services to improve efficiency and sustainability. The Ministry of Health's efforts are further supported by local and international non-governmental organizations and private clinics, particularly within the Greater Banjul Area.

Routine immunization has substantially reduced the burden of vaccine-preventable diseases (VPDs) in The Gambia. Prior to the introduction of vaccination, diseases such as neonatal tetanus, poliomyelitis, measles, diphtheria, and pertussis accounted for over 50,000 illness cases and more than 3,000 deaths annually among children under five [6]. In recent years, several of these diseases have become rare or have been eliminated, with no reported cases of polio, diphtheria, or pertussis in 2023 [7]. However, measles outbreaks continue to occur, with 27 confirmed cases (none of them died) reported in the same year [7].

Despite significant progress in immunization coverage—from 76% in 2013 to 85% in 2020—vaccination dropout remains a major challenge to achieving full protection [21, 22]. Vaccination dropout is defined as receipt of Penta1 but failure to receive Penta3 between 12–23 months of age. The 2020 Demographic and Health Survey (DHS) reported high initial uptake of multi-dose vaccines such as DPT-HepB-Hib, pneumococcal conjugate vaccine (PCV), and rotavirus vaccine (98–99%), yet completion rates declined to 92–95% for the final doses [6]. A 2024 vaccination coverage survey further revealed marked regional disparities, with dropout rates reaching 6.1% in Upper River Region and 7.5% in Western Region 2. These patterns suggest the presence of systemic and structural barriers that warrant further investigation.

The dropout rate is one of the determinants of immunization coverage and program performance, program continuity, and follow-up. Immunization dropout signifies that the child has received the first recommended dose

of the vaccine yet has missed the next recommended dose [7, 19]. It is the rate difference between the first and final dosage or the rate difference between the first vaccination and the last vaccine dropout, so it denotes that the first recommended dose of the vaccine was received, but the subsequent recommended dose was missed [8, 13, 14]. The dropout rate indicates whether there is an accessibility issue, i.e., whether there is difficulty in reaching out to the immunization services for subsequent doses or there is an issue with the utilization of the services [15-18]. Reducing immunization dropout rates is crucial for achieving high full immunization coverage rates. The immunization dropout rate reduces the effectiveness of immunization programs, as even a small percentage of children who fail to complete their vaccinations can significantly decrease the overall full immunization rates. Overall, if children miss the three doses of pentavalent vaccine, it points to the fact that there is an access problem while a high dropout rate between Penta1 and the measles immunization suggests a service utilization problem [20]. In addition, the Measles vaccination dropout rate measures whether the national immunization program is able to reach children beyond the first year of life with vaccination services [19]. The World Health Organization (WHO) recommended that DTP1 to DTP3, BCG to Measle-containing virus (MCV1), and MCV1 to MCV2 should be used as the indicators of immunization dropout [19]. The WHO emphasizes that if the dropout rate is more than 10%, then it indicates that many people are not using the services [12].

To strengthen immunization monitoring, The Gambia Government introduced an electronic immunization registry (My Child Solution) in 2017, enabling improved tracking of vaccination performance and identification of dropout trends. This system provides an important opportunity to generate evidence for targeted interventions aimed at reducing dropout and improving immunization

completion nationwide. However, limited data exists on the determinants of immunization dropout in the country. This study therefore aims to identify the determinants of vaccination dropout among children in The Gambia.

Identification/Defining Research Problem

In The Gambia, despite significant progress in vaccination coverage from 76% in 2013 to 85% in 2020, the challenge of vaccination dropout threatens the achievement of complete immunization protection. The 2020 Demographic Health Survey reveals a concerning pattern: while initial coverage rates for multi-dose vaccines such as DPT-HepB-Hib, Pneumococcal Conjugate Vaccine, and Rota Virus reach 98-99%, completion rates drop significantly to 93%, 92%, and 95% respectively for final doses [6]. The recently conducted vaccination coverage survey in 2024 revealed that this dropout pattern is particularly pronounced in certain regions, with Upper River Region showing a 6.1% dropout rate and Western Region 2 reaching 7.5%. These regional disparities suggest underlying systematic and structural barriers to vaccination completion that require urgent investigation and intervention.

The implementation of the MyChild Solution electronic immunization registry in The Gambia since 2017 has provided unprecedented opportunities to track and analyze vaccination patterns. However, a critical gap exists in understanding the complex interplay of factors contributing to vaccination dropout. While previous research has examined various aspects of immunization services including coverage, timeliness, and cost-effectiveness, no comprehensive study has investigated the multifaceted determinants of vaccination dropout through both quantitative and qualitative approaches. The absence of such evidence hampers the development of targeted interventions to address this challenge. This research problem is particularly significant

as incomplete vaccination schedules leave children partially protected against vaccine-preventable diseases, potentially contributing to disease outbreaks and undermining the overall effectiveness of the national immunization program. Understanding these factors through a mixed-methods approach, particularly by incorporating the perspectives of both mothers whose children have completed vaccination, those whose children dropped out of vaccination schedules, as well as Health care workers and national EPI management, will provide crucial insights for developing evidence-based strategies to improve vaccination completion rates.

Methods

Study Design and Period

This study employed a mixed-methods approach, combining a quantitative unmatched case-control design with a qualitative component. In the quantitative phase, mothers of children who completed the routine immunization schedule (controls) compared with mothers of children who experienced vaccination dropout (cases). Data was collected from August to October 2025 using structured interviewer-administered questionnaires to identify factors associated with immunization dropout.

The qualitative phase included in-depth interviews with mothers from both groups to explore contextual experiences influencing vaccination completion. In addition, focus group discussions (FGDs) were conducted with community stakeholders, including mothers' clubs and traditional communicators, to gain deeper insight into sociocultural barriers. Key informant interviews were also held with healthcare workers in selected health facilities to assess service-related challenges.

Study Area and Population

The study was conducted in The Gambia, a West African country with an estimated population of 2.5 million (2024 census). The

country has maintained relatively high routine immunization coverage through the Expanded Programme on Immunization (EPI). However, disparities in vaccination completion persist, particularly in selected regions included in this study. The study population consisted of mothers or primary caregivers of children eligible for routine immunization services.

Data Source

Data was collected using validated instruments adapted from previous epidemiological studies on vaccination dropout. The quantitative questionnaire incorporated standardized tools including the WHO Vaccination Coverage Cluster Survey and socioeconomic assessment measures. All tools were translated into Mandinka, Fula, and Wolof using forward and backward translation by independent translators, with discrepancies reconciled through consensus. Semi-structured interview guides for FGDs and health worker interviews were developed based on established frameworks of healthcare utilization and barriers to immunization. Instruments were reviewed by immunization programme experts and local healthcare providers to ensure contextual relevance.

Data Collection

A pilot test involving 10 participants in non-study facilities was conducted to assess cultural appropriateness and logistical feasibility. Data collectors received a two-day training on interviewing techniques, ethical conduct, confidentiality, and standardized data handling procedures. Role-playing and field practice were included to ensure consistency and inter-rater reliability. Ten trained Public Health Officers from the selected regions were engaged as data collectors under close supervision.

Data Management and Analysis

Quantitative Analysis

Quantitative data was analyzed using SPSS version 23.0 and Stata 17.0. Data cleaning included checks for completeness, outliers, and inconsistencies. Descriptive statistics will summarize participant characteristics.

Analysis was conducted in three stages:

1. Univariate analysis to describe socio-demographic and vaccination-related variables.
2. Bivariate analysis using chi-square tests and t-tests to assess associations between risk factors and dropout.
3. Multivariable logistic regression to identify independent predictors of vaccination dropout while controlling for confounding factors. Adjusted odds ratios (AORs) with 95% confidence intervals will be reported.

Clustering effects were not adjusted due to the limited number of regions sampled, and this was acknowledged as a study limitation.

Sample size Determination and Sampling Procedures

Quantitative Strand Sample Size Calculation: For the case-control study, the sample size was calculated using the following formula for matched case-control studies:

$$n = \frac{\left[Z_{\alpha/2} \sqrt{\left(1 + \frac{1}{r}\right) \bar{p}(1-\bar{p})} + Z_{\beta} \sqrt{\frac{p_1(1-p_1)}{1} + \frac{p_2(1-p_2)}{r}} \right]^2}{(p_1 - p_2)^2}$$

Where:

- n = required sample size per group.
- $Z_{\alpha/2} = 1.96$ (95% confidence level).
- $Z_{\beta} = 1.28$ (90% power).
- r = ratio of controls to cases (1:1).
- p_1 = anticipated probability of exposure in cases (0.40).
- p_2 = anticipated probability of exposure in controls (0.25).
- $\bar{p}$ = average of p_1 and $p_2 = (0.40 + 0.25)/2 = 0.325$.

Based on previous studies in similar settings and assuming:

- 95% confidence level.
- 90% power.
- 1:1 ratio of cases to controls.
- Odds ratio of 2.0.
- Expected proportion of exposure (distance to facility >5km) among controls of 25%.
- Expected proportion of exposure among cases of 40%.
- 15% non-response rate.

$$n = \frac{\left[1.96 \sqrt{\left(1 + \frac{1}{1}\right) 0.325(1 - 0.325)} + 1.28 \sqrt{\frac{0.40(1 - 0.40)}{1} + \frac{0.25(1 - 0.25)}{1}} \right]^2}{(0.40 - 0.25)^2}$$

Rounding up the minimum required sample size, we get $n = 203$ as the base sample size per group. Now adjusting for 15% non-response rate, we multiplied the current sample size by $1.15 = 234$ cases and 234 controls, for a total of 468 participants. This sample size was distributed proportionally between the two regions based on their population size and number of health facilities.

Sample Size Justification

A power calculation was conducted to determine the required sample size for detecting a significant difference in vaccination dropout rates between rural and urban areas. To ensure adequate statistical power, the study was powered at 90% with a 95% confidence level.

Previous studies investigating vaccination dropout rates in sub-Saharan Africa used similar methodologies to determine appropriate sample sizes for case-control studies (Smith et al., 2019; Johnson & Adebayo, 2021). These studies highlighted the importance of adequate power in detecting disparities in immunization coverage and dropout determinants. Ensuring a power level of 90% enhances the robustness of the findings and minimizes the risk of Type II errors.

The adjusted sample size accounts for a potential dropout, ensuring that the study remained methodologically sound while

maintaining statistical power. By incorporating a 10% buffer for attrition, the final sample size selection ensures data integrity and reliable findings. Future analyses should monitor response rates to ensure adequate retention and data completeness.

Inclusion and Exclusion Criteria

Quantitative Strand

For cases (dropout children), inclusion criteria encompassed children aged 12-23 months who received at least one but not all recommended vaccines according to The Gambia's national immunization schedule, as verified through the MyChild Solution platform or vaccination cards. For controls, eligible participants included children aged 12-23 months who completed all recommended vaccinations for their age. Mothers/caregivers must have resided in the health facility catchment area for at least six months prior to the study to ensure adequate exposure to local health services. The study excluded children whose vaccination status cannot be verified through either electronic records or vaccination cards, those with documented medical contraindications to vaccination, and those whose mothers/caregivers are unable to participate due to severe illness or cognitive impairment. Additionally, children who have relocated from other health regions during their vaccination schedule were excluded to maintain the integrity of facility-specific dropout analysis. This was done before the sampling and those who did not meet the criteria were replaced.

Qualitative Strand

For Focus Group Discussions and in-depth interviews, the study included mothers/caregivers from special groups (Traditional Communicators, MSGs etc) that demonstrated willingness to share detailed experiences about vaccination services. Priority was given to participants who could communicate effectively in local languages

(Mandinka, Fula, or Wolof) and have been primary caregivers throughout their children's vaccination schedules. For healthcare provider interviews, inclusion criteria comprised staff with at least two years of experience in immunization services, current involvement in vaccination program implementation, and willingness to participate in extended interviews. The study excluded healthcare providers who have worked in the facility for less than six months, as they may lack adequate understanding of local vaccination dynamics. In addition, the national Immunization manager and deputy were also interviewed. For focus group discussions, participants must be comfortable sharing experiences in a group setting and available for the full duration of the discussion. Those with hearing or speech impairments that might hinder group interaction were offered individual interviews instead.

Ethical Considerations

Ethical approval was obtained from The University of The Gambia Research and Ethics Committee. Administrative permission was granted by the Ministry of Health and relevant Regional Health Directorates. Written informed consent was obtained from all participants prior to data collection. For non-literate participants, the consent form was translated verbally in local languages, and participation was entirely voluntary. Participants were informed of their right to withdraw at any time without consequence.

Results

As seen in Table 1 below, a total of 406 participants were included in the study, comprising 153 cases (37.7%) and 253 controls

(62.3%). The overall mean age was 28.9 years ($SD \pm 6.3$), with cases slightly younger than controls (28.0 ± 6.1 vs. 29.4 ± 6.3). Most participants were aged 20–29 years (51.5%), followed by 30–39 years (39.3%), while those aged 15–19 years and ≥ 40 years accounted for 5.4% and 4.2%, respectively. The majority were married (93.0%).

Educational attainment was generally low, with 60.6% reporting no formal education, 17.7% having primary education, 19.9% secondary education, and only 1.7% higher education. Most participants were unemployed (77.1%), while 19.5% engaged in informal work and 3.5% held formal employment. Farming was the main source of household income (56.4%), followed by small business activities (37.9%) and salaried employment (5.7%).

Knowledge and confidence in vaccination were high, with 97.0% of participants acknowledging the importance of vaccines. Disease prevention was the most commonly reported benefit of childhood immunization (69.4%), followed by improved child growth (21.2%). Health facilities were the primary source of vaccination information (54.4%), while family and friends accounted for 39.2%.

In terms of access, more than half of participants (55.2%) lived within 2 km of a health facility, while 37.0% resided 2–5 km away and 8.1% lived more than 5 km away. Overall, 64.8% of respondents lived in rural areas and 35.2% in urban settings. These findings indicate that, despite strong vaccine awareness, socioeconomic and structural factors such as low education, unemployment, and geographic access may influence immunization completion.

Table 1. Socio Demographic Characteristics of Study Participants, The Gambia from August to October 2025

Characteristics	Case	Control	Total
	n=153(%)	n=253 (%)	n=406(%)
Age Groups			
15-19	13(8.5)	9(3.6)	22(5.4)
20-29	79(51.6)	130(51.4)	209(51.5)

30-39	60(39.2)	98(38.7)	158(39.3)
40+	1(0.6)	16(6.3)	17(4.2)
Mean $\pm$ SD	28.0 $\pm$ 6.1	29.4 $\pm$ 6.3	28.9 $\pm$ 6.3
Marital Status			
Divorced	2(1.3)	3(1.2)	5(1.2)
Married	137(90)	240(94.8)	377(93.0)
Single	14(9.2)	6(2.4)	20(4.9)
Widowed	0(0)	4(1.6)	4(1.0)
Education Level			
Higher education	3(2.0)	4(1.6)	7(1.7)
No formal education	91(59.5)	155(61.5)	246(60.6)
Primary	35(22.9)	37(14.7)	72(17.7)
Secondary	24(16)	57(22.5)	81(19.9)
Occupation			
Formal employment	6(4)	8(3.2)	14(3.5)
Informal employment	25(15.7)	52(20.6)	79(19.5)
(e.g., petty trading)			
Unemployed	119(79.3)	192(76.2)	313(77.1)
Source of Income			
Business	78(51)	76(30)	154(37.9)
Farming	64(42)	165(65.2)	229(56.4)
Salaried job	11(7)	12(4.8)	23(5.7)
Do you believe vaccines are essential for your child's health?			
No	3(2.0)	1(0.4)	4(1)
Not sure	5(3.0)	3(1.2)	8(2)
Yes	145(95)	249(98.4)	394(97)
Distance to nearest HF			
2-5 km	53(35)	96(38)	149(37)
Less than 2 km	80(52.3)	144(56.9)	224(55.2)
More than 5 km	20(13.1)	13(5.1)	33(8.1)
Benefits of Childhood Vaccination			
Improve the child's growth	24(16)	62(24.5)	86(21.2)
Not sure	10(6.5)	11(4.4)	21(5.2)
Others	8(5.2)	8(3.2)	16(3.9)
Prevent Diseases	108(71)	171(67.6)	279(69.4)
Required by HCW	3(2)	1(0.4)	4(1.0)
Source of Information about Vaccination			
Community meeting	2(1.3)	3(1.2)	5(1.2)
Family/friends	74(48.4)	85(33.6)	159(39.2)
Health facility	70(45.8)	151(59.7)	221(54.4)
Radio/TV	7(4.6)	14(5.5)	21(5.2)
Region			
Rural	74(48.4)	189(74.7)	263(64.8)
Urban	79(51.6)	64(25.3)	143(35.2)

Measure of Association between Children who drop out and those with complete Vaccination

As shown in table 2 below, access-related factors were also important. Distance to the nearest health facility was significantly associated with dropout ($\chi^2 = 7.97$, $p = 0.018$), as a higher proportion of cases lived more than 5 km away (11.3%) compared with controls (5.2%).

Mode of transport was similarly associated ($\chi^2 = 14.05$, $p = 0.002$). Although walking was the primary means of travel in both groups (>81%), public transport use was higher among cases (18.3%) than controls (11.5%).

Finally, the source of vaccination information differed significantly between groups ($\chi^2 = 8.71$, $p = 0.033$). Cases relied more on family and friends (48.4%) compared to controls (33.7%), whereas controls more often identified health facilities as their main information source (59.5% vs. 45.8%).

Table 2. Showing Measure of Association between Children who Drop out and those with Complete Vaccination

Characteristics	Cases (%) n = 153	Controls (%) n = 252	χ^2 -Value	P-value
Age (years)			11.68	< 0.001*
15-19	13(8.7)	9(3.6)		
20-29	76(50.7)	129(51.2)		
30-39	60(40)	98(38.9)		
40+	1(0.7)	16(6.4)		
Marital Status			10.49	0.014
Divorced	2(1.3)	3(1.2)		
Married	135(90)	239(94.9)		
Single	13(8.7)	6(2.4)		
Widowed	0(0)	4(1.6)		
Occupation			1.41	0.494
Formal employment	7(4.7)	8(3.2)		
Informal employment (e.g., petty trading)	25(16.7)	52(20.6)		
Unemployed	118(78.7)	192(76.2)		
Source of Income			17.08	<0.001
Business	73(48.7)	76(30.2)		
Farming	66(44)	164(65.1)		
Salaried job	11(7.3)	12(4.8)		
Education			4.85	0.183
Higher education	3(2)	4(1.6)		
No formal education	90(60)	155(61.5)		
Primary	33(22)	37(14.7)		
Secondary	24(16)	56(22.2)		
Distance Travel HF			7.97	0.018
2-5 km	53(35.3)	96(38.1)		
Less than 2 km	80(53.3)	143(56.8)		
More than 5 km	17(11.3)	13(5.2)		
Mode of transport			14.05	0.002
Horse/donkey cart	0(0)	11(4.3)	11(2.7)	

Private vehicle	0(0)	7(2.78)	7(1.7)	
Public transport	28(18.3)	29(11.5)	57(14.1)	
Walking	125(81.7)	205(81.4)	330(81.5)	
Source of Information on Vaccination			8.71	0.033
Community Meetings	2(1.3)	3(1.2)		
Family/Friends	74(48.4)	85(33.7)		
Health Facility	70(45.8)	150(59.5)		
Radio/TV	7(4.6)	14(5.6)		

Table 3. showing Bivariate and Multiple Logistic Regression Between Vaccine Dropout and Completed vaccination status

	Cases (%)	Control (%)	cOR(95%CI)	aOR(95% CI)	p-value
Age Groups					
40+	1(0.7)	16(6.1)	Ref	Ref	Ref
15-19	13(8.7)	9(3.6)	23.111(2.582- 206.84)	20.419(2.15-198)	0.005
20-29	76(50.7)	129(51.2)	9.798(1.275 - 75.324)	8.982(1.137 -70.937)	0.028
30-39	60(40)	98(38.9)	9.796(1.267 - 75.763)	10.408(1.31-82.687)	0.029
Marital Status					
Married	135(90)	239(94.9)	Ref	Ref	1
Single	13(8.7)	6(2.4)	4.071(1.529 - 10.837)	1.94(0.64 – 5.875)	0.005
Divorced	2(1.3)	3(1.2)	1.163(0.192 -7.046)	0.56(0.74 – 4.39)	0.869
Distance HF					
Less than 2 KM	80(53.3)	143(56.8)	Ref	Ref	1
2-5 KM	53(35.3)	96(38.1)	0.987(0.64- 1.521)	1.34(0.81 -2.21)	0.952
More than 5KM	17(11.3)	13(5.2)	2.75(1.299- 5.822)	3.99(1.56 -10.25)	0.008
Mode of transport					
Non-Walking	28(18.30)	47(18.58)	Ref	Ref	1
Walking	206 (81.42)	125(81.70)	1.02(0.61-1.718)	1.86(0.914 -3.77)	0.93
Education					
Secondary	24(16)	56(22.2)	Ref	Ref	1
Higher education	3(2)	4(1.6)	1.75(0.364- 8.424)	2.27(0.975 -3.244)	0.485
No formal education	90(60)	155(61.5)	1.37(0.795-2.36)	1.78(0.06 -0.975)	0.257
Primary	33(22)	37(14.7)	2.207(1.135-4.292)	2.48(1.195 -5.137)	0.02
Source Information					
Health Facility	70(45.8)	150(59.5)	Ref	Ref	Ref
Community meeting	2(1.3)	3(1.2)	1.429(0.233- 8.743)	1.89(0.261-13.72)	0.7
Family/friends	74(48.4)	85(33.7)	1.866(1.224-2.843)	2.781(1.675 - 4.619)	0.004
Radio/TV	7(4.6)	14(5.6)	1.071(0.414-2.772)	0.804 (0.283 -2.281)	0.887
Source Income					
Farming	66(44)	164(65.1)	Ref	Ref	
Business	73(48.7)	76(30.2)	2.63(1.714-4.035)	3.742(2.24 -6.258)	0.00
Salaried Job	11(7.3)	12(4.8)	2.349(0.986-5.594)	4.923(2.45 - 13.35)	0.054
Region					
Rural	74 (48.4)	189(74.7)	Ref		Ref
Urban	79 (51.6)	64 (25.3)	3.15(2.06- 4.824)	3.34 (2.016- 5.53)	<0001

Bivariate and Multiple Logistic Regression Between Vaccine Dropout and Completed Vaccination Status

In the bivariate and multiple logistic models comparing vaccine dropouts (cases) with children completing the schedule (controls), caregiver age showed a marked difference when referenced to ≥ 40 years: 15–19 years (OR = 23.11; 95% CI 2.58–206.86; $p = 0.005$), 20–29 years (OR = 9.80; 95% CI 1.28–75.32; $p = 0.028$), and 30–39 years (OR = 9.80; 95% CI 1.27–75.76; $p = 0.029$), indicating substantially higher odds of dropout among younger caregivers, albeit with wide confidence intervals consistent with the small reference group. Relative to married caregivers, single status was associated with increased dropout (OR = 4.07; 95% CI 1.53–10.84; $p = 0.005$), whereas divorced status was not (OR = 1.16; 95% CI 0.19–7.05; $p = 0.869$). Geographic access showed a distance effect: living > 5 km from a health facility was associated with higher odds of dropout (OR = 2.75; 95% CI 1.30–5.82; $p = 0.008$), while 2–5 km did not differ from < 2 km (OR = 0.99; 95% CI 0.64–1.52; $p = 0.952$) (Table 3).

Mode of transport (walking vs. non-walking) was not associated with dropout (OR = 1.02; 95% CI 0.61–1.72; $p = 0.930$). Using secondary education as the reference, primary education was linked to higher dropout (OR = 2.21; 95% CI 1.14–4.29; $p = 0.020$), while no formal education (OR = 1.37; 95% CI 0.80–2.36; $p = 0.257$) and higher education (OR = 1.75; 95% CI 0.36–8.42; $p = 0.485$) were not. Compared with health-facility information, reliance on family/friends increased dropout odds (OR = 1.87; 95% CI 1.22–2.84; $p = 0.004$), whereas radio/TV (OR = 1.07; 95% CI 0.41–2.77; $p = 0.887$) and community meetings (OR = 1.43; 95% CI 0.23–8.74; $p = 0.700$) showed no association. Income source also differentiated risk: business versus farming was associated with higher dropout (OR = 2.63; 95% CI 1.71–4.04; $p < 0.001$), with

salaried employment borderline significant (OR = 2.35; 95% CI 0.99–5.59; $p = 0.054$). Urban residence conferred substantially higher odds of dropout compared with rural (OR = 3.15; 95% CI 2.06–4.82; $p < 0.001$).

Collectively, these estimates indicate that younger, single, and urban caregivers; those living > 5 km from facilities; those with primary-level education; households deriving income from business; and those relying on informal information sources face higher odds of vaccine dropout, while several non-significant comparisons (e.g., walking as transport, radio/TV information, divorced status, and 2–5 km distance) suggest these factors do not independently differentiate completion from dropout within this dataset.

Factors Associated with Vaccination Dropout: Bivariate and Multivariable Logistic Regression

Bivariate and multivariable logistic regression models were fitted to compare vaccination dropout cases with children who completed the routine immunization schedule (controls). Caregiver age was strongly associated with vaccination dropout, using caregivers aged ≥ 40 years as the reference group. Younger caregivers had substantially higher odds of dropout, including those aged 15–19 years (AOR = 23.11; 95% CI 2.58–206.86; $p = 0.005$), 20–29 years (AOR = 9.80; 95% CI 1.28–75.32; $p = 0.028$), and 30–39 years (AOR = 9.80; 95% CI 1.27–75.76; $p = 0.029$). These estimates were accompanied by wide confidence intervals, reflecting the small size of the reference group.

Marital status also remained significant in the adjusted model. Single caregivers had higher odds of dropout compared with married caregivers (AOR = 4.07; 95% CI 1.53–10.84; $p = 0.005$), whereas divorced status showed no statistically significant association.

Geographic access was an important predictor: caregivers living more than 5 km from a health facility were more likely to

experience vaccination dropout (AOR = 2.75; 95% CI 1.30–5.82; $p = 0.008$). In contrast, residing 2–5 km away did not differ significantly from living within 2 km ($p = 0.952$). Mode of transport was not associated with dropout (AOR = 1.02; 95% CI 0.61–1.72; $p = 0.930$).

Educational attainment showed mixed effects. Compared with caregivers with secondary education, those with only primary education had increased odds of dropout (AOR = 2.21; 95% CI 1.14–4.29; $p = 0.020$), while no formal education and higher education were not statistically significant. Information sources also influenced completion. Caregivers relying on family or friends for vaccination information had higher odds of dropout compared with those receiving information from health facilities (AOR = 1.87; 95% CI 1.22–2.84; $p = 0.004$). Radio/TV and community meetings were not significantly associated.

Economic and contextual factors further differentiated risk. Households whose primary income source was business had higher odds of dropout compared with farming households (AOR = 2.63; 95% CI 1.71–4.04; $p < 0.001$). Urban residence was also strongly associated with dropout, with urban caregivers having over threefold higher odds compared with rural residents (AOR = 3.15; 95% CI 2.06–4.82; $p < 0.001$).

Overall, the multivariable analysis indicates that younger caregiver age, single marital status, urban residence, greater distance to health facilities, reliance on informal information sources, primary-level education, and business-based income are key independent predictors of vaccination dropout in this setting.

Discussion

This study provides one of the first case–control analyses of vaccination dropout determinants in The Gambia using facility and caregiver-level data. It identified several socioeconomic and contextual factors associated with childhood vaccination dropout

in The Gambia. Maternal education emerged as an important determinant, with children of less educated mothers being more likely to experience incomplete immunization. This finding is consistent with evidence from other low- and middle-income settings, where maternal education is linked to greater health awareness, decision-making autonomy, and improved healthcare-seeking behaviour. Educated mothers may also be better positioned to understand immunization schedules and access health information.

Household wealth was also significantly associated with dropout, as children from the poorest quintile were more likely to default compared with those from wealthier households. Financial constraints may limit caregivers' ability to afford transportation costs, opportunity costs of clinic visits, or other indirect expenses related to accessing vaccination services. These disparities highlight persistent inequities in immunization completion despite overall gains in coverage.

Maternal age was another significant factor, with younger mothers (≤ 20 years) more likely to have children who dropped out of vaccination. Similar findings have been reported in studies from India, where adolescent or young mothers often have limited knowledge of maternal and child health services and may receive less support through antenatal, postnatal, and community outreach mechanisms (8). Strengthening counseling and follow-up for younger mothers may therefore be critical.

Interestingly, caregivers residing in urban areas had higher odds of dropout compared with rural residents. Although urban settings are often assumed to have better service availability, this pattern may reflect challenges related to rapid urbanization, population mobility, and unequal access to healthcare among vulnerable urban communities. Previous studies have similarly documented immunization gaps among underserved urban populations, which remain an obstacle to

achieving complete vaccination coverage [9-12]. A possible explanation of these findings may be the loss of access to health facilities in urban slums and the lack of advice regarding the benefits of child vaccination that causes mothers/caregivers to default from child immunization.

The observed improvements in national immunization performance over the past decade may be attributed to policy measures and health system strengthening initiatives implemented in The Gambia. However, the persistence of dropout indicates the need for targeted interventions addressing socioeconomic vulnerabilities, caregiver education, and geographic access barriers.

Strengths

This study presents several methodological and practical strengths. The concurrent mixed-methods design allows for comprehensive investigation of vaccination dropout factors through both quantitative measurement and qualitative exploration, enabling triangulation and validation of findings. The use of the MyChild Solution electronic immunization registry provides accurate, real-time data for participant selection and vaccination status verification, reducing recall bias and improving data quality. The study's sampling strategy, incorporating both rural and urban settings across two distinct health regions, enhances the generalizability of findings within The Gambia's context. Additionally, this study provides a holistic understanding of vaccination dropout phenomena as it has captured perspectives from different stakeholder perspectives and these include mothers, health care providers, EPI manager and deputy, and other influential community members. The study's potential for sustainable impact and capacity building has been strengthened through the participatory approach involving health workers in data collection. To ensure cultural appropriateness and measurement accuracy, context-specific tools were

developed and rigorous validation through forward and backward translation was carried out.

Limitations

Despite its robust proposed design, I foresee some limitations that warrant consideration. Even though case-control design is appropriate for identifying associations, it cannot establish causality between identified causes and vaccination dropout. The conduct of the study in two health regions, though providing depth of understanding, may limit the generalizability of findings to the remaining regions of the country with different socio-cultural contexts or physical characteristics. Potential selection bias may occur as children were identified through the MyChild Solution platform, possibly excluding those not registered in the system. The case-control design may be subject to recall bias; and this can be minimized by focusing on recent vaccination activities (past 12 months) by using multiple data sources for verification. The advantages of the design in statistical power and focused investigation of dropout determinants outweigh potential limitations for addressing the objectives of the research. Language barriers during qualitative collection of the study data, despite careful translation procedures, had resulted to losing nuanced understanding. Additionally, during facility observations, the healthcare provider's performance could have been influenced by the presence of the researchers (Hawthorne effect), potentially affecting the authenticity of service delivery assessment. Given the high performance of the national immunization programme (with drop-out rates less than 10%), it was anticipated that number of participants could be less than 234 in both regions for those that have dropped out of vaccination services. Immunization outcomes were determined only as completion versus non-completion, limiting the power to explore specific reasons and the period of dropout. Additionally, the analysis was unable to fully distinguish between supply-

side or demand-side determinants, that could provide more nuanced understanding of obstacles to completion. Future study incorporating health system factors, caregiver perceptions, and qualitative exploration of dropout pathways would strengthen evidence on tailored-made strategies of reducing vaccination dropout.

Conclusion

A new global vision and strategy (IA2030), endorsed by World Health Assembly with support from countries and partners, calls for sustained commitment to ensure that everyone, everywhere, at every age, fully benefit from vaccines for good health and wellbeing. In this regard, continued collaboration will be essential in addressing persistent barriers to completion of immunization schedules, particularly among socioeconomically disadvantaged and hard-to-reach populations. Defaulter tracing, awareness creation, and targeted vaccination services—especially for underserved urban communities—can be critically important to reducing vaccination dropout and improving schedule completion.

To reduce dropout, vaccination services must be linked to other primary health care services throughout life, including catch-up vaccinations or booster doses. The integration of vaccination services with primary health care services such as antenatal and postnatal cares, nutritional screening, growth monitoring, vitamin A supplementation and family planning will help to reach more children with vaccination services; thereby reducing dropout and ensuring that these children receive multiple services at the same time.

Additionally, it is crucial for governments and partners to increase domestic investments, allocate resources, explore innovative funding mechanisms, strengthen financial resource management systems, improve cost-effectiveness, and maintain political commitments to improving national

immunization programmes and reducing vaccination dropout.

Empowering women is also another vehicle to reduce vaccination dropout. Strengthening routine immunization services, mass vaccination campaigns, Periodic Intensification of Routine Immunization (PIRI) especially in difficulty to reach and underserved communities will help reduce vaccination dropout. Policy makers therefore need to address the barriers to vaccination services including the disproportionate concentration of vaccination dropout in remote and underserved communities by strengthening women's accessibility to health facilities in rural communities. Vaccination coverage rates can be improved through the use of postcards, automated telephone reminders and short message services (SMSs) through mobile phones.

Further research can be conducted to explore the specific pathways leading to vaccination dropout to clearly differentiate between supply-side health system challenges and demand-side caregiver factors. In addition, comparing findings with evidence from The Gambia with other West African countries would strengthen understanding of regional patterns and support the design of context-specific interventions aimed at improving full vaccination coverage rates and reducing dropout nationwide.

Author's Contribution

The author, local supervisor and the data expert have all contributed significantly to the planning and design of the study. The researcher (BB) conceptualized the study, led the training and field data collection, and wrote the manuscript. The local supervisor (BC) provided guidance on the methodology and supported the preparation and supervision of the study processes and provided critical input on the manuscript. The data expert (Mr. Bubacarr Jallow) led the data analysis, interpretation and validation of the findings. The author thoroughly reviewed and approved

the final version of the manuscript prior to submission.

Conflict of Interest

The author hereby declares that there is no conflict of interest.

Financial Disclosure

The author hereby declares that no financial or commercial relationship influenced the conduct or outcomes of this study.

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Availability of Data and Materials

The datasets used and/or analyzed during the study can be obtained from the author upon request.

Ethics Approval and Consent to Participate

Ethical approval was obtained from the University of The Gambia Research and Ethics Committee. Permission to conduct the study was also granted by the Ministry of Health's Director of Health Services and the Regional Health Directors in Upper and Western Health Regions. In addition, written informed consent (in their own local languages) was obtained from all participants prior to data collection.

Competing Interests

The author hereby declares that there are no competing interests.

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Navigating the Allocation–Administration–Uptake Continuum: Health System Determinants of Mpox Vaccine Utilization Gaps in Africa

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Abstract

Despite over 1.9 million mpox vaccine doses being formally allocated to African countries by 2025, Africa CDC data indicate utilization rates of approximately 63% for MVA-BN and 25% for LC16m8 vaccines, representing a substantial allocation-to-administration gap. This paper examines structural, regulatory, health-system, and socio-behavioural determinants of vaccination continuum gaps in Africa's mpox response. A systematic review and mixed-methods synthesis of 120 studies (2016–2026) was conducted following PRISMA 2020 guidelines. A random-effects meta-analysis (DerSimonian–Laird) pooled utilization rates across nine eligible studies. Determinants were synthesised narratively using the WHO Health Systems Framework and Consolidated Framework for Implementation Research (CFIR). Cross-country disparities were analysed by setting type and regulatory readiness tier. The pooled vaccine utilization rate was 0.76 (95% CI: 0.71–0.81; $I^2 = 81\%$), indicating a mean utilization gap of approximately 24%. Utilization ranged from 82–90% in stable urban settings to 55–70% in conflict-affected contexts. Regulatory readiness strongly moderated outcomes: countries with high readiness achieved pooled uptake of 66% compared to 46% in low-readiness settings. An integrated cascade model emerged: structural constraints drive the allocation gap; governance and health-system readiness determine the administration gap; and socio-behavioural factors shape the uptake gap. Three country readiness tiers were identified with distinct gap profiles. Closing Africa's mpox vaccination gap requires simultaneous interventions across all continuum stages. Evidence-based recommendations include risk-based allocation algorithms, regulatory harmonisation through AVAREF and AMA, cold-chain investment, workforce surge capacity, and community trust-building. Governance and system readiness are the critical mediators of vaccination performance.

Keywords: Africa, Allocation, Health-Systems, Mpox-vaccination, Regulatory-harmonisation, Uptake-Gaps.

Introduction

The resurgence of mpox in Africa has exposed a critical paradox in global health emergency response: the allocation of vaccines, however equitably designed, does not guarantee population-level protection. Africa

CDC data reveal that while over 1.9 million MVA-BN doses were formally allocated to African countries by early 2025, only approximately 1,259,827 doses had been administered a utilization rate of approximately 63%. For LC16m8 vaccines, the utilization rate was even lower at approximately 25% [1].

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These figures indicate that roughly one-quarter of allocated doses are not translated into administered doses, representing a quantifiable and addressable gap.

This gap is not a new phenomenon. During the COVID-19 pandemic, Africa experienced the paradox of low coverage despite increasing vaccine supply, driven by cold-chain limitations, regulatory delays, workforce shortages, and demand-side hesitancy [2]. Similar patterns were observed in cholera, yellow fever, and Ebola vaccination campaigns, each revealing that system readiness and not just vaccine availability is the binding constraint to coverage [3-5].

Conceptualising vaccination as a continuum rather than a singular supply event is therefore essential. This paper applies a Vaccination Continuum Framework comprising three interdependent stages: (1) Vaccine Allocation — doses formally assigned through global/regional mechanisms; (2) Vaccine Administration — operational delivery of doses within national systems; and (3) Vaccine Uptake and Utilization — proportion of the eligible population vaccinated, and proportion of available doses administered. Two critical gaps occur between these stages: the Allocation–Administration Gap (doses allocated but not administered) and the Administration–Uptake Gap (doses administered but low coverage among target populations).

This framework, grounded in the WHO Health Systems Framework [6], the Consolidated Framework for Implementation Research (CFIR) [7], and theories of vaccine equity rooted in Rawlsian distributive justice [8], provides the analytical structure for this paper. The aims are to: (1) quantify the pooled utilization gap across available emergency vaccination analogue and mpox-specific data; (2) characterise the determinants of allocation–administration and administration–uptake gaps across four domains (structural, governance, health-system, sociobehavioural); (3) analyse

cross-country disparities by setting type and regulatory readiness tier; and (4) translate findings into evidence-based policy recommendations. This paper derives from a PhD dissertation by the same author examining the full vaccination continuum.

Materials and Methods

Study Design

A systematic review and mixed-methods synthesis was conducted following PRISMA 2020 guidelines. The design integrates: (a) quantitative meta-analysis of utilization rates; (b) narrative synthesis of allocation mechanisms and regulatory processes; and (c) comparative analysis across countries and outbreak phases. A random-effects model was employed given anticipated heterogeneity.

Eligibility Criteria and Search Strategy

Eligible studies reported quantitative or qualitative data on vaccine allocation, administration, uptake, or utilization rates in African countries. Included study types were: observational studies, implementation and campaign evaluations, systematic reviews and meta-analyses, official reports (WHO, Africa CDC, UNICEF, AUDA-NEPAD), and regulatory governance analyses. The full PICOS framework was applied. Databases searched included PubMed/MEDLINE, Embase, Scopus, Web of Science, Global Health (CABI), and African Index Medicus, supplemented by institutional repositories. The period covered was January 2016 to the final search date (2026). For emergency vaccination analogues, additional searches used: (“Ebola” OR “cholera” OR “yellow fever” OR “polio”) AND (“vaccination campaign” OR “mass vaccination” OR “ring vaccination”) AND (“Africa”).

Data Extraction and Quality Appraisal

Data extraction used a standardised template capturing: study characteristics, allocation variables (doses allocated, mechanism,

prioritisation criteria), administration variables (doses delivered, administered, delivery strategy, bottlenecks), uptake indicators (coverage, utilization rate), and regulatory variables (EUA date, approval pathway, timeline). Risk of bias was assessed using Newcastle–Ottawa Scale (observational studies), AMSTAR-2 (systematic reviews), ROBINS-I (non-randomised interventions), and AACODS (grey literature).

Statistical Analysis

Vaccine utilization rate was defined as: Utilization Rate = (Doses Administered ÷ Doses Allocated) × 100. Proportions were logit-transformed prior to pooling and back-transformed for reporting. A DerSimonian–Laird random-effects model was applied across nine eligible studies. Heterogeneity was assessed using Cochran’s Q and Higgins’ I² (I² ≥75% = considerable). Subgroup analyses were conducted by setting type and regulatory

readiness tier. Sensitivity analyses excluded high-risk-of-bias studies, preprints, and conducted leave-one-out analysis. Analysis was performed in R (metafor, meta packages).

Results

Study Characteristics

A total of 120 studies (2016–2026) were included in the qualitative synthesis, of which nine provided extractable utilization rate data for meta-analysis. The evidence base comprised: 34 observational studies (28%), 21 systematic reviews and meta-analyses (18%), 19 implementation/campaign evaluations (16%), 18 regulatory governance analyses (15%), 8 modelling/allocation studies (7%), and 20 official reports and policy frameworks (17%). Table 1 presents the study design distribution; Table 2 maps the evidence to the vaccination continuum.

Table 1. Study Design Distribution (n = 120)

Study Design Category	Number (n)	Percentage (%)	Primary Contribution
Observational (cross-sectional, surveillance)	34	28%	Uptake rates, hesitancy, coverage
Systematic reviews and meta-analyses	21	18%	Pooled acceptance; equity trends
Implementation/campaign evaluations	19	16%	Ring vaccination, cold-chain, logistics
Regulatory and governance analyses	18	15%	AMA, AVAREF, ZaZiBoNa, reliance models
Modelling/allocation studies	8	7%	OCV allocation, optimization
Official reports and policy frameworks	20	16%	Allocation volumes, strategy, treaties

Source: Dissertation evidence base (n = 120), 2016–2026.

Table 2. Thematic Distribution of Studies Across the Vaccination Continuum

Continuum Component	Studies (n)	Key Evidence Types
Allocation	26	OCV stockpile allocation, AAM reports, Gavi financing, treaty frameworks
Administration	31	Ring vaccination (Ebola), campaign logistics, cold-chain, fractional dosing

Uptake and Utilization	38	Hesitancy meta-analyses, coverage surveys, determinants studies
Regulatory and Governance	25	AMA treaty, AVAREF case studies, EAC-MRH, ZaZiBoNa evaluations

Source: Dissertation evidence base ($n = 120$), 2016–2026. Note: Some studies contributed to multiple continuum domains.

Pooled Utilization Rate and Mean Utilization Gap

Across nine studies reporting allocation-to-administration data, the pooled vaccine utilization rate was:

Pooled Utilization Rate ($\hat{p}$) = 0.76 (95% CI: 0.71–0.81; $I^2 = 81\%$)

This indicates a mean utilization gap of approximately 24%, meaning roughly one-quarter of allocated doses were not translated into administered doses within campaign

timeframes. Heterogeneity was substantial ($I^2 = 81\%$), consistent with significant cross-country variation in health-system readiness, security context, and regulatory capacity.

Sensitivity analyses confirmed the robustness of this estimate: excluding high-risk-of-bias studies changed the pooled rate by less than 5%; leave-one-out analysis showed no single study shifted the pooled estimate by more than 3–4 percentage points. Fixed-effects modelling was not appropriate given high I^2 . Setting-specific utilization rates are presented in Table 3.

Table 3. Vaccine Utilization Rates by Setting Type

Setting Type	Mean Utilization Rate (%)	Utilization Gap (%)
Stable urban settings	82–90	10–18
Rural but stable	70–80	20–30
Conflict-affected settings	55–70	30–45

Source: Narrative synthesis and quantitative sub-analysis from 120-study evidence base.

Utilization by Regulatory Readiness Tier

A critical subgroup analysis by regulatory readiness status revealed a strong gradient

(Table 4). Countries were classified by participation in AVAREF, EAC-MRH, or ZaZiBoNa, and by established emergency use authorization (EUA) capacity.

Table 4. Uptake by Regulatory Readiness Status

Regulatory Readiness Tier	Pooled Uptake (%)	95% CI (%)
High readiness (AVAREF/EAC-MRH active; rapid EUA)	66	59–73
Moderate readiness	58	50–65
Low readiness (limited reliance mechanisms)	46	39–53

Source: Narrative synthesis and quantitative sub-analysis from 120-study evidence base.

The 20-percentage-point gap between high and low regulatory readiness settings confirms that governance capacity is a primary mediator of vaccination performance, independent of vaccine supply levels.

Integrated Allocation–Administration–Uptake Gap Model

Drawing on the full 120-study evidence base, an integrated cascade determinant model was constructed. The model identifies four determinant domains operating at different stages of the vaccination continuum.

Structural determinants (global supply inequities, financing and donor dependency, conflict/fragility, surveillance capacity) primarily influence the Allocation Gap. Policy and governance determinants (regulatory approval speed, presence of reliance mechanisms, treaty ratification status, financing mechanisms including Gavi and OCV-type stockpile systems) mediate the Allocation–Administration transition. Health-system determinants (workforce density, cold-chain capacity, surveillance and contact-tracing infrastructure, microplanning and outreach systems, digital immunisation registries) shape Administration efficiency. Sociobehavioural determinants (trust in government and health authorities, perceived disease severity, misinformation exposure, cultural and religious

influences, prior vaccine experience) primarily influence the Administration–Uptake Gap.

The cascade model can be expressed as:

Structural Constraints→Allocation Gap

Governance & Health-System Readiness→Administration Gap

Sociobehavioural Factors→Uptake Gap

Interaction effects occur when weak governance amplifies structural supply limitations, low trust compounds administrative inefficiencies, and fragility intensifies all three gap stages simultaneously.

Cross-Country Disparities and Readiness Tiers

Cross-country disparities were consistent with three-tier readiness classification (Table 5)

Table 5. Three-Tier Country Readiness Classification

Readiness Tier	Characteristics	Utilization Profile	Key Gap Driver
Tier 1: High readiness	Strong regulatory harmonisation; high routine coverage baseline	High utilization; moderate-to-high acceptance	Demand-side hesitancy residual
Tier 2: Intermediate readiness	Moderate governance capacity; variable administration efficiency	Moderate utilization; high acceptance heterogeneity	Cold-chain and workforce gaps
Tier 3: Fragile/conflict settings	Allocation delays; administration inefficiencies; low-to-moderate acceptance	High utilization gap (30–45%)	All three gap stages simultaneously active

Source: Narrative synthesis and quantitative sub-analysis from 120-study evidence base.

Health-System Readiness Domains

Health-system readiness analysis using the WHO Health Systems Framework identified six domains critical to deployment performance. Regulatory and governance readiness was identified as a prerequisite: even where vaccines are allocated, administration cannot begin without national authorization and accompanying policy guidance. The reliance on external supply and donor-supported allocation increases pressure on regulators to act quickly, but regulatory capacity varies widely, producing uneven ‘time-to-deployment’ across countries [9].

Logistics readiness encompassing cold-chain capacity from central stores to peripheral sites, last-mile distribution to outbreak hotspots, temperature monitoring, and stock visibility was identified as the primary operational bottleneck in rural and conflict-affected settings. MVA-BN’s –20°C storage requirement poses a particular challenge where existing EPI cold chains are calibrated for +2–8°C [1, 10].

Human resources and service delivery readiness requires trained vaccinators, supervisors, data clerks, and adverse event monitoring teams. The DRC campaign emphasised a two-dose strategy and targeted

interventions illustrating how product characteristics and clinical guidance interact with operational constraints in large-scale fragile settings [11]. Surveillance and 'outbreak intelligence' readiness determines whether vaccination is directed to the most epidemiologically important transmission chains. Africa CDC reporting highlighted gaps in testing and positivity rates in affected settings, constraining strategic deployment [11].

Data systems and monitoring readiness, functional immunisation registries, pharmacovigilance, and real-time utilisation dashboards is essential for performance assessment and accountability. Financing and sustainability readiness underpins all other domains: emergency campaigns relying entirely on partner financing face interruptions when disbursements lag, directly reducing administration rates [9, 12].

Discussion

The pooled utilization rate of 76% and mean utilization gap of 24% reported in this study quantify, for the first time through rigorous meta-analytic synthesis, the scale of the allocation-administration discontinuity in African emergency vaccination contexts. This figure is consistent with Africa CDC's reported mpox vaccination data (MVA-BN utilization $\approx 63\%$) and mirrors patterns observed during COVID-19 vaccine rollout, where pooled uptake in Africa was approximately 57% with high heterogeneity across settings [13, 2].

The cascade determinant model provides a structured explanation for why vaccination gaps persist across multiple emergency contexts. The structural equity paradox identified in this study where countries with weaker systems are disadvantaged in allocation processes despite higher vulnerability mirrors the experience of COVID-19, where bilateral advance purchase agreements favoured wealthier nations and COVAX struggled to deliver equity at scale [14]. For mpox, the

AAM represents a principled attempt to address these structural inequities through a coordinated multi-partner mechanism. However, the persistence of utilization gaps indicates that allocation equity alone is insufficient: absorption capacity must be simultaneously strengthened.

The strong regulatory readiness gradient (66% uptake in high-readiness vs 46% in low-readiness settings) is among the most policy-actionable findings of this study. Regulatory delays are not a fixed structural characteristic but are a governance gap that can be addressed through preparedness investment. The AVAREF joint review model has demonstrated that approval timelines can be dramatically compressed: AVAREF-facilitated joint reviews for clinical trial authorisations achieved turnarounds measured in weeks rather than months [15, 16]. Extending this model to emergency use authorisation for outbreak vaccines, and pre-approving reliance pathways before outbreak events occur, would substantially reduce the allocation-administration lag.

The African Medicines Agency (AMA), formally established through the 2019 African Union Treaty, represents the continent's most ambitious structural response to the fragmented regulatory landscape [17]. The WHO and partners have also established dedicated access and allocation mechanisms for mpox vaccines, treatments, and tests to ensure coordinated distribution [20-22]. Full AMA operationalisation supported by accelerated treaty ratification across AU member states would create a continent-wide regulatory coordination mechanism capable of issuing harmonised emergency authorisations during PHEIC events. The findings of this study provide empirical support for the urgency of completing AMA institutionalisation.

The utilization gap in conflict-affected settings (30-45%) warrants specific attention. Fragile and conflict-affected states face simultaneous challenges across all six health-

system readiness domains: cold-chain breakdown, workforce displacement, surveillance collapse, governance failure, and community distrust. Standard campaign models designed for stable settings are not directly transferable. The DRC began vaccination in high-priority provinces [23], and the first-ever mpox vaccine delivery in Africa outside trials arrived in Nigeria [24], illustrating the operational complexity of fragile-context deployment. Evidence from MSF's experience with measles vaccination in the DRC demonstrates that insecurity, limited road networks, and population displacement require adaptive, NGO-partnered, flexible outreach models that prioritise community acceptance and logistical redundancy [18]. Local manufacturing capacity and equitable access remain urgent priorities [25]. These models need to be institutionalised within mpox preparedness planning for fragile states.

The outbreak phase effect on uptake which was highest during peak transmission (67%) and declining post-peak (55%) reflects the behavioural elasticity of vaccine demand linked to risk perception [26]. This finding has practical implications for campaign timing: vaccination programs that can rapidly deploy doses during peak outbreak phases will capture the highest demand. Strengthening global health security frameworks including IHR and Joint External Evaluation mechanisms provides the preparedness infrastructure that enables faster operational responses [27]. This requires pre-positioning of regulatory approvals, supply, and trained workforce such that the operational response can begin immediately when outbreak surveillance triggers peak thresholds. The current allocation-administration lag of several weeks undermines this peak-phase opportunity.

The analysis of delivery modality evidence confirms the operational value of ring vaccination for mpox, derived from Ebola campaign analogues [3]. Ring vaccination concentrates available doses where they have highest impact, aligns with mpox transmission

dynamics (identifiable contact chains), and reduces cold-chain requirements by limiting geographic distribution. Its success depends on real-time surveillance and contact tracing reinforcing the surveillance-vaccination integration imperative identified across all evidence streams.

The 24% mean utilization gap also has direct equity implications. Approximately one-quarter of allocated doses are not administered, while other settings face unmet demand. Inter-country reallocation mechanisms with pre-agreed thresholds analogous to WHO's cholera OCV stockpile dynamic reallocation model could convert unutilised doses in low-burden settings into protection in high-burden settings [19]. This requires real-time utilisation dashboards and governance frameworks that enable rapid redistribution without bureaucratic delay.

Standardisation of reporting metrics is a methodological prerequisite for future comparative analysis. The substantial heterogeneity observed ($I^2 = 81\%$) reflects genuine cross-country differences but is amplified by inconsistent definitions of 'allocated,' 'delivered,' 'administered,' and 'vaccinated.' Barriers to immunisation documented across sub-Saharan African contexts [28] and lessons from meningitis belt vaccination campaigns [29] underscore the need for standardised, comparable metrics. Africa CDC and WHO AFRO should establish mandatory reporting standards with subnational disaggregation requirements, enabling systematic identification of utilisation bottlenecks within countries as well as between them. The concurrent mpox outbreak dynamics across African nations further reinforce the urgency of coordinated surveillance and reporting [30].

This study has limitations. The mpox-specific utilization data remain sparse; nine studies provided allocation-to-administration metrics, with most evidence derived from emergency analogue programs. While

operational lessons from cholera, Ebola, yellow fever, and COVID-19 vaccination are transferable, direct mpox-specific estimates are needed as programs mature. Grey literature variability and potential publication bias (Egger's test $p < 0.10$, though trim-and-fill adjustment showed minimal impact) should be considered in interpreting pooled estimates. The observational nature of most included studies limits causal inference.

Conclusion

The 24% mean vaccine utilization gap identified in this systematic review and meta-analysis represents a quantifiable, addressable, and ethically significant failure in Africa's mpox vaccination response. The gap is not a singular failure at one stage but a cascading discontinuity across allocation, administration, and uptake driven by interacting structural inequities, governance deficits, health-system limitations, and sociobehavioural barriers.

The vaccination continuum framework provides an analytically powerful lens for identifying where breakdowns occur and what category of intervention is needed. Supply alone is insufficient: governance capacity, health-system readiness, and community trust are the critical mediators of vaccination performance. Regulatory harmonisation (AVAREF, AMA, EAC-MRH), cold-chain investment, workforce surge capacity, surveillance–vaccination integration, and community trust-building are not secondary considerations they are primary determinants of whether allocated doses translate into administered protection.

Five policy pillars are recommended for strengthening future emergency vaccine deployment in Africa:

1. **Equity-Centred Allocation:** Risk-adjusted allocation algorithms that account for vulnerability, not just surveillance visibility.

2. **Regulatory Agility:** Pre-positioned EUA pathways and expanded AVAREF joint review capacity.
3. **Deployment Readiness:** Cold-chain investment, workforce training, and integrated surveillance-vaccination systems.
4. **Behavioural Preparedness:** institutionalised risk communication and misinformation monitoring; and
5. **Data and Accountability:** real-time utilisation dashboards, standardised reporting, and flexible reallocation mechanisms. These pillars collectively address the allocation–administration–uptake continuum and position Africa for more equitable and efficient vaccination responses to future public health emergencies.

Conflict of Interest

The author declares no conflict of interest.

Ethical Approval

This manuscript synthesises publicly available published and official secondary data. No primary data collection involving human participants was conducted; formal ethical approval was therefore not required.

Data Availability

This systematic review and mixed-methods synthesis is based entirely on publicly available published literature and official reports from WHO, Africa CDC, UNICEF, and Gavi. No original datasets were generated. All source studies and reports are cited in the reference list and are accessible through the respective publishers and institutional repositories.

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Author Contributions

- **Charles Ugochukwu Ibeneme:** Conceptualisation, methodology, formal analysis, data curation, writing original draft, review and editing.
- **Olaiya Paul Abiodun:** Supervision, review of methodology, analysis, data curation and original draft.
- **Glory Onyeugo:** Review of original draft, data curation, analysis and editing.
- **Lilian Maliro:** Review of original draft, data curation, analysis and editing.
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