

An Investigation into NAFDAC Intervention on the Incidence of Fake and Counterfeit Drugs in Nigeria

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Abstract

Various interventions, including innovative technologies, have been used to solve problems. Over the years, the Nigerian government has introduced a good healthcare delivery system, including providing quality, efficacious and affordable drugs. The study used a qualitative design method adopting a focus group discussion approach. The selected states for the study are Lagos, Kano, Anambra and FCT Abuja. The study population comprised NAFDAC stakeholders who are dealers in pharmaceutical products or Marketing Authorization Holders (MAHs) of medicines, Consumers and Policymakers. The focus group participants were selected based on convenience sampling. The interventions highlighted were Mobile Authentication Services (MAS), on-the-spot checks on drugs through a TruScan, Black-Eye and Radio Frequency Identification Devices (RFID). The respondents also highlighted using NAFDAC registration numbers and holograms as important ways of checking the features of medicine before using it. The participants also highlighted the lack of public awareness about these interventions and the need for proper regulation and enforcement of laws against the sale and distribution of fake drugs as challenges that hinder the successful development and implementation of interventions against fake and counterfeit drugs. The participants suggested KYC measures to address issues within the supply chain to evaluate the effectiveness of their current strategies. Regular meetings, advocacy efforts, and educational workshops are recommended to raise awareness and educate stakeholders about their roles and responsibilities in pursuit of addressing the challenges related to counterfeit drug interventions.

Keywords: *Focus group discussion (FGD), Investigation, Intervention, Counterfeit, Technology.*

Introduction

Delivering low-quality drugs in developing nations poses a serious clinical and public health risk [1]. According to the World Health Organisation, 10% and 25% of medications supplied in underdeveloped countries are counterfeit [2-4]. Africa and parts of Asia have been struck the hardest, followed by Latin America. The frequency of counterfeit medicines in Nigeria has fallen considerably, from 41% in 2002 to 16.7% in 2006 to 10% in 2011 [2, 3, 5]. While it is true that all fake drugs

will be of poor quality, this does not always constitute a counterfeit if the producer did not intend to deceive anybody [6].

The efforts of manufacturers to protect and distinguish their products from fake ones fail in the long run as technologies being employed by counterfeiters surpass theirs [7]. Over the years, the Nigerian government has tried to introduce a good healthcare delivery system, including providing quality, efficacious and affordable drugs. Therefore, the government, through the Federal Ministry of Health (FMOH), put intervention programs and policies in place to

meet these needs. That led to the establishment of the National Agency for Food and Drug Administration and Control (NAFDAC) on January 1, 1994, as a parastatal of the Federal Ministry of Health [3], [8]. In rising to the challenge of counterfeiting (including food, medicines, and other health products), NAFDAC is working hard to curb the menace of SFs in conjunction and collaboration with the health regulatory authorities of other countries [8]. Various interventions, including innovative technologies, have been used to solve problems. The previous and current Directors General of NAFDAC has introduced many strategies to fight the anti-counterfeiting war [9].

One major contributing factor to the prevalence of counterfeit medicines in Nigeria is the continued presence of the highly unregulated open drug markets across major cities of Nigeria, where medicines are sold in the open air on street corners, at kiosks, and stalls. These markets are sources and conduits for counterfeit medicines in Nigeria and other countries [7]. Notable open drug markets in Nigeria include those located in Lagos (Idumota market), Kano (Sabon-Gari market), and Onitsha (Head-bridge market). Despite this, according to Ubajaka et al. (2016) [7], it will also be tough to avoid counterfeit drugs from being induced into the Nigerian pharmaceutical supply chain largely because more than 70% of drugs circulating in Nigeria are imported from India or China. The duo is believed to be the biggest source of counterfeit drugs. It was, therefore, imperative that the assessment of these various deployed interventions be investigated through a focus group discussion on the Incidence of fake and counterfeit drugs in Nigeria.

Materials and Methods

Study Design

The study used a qualitative design method while adopting a focus group discussion approach. The qualitative study aimed to get insightful comments from relevant stakeholders. The qualitative study was done with a

convenient sampling procedure, and a non-probability sampling approach to identify the relevant officers, stakeholders, and consumers with adequate knowledge of the research topic and selection.

Study Location

The selected states for the study are Lagos, Kano, Anambra and FCT Abuja. Lagos is Africa's largest and former capital city in terms of population, with about 15.3 million people living there. It is also the 4th largest economy in Africa. Kano state is the most populous in the country according to the national census done in 2006, with an estimated 20,000,000 in the year 2020. Anambra state has over 9 million residents in the state based on the 2022 census report. FCT, Abuja has a population of about 1,693,400, according to the 2022 population estimate. These states have the highest number of stakeholders due to the highly unregulated open drug markets in these states and the pharmaceutical industry. In contrast, most non-governmental organisations and development agencies involved in pharmaceutical product importation and distribution are located in Abuja.

Study Population

The study population comprised NAFDAC stakeholders who are dealers in pharmaceutical products or Marketing Authorization Holders (MAHs) of medicines, Consumers and Policymakers. The states are Lagos, Kano, Anambra, and Federal Capital Territory (FCT), with the most stakeholders.

Data Collection

A Focus Group Discussion of representatives from stakeholders, policymakers and general consumers was conducted. Participants asked questions such as their perceptions of various interventions and adoption or use of cutting-edge technologies (CETs); i.e. 'when, where, how, and why' to detect and mitigate against the influx of poor-quality medicines along the supply chain by their respective organisations or

groups; the types of CETs in use and reasons for using them; the benefits and limitations of different interventions including the CETs; and what is needed to utilize the various innovative technologies better. All interview guides cover issues around medicine quality, the status of various deployed strategies, and post-marketing surveillance (PMS) activities. The focus group participants were selected based on convenience sampling.

Ethical Consideration

Ethical approval was sought and obtained from the Federal Government Institutional Review Board and the National Health Research Ethics Committee of the National Institute of Medical Research, affiliated with the Federal Ministry of Health. In addition, verbal and written consents were obtained from respondents before administering questions and personal identifiers were removed from summary data. Also, data collected will be securely stored, and the names of individuals were excluded not to identify the individuals and families or groups.

Results

Interventions Introduced by NAFDAC

The respondents began by explaining the different interventions introduced by NAFDAC to identify and curb incidences of fake and counterfeit drugs. These interventions include Mobile Authentication Services (MAS), which consumers can use to verify the authenticity of drugs through text messaging. Other interventions utilised by NAFDAC include on-the-spot checks on drugs, which are done using a TruScan hand-held device, the Black-Eye (The Black Eye test kit is bench-top equipment developed in Israel which uses Infra-Red Technology for the detection of counterfeit medicines etc) and Radio Frequency Identification Devices (RFID). The respondents also highlighted the importance of media and publicity in educating the public about ways of checking the features of medicine before using

it. These features include the NAFDAC registration number and holograms.

Challenges Responsible for Successfully Developing These Techniques

The FGD participants identified several challenges responsible for successfully developing these interventions. One of the challenges highlighted was the public's lack of awareness about these interventions' existence. Participants also pointed out the need for proper regulation and enforcement of laws against selling and distributing fake and counterfeit drugs. They also emphasised the need for NAFDAC to collaborate with other agencies and stakeholders to tackle the issue of fake and counterfeit drugs effectively.

During the FGD, the participants shared their thoughts on the interventions introduced by NAFDAC and the challenges responsible for successfully developing these techniques. One participant pointed out the importance of educating the public about identifying counterfeit drugs. At the same time, another emphasised the need for stricter laws and enforcement against the sale and distribution of fake drugs. Another participant highlighted the role of technology in identifying counterfeit drugs, saying technology is a key player in identifying fake drugs. For instance, using serial numbers on drug packages can help track the source of the drug.”

Overall, the FGD discussed the different interventions introduced by NAFDAC to combat the Incidence of fake and counterfeit drugs in Nigeria. The participants also highlighted the challenges responsible for successfully developing these techniques. The report concludes that NAFDAC needs to collaborate with other stakeholders to tackle the issue of fake and counterfeit drugs effectively and to enforce laws and regulations against the sale and distribution of such drugs. The public needs to be educated on identifying counterfeit drugs and taking advantage of the interventions provided by NAFDAC.

Respondent's Perception of whether the Drug Regulatory Agency (NAFDAC) should have an Anti-counterfeiting Strategy or Approach to Fight Counterfeit Medicine

This report presents stakeholders' responses during the FGD on anti-counterfeiting strategies to fight counterfeit medicine in Nigeria. The second question of the FGD was, *"Do you think a drug regulatory agency (NAFDAC) should have an anti-counterfeiting strategy or approach to fight counterfeit medicine?"* The report highlights the key points made by the stakeholders and their opinions on the matter.

A Pharmacist who works with NAFDAC and is the WHO focal person for substandard and falsified medicines was the first to respond to the question. He emphasised that NAFDAC has already implemented several regulatory interventions to combat the issue of substandard and falsified medicines in Nigeria. These interventions include the Controlled Pre-shipment Assessment in China and India leading to the issuance of a Clean Report of Inspection and Analysis (CRIA). A process which ensures that products imported into the country have passed through the inspection and analysis process in the export country. He also mentioned that NAFDAC had intensified manufacturers' compliance with good manufacturing practices and regularly monitored the quality of medicines in circulation through product quality surveys. According to the participant, these interventions have reduced the prevalence of substandard and falsified drugs, particularly on the anti-malaria and antibiotic side.

Another stakeholder supported the idea of having an anti-counterfeiting strategy in place. The respondent emphasised that counterfeit medicine poses a significant threat to public health and safety and that NAFDAC should take a more proactive approach to fight it. The participant further suggested that NAFDAC should collaborate with other regulatory agencies and stakeholders in the healthcare sector to tackle the issue.

Another participant, a representative from a pharmaceutical company, believed that NAFDAC's current interventions were insufficient in the fight against counterfeit medicine. He called for adopting more advanced technologies, such as track and trace, to ensure that the entire supply chain is transparent and that counterfeit medicines can be easily detected and traced. The GS1 consortium has recommended the common principles of industrial product marking with a special part of the 2-D Data Matrix code for serialization integration in drug identification by the pharmaceutical industry [10].

Overall, the stakeholders in the FGD agreed that NAFDAC should have an anti-counterfeiting strategy to fight counterfeit medicine in Nigeria. While some stakeholders believed that NAFDAC's current interventions were sufficient, others called for adopting more advanced technologies and collaborating with other stakeholders to tackle the issue. NAFDAC needs to consider these stakeholders' opinions and adopt a more holistic approach to combat the issue of counterfeit medicine in Nigeria.

Report on Focus Group Discussion on Identifying Good Quality Medicines

Respondents shared their perspectives on how to differentiate between genuine and counterfeit drugs.

One of the respondents highlighted the importance of the NAFDAC registration number. They said the registration number is the first thing to look for when inspecting drugs. A participant said, *"If a drug does not have a NAFDAC registration number, it is most likely a fake one, and it should not be used."* The respondent also pointed out that packaging is essential in identifying good quality medicines. According to a respondent, *"Counterfeiters often do not pay attention to the packaging, and the quality is usually poor. Therefore, the packaging should be inspected, and if it is not in tandem with what one is used to, it should raise questions. The medicine should not be used."*

Also, a respondent said, *“The person selling the medicine should be able to show receipts of where they purchased the products. If they cannot show a receipt, it indicates that the products are probably counterfeit.”*

Another respondent suggested that NAFDAC should do a KYC (know your customer) like the banks. He argued that the problem of fake drugs comes from two categories of customers: those who do not follow the legal procedures and guidelines set by NAFDAC and those who register some products but use them as a package to produce fake ones. He also suggested that NAFDAC researches its schemes’ impact and effectiveness to know if an adjustment is needed to make them more effective.

One of the participants, a female pharmacist, contributed by highlighting spelling errors on the packaging, medication appearance, and compromised packaging as factors in identifying poor-quality medicines. The participant expressed awareness of the Mobile Authentication Service (MAS) but was unsure how effective it is. She also mentioned the introduction of TruScan and Black Eye several years ago but was unsure of their current usage. The respondent also pointed out that not every medication that comes into Nigeria has a NAFDAC number, and some medicines do not require a NAFDAC number. However, these medicines should not get into the general circulation or supply chain, but this is not always the case, and accountability is needed in different programs where donated drugs are used for interventions.

Overall, the study participants identified several measures to identify good quality medicines, including checking for a NAFDAC registration number, looking at the packaging, and requesting seller receipts. They also suggested that NAFDAC should consider implementing KYC measures and conduct research to assess the effectiveness of their current strategies. The participants also raised concerns about donated medicines that sometimes enter the general market.

Respondents’ Perceptions towards the Focus Interventions and Use of Quality Technology Detection of Regulated Drugs in Each Geographical Area in Nigeria

During the FGD, participants’ perceptions towards the focus interventions and the use of quality technology for detecting regulated drugs in each geographical area were explored. The discussion was directed towards the use of cutting-edge technology, particularly the NAFDAC TruScan, and the effectiveness and frequency of their use.

A respondent who is also a pharmacist informed the group about the recent procurement of 40 new versions of the NAFDAC TruScan, which is not only for qualitative and quantitative analysis but also for deploying it in the field for detection. He said the agency is also procuring another handheld device called RS Scanner. He emphasised that deploying these devices would help the agency fight against infiltrating the drug distribution chain with substandard and falsified medical products. He suggested that there should be a collaboration with various stakeholders, and the public should be aware of these devices, particularly community pharmacies.

“I have two pieces of information regarding the use of cutting-edge technology. As some participants said about using the NAFDAC TruScan, the last time we used a TruScan effectively was 12 years back, and we cannot rely on such data now. “I wish to inform you that the agency has recently procured 40 new versions of the TruScan, which is not only for qualitative and quantitative analysis now.” “We were working towards deploying it at the beginning of this last quarter. However, because of some little administrative changes here and there, it has to be deferred.” “I can assure us that before the full deployment of this latest technology, I must say that there is no regulatory Authority anywhere in the world that has the same quantity of Truscans that we have alongside the planned deployment of these Truscans. “

When asked about their perceptions of the technology’s effectiveness and how frequently

they would like to use it. The respondents appreciated the agency's variety of approaches towards the fight against substandard and illicit drugs. They suggested that the agency should also look into the human aspect of it, as the devices need to be deployed to users. They further emphasised the need to empower the Pharmacovigilance directorates to handle the illicit products that come in through unmanned open borders. They also stressed that there is a need to look at the various channels through which drugs are sold in the country and give it a holistic approach.

Overall, the participants discussed the need to use cutting-edge technology to mitigate the rate of substandard pharmaceutical products in Nigeria.

They agreed that using NAFDAC TruScan could help detect substandard and falsified medical products. These devices should be deployed in collaboration with various stakeholders and public awareness. The participants also suggested that the agency should empower the pharmacovigilance directorates to handle illicit products that come in through open borders that are not manned. They recommended a holistic approach to tackle the problem of substandard and falsified medical products in Nigeria.

Discussion

Counterfeit medicines pose a considerable threat to a population's health and economic aspects. It is a global problem in almost all developing and developed countries [11]. In many cases, they are dangerous and detrimental to public health regarding human suffering and burden on health services [12]. This section discusses the findings from the result of this study, compares the findings with other studies and provides recommendations.

The findings from the respondents' discussion in this study provide valuable insights into the efforts made by NAFDAC to identify and curb the Incidence of counterfeit and substandard drugs in Nigeria. The study reveals

that NAFDAC has adopted several interventions, including Mobile Authentication Services (MAS), on-the-spot checks on drugs using the TruScan, the Black-Eye and Radio Frequency Identification Devices. Mobile authentication services are a vital intervention by NAFDAC, as they provide consumers with a quick and easy way to verify the authenticity of drugs [13]. By sending a text message, consumers can access critical information about the drug, including its registration status and whether it is genuine or counterfeit. This intervention is particularly crucial in a country like Nigeria, where the distribution of counterfeit drugs is rampant, and consumers often lack the knowledge and resources to verify the authenticity of drugs [14]. On-the-spot checks using the TruScan, Black-Eye and Radio frequency identification devices are also essential interventions by NAFDAC. These technologies enable NAFDAC officials to detect and intercept counterfeit drugs at various points in the distribution chain, including at ports of entry and local pharmacies. This approach is critical in preventing counterfeit drugs from reaching consumers and mitigating the harm caused by substandard and falsified medical products [13].

Moreover, the importance of media and publicity in educating the public about the features of genuine drugs cannot be overstated. The NAFDAC registration number and holograms are key features consumers can use it to identify genuine drugs [15]. NAFDAC can empower consumers to identify and avoid counterfeit drugs by educating the public on these features.

The participants in this focus group discussion (FGD) highlighted several challenges that hinder the successful development and implementation of interventions against fake and counterfeit drugs. One of the key challenges identified was the lack of public awareness about the existence of these interventions. Without sufficient knowledge, the public may be unable to utilise the available tools and services to

verify the authenticity of drugs, thus leaving them vulnerable to counterfeit products [16-18]. Another challenge raised by the participants was the need for proper regulation and enforcement of laws against the sale and distribution of fake drugs. Stricter laws and their effective enforcement are crucial in deterring counterfeiters and ensuring that they face appropriate consequences for their actions [14]. This emphasises the importance of a robust legal framework and NAFDAC's role in ensuring compliance and holding offenders accountable. The participants also emphasised the significance of collaboration between NAFDAC and other agencies and stakeholders in effectively addressing fake and counterfeit drugs. Counterfeit drugs are a complex problem that requires a multidimensional approach involving various stakeholders, including law enforcement agencies, healthcare professionals, pharmaceutical manufacturers, and the public. By working together, these entities can pool their resources, expertise, and influence to combat counterfeit drug production, distribution, and sale more effectively [8]. During the FGD, participants recognised the importance of educating the public about identifying counterfeit drugs. Increasing public awareness can empower individuals to recognise warning signs and take appropriate actions to avoid counterfeit products [19].

Additionally, technology was identified as a crucial tool in identifying fake drugs. By leveraging technologies such as serial numbers on drug packages, it becomes possible to track and trace the source of drugs, enabling better enforcement and prevention measures. The challenges that hinder the successful development and implementation of interventions against fake drugs in this study were consistent with the findings from a study by Adigwe et al. (2022) [20] on the challenges associated with addressing counterfeit medicines in Nigeria.

Furthermore, the stakeholders' responses during the focus group discussion (FGD) shed

light on their perceptions regarding the need for an anti-counterfeiting strategy or approach by the drug regulatory agency, NAFDAC, to combat counterfeit medicine in Nigeria. The stakeholders in the FGD reached a consensus that NAFDAC should have an anti-counterfeiting strategy to combat counterfeit medicine in Nigeria. While some stakeholders expressed satisfaction with NAFDAC's existing interventions, others called for incorporating advanced technologies and greater collaboration with relevant stakeholders. These perspectives highlight the need for NAFDAC to consider a holistic approach, considering stakeholders' opinions, to effectively address the issue of counterfeit medicine in the country. By incorporating advanced technologies, collaborating with stakeholders, and continually evaluating and improving their strategies, NAFDAC can strengthen their efforts to combat counterfeit medicine and ensure the safety and well-being of the Nigerian population [21].

The respondents in the study shared their perspectives on differentiating between genuine and counterfeit drugs, highlighting important factors and measures to consider. The study participants emphasised the importance of several measures to identify good quality medicines, including checking for a NAFDAC registration number, inspecting packaging, and requesting seller receipts.

They also suggested that NAFDAC should consider implementing KYC measures to address issues within the supply chain and conduct research to evaluate the effectiveness of their current strategies. The concerns about donated medicines entering the general market highlight the need for improved accountability and monitoring in various programs. These insights provide valuable perspectives for NAFDAC to enhance their efforts in combating counterfeit drugs and ensuring the Nigerian population's availability of safe and genuine medicines.

Based on the findings from this study, the participants in the FGD expressed their

perceptions regarding the focus interventions and the use of quality technology for detecting regulated drugs in different geographical areas of Nigeria. The discussion revolved around implementing cutting-edge technology, specifically the NAFDAC TruScan, and its effectiveness and frequency of use. The participants recognised the necessity of utilising cutting-edge technology to mitigate the prevalence of substandard pharmaceutical products in Nigeria.

They agreed that the NAFDAC TruScan could effectively detect substandard and falsified medical products. To ensure the success of these interventions, the participants recommended collaboration with stakeholders and raising public awareness. They also emphasised the importance of empowering pharmacovigilance directorates and adopting a comprehensive approach to address the issue of substandard and falsified medical products in the country.

Summary

This research concerns an investigation into NAFDAC intervention to identify substandard and falsified drugs in Nigeria. The findings of this study highlight several important aspects regarding the Incidence of fake and counterfeit drugs in Nigeria.

Limitation

The study focused on a specific group in Nigeria; hence, generalising the findings may be limited. The outcomes may not reflect the viewpoints and experiences of people in different areas or nations. Furthermore, the findings may not be relevant to various circumstances or groups.

Conclusion

The study shed light on the various interventions and challenges in Nigeria's fight against fake and counterfeit drugs. NAFDAC has adopted several strategies, including Mobile Authentication Services and on-the-spot checks, utilising technologies such as TruScan, Black Eye and RFID. However, the stakeholders in the focus group discussion highlighted several obstacles that hinder these interventions' successful development and implementation. The lack of public awareness about the existence of these interventions, the need for proper regulation and enforcement of laws, and the chaotic distribution chain were identified as key challenges. Stakeholders emphasised the importance of NAFDAC's comprehensive anti-counterfeiting strategy and implementing measures such as checking for NAFDAC registration numbers, inspecting packaging, and requesting seller receipts to identify genuine medicines. Collaboration and communication among stakeholders were crucial in the fight against counterfeit drugs. Regular stakeholder meetings, advocacy, and educational workshops were recommended to create awareness and educate stakeholders on their responsibilities. The challenges associated with counterfeit drug interventions require constant vigilance, innovation, and the involvement of all stakeholders.

Conflict of Interest

The author declares no conflict of interest.

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