SOCIO-CULTURAL FACTORS INFLUENCING EARLY DIAGNOSIS AND PREVENTION OF HIV AMONG WOMEN OF REPRODUCTIVE AGE IN SOUTHWESTERN NIGERIA

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ABSTRACT

INTRODUCTION
Culture and social status are key determinants of attitude and behaviour towards prevention and control of many diseases of Public health importance including HIV.

OBJECTIVES
This study determines socio-cultural barriers to early diagnosis and prevention of HIV among women of reproductive age in Southwestern Nigeria

METHODS
Descriptive cross sectional qualitative study among women of reproductive age group and health care givers concerning socio and cultural factors influencing diagnosis and prevention of HIV. Five Focus Group Discussions (FGD) of 8 eligible respondents each were conducted using a pretested FGD guide in collecting data from the randomly selected subjects. Data was analyzed using simple content analysis.

RESULTS
Cultural and social factors influencing HIV vulnerability and transmission identified include low education status, poor awareness among women, low employment and economic power, adverse religious beliefs and practices, reluctance to accept teaching of FLHE in schools and the public, stigma and discrimination even from the health care workers affecting health seeking behaviour. Other factors include polygamy, male dominance, low decision power and value of women, remarrying after divorce, widowhood rights, wife inheritance and sharing, early marriage, and some cultural breastfeeding practices encouraging HIV transmission.
CONCLUSION

Raising community awareness by traditional, cultural and religious gatekeepers becomes imperative to circumvent many of the identified social and cultural factors constituting barriers and influencing HIV diagnosis and prevention

KEY WORD

Socio-cultural factors, HIV, STIs, women of reproductive age

INTRODUCTION

The global HIV epidemic continues to expand, with an estimated five million people becoming infected each year.\(^1\) In sub Saharan Africa, 61% of adults living with HIV are women.\(^2\) As more women contract the virus, the number of children infected by their mothers has been growing\(^1\). HIV prevalence in Nigeria stabilizes at 4.1% going by national data in the last 2 years despite ongoing prevention efforts as well as treatments; care and support for People Living With HIV/AIDS (PLWHAs).\(^3\) Governments have spent huge resources on prevention efforts. These include primary prevention (both population and high risk strategies), early diagnosis through opt out HIV screening, and treatment, care and support as secondary prevention efforts not leaving tertiary prevention behind. Over the years, little emphasis had been placed on cultural and socioeconomic context of HIV infection, an issue that continue to modify disease transmission and hence the HIV national response.

Culture determines social relations and gender roles, and has profound impact on the total life of members of a cultural group or community. Culture, traditions, social class and religion have influence on behaviour, attitude and practices of Nigerians\(^4\). Issues relating to sexuality and breastfeeding among others have implications for existing socialization and culture mix. These equally have roles to play in modifying the epidemiology and control of HIV among women.\(^5\) The 2007 national guidelines which advocated exclusive breastfeeding for all HIV pregnant mothers provided AFASS criteria were met, may have likely undermine the universality of the culture of breastfeeding for all newborn most especially in the African sub region.\(^6\) The education status of women, poverty, malnutrition, gender inequality, inability to negotiate sex, poor economic powers and social status are examples of ways in which women becomes vulnerable to HIV

Health seeking behaviour of women is a social issue with great gender peculiarity. Coupled with societal stigma and human rights violations associated with HIV infections, \(^7\) a study to determine these socioeconomic and cultural factors is long overdue. These information would assist to modify both primary and secondary prevention efforts towards reduction in disease prevalence. This study determines socio-cultural barriers to early diagnosis and prevention of HIV among women of reproductive age in Southwestern Nigeria
METHODS

**Study Area:** Osogbo, the capital of Osun State in Southwestern Nigeria was the study area. It has a population of 3.5 million people according to the last national census. Prevalence of HIV in Osogbo was a bit lower than the national average put at 4.1%. Most HIV care work takes place at the secondary and tertiary care level while Primary health care centers are mainly for Counseling and Testing services. There is a teaching hospital and a general/state hospital in the town.

**Study design:** was a combined community and health facility based descriptive cross sectional qualitative study of socio-cultural factors influencing early diagnosis, management and prevention of HIV among women of reproductive age in Osogbo in Southwestern Nigeria

**Study population:** All women of reproductive age group 15-49 years in the city constituted the reference population while those who took part in the study constituted the study population.

**Sampling:** One out of the two Local Government Areas in Osogbo was selected by simple random sampling employing simple balloting. From the ten wards in the local government, three were chosen at random. Eight eligible women per ward were conveniently selected to join their counterparts from other wards to make a total of 24 subjects. These were randomly divided into 3 FGD groups employing simple balloting

For the health care workers supporting the general and teaching hospital in the city, 4 female social workers and 4 female nurses (all working in HIV related units) in the state general hospital were selected to join same number of selected counterpart from the teaching hospital, making a total of 16. These health care workers were divided into two FGD groups using simple random sampling method.

**Data collection:** A total of five focus group discussions were held using a pre tested focus group discussion guide. Discussions were made in both English and vernacular to ensure good understanding of questions. The use of an independent observer was employed during the discussion to further guide this focus group discussion. Variables examined include social and cultural issues affecting HIV diagnosis and prevention in their communities.

**Ethical clearance:** to conduct the study were obtained from the Health Research Ethics Committee of Osun state university. Further permissions were obtained from local heads of communities. Written informed consent was obtained from each of the discussants.

**Data management:** Qualitative responses were analyzed using simple content analysis. in terms of nature and responses to questions as well as cogency and frequency of points raised in the various questions. An excel sheet was used to enter socio-demographic data of the discussants and resulting analyzed data was presented in form of a simple frequency table.
FGD RESULTS

In response to factors making women more vulnerable to HIV than men, all discussants agreed that women were more vulnerable. Reasons given include low educational status and low awareness among women (three quarter of discussants), women being a weaker sex (a quarter of respondents), low employment and economic power which make them succumb to sexual pressure from men for financial gains (about two thirds of respondents), cultural practice like polygamy and male dominance (half of respondents), low decision power in relationships and families (half of discussants) and religious beliefs (half of discussants).

Discussants believed that women have not been coming out for Voluntary Confidential Counselling and Testing because of fear of stigma and discrimination (all discussants), since HIV have no cure yet (a third of discussants), fear among married women that their husbands may send them parking out of their matrimonial homes if found HIV positive (three quarter of discussants), religious shame if found HIV positive (half of discussants) and association of HIV with promiscuity (half of discussants).

Sexual transmission has not reduced among women because of some socio-cultural practice such as polygamy (all discussants), wife inheritance and remarrying after death of husbands (half of discussants), early and forced marriage which predispose women earlier to sex and sexually transmitted infections (half of discussants) and religions forbidding mentioning sexual issues in public (another half).

Family Life Health Education (FLHE) has not been taught in schools and public places as proposed by governments because religions and cultures frowned at it as if it would teach students the confidence to be promiscuous. In addition, parents and some teachers kicked against it for the same religious and cultural beliefs.

On condom use, about half of discussants believed that our culture does not support condom use. Christianity generally does not support contraception (a third of discussants), while culture does not permit a woman negotiating condom use during sexual intercourse with her husband otherwise she is suspected of infidelity (half of respondents).

On culture and breastfeeding, all discussants agreed to the universality of breastfeeding and its cultural acceptability. Any condition that will prevent a woman from breastfeeding her child may give rise to suspicion of a HIV or other chronic disease (half of discussants). In addition, it may lead to friction between mother in-laws who would insist on breastfeeding her grandchild; and the woman who may have decided not to breastfeed for some reasons including health grounds (half of respondents). Half of respondents believe that affordability and safety may be an issue in exclusive replacement feeding. All said all religions preaches breastfeeding.

Stigma and discrimination can reduce if women are well educated (half of discussants,) if they have good economic powers (half of discussants), if some cultural practices can be
abrogated (three quarter of respondents) and if religions could be more flexible on contraception and raising sexual awareness and teaching FLHE in public and schools to young women (all discussants)

**DISCUSSIONS**

Culture is regarded as the resume of life of a community, a way of life among some people which guides their day to day living, norms and practices. The custodians of culture are the traditional and faith based institutions, they are gate keepers of attitude and behaviour are critical assets in the fight against HIV/AIDs.

Reasons give by discussants to affect women vulnerability to HIV supports other studies in which sexual violence and coercion, unequal access to education, economic options and legal protections was found to be major factors that increase women vulnerability to HIV.

In some Nigerian cultures, men think that only women should be tested and treated for STIs. So eventually men would get STIs without it being reported or treated. The implication of this trend is that men could freely infect their wives and others in sexual relationship, thus increasing societal prevalence of STIs including HIV.

Culturally, a wife is not expected to refuse sexual advances and request from her husband even in the face of HIV threat. She may be accused of sexual infidelity and may be charged to be guilty of committing abominable sexual offence. By this, women are not able to negotiate safer sex, and this has implications for HIV transmission. Many men also believe that condoms should only be used in commercial text with prostitutes

Culture of patriarchy-men making all decisions, and women must be submissive- takes place in almost all cultures and communities as mentioned by discussants in this study. This supports another Nigerian study in which the current high prevalence of HIV and in women and low level of coverage of PMTCT was said to be largely due to the influence of cultural practice.

Early marriage and child bearing as mentioned by discussants will expose women to earlier sexual activity and sexual risks including HIV. This is supported by another similar study. Polygamy is still practiced in many cultures almost all over the world. If one of the women is sexually unfaithful, the probability is high that this cohort of sexual links within same family could transmit HIV among themselves. The Islamic religion for example openly support polygamy, and Muslim men may marry up to four wives at a time.

Among the Benue people in Nigeria, the cultural practice of wife sharing and wife hospitality would only contribute to the sexual woes of women as some close members of a wife are traditionally entitled to same women who are in a marriage relationship. Failure of women to adhere with such cultural practice, many believe would make her incur the wrath of the gods.
Among the Bahimas people (Nkore in Uganda), the father of a bridegroom have the right to test have gone by having the first sexual access to the new bride.\textsuperscript{11} Also among the Bahimas, adultery is forbidden for women but men have the right to go outside for sexual pleasures.

Widow inheritance is another cultural practice that increase sexual risk of women and which may affect her vulnerability. Others include marital instability or divorce in which the woman wants to re marry and have children for the new husband.\textsuperscript{10}

Cases of sexual violence such as rape are common occurrences these days,\textsuperscript{12} which also increase vulnerability of women to HIV and STIs. Since many of these cases were not reported, then testing for STIs including HIV, and subsequent treatment becomes an issue because the associated stigma and discrimination would affect her health seeking behaviour and many would not turn up to confess and treat the medical condition.

The low socioeconomic factors mentioned by respondents as reasons for vulnerability and social factors militating against testing, and treatments for HIV is a big determinant. These may include low education (and hence poor awareness), poverty (and hence poor affordability of contraceptives and STIs management), poor decision power that makes them to succumb to sexual pressure from men (due to potential economic gains) and lack of stable occupation and income. All these would affect prevention efforts against STIs. This supports another study in which those with a lower socioeconomic status were more likely than those with a higher socioeconomic status to be infected with HIV-1 (17\% versus 4\%), syphilis (66\% versus 24\%) and hepatitis B (52\% versus 26\%).\textsuperscript{13} In another related study\textsuperscript{14} higher socioeconomic status was associated with a more mobile lifestyle, later sexual debut and marriage among both sexes, and condom use among women aged 25-49.

Discussants mentioned reluctance of the community towards raising sexual awareness and teaching of FLHE in schools, for religious and cultural reasons as possible reasons for changing epidemiology of HIV most especially among young women. This supports other studies in which mixed feelings characterized introduction of FLHE in secondary schools.\textsuperscript{15,16} Teaching and raising awareness would give women the right information in terms of STIs self prevention and what to do and where to go in case they need medical attention.

Stigma and discrimination for cultural and social reasons have prevented many women from accessing HIV care including testing, as supported by another study.\textsuperscript{17-19} This is happening in Nigeria for example despite the existence of national policy against stigma and discrimination against PLWHAs. Discrimination has gone far in Nigeria to the extent that health care workers are involved, and the conflict in disclosure have affected prevention and treatment efforts for many PLWHAs as reported in a study.\textsuperscript{7} Eventually the client goes for traditional and alternative treatments including religious and spiritual care which eventually may lead to delays in accessing orthodox medical care and prompt management of impending complications. This is supported by another study on use of alternative medical therapy among PLWHAs\textsuperscript{20}.
Discussants responses on cultural acceptability of breastfeeding may be so significant most especially as the 2007 national guidelines on PMTCT advocates options of infant feeding including exclusive replacement feeding (among PLWHAS). Thus the society becomes suspicious of a disease among women who choose not to breastfeeds, the mother-in-laws who are not informed about disclosure (for fear of stigma) would insist on exclusive breastfeeding for cultural reasons. Eventually friction occurs between the woman and her mother-in-law due to competing interests, and family breakage becomes imminent. Many women may eventually mix-feeds, an action that may facilitate MTCT. In a supportive study, choice of IFC depends on ability of women to make a choice during ANC and availability of an enabling environment to practice the selected methods of IFO.\(^6\)

In addition, the social issue of affordability could constitute challenges to exclusive replacement feeding in an environment like ours where women have low socio economic powers. This social and cultural challenge had been resolved with the 2010 national guidelines advocating that all HIV positive women of reproductive age should be encouraged to exclusively breastfeeds under cover of Antiretroviral drugs (ARVs)

**CONCLUSION**

Several cultural and social influences affect the epidemiology of HIV/AIDS among women, including testing, management and prevention. As most of these issues bothers down on health education, the need to raise awareness among traditional, cultural and religious gatekeepers becomes imperative. It is also important to take all positive measures to improve social and economic status of women.

**ACKNOWLEDGEMENT**

Author would like to express his gratitude to the heads of communities and individual participants (community members and health care workers) who took part in this study.

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## Socio-demographic characteristics of focus group discussants

<table>
<thead>
<tr>
<th>Variables (n=40)</th>
<th>Frequency</th>
<th>Percentage</th>
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<tbody>
<tr>
<td><strong>Age in years</strong></td>
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<tr>
<td>21-30</td>
<td>19</td>
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<tr>
<td>31-40</td>
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<td>32.5</td>
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<tr>
<td>41-50</td>
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<tr>
<td>Male</td>
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<tr>
<td>Others/none</td>
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<td><strong>Marital status</strong></td>
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<td>Count</td>
<td>Percentage</td>
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<tr>
<td>Widowed/divorced</td>
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</tr>
<tr>
<td>Others</td>
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STUDIES ON ANTI-DIABETIC ACTIVITY OF CLEOME VISCOSA IN ALLOXAN-INDUCED DIABETIC RATS

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ABSTRACT

Cleome viscose (L.) belonging to family (Capperdiceae), commonly called “Sticky spider flower”, is a terrestrial, annual, erect, aromatic herb. The plant has high medicinal value as it is traditionally used for its antiemetic, wound healing, antimicrobial, hepatoprotective and anti-oxidant properties. The aim of the proposed work is to evaluate the therapeutical potential of Cleome viscosa in alleviating diabetes by assessment of liver and kidney function and lipid profile parameters in alloxan-induced diabetic rats. A significant elevation (P<0.001) of blood glucose, SGPT, SGOT, ALP, urea, uric acid, creatinine and lipid profile in control groups was observed as compared to normal groups. However, there was significant reduction (P<0.001 and P<0.001) in the tested biochemical parameters in both the groups treated with extract as compared to the control group and the effect was compared with the standard drug, Metformin. From these results, it can be concluded that the methanol extract of Cleome viscosa possesses significant ability to reduce the diabetes complications

KEY WORDS

Cleome viscosa, diabetes, complications, neuropathic pain, lipid profile, liver and kidney function.

INTRODUCTION

Diabetes is a metabolic disorder resulted from the destruction of insulin secreting pancreatic β-cells, defect in insulin production, insulin action, or both, characterized by hyperglycemia. The chronic hyperglycemia results in long-term complications of diabetes include peripheral neuropathy causing foot ulcers, autonomic-neuropathy, causing stroke, ischemic heart diseases and peripheral vascular disease, sexual functions; nephropathy causing renal failure; retinopathy with loss of vision. Quality of life is diminished. It reduces the life expectancy[1]. The metabolic
complications of diabetes are diabetic ketoacidosis, hyperosmolar non-ketotic coma, Lactic acidosis, and hypoglycemia. Ketoacidosis and hyperosmolar non-ketotic coma are due to insulin deficiency. Hypoglycemia results from the treatment, either with oral agents or insulin. Hypoglycemia common in patients treated with insulin[2]. Prolonged exposure of tissues to hyperglycemia results in various complications including premature atherosclerosis, retinopathy, nephropathy and gangrene of the limbs. It is thought to be due to reduced blood supply to these structures because of thickening of the capillary walls. Accumulation of glycosylated products in the vessel walls may be responsible for the thickening. More amount of intercellular over conversion of intracellular glucose is converted to sorbitol by the enzyme aldose reductase. This sorbitol exerts osmotic effect resulting in tissue damage particularly in the retina and peripheral nerves. Hence, it is necessary to maintain normal blood glucose levels to prevent or delay the onset of complications of diabetes[3].

Cleome viscosa is a terrestrial, annual, erect, aromatic (fetid smell) herb reaches up to 120cm tall. Taproots are white or brown in colour. Stem is erect, rounded, solid, (glandular) hairy. Stipules are absent. Leaves are compound, trifoliolate, alternate spiral, stalked, leaflets elliptic, (glandular) hairy on both side, margin entire, apex acute, base acute, pinnately veined. Flowers are bisexual, single, axillary, stalked, yellow, petals 4 and free. Fruit is a capsule, opening by two valves[4]. Gram negative species. Free radical scavenging activity of Cleome viscosa extract was studied in vitro by Lakshmi and Bindu (2013) and was found to be have significant activity

**MATERIALS AND METHODS**

**PLANT MATERIAL**

Plant sample of Cleome viscosa were collected in the month March, 2014 from S.V. University, Tirupathi, India; and verified by Prof. Dr. M. Madhava Chetty, Department of Botany, S. V. University, Tirupathi, Andhra Pradesh, India.

**PREPARATION OF EXTRACT**

The collected fresh plant materials were dried in shade (2 days) and then dried in a hot air oven at 25°C for three days and they were made in to coarse powder with the use of mixer grinder. The powder of Cleome viscosa obtained were weighed separately and transferred to a round bottomed flask and then went to continuous heat extraction with soxhlet apparatus using 70% methanol for 24 hours. Then the extract of methanol was concentrated. Extract obtained was dried by placing it on a big petri plate on electric water bath (70°C) and then kept in an oven at 30°C for 2 hour. The extract obtained was kept for drying and stored in vacuum desiccators. The percentage yield of the extract was 6.29%.
PHYTOCHEMICAL SCREENING

The crude extract was investigated for the presence of various phytoconstituents by using the standard methods.

EXPERIMENTAL ANIMALS

The Wister albino rats of either sex (200-250g) were obtained from the central animal house of Sigma Institute of Clinical Research & Administration Pvt. Ltd., Hyderabad, India. Animals were housed at a temperature of 24±2°C and relative humidity of 30-70% environment with a constant 12 h light and dark cycle was followed. All animals had free access to water and standard pellet laboratory animal diet. Animals were acclimatized to laboratory conditions before the experiment. All experiments and protocols described in present study were approved by the (IAEC) Institutional Animal Ethics Committee (769/2011/CPCSEA) approved the study protocol.

ACUTE ORAL TOXICITY STUDY

Acute toxicity studies were performed according to OECD-423 guidelines[9] Category IV substance (acute toxic class method). Albino mice (n=3) of either sex selected by random sampling technique were employed in this study. The animals were fasted for 4 h with free access to water only. The Sandy and freely draining soils in open woodland scrub and on scree slopes in dry areas. Occasionally, a noxious weed. In Spain, it is a troublesome weed on irrigated crops in arid areas[5]. Plant contains flavonoids, tannins, saponins, and alkaloids and steroids, tannins, fatty acids. Plants contain volatile principle with a smell similar to mustard[6]. The leaves are diaphoretic, rubefacient and vesicant. They are used as an external application to wounds and ulcers. The juice of the leaves has been used to relieve earache. The seeds are anthelmintic, carminative, rubefacient and vesicant. The seed contains 0.1% viscosic acid and 0.04% viscosin.

In the Unani system of medicine, the seeds of the plant are documented as anthelmintic and detergent, and are given to treat fever and diarrhea. The seeds are used for anthelmintic while the leaves are useful for healing wounds. A poultice made from the plant is efficacious as a counterirritant in chronic painful joints. Panduraja et al., studied the wound healing activity of methanol extract of Cleome viscosa on rats[7] and it was found to have significant wound healing activity. Upadhyay et al., 2008[8] carried on the antimicrobial assay on aqueous extract of Cleome viscosa on various microbial species and found that they have significant activity on Gram positive and phytosterols, flavonoids, steroids and alkaloids are present and gums and mucilages, proteins and amino amino acids.

ACUTE ORAL TOXICITY STUDY

The extract of Cleome viscosa did not show any mortality and toxicity even at highest dose of
2000mg/kg body weight employed. The present research study was carried out using two different doses (low and high). The methanol extract of Cleome viscosa such as 200 and 400mg/kg body weight for diabetic complication.

**EFFECT OF THE EXTRACT ON BLOOD GLUCOSE LEVELS**

Effect of methanol extract of *Cleome viscosa* on blood sugar levels (BSL) in Alloxan-induced diabetic rats was studied[14]. Blood sugar levels of normal group did not alter significantly throughout study. In control group blood glucose levels increased steadily on 1st day (250.50±1.54) to 14th day (261.33±1.05). On treatment of MCV at 200mg/kg, gradual reduction of BSL was observed from 1st day (181.00±1.32) to 14th day (121.50±1.00), similarly on treatment with MCV at 400mg/kg, the BSL were from 1st day (200.3±2.96) to 14th day (101.30±0.85).

**Table 4: Effect of methanol extract of *Cleome viscosa* on blood sugar**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>0 day</th>
<th>1st day</th>
<th>7th day</th>
<th>14th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (0.9% saline)</td>
<td>44.66±1.43</td>
<td>122.83±1.17</td>
<td>176.80±1.64</td>
<td>181.10±1.11</td>
</tr>
<tr>
<td>Control (Alloxan 120mg/kg)</td>
<td>99.33±1.33*</td>
<td>250.50±1.54*</td>
<td>254.3±1.28@</td>
<td>261.33±1.05@</td>
</tr>
<tr>
<td>Standard (Metformin 14.2mg/kg)</td>
<td>37.27±1.04*</td>
<td>245.83±0.95*</td>
<td>214.50±1.4&amp;</td>
<td>145.85±0.79&amp;</td>
</tr>
<tr>
<td>MCV 200mg/kg</td>
<td>69.83±1.25*</td>
<td>181.00±1.32*</td>
<td>180.00±1.08&amp;</td>
<td>121.50±1.00&amp;</td>
</tr>
<tr>
<td>MCV 400mg/kg</td>
<td>59.00±1.17*</td>
<td>200.30±2.96*</td>
<td>199.60±0.88&amp;</td>
<td>101.30±0.85&amp;</td>
</tr>
</tbody>
</table>

Data expressed was Mean ± S.E.M. n=6, * = not significant, ANOVA followed by Dunnett’s multiple comparison test &P<0.001 as compared control group; and @P<0.001 as compared normal group.

**EFFECT OF THE EXTRACT ON BIOCHEMICAL PARAMETERS**[15-21]

The effect of methanol extract of *Cleome viscosa* on SGOT, SGPT, ALP, Urea, Uric acid, and Creatinine in Alloxan-induced diabetic rats was studied and the results were given in Table 5. There was a significant increase in these enzyme levels in control group of animals (P<0.001)
compared to the normal group of animals. There was significant reduction (P<0.05 and P<0.05) on treatment of MCV at the dose of 200mg/kg and 400mg/kg. There was a significant reduction in the standard group of animals (P<0.001) compared to the control group of animals. However, there was significant reduction (P<0.001) and (P<0.001) in both treated groups with MCV at 200mg and 400mg as compared to the control group of animals.

**EFFECT OF THE EXTRACT ON LIPID PROFILE**

The effect of methanol extract of Cleome viscosa on cholesterol, triglycerides, and HDL in Alloxan-induced diabetic rats were studied using standard models and the results were illustrated in Table 6. A significant elevation (P<0.001) was observed in the control group compared to normal group. There was significant reduction (P<0.001) in the standard group compared to control group at the dose of 200mg/kg and 400mg/kg. There was a significant reduction in the standard group of animals (P<0.001) compared to the control group of animals. However, there was significant reduction (P<0.001) and (P<0.001) in both treated groups with MCV at 200mg and 400mg as compared to the control group of animals.

However, there was a significant reduction (P<0.001 and P<0.001) in both treated group at the dose of MCV 200mg, MCV 400mg/b.w., respectively, compared to the control group.

**STATISTICAL ANALYSIS**

The Statistical analysis software Graphpad Prism Version 5 was used for statistical analysis of the present studies.

**Table 5: Effect of methanol extract of Cleome viscosa on biochemical parameters on liver**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>SGOT (U/L)</th>
<th>SGPT (U/L)</th>
<th>ALP (U/L)</th>
<th>Urea (mg/dl)</th>
<th>Uric acid (mg/dl)</th>
<th>Creatinine (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (0.9% saline)</td>
<td>24.3±1.03</td>
<td>43.7±0.80</td>
<td>25.0±1.01</td>
<td>68.91±1.18</td>
<td>3.2±0.50</td>
<td>5.2±0.64</td>
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<tr>
<td>Control (Alloxan 120mg/kg)</td>
<td>42.52±0.63 @</td>
<td>48.2±1.09 ^</td>
<td>42.1±1.06 $</td>
<td>66.89±1.25 @</td>
<td>3.38±0.53 @</td>
<td>5.9±1.46</td>
</tr>
<tr>
<td>Standard (Metformin 14.2mg/kg)</td>
<td>36.5±1.02 *</td>
<td>34.14±0.77 &amp;</td>
<td>32.6±0.69 $</td>
<td>56.24±0.63 $</td>
<td>3.03±0.73 $</td>
<td>5.0±0.69 $</td>
</tr>
<tr>
<td>MCV 200mg/kg</td>
<td>39.4±1.23 #</td>
<td>27.3±1.06 $</td>
<td>33.3±0.82 $</td>
<td>49.51±3.06 *</td>
<td>2.00±0.85 $</td>
<td>4.8±0.68 $</td>
</tr>
</tbody>
</table>
Table 6: Effect of methanol extract of *Cleome viscosa* on biochemical parameters on liver

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Cholesterol (mg/dl)</th>
<th>Triglycerides (mg/dl)</th>
<th>HDL (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (0.9% saline)</td>
<td>32.88±0.73</td>
<td>66.79±0.88</td>
<td>75.81±1.03</td>
</tr>
<tr>
<td>Control (Alloxan 120mg/kg)</td>
<td>83.83±0.36@</td>
<td>92.84±0.74@</td>
<td>54.46±0.73@</td>
</tr>
<tr>
<td>Standard (Metformin 14.2mg/kg)</td>
<td>41.63±0.80&amp;</td>
<td>50.60±0.71&amp;</td>
<td>77.99±0.63&amp;</td>
</tr>
<tr>
<td>MCV 200mg/kg</td>
<td>45.6±0.92&amp;</td>
<td>54.84±0.77&amp;</td>
<td>66.10±0.46&amp;</td>
</tr>
<tr>
<td>MCV 400mg/kg</td>
<td>53.81±0.80&amp;</td>
<td>54.50±0.54&amp;</td>
<td>65.76±0.91&amp;</td>
</tr>
</tbody>
</table>

Data expressed was Mean ± S.E.M. n=6,

ANOVA followed by Dunnett’s multiple comparison test #P<0.05; *P<0.01; &P<0.001 as compared to control group; and @P<0.001, $P<0.01, and ^P<0.05 as compared normal group.

**CONCLUSION**

The findings of the study reveal that oral administration of methanol extract of *Cleome viscosa* exhibited significant antidiabetic and hepatoprotective effect and the protective effect was compared with the standard drug (Metformin). Further, oral use of the extract might positively affect the functional capacities of various rat tissues, particularly blood, kidney and nerves against toxic action of Alloxan at the dose of 120mg/kg b.w. These results clearly support the traditional use of *Cleome viscosa* in the treatment of diabetes mellitus and further on diabetic complications shedding more light in the efficacy of the plant. Thus, *Cleome viscosa* appears to a valuable plant and ideally suited to be used in treatment of diabetes mellitus and further studies are required to assess the usefulness of the plant in diabetic complications, since this is a non-toxic plant.
REFERENCES


STRATEGY OF CONTEXTUAL BEHAVIORAL SCIENCE

Article Review by Praneeth Kamarapu, India
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SOURCE

INTRODUCTION
This review critically reviews the article ‘Contextual Behavioral Science: Creating a science more adequate to the challenge of the human condition’ in the journal Science Direct Journal. The review will first summarise the article. Secondly, it will briefly analyse the effectiveness of the article’s structure, investigating how the information is set out and whether the reader can access it efficiently. Thirdly, the review will critique the article, evaluating its authority, currency, accuracy. Overall the article was well written, clear and relevant.

ARTICLE SUMMARY
The purpose of the article is to include physicians, social workers, nurses, midwives, and community healthcare workers working with vulnerable populations Behavioral medicine practitioners. Behavioral medicine is at the intersection of three practice models familiar to practitioners in developing countries, namely:

i). The Medical Model,

ii). The Traditional Medicine Model and

iii).The Public Health Model.

The article provides the goals for nature, scope, and purpose of Contextual Behavioral Science (CBS). Emerging from behavioral psychology but expanding from those roots, CBS is based on contextual assumptions regarding the centrality of situated action, the nature of epistemology versus ontology, and a pragmatic truth criterion linked to the specific goal of predicting-and-influencing psychological events with precision, scope, and depth.
ARTICLE STRUCTURE

The present article describes the nature, scope, and purpose of Contextual Behavioral Science (CBS). Emerging from behavioral psychology but expanding from those roots, CBS is based on contextual assumptions regarding the centrality of situated action, the nature of epistemology versus ontology, and a pragmatic truth criterion linked to the specific goal of predicting-and-influencing psychological events with precision, scope, and depth. These assumptions and goals explain the characteristic features of CBS including its environmentalism, focus on theory and principles, and its reticulated or networked program of theory development, research and practice.

Domains of development include increased linkage to multi-dimensional and multi-level evolution science; development of principles that describe the interaction of behavior and symbolic events with genetic, epigenetic, and cultural dimensions; expansion of theoretical and model development to a broader range of areas of human complexity; advances in measurement theory and practice; the development of techniques and components linked to contextual processes and principles; broad testing of these methods; additional research on mediation and moderation; more concern for effectiveness and training; and enhancement of a diverse development community.

AUTHORITY

The journal, the Science Direct Journal, is a publication of the American Public Health Association. The author Steven C. Hayes from the Department of Psychology, University of Nevada, Reno, NV 89557-0062, USA.

ACCURACY

The source of the information in the article was a current research project. It was also backed up and supported by a comprehensive, recent reference list with these sources cited in-text to support both the literature review and the research itself. The strict editorial and refereeing processes also contributed to the article’s accuracy.

CURRENCY

The journal was published in Oct 2012, while the article was accepted for publication in Sep 2012. The research it describes was current and the article cites up-to-date references in the body of the text. Therefore the article is current.

RELEVANCE

This was an academic Journal of Contextual Behavioral Science, which has high credibility in an research in public health context. It was written to inform researchers and students rather than to
maintain maximum health percentage in public. It would be relevant to groups but particularly any academic interested in community based innovations and in health generally. It could be a difficult article to read and understand. This is an important article to students in department of psychology.

**OBJECTIVITY**

The main objective of the article includes CBS is a broad program of research and practical development. CBS is best viewed as part of multi-dimensional and multi-level evolution science. It emerged from behavioral psychology, but stands on its own. Its assumptions explain its environmentalism, focus, and reticulated approach. CBS has scores of important practical and empirical areas for exploration.

**CONCLUSION**

This review has both summarized and correctly reviewed Steven C. Hayes’s article ‘Contextual Behavioral Science: Creating a science more adequate to the challenge of the human condition’. The content, structure, strengths and limitations of the article were analyzed and reviewed. The article has contributed to the literature in terms of its valuable critique of current research study on psychology and their health issues and the implications provided for both health interventions and future research collaborative possibilities.

**REFERENCES**


IMMUNOMODULATION IN THE CRITICALLY ILL

Article Review by Julius Fru Che, Cameroon

(B.Sc to M.Sc in Clinical Research, Texila American University)

Email: - juche84@yahoo.com

SOURCE


INTRODUCTION

The immune response is an essential network of cells, tissues, and organs that work together to provide a defence mechanism for the host organism. The primary targets of the immune system are microbes, parasites, and fungi that can cause infections. However, the system may become defective, disorganized or overactive, reacting to host tissues and causing disorders such as arthritis, allergic reactions and implicated in other conditions such as diabetes melittus[16] among others, probably due to the recently identified Th 17. With such vital role, a mechanism of modulating the action of the system is essential.

The immune system is composed of two arms that work closely together, the innate immune system being more active early in an immune response while the adaptive immunity becomes progressively dominant over time.

Current medications used to modulate the immune system mainly exploit the mechanism of action of the immune system, blocking or enhancing some essential steps in the immune response cascade to provide their actions.

In the critically ill patient, the role of the immune system becomes even more evident as various conditions may come into play simultaneously, hence the essence of the current study.

During the review of the article, ‘Immunomodulation in the critically ill’ a publication of the British Journal of Anaesthesia, the reviewer will provide a summary of the article, then analyse the structure followed by a critique of the work. This will be followed by an analysis of the objectivity and stability of the article. The review will also analyse the tables presented in the article. Recent advances related to the topic will also be examined followed by a conclusion of the article review.
REVIEW OF LITERATURE

Immunity indicates protection from a disease, and this state is afforded by the immune system whose function is to detect and eliminate foreign substances that may cause tissue injury or disease.

Being such a vital system, the immune system has received an overwhelming interest from researchers in a bid to find new immunomodulatory medications. As a consequence, literatures abound in this topic with the results as varying as the authors. Some of this literature will be reviewed below.

Goodman & Gilman\(^5\) classified the immunomodulators as immunosuppressants, tolerogens and immunostimulants. Their immunosuppressants included glucocorticoids, calcineurin inhibitors, antiproliferative agents and biologics (antibiotics). They noticed the importance of these drugs but noted their dark sides which involves life-long treatment and nonspecific immune system suppression thus exposing the patient to higher risk of cancer and infection.

They also found a handful of immunostimulants to be used in clinical practice, among which were levamisole, recombinant cytokines, Bacillus Calmette Guerin and the notorious thalidomide, which despite its unenviable legacy of birth defects when administered to pregnant women, is said to still be indicated in the treatment of multiple myeloma and erythema nodosum leprosum, although in a very well controlled environment.

To minimize the side effects of both the immunostimulants and the immunosuppressants therefore, Goodman and Gilman proposed more studies on the tolerogens which if successful, would represent a true cure for many conditions.

Dermot Gleeson, Michael A. Heneghan\(^7\), while writing the guidelines of the management of autoimmune hepatitis, focused their attention in the management of autoimmune hepatitis where they stated that major strides had been made in the 1970s and 1980s in the management of this condition but that in recent years, there has been an acute insufficiency in clinical studies in the condition which has led to many unresolved questions in the subject matter.

On a brighter note, while writing in the Journal of Clinical and Experimental Immunology, Jolles et al\(^2\), lauded the recent advances in the understanding of the mechanism of action of and expansion in the use of intravenous immunoglobulins while noting that their major drawback was the cost of preparation and the logistical problems associated with their administration.

ARTICLE SUMMARY

The article *Immunomodulation in the critically ill* was aimed at elucidating the intricate cascade of activities resulting to immune response while providing critical insights into the role of immunomodulators in the management of conditions in the intensive care unit and their use in
the critically ill. It was also aimed at evaluating the different clinical studies that have been carried out in a bid to find new immunomodulators.

To attain these objectives, the researchers presented an overview of the functioning of the immune system, highlighting its regulation while making an inventory of the different disease conditions that are common in the critically ill patients that necessitate the use of immunomodulators together with possible management strategies as well as the different studies that have been and are currently being conducted to find new drugs to manage the given conditions.

The main findings of this study were that immunomodulation had both beneficial and undesirable effects with the level of immunomodulation apparently important—high dose vs low dose, short duration vs long duration; and the timing were also found to be seemingly crucial. The researchers also concluded that many of the studies to find new immunomodulators may have proved to be futile because the stage in the inflammatory process of the patients recruited for the studies were unknown.

The recommendation was therefore the necessity of evaluating the stage in the inflammatory process that the patient is at and then tailoring the appropriate therapy to the individual patient.

ARTICLE STRUCTURE

Immunology is one of the most difficult to understand aspects of biology for a novice, therefore the structure of an article on the subject can either attract or deter potential readers, an aspect that Webster et al seem to understand perfectly well.

In writing the article, Webster and colleagues started with an abstract that presented a very perfect summary of the article.

They continued presenting the article in a chronological manner with a background to the subject, providing an essential insight into the immune system and the basics of its function.

Following the background was an exploration of the various medications that have immunomodulatory potential that are used in the clinical setting.

This was trailed by an emphasis on the use of immunomodulators in the management of sepsis and acute respiratory distress syndrome, conditions common in the critically ill and in whose management are implicated immunomodulators.

Subsequently, the researchers presented a review of the different approaches that have been exploited in the not too distant past and some that are still being studied in a bid to discover new immunomodulators and explored the possible reasons why most of these studies have failed and provided a way forward into future studies on the subject.
The researchers concluded the article with a statement on the source of funds for the study.

The fact that the article was presented in short paragraphs that concentrate on a particular aspect of the subject makes reading very feasible. Summarizing, the article was well structured to enable easy understanding of a very complete content, even for a novice.

ARTICLE CRITIQUE

AUTHORITY

The authority of the article can be assessed from the following perspectives.

The authors: having been written by two academics in the academic Unit of Intensive Care and Anaesthesia of the University of Aberdeen and who have co-authored many other articles gives this article an enviable authority.

The Journal: the article’s publication in the British Journal of Anaesthesia, the oldest and largest independent journal of anaesthesia, which reviews article to ensure they have the highest standards make the work a credible and authoritative source of information.

Funding: with funding from reputable sources as the Medical Research Council (a UK government agency), the Intensive Care Society (UK promoter of intensive care and critical care medicine) and the British Journal of Anaesthesia lends a lot of authority to the article.

With the above mentioned, it can be satisfactorily concluded that the article can be considered an authority in the subject matter.

ACCURACY

The article *Immunomodulators in the critically ill* can be said to present a very accurate piece of research. This statement can be supported from the fact that most of the literature referenced in the write-up supported the findings of the researchers. They all had a common consensus in the fact that the works cited also appreciated the role of the immunomodulators in managing conditions associated with the critically ill patient.

They may have been some variations in the interpretation of their findings but most of the articles shed light on the fact that studies to find new immunomodulators have failed due to various reasons and there is a need of a radically new approach in research in this field of science.

With this background, the article can be said to be accurate with respect to its references.

CURRENCY

In writing this article, the authors made reference to eighty five publications dating as far back as
1976 to publications as recent as 2008. Also the article makes reference to very recent discoveries in the field of such as the recent study on the toll-like receptor 4. These make the article very comprehensive and informative. With such recent referencing coupled with the fact that the article was actually published on May 27, 2008 after review makes the article a very recent publication. The discussion reflects current thinking about these conditions.

**RELEVANCE**

With more and more patients being admitted in the intensive care units than in the past, and with the recent shedding of light on the role of the immune system in the management of some very severe conditions implicating the immune system, there is general interest in articles of this sort, hence its relevance.

However, the very comprehensive nature of the subject matter undermines the article’s relevance to the general public as they will find it very difficult to understand. The article is nonetheless very relevant to the scientific world and especially to those involved in academic and medical research.

With respect to the content, I think it very much reflects the title of the article; hence the content is very relevant to the title.

**OBJECTIVITY**

The information provided by the article was well developed without any sign of bias on the part of the authors. The literature matched with the author’s findings in most of the cases.

The data presented were not only objective and informative but were very well tailored for the understanding of a novice in the field.

The objectivity of the article was further supported by the fact that the findings and conclusions of the authors were in line with the recent and contemporary thinking in the subject matter.

**STABILITY**

Having been carried out in an academic setting by highly qualified academics and having been published in a journal with such a reputation, the article is stable as a source of information.

**ANALYSIS OF TABLES AND FIGURES**

The article had four tables and three figures

Figure 1 showed the intracellular signalling pathways and how external inflammatory stimuli induce cytokine synthesis. Figure 2 was a superimposition on Figure 1 of the various sites at which immunotherapy can be altered by modification of the signalling pathway.
Figure 3 indicated the various phases of sepsis and sought to explain anomalies that are associated with immune response.

Table 1 detailed some recent and ongoing trials of immunotherapy at the time while Table 2 presented the immune effects of opioids with Table 3 reviewing the definitions of sepsis and shock according to the American Thoracic Society and the American Society of Critical Care Medicine while Table 4 presented the problems and challenges of immunotherapy in human sepsis.

In all, the figures were quite informative to the reader and the tables, straightforward, providing some essential insight into the subject matter to an informed reader.

**RECENT ADVANCES RELATED TO THE TOPIC**

**SOURCE**


In a related article, Immunomodulators: A pharmacological Review, published in the International Journal of Pharmacy and Pharmaceutical Sciences on November 13, 2012, Patil et al sought to make an inventory of all immunomodulators, natural or synthetic, providing a basis of their mechanism of action as well as their classification, therapeutic uses and side effects.

To achieve this goal, Patil et al went about reviewing all the relevant literature about the contemporary immunomodulators while at the same time reviewing studies of new plants and chemicals with potential immunologic properties.

As part of their findings, they noted the improvements that have been made in recognizing the contributions of natural herbs in the advances of immunomodulation.

Noticeable, was the revelation of recent studies carried out in Russia on some Siberian plant extracts. These studies proved *Cirsium setosum*, *Aconitum baikalense*, and *Saussurea controversa* as potent natural immunomodulators. The extract of these plants, though dissimilar chemically, had shown similar effects on the immune system and have been successfully used in the treatment of benign and malignant tumours, anti-biotic resistant infections, polyarthritis and psoriasis among others which conventional medicines find difficult to manage.

Even though their article came three years after that of Webster et al, Patil et al had similar lines of thought on the fact that immunomodulation is an aspect of science that is still very much uncovered and complicated and on which much research is still needed to shed light on some of its enigmas.

They also similarly concluded that the immunomodulators are becoming a viable adjunct to
conventional treatment protocols and stand a huge chance of becoming the treatment of choice of many disease conditions in the 21st century.

CONCLUSION

The immune system has evolved to protect the host from invading pathogens and to eliminate disease. Protection from infection and disease is provided by the collaboration of the innate and adaptive immune systems. At its best, the immune system is intricately responsive to invading pathogens while retaining the capacity to recognize self-antigens to which it is tolerant.

In the critically ill, this role becomes even more important as these patients are more in need of a responsive, yet tolerant immune system.

Webster and Galley, in their article ‘Immunomodulation in the critically ill’ presents an objective evaluation of the state of knowledge in the field of immunomodulators and presents the findings of studies designed to find new immunomodulating drugs.

The study findings reveal the importance immunomodulation in the critically ill patient while stressing the need importance of closely evaluating the state of any client for immunomodulation and the need to tailor medications to the specific need of such patients.

It also presents the common fate that most studies designed to find new drugs with immunomodulatory potential have suffered. In an attempt to provide answers to the puzzles of the studies described, the article recommends, among other things, the need for closer monitoring of patients and the use of more than one agent at any time. Also, well-designed studies using a more focused patient group were required.

Upon implementation of these recommendations, new arenas for discovery of immunomodulatory agents may be exploited while elucidating other properties of these agents as the diagnostic capacity of soluble Toll-like receptors (sTLR)[17], among other uses.

REFERENCES


PSYCHOSIS AND CO-MORBID PITUITARY ADENOMA (PROLACTINOMA): A MANAGEMENT DILEMMA

Article Review by Ogunnubi Peter, Nigeria  
(Master of Public Health, Texila American University)  
Email: - petersoluseun@yahoo.com

ABSTRACT

This paper is a clinical as well as diagnostic description of the presentation, investigation and pharmacological management of an 18-year-old young woman with first episode of mental illness; and recently diagnosed pituitary microadenoma (prolactin secreting type).

It brings to light the possible role of prolactin in the development of psychosis, the treatment difficulties commonly encountered in the choice of antipsychotics and / dopamine agonists and the need for an interdisciplinary team approach when patients presents with such complex symptoms.

INTRODUCTION

This case report is a clinical description of Miss BA, a 18-year old woman, who presented for the first time with symptoms of psychosis, which were; visual hallucination, auditory hallucination, persecutory delusion labile affect, delusional misidentification, Aggression, and disorganized behaviour.

She was subsequently placed on antipsychotic (i.m Haloperidol and Tabs Risperidone). Symptoms however became worse 2days after making the psychiatrist to discontinue risperidone.

She was then placed on intravenous diazepam 5mg prn. She however became even more disturbed and could not sleep for two days; thus prompting the need to recommence antipsychotic, only that this time around, it was changed to Tabs Olanzapine 10mg nocte.

After two weeks of using the Olanzapine with no improvement in symptoms, consults were sent to the Endocrinologist who was strongly of the opinion that the Olanzapine should be continued as it may be causing more harm than good by elevating the prolactin level. He then placed the patient on Cabergolin (a dopamine-agonist).

But it became clear after 2 weeks with no response to treatment that there may be a complete interaction with the hyperprolactinemia and the psychosis or the drugs she is receiving for the
hyperprolactinemia (i.e. Cabergoline), even though from the onset, the psychotic symptoms were thought to have arrived primarily, with the finding of microadenoma on the MRI, being an accidental finding.

The clinical effects of increased prolactin levels are poorly understood; even though there are some evidence that increases in serum prolactin level may be associated with severe psychiatric disorders (1).

Dopamine antagonists are used to treat psychiatric symptoms (because of the increase dopamine level), while dopamine agonists are used to treat hyperprolactinemia (thus further increasing the dopamine level). As a result of the potential counteractive nature of the treatment, effective management of individuals who present with both problems is thus extremely difficult (2). Moreso, lack of guidelines regarding the monitoring for hyperprolactinoma in patients receiving antipsychotics only serves to exacerbate the problem (3), otherwise it would have made it possible to know at what level of dopamine is psychotic symptom exacerbated.

This case presentation therefore aims to showcase the importance of teamwork and integrating psychiatry and physical treatment modalities.

**CASE PRESENTATION**

History of the presenting complaints revealed that, Miss BA is from a polygamous setting, the last child of two from a divorced marriage as far back as when patient was 9 years old.

Pregnancy, birth and early childhood history was said to be uneventful. Developmental milestone was said to be at par with other siblings. There was no known medical problem in the past. There is however positive history of mental illness in the paternal grandmother.

Her academic performance however was adjudged to be average, and was able to finish her secondary level of education without repeating any class. She was about to gain admission into the tertiary college (polytechnics) a week before the symptoms began, even though she was said to have been in high spirit concerning the admission.

Premorbidity described as a quiet and easy going person who hardly made friends, but said to have had positive attitude to life.

Miss BA symptoms started a day prior to presentation at the private hospital when she suddenly became sad over her neighbour’s living condition which she described as very pathetic, she then started talking irrationally claiming that children within the neighbourhood were teasing and beating her, she also started sleeping poorly and exhibited vivid visual hallucination as she claimed she could see those children while on the ward; claiming they had come with evil intentions; There was also delusional misidentification as she recognized everyone at a glance, (including the strangers who came into the hospital and would give them whatever name she could come up with, for example, on seeing the attending psychiatrist for the first time she called...
him Joshua! claiming assuredly to have met him before). There were episodes of weeping spells, disorganized behaviour and wondering tendency. There was however no history of head injury or any febrile illness prior to the onset of symptoms.

While in the hospital, (which she refused to accept as hospital, but claimed it was a “Jerusalem” with angles all around); she was occasionally aggressive, especially when prevented from having her ways.

There was also elements of grandiosity as she claimed she was a lawyer, a pastor and engineer, without any proof to ascertain all of these.

She had impaired memory and had difficulty following a train of thoughts.

Mental state examination revealed irrelevant speech, labile affect; her thought content and form were that of persecutory delusion and derailment respectively; perceptual abnormalities identified were visual hallucination and 2nd person auditory hallucination (making derogatory statements). She was also disoriented in time, place and person, (but with occasional lucid interval). Her attention, concentration, and memory were impaired. Judgement was poor and she lacked into her problem.

There were also physical and somatic features (including diarrhea, hyperphagia). She has a moon fascie with multiple striae all over her two thighs and bilateral non pitting oedema.

An assessment of Acute Schizophrenia-like Psychotic Disorder was made to rule out Organic mood disorder.

Laboratory investigations such full blood count, hormonal profile (FSH, LH, Prolactin, T₅ T₄ were all done), all were (N) except for the prolactin hormone level, which was discovered to be fourfold higher, even though as at this time she had only been placed on antipsychotic for two days.

The CT scan and magnetic resonance imaging (MRI) scan of the brain done revealed a lesion less than 10mm within the sellar tursica of the pituitary gland.

Blood and urinary samples were taken and sent to India for cortisol estimation, to ascertain diagnosis of cushion – syndrome (the result however did not come back before the patient left the hospital).

Miss BA, was initially placed on i.m Haloperidol 5mg 12hrly; and Tabs Risperidone 1mg b.d. This was later changed to Tabs Olanzapine 10mg nocte.

The MRI revelation of Prolactinoma (pituitary microadenoma) and poor response following the use of the antipsychotics lead to the discontinuation of the antipsychotics by the attending Endocrinologist and dopamine agonist-Cabergoline was instituted.
There was however little or no improvement after about 2 weeks on Cabergoline, and Miss BA was eventually discharged home against medical advice by the father to seek other local interventions even though miss BA was still in psychotic state.

**DISCUSSION**

Miss BA presented with a constellation of risk factors for mental illness ranging from; positive history of mental illness in the paternal grandmother, her possibly schizoid personality trait, the possibly cushion syndrome, the pituitary microadenoma (Prolactinoma); and the family dynamics from the parents’ divorce. Any of these could have predisposed her into having mental illness, and not the hyperprolactinemia as the endocrinologist argued.

It is possible that Miss BA could have gotten better, has it been that the antipsychotics were continued and allowed to work for a longer period before the Physicians jumped into the conclusion that patient’s psychotic problem was secondary to the underlying organic pathology (Prolactinoma) and that the antipsychotic was worsening her conditions, hence believed that taking care of the hyperprolactinemia will ultimately lead to resolution of the psychotic symptoms.

An important issue that evolved during the cause of Miss BA’s treatment was that, with increasing specialization, medical treatment has moved towards the direction of team work and multidisciplinary approach.

There is increasing evidence for the interaction between physical and mental health (4), for example it has been found that standardized mortality rates increased three fold in patients with schizophrenia particularly with reference to disease of the cardiovascular, respiratory, digestive endocrine and nervous system (5).

The world Federation for Mental Health even highlighted some factors that often result in people with mental illness not receiving adequate health care in relation to their overall health needs; one of such is discrimination and the separation of health care for physical illness from mental health (6). It is notable that separation of physical and mental health care often fragments the total care offered to individuals suffering from a mental illness, perhaps explaining why physical, illness often goes undetected in psychiatry patients (7).

There is no extensive literature on patients with both psychosis and a pituitary tumor (the author), but acute psychosis has been reported elsewhere in a woman with a known prolactinoma (8), and in three patients with psychoses and concomitant prolactin – producing tumors (9).

A reviewed of the literature on bromocriptine (another dopamine agonist such as cabergoline) and psychosis concluded that confusion, hallucination, and delusion have often been reported with the use of bromocriptine (10, 11).
In addition, cabergoline-induced psychotic exacerbation in schizophrenic patients has been discussed elsewhere (12).

Miss BA’s prolactin level was 102ng/mL, normal level is between 2-29ng/mL (13, 14), such an elevation can occur from stress medication (for example, the antipsychotics), a pituitary tumor, and so forth (15). Miss BA had experienced all of these. It is also not impossible that both the pituitary tumor—which is a space occupying lesion, or the high prolactin produced by the microadenoma led to Miss BA’s psychiatric illness. It could even be that she had a co-morbid psychiatry illness (with the? cushion syndrome, and the pituitary adenoma being incidental findings).

It is also possible that the dopamine agonist (cabergoline) which Miss. BA was receiving for the pituitary adenoma promoted and prolonged her psychotic thinking. It could also have been due to the stoppage of the antipsychotics often a week without giving enough time to either change or increase the dose of the antipsychotics before concluding that they were not effective. Although, some authors have reported prolactinoma growth with Risperidone treatment and suggested using other antipsychotic medications, which do not affect prolactin secretion, such as Aripripazole (a dopamine partial agonist) (1, 16).

This could not have however been easily possible in Miss BA’s case considering the fact that the discovery of prolactinoma was 2 days just after starting the Risperidone.

And for the fact that Aripripazole is not easily available in many developing countries, such as Nigeria, Miss BA may not have readily benefited from its use.

Other authors have also recommended the use of Clozapine (another atypical antipsychotic but with lesser effect on dopamine receptor) (9), which is what Miss B could have benefited from has it been that she was discharged against medical advice.

Also successful treatment of schizophrenia with no elevation of serum prolactin levels using combination of Olanzapine and Quetiapine (an atypical antipsychotic) has been reported in a patient who could not tolerate Clozapine (17), but Quetiapine is also not readily available in Nigeria for Miss BA to have benefited from either.

**CONCLUSION**

This case study thus highlights the role of prolactin in psychotic illness, the complexities involved in the management of patients with both psychiatric and medical problems and also the interdisciplinary team approach when patients present with such multiple and complex symptoms.
INVESTIGATION TABLES

LABORATORY INVESTIGATIONS

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>E/U/Creatinine</td>
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</tr>
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<td>Normal</td>
</tr>
<tr>
<td>LH</td>
<td>Normal</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Normal</td>
</tr>
<tr>
<td>Fasting Blood Sugar</td>
<td>7.6mmol/l</td>
</tr>
<tr>
<td>Prolactin</td>
<td>102ng/mL</td>
</tr>
<tr>
<td>Oestradiol</td>
<td>Normal</td>
</tr>
</tbody>
</table>

RADIOLOGICAL INVESTIGATIONS

- CT Scan: inconclusive, but suggestive of a pituitary microadenoma. MRI advised.
- MRI: revealed an 8mm X 6mm tumor in the sella tursica of the pituitary fossa, confirming a microadenoma. Advised to match up the radiological findings with the clinical presentations.

REFERENCES


ABSTRACT

BACKGROUND

Clinical trial monitoring is broadly based on protecting the rights and the well-being of the human research subjects, overseeing the progress of the trial, and ensuring that the trial is conducted in compliance with the applicable regulations, SOPs and study documents. The systematic application of the recently introduced Risk Based Monitoring (RBM) technique is facilitating a collaborative vigilance approach, and a new definition of clinical trial monitor is evolving. A clinical trial monitor no longer seems to be a single entity but a group of people from cross functional teams that share joint accountability for overall data monitoring and quality governance framework.

OBJECTIVE

To explore the evolving role of a clinical trial monitor and other key study team members in the Risk Based Monitoring landscape.

METHOD

A literature search was conducted, followed by several discussions and brain storming sessions with key functional study team members currently working in the RBM pilot trials. Some limitations with this methodology were a lack of available literature specific to the topic under study, as well as the lack of sufficient industry experience in the implementation of the RBM practices at present.

CONCLUSION

Conventional monitoring was based mostly on data review in silos by the monitors. RBM and the associated technologies have created an opportunity to assess the study and center specific risks at each level of the data hierarchy by the appropriately qualified study team members for a continuous governance of clinical study data. The roles and responsibilities of these core study
team members are continuously shifting and it is likely that this shift, along with training and continuous adaptation, will re-define the face of a clinical trial monitor while also leveraging the quality of clinical trial outcomes overall.

A clinical trial monitor role has been critical to ensuring the rights and well-being of the clinical research participants, and assuring the scientific integrity of the data collected. Before the advent of Risk Based Monitoring (RBM) and associated technological interfaces, a monitor had been the one that was typically engaged in the review of individual subject related data points embedded in the case report forms (CRFs). Additionally, in the traditional setting, frequent on-site monitoring with 100% source data verification had been deemed as the “gold standard” for meeting regulatory obligations. Through these on-site monitoring visits, the clinical trial monitor had been assessing and reporting non-compliance, data related errors, and trends at a specific site or sites via on-site monitoring of the data. The key challenges with this approach had been that monitors were reporting mostly data recording and site procedural compliance related errors based on review of the subject data during their visit to the centers. These assessments had been specific to the centers assigned to them and not a holistic view of all the data for the entire study. Additionally, this approach did not address the study design or analytical types of errors.

There has been a correlation between these challenges and the fact that, over the last several years, the types and nature of deficiencies identified through the regulatory inspections have not changed much. Lack of systematic quality assurance and governance throughout the life cycle of a clinical trial has been at the crux of these challenges. RBM may have brought that paradigm shift for the clinical trial industry. Four prominent organizations (CTTI, EMA, FDA and PMDA) and TransCelerate’s initiative have contributed to the evolving concept of RBM by providing guidance in the context of risk and quality assurance between 2008 and 2013.

The FDA issued guidance for the industry on the “Oversight of Clinical Investigations-A Risk-Based Approach to Monitoring (RBM)” makes it clear that sponsors can use a variety of approaches to managing data quality through technology enabled data driven actions, by targeting monitoring activities to where they will deliver the best benefit to the study and patients. This guidance has generated a keen interest among the sponsors and clinical trial sites about its implications and adaptability. Sponsors are diligently working on successful implementation of these strategies. Currently there are 54 active RBM trials (Phase I-IV) that have begin to utilize the TransCelerate RBM methodology across 10 sponsors, within multiple therapeutic areas.

RBM and the associated technological infrastructure initiated at present are creating an opportunity to have the data available in-stream and for the appropriately qualified study team members to assess study, and center specific risks at each level of the data hierarchy for a more systematic governance of clinical study data (Figure 1). RBM related technological platforms are
also allowing for custom landing pages and enterprising the monitoring landscape. These platforms allow for a cross-functional study team member e.g. clinical experts, medical experts, operational management experts and data management experts to have immediate visibility to center-specific data as they are entered and related analytics, metrics, and study performance dashboards. This type of a just-in-time centralized data visualization, surveillance, coupled with triggers and thresholds, allows for the interpretation and identification of areas of concern by the different subject matter experts. This, in turn, sanctions simultaneous mitigation creating an end-to-end holistic data monitoring infrastructure. Therefore, the RBM ecosystem is facilitating fluidity to data monitoring leading to a more collaborative cross-functional team-based data vigilance approach.

**CHANGING ROLE OF THE STUDY TEAM MEMBERS**

**CLINICAL, MEDICAL AND STATISTICAL TEAM MEMBERS**

Within the risk-based landscape, the medical and clinical study team member’s role is being redefined and they are now designing fit-for-purpose predictive protocols based on upfront classification of critical data and study processes needed for multi-level risk identification. These types of predictive protocol, which go through peer review, help manage trial design-related issues. The statistician is also being involved at the protocol design phase, so that the reporting and analysis plan could also be aligned with the critical data and adjusted for the identified risks. These scientifically and medically qualified study team members are proactively reviewing incoming data, identifying trends and triggers associated with the data and assessing the impact of errors on human subject protection and data integrity. The feedback received from the clinical team members allows for the clinical trial monitor to continuously shift their monitoring and source data verification strategies at a specific site. This focused central monitoring by the subject matter experts is presumed to expectantly lead to continuous mitigation of critical issues pertaining to human subject safety and data integrity. As a result, there is interdependence (Figure 1) undertaken between the clinical trial monitor and the study team members in driving the culture shift towards a more in-stream data visualization, review, and quality governance.
DATA MANAGER

Similarly, data manager’s role in the end to end study delivery has significantly broadened, which requires leading interactions with the monitoring team with conversations to translate the protocol into the case report forms; study specific monitoring plan, source data sampling plan and also with the technical team to translate the identified Key Risk Indicators (KRIs) into visuals. Data Managers are playing a more active role in centralized data analysis, trend and trigger identification. They are taking on a bit of the project management type focus on monitoring plan, source data verification and center specific monitoring sampling strategy. There also seems to be a greater overlap of roles between the data leader and the clinical trial monitor as they begin to identify the outlier sites, systematic, regional-cross site issues via the use of the in-stream informational analytics. The data managers in RBM are instrumental in designing the site specific source data sampling and monitoring activity plans based on the site specific triggers identified. RBM has shifted the role of a traditional Clinical Data Manager from a “data curator” to a very critical “information based” function which requires them to monitor and interpret the data in a routine fashion as they are received. The data managers are thus predicting study related
outcomes signals based on real time analysis of the risk indicators identified \[8\]. In addition, data managers also are now engaged in the training of visuals technology and communicating findings and issues to the study team members and the monitors. Therefore, in the new RBM ecosystem, they are also performing a traditional monitor’s task by reviewing data reported and analyzing the signals that might adversely impact the rights and safety of the clinical trial subjects.

**OPERATIONAL OR STUDY MANAGER**

In the same paradigm, a study or operational manager’s role is also being redefined as they lead the study towards an integrated, convergent, holistic, just-in-time data monitoring and quality by design paradigm \[2\]. Within this platform, the study manager is engaged from protocol design to study report generation. They are essential to ensuring that the study protocol is sliced and diced appropriately during the design phase to embed key risk indicators (KRIs) in regards to impact on patient safety and interpretation of results. Along with the establishment of predictive protocols, they are also assisting in designing operational plans that helps support an adaptive review and centralized monitoring of incoming data based on the risk assessment and supported analytics.

In addition, study managers are responsible to ensure appropriate analytics are in place to perform centralized review and just-in-time interpretation of study data. Within the risk based archetype, they are required to liaise with more stakeholders, are accountable in ensuring that all functional team members have reviewed the analytic ready data accordingly to their functional expertise; the risks are assessed, adjusted and mitigated to improve the probability of success. All in all, they play the role of the conductor in leveraging real time data review from numerous functions and applying the knowledge created to execute just-in-time decisions that improve trial efficiency and patient safety. They also play a key role in data review, trend analysis and trigger assessments. They are accountable for having continuous conversation with monitors on site and study specific risk indicators, targeting and tailoring the center specific monitoring plans on an ongoing basis and helping them flex the implementation of monitoring strategies at the center level through the course of the study. Therefore, in the new RBM ecosystem they are also performing a traditional monitor’s task by ensuring incoming data as received is complete and the analyzing the signals that might adversely impact the rights and safety of the clinical trial subjects and quality of the data reported.

**CLINICAL TRIAL MONITORS**

Within the Risk Based Monitoring paradigm, the most significant change that a clinical trial monitor has to go through is behavioral. There needs to be adjustments by the clinical trial monitors in abandoning the traditional 100% source data verification \[9\] psychology. They will need to re-educate themselves in risk based source document verification philosophy which is
based on targeted critical data driven sampling strategy. The most challenging aspect would be willing to shrug off the inherent perception associated with the “off-site” monitoring while still holding on to the merit of the in-person monitoring. The clinical trial monitors in the risk based monitoring environment are consistently utilizing risk indicators; risk assessment practices and tools for value driven discussions with their sites. They have to be technologically savvy to decipher the data visualization predictive tools to escalate risk-decisions identified and execution of corrective and preventative plan. The clinical trial monitors will have to rely on the assessment and analysis made by the cross functional study team members in driving their site specific monitoring strategies leading to a more engaged and collaborative monitoring overall. In addition, the clinical trial monitors must have the willingness to understand and adapt new technology and innovations as we move more and more towards cloud based architecture, electronic document collaboration, and centralized content repositories. This type of shared data monitoring throughout the life of a study will aid in the delivery of effective risk based quality governance framework and lead to the changing face of the monitor in the future. As technology becomes the mainframe of monitoring, a clinical trial monitor may evolve to be someone with not only scientific and clinical expertise but someone with combination of these and the technological expertise.

These affirmative changes in the real time monitoring archetype, comes with its own challenges. Some of the current challenges are highlighted below.

- Streamlining the training and understanding of risk based monitoring among all stakeholders including clinical research sites
- Implementing behavioral and skill related change management system
- Effective and consistent utilization of risk indicators; risk assessment practices and tools by different cross functional team members
- Appropriately implementing RBM model in a global landscape
- Continuously evaluating and re-defining the model and implementation strategies

In conclusion, conventional monitoring was based mostly on data reviewed in silos by the monitors. RBM is bringing a paradigm shift from the conventional means [9]. This will need coordinated, focused and streamlined efforts to be successful, leading to a team based approach [10], [11]

Risk Based Monitoring is creating interdependency in data monitoring and quality governance framework. A monitor no longer seems to be a single entity, but a group of people from cross functional teams that share a joint accountability. However, the adoption of the risk based principles and the quality governance framework is still at its infancy and will need to go through the behavioral and technical adjustments in the years to come before it hits its maturation. All
stakeholders in the clinical research environment will not only need to be aware, educated and trained, but also willing to change, re-train and adapt, and then we may be able to see improved safety and quality in clinical trial outcomes overall.

DECLARATION OF CONFLICTING INTERESTS

The Author(s) declare(s) that there is no conflict of interest.

DECLARATION OF FUNDING/GRANT

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CREDITS

This paper was reviewed by Texila American University Faculty Advisors Dr. Manoj P. Jadhav and Dr. Amandeep Singh.

REFERENCES


SPECIAL ISSUES IN CLINICAL RESEARCH: CONFLICT OF INTEREST, POST TRIAL DRUG ACCESS AND USE OF PLACEBO IN CLINICAL TRIALS

Article Review by Maduri Patel, Kannan Sridharan, Jayesh Patel, Shraddha Ghai, India
(PhD in Clinical Research, Texila American University)
Email: madhuri_zeal_112@yahoo.com

ABSTRACT

The aim of this study is to identify ethical issues and challenges in clinical research in India. This study provides clear picture of special ethical issues in clinical research such as conflict of interest, post trial access to investigational product and use of placebo. We examined clinical research professional perceptions on those issues.

Individuals (N=385) working in field of clinical research in India have participated in the study. This study involves self administered survey research for collection of data and information from participants through their responses. The survey questionnaire was validated by colleagues and guides and experts in the field. The survey elicited responses based on general experience and opinions of clinical research professionals. Participants were given the option to complete the survey on the internet. Surveys completed via the internet were stored in Microsoft excel. For data analysis SPSS software have been used and descriptive analysis have been conducted.

A total of 389 surveys were received, of which 385 were considered complete and used for this analysis. The respondents were from India, currently working in clinical research field. Demographic information pertaining to respondents such as education, type of organization age, experience etc have been collected, whether they had ethics training ever, and if yes which type of training they had. The data shows that majority have responded that they are not favouring post trial access to investigational product or it is not ethical. Further to that, participants were asked to select reasons for their opinion on post trial access to investigational product. If participant believes that post trial access to investigational drug is ethical, they have selected applicable reasons for their opinion. Majority of respondents favour use of placebo in clinical trials in general. If participant is favouring the use of placebo, further they have provided their opinion on possible steps to be taken care of in placebo controlled trial. Participants has been asked to rate the factors which can promote or causes conflict of interests in clinical trials. As per data, financial gain is the most affecting factor causing conflict of interests. Comparing
responses employer wise, CROs, ECs and Study sites are rating “recruitment target” more than sponsors. The data shows that industry influence, patent or other commercial benefits are not highly affecting.

KEY WORDS

Placebo, Conflict of interest, post trial access, ethics

INTRODUCTION

Clinical research is well defined and organized research conducted on human beings, to provide information on drug’s safety and efficacy. There are international and national recognised clinical research guidelines that form the basis for conduct of ethical clinical trials. Many human research codes and guidelines have developed over the past century such as the Declaration of Helsinki, Nuremberg Code- a set of ethical principles for research on human being. These ethical principles formulated after discovery of inhumane behaviour with humans. Ethics in clinical research largely focuses on acceptable conditions for exposure of clinical trial participants to burden and risk for the benefit of society. The focus of ethical clinical trial has been on protocol review, monitoring of subject safety and welfare, study design, informed consent etc. this article describe the special issues arises in conduct of clinical trial i.e. post-trial access of investigation product, use of placebo in clinical trials and conflict of interests.

Investigators are failing to disclose financial ties, considerable payments, gifts to physician. To prevent the situation every entity involved in clinical trials should take initiative to adopt stringer policies. Hundreds of journals publish innumerable research paper, and based on these literature clinical guidelines are prepared. Thus biomedical research also feeds the judicious use of current best evidence for treatment and patient care decision. Conflict of interest is a condition and therefore circumstances determine presence of conflict of interest.

Post-trial access (PTA) to investigational product has been a matter of discussion since late 1980s, linked with trial carried out for acquired immunodeficiency syndrome in developing country. However, the complexity of the issues is not ways to address and required specific discussion. This concern is certainly in developing countries due to poverty, illiteracy, limited resources, insufficient access to healthcare services and lack of familiarity with clinical research. Post-trial access to study drug is merely not ethical issue but also includes legal and policy issues and disputes.

METHODOLOGY

The study involved a self administered survey and was approved by the Texila American University Advisory Committee. It consisted of 35 questions, covering informed consent, ethics committee reviews, post trial access of investigational product, financial and non conflict of interests, regulatory rules and guidelines, ethical codes and principles, use of placebo,
misconducts, documentations, clinical researchers’ recommendations. The survey questionnaire was peer reviewed by colleagues and guides and experts in the field. The survey elicited responses based on general experience and opinions of clinical research professionals. Questions related to conflict of interests, post trial access and conflict of interests will be reported in this paper. The study has no source of external funding and funded by the author. Snowball sampling method was used for data collection as respondents are difficult to locate. Few clinical researchers have been located and contacted via email and/or telephone, and invited to participate in the survey. Then asked those participants to provide information needed to locate other individuals who were eligible to participate in the survey. Invitation to participate in survey was assumed to have reached 380 participants. Participants were given the option to complete the survey on the internet. Data collection took place over five months. No incentive was given to participants. Surveys completed via the internet were stored in Microsoft excel. Survey in which minimum 10 % of questions were answered was considered “complete” and was used for data analysis. This database was used to determine frequency of responses by each variable and multivariate analysis to evaluate correlation of two or more variables. To measure the strength of association between variables, tests of significance, such as x2 test and respective p values, were calculated.

RESULT

A total of 389 surveys were received, of which 385 were considered complete and used for this analysis. The survey was designed such that there were skip patterns for some questions; therefore the number of responses (n) varies for different questions. The respondents were from India, currently working in clinical research field. Demographic information pertaining to respondents is shown in figure number 1 to 3 (age, Education, type of organization) Figure 1 shows, 169/385 (43.9%) of participants are 36 to 45 years of age followed by 21 to 35 Years 142/385 (36.9%) and 46 to 60 years 74/853(19.2 %). Type of organization where participants are working or belong to is shown in figure 3. Out of 385 participants, 181/385 (47 %) are working with site and 162/385 (42.1%) are associated or working with CROs. 19/385 (4.9 %) of participants are working in EC and 19/385 (4.9 %) with sponsor companies. These data shows that most of the research activities must be taken care by CROs and research sites. As per current practice, most of the sponsors are outsourcing research activities to CROs, so it is obvious that much less people from sponsors’ end are involved in clinical trials.
Table 1 shows the number of years working experience of participants in clinical research. The data shows that 146/385 (37.9%) participants have 11 to 15 years of experience in field of clinical research, while only 10/385 (2.6%) are having less than 2 years of experience. 236/385 (61%) of sample had more than 10 years of research experience.

<table>
<thead>
<tr>
<th>How long have you been working in field of Clinical research?</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 2 years</td>
<td>10 (2.6%)</td>
</tr>
<tr>
<td>3-5 years</td>
<td>39 (10.1%)</td>
</tr>
<tr>
<td>6-10 years</td>
<td>100 (26.0%)</td>
</tr>
<tr>
<td>11-15 years</td>
<td>146 (37.9%)</td>
</tr>
<tr>
<td>16-20 years</td>
<td>74 (19.2%)</td>
</tr>
<tr>
<td>More than 20 years</td>
<td>16 (4.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>385 (100.0%)</td>
</tr>
</tbody>
</table>
In the questionnaire, participants are asked whether they ever had formal research ethics training. Table 2 shows 233/385 (60.5%) of participants have responded that they had formal research ethics training while 152/385 (39.5%) had never attended formal ethics training during their career. Further to that, participants are asked which type of research ethics training they have attended if they have answered yes. It is also possible that few participants have attended more than one type of training. Figure 4 shows the type of ethics training participants have attended. Our data suggests that we need to develop research ethics program and courses. Online program can be more useful as more professionals can be benefited and international standards of ethics can be developed.

**Table 2: Formal research ethics training**

<table>
<thead>
<tr>
<th>Have you ever had formal research ethics training?</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>233 (60.5%)</td>
</tr>
<tr>
<td>No</td>
<td>152 (39.5%)</td>
</tr>
<tr>
<td>Total</td>
<td>385 (100.0%)</td>
</tr>
</tbody>
</table>

Our data shows that only 101/356 (28.4%) of respondents have ever served in EC, and 255/356 (71.6%) have never served in EC.
Table 3: Post trial access to investigational product

<table>
<thead>
<tr>
<th>Should post-trial access to investigational drug is ethical?</th>
<th>CRO</th>
<th>EC</th>
<th>Study Site</th>
<th>Sponsor</th>
<th>Other/SMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>162 (100.0%)</td>
<td>19 (100.0%)</td>
<td>180 (100.0%)</td>
<td>19 (100.0%)</td>
<td>4 (100.0%)</td>
</tr>
<tr>
<td>Yes</td>
<td>24 (14.8%)</td>
<td>7 (36.8%)</td>
<td>59 (32.8%)</td>
<td>6 (31.6%)</td>
<td>3 (75.0%)</td>
</tr>
<tr>
<td>No</td>
<td>138 (85.2%)</td>
<td>12 (63.2%)</td>
<td>121 (67.2%)</td>
<td>13 (68.4%)</td>
<td>1 (25.0%)</td>
</tr>
</tbody>
</table>

Figure 5: Reasons if participant favouring post trial access to investigational product

During the survey, participants have been asked whether they support post trial access to investigational product to subjects. The data shows that majority have responded that they are not favouring post trial access to investigational product or it is not ethical. Table no. 3 shows the summary of their responses. Participants from CROs 138/162 (85.2%) believe that post trial access to investigational drug is not ethical and 3/4 (75 %) from other organizations or SMOs believe that it is not ethical. 13/19 (68.4 %) participants working with Sponsor believe that it is not ethical. When looking at responses from study site and EC members respectively 59/180 (32.8%) and 7/19 (36.8%) participants believe that it is ethical.

Further to that, participants were asked to select reasons for their opinion on post trial access to investigational product. If participant believes that post trial access to investigational drug is ethical, they have selected applicable reasons for their opinion. Figure 5 shows that 36% of participants have selected “If the IP is found to be beneficial and not going to be marketed” and
30% of participants have selected “Trial subjects may not afford the commercial drug and it could be given at no cost to reciprocate their contribution to science”. 18% believes that “Patient may benefit and get used to the drug where in it would be difficult for investigator to withdraw the drug post trial completion”, while 16% have selected “Humanitarian grounds only in case of terminal illness”. Figure 6 shows the reasons if participants do not favour post trial access to investigational product. 48% participants have selected “post end of study could change the efficacy/safety information to preclude such treatment”.

Figure 6: Reasons if participant not favouring post trial access to investigational product

Table 4: Use of placebo in clinical trial

<table>
<thead>
<tr>
<th>Do you favour use of placebo in clinical trial in general?</th>
<th>CRO</th>
<th>EC</th>
<th>Study Site</th>
<th>Sponsor</th>
<th>Other/SMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>150 (100.0%)</td>
<td>18 (100.0%)</td>
<td>178 (100.0%)</td>
<td>19 (100.0%)</td>
<td>4 (100.0%)</td>
</tr>
<tr>
<td>Yes</td>
<td>145 (96.7%)</td>
<td>16 (88.9%)</td>
<td>168 (94.4%)</td>
<td>18 (94.7%)</td>
<td>3 (75.0%)</td>
</tr>
<tr>
<td>No</td>
<td>5 (3.3%)</td>
<td>2 (11.1%)</td>
<td>10 (5.6%)</td>
<td>1 (5.3%)</td>
<td>1 (25.0%)</td>
</tr>
</tbody>
</table>
Whether participants favour use of placebo in clinical trials is shown in Table 4. Majority of respondents favour use of placebo in clinical trials in general. If participant is favouring the use of placebo, further they have provided their opinion on possible steps to be taken care of in placebo controlled trial, as shown in Table 5, where group analysis is presented.

**Table 5: Justifications in which situation Placebo should be used**

<table>
<thead>
<tr>
<th>Justification</th>
<th>CRO</th>
<th>EC</th>
<th>Study Site</th>
<th>Sponsor</th>
<th>Other/SMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>145 (100.0%)</td>
<td>16 (100.0%)</td>
<td>165 (100.0%)</td>
<td>18 (100.0%)</td>
<td>3 (100.0%)</td>
</tr>
<tr>
<td>The said disease had no defined/established standard of care</td>
<td>96 (66.2%)</td>
<td>6 (37.5%)</td>
<td>62 (37.6%)</td>
<td>6 (33.3%)</td>
<td>1 (33.3%)</td>
</tr>
<tr>
<td>Adequate rescue procedures for patient withdrawal and safety management ensured</td>
<td>68 (46.9%)</td>
<td>8 (50.0%)</td>
<td>99 (60.0%)</td>
<td>10 (55.6%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Back-up investigators present at the site for additional oversight</td>
<td>26 (17.9%)</td>
<td>5 (31.3%)</td>
<td>47 (28.5%)</td>
<td>4 (22.2%)</td>
<td>2 (66.7%)</td>
</tr>
<tr>
<td>Additional monitoring ensured by the sponsor/CR O</td>
<td>77 (53.1%)</td>
<td>9 (56.3%)</td>
<td>70 (42.4%)</td>
<td>11 (61.1%)</td>
<td>2 (66.7%)</td>
</tr>
<tr>
<td>Standard treatment should also be available with placebo</td>
<td>34 (23.4%)</td>
<td>4 (25.0%)</td>
<td>28 (17.0%)</td>
<td>4 (22.2%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 6: Conflict of interest

| Rate the following areas of conflict of interest in clinical trial according to their existence. (1 is minimum, 10 is maximum) | Median |
| --- | --- | --- | --- | --- | --- |
| | CRO (1-10) | EC (1-10) | Study Site (1-10) | Sponsor (1-10) | Other/SMO (1-10) |
| Academic (Desire for prestige, power, faculty advancement, interest in obtaining positive results, pressure/desire to publish, recruitment target) | 4.0 (1-7) | 4.0 (3-7) | 4.0 (2-9) | 5.0 (2-10) | 4.5 (1-7) |
| Institutional conflict of interest | 5.0 (1-8) | 5.0 (4-7) | 5.0 (1-9) | 5.0 (2-8) | 6.5 (2-8) |
| Personal (Preference for family and friend, desire to alleviate human pain and suffering) | 3.0 | 3.0 | 3.0 | 5.0 | 4.5 |
| Compromise in appointment or promotion | 3.0 (1-9) | 3.0 (1-6) | 3.0 (1-8) | 3.0 (2-10) | 4.0 (1-4) |
| Its relative weight in professional decisions on meeting recruitment targets may pose problem | 7.0 (1-9) | 7.0 (3-8) | 7.0 (1-9) | 3.0 (1-7) | 5.5 (1-6) |
| Industry influence, patent or other commercial etc | 1.0 (1-9) | 2.0 (1-9) | 2.0 (1-10) | 3.0 (1-8) | 7.0 (5-9) |
During the survey, participants have been asked to rate the factors which can promote or cause conflict of interests in clinical trials. Table 6 shows the summary of responses. As per data, financial gain is the most affecting factor causing conflict of interests. Comparing responses employer wise, CROs, ECs and Study sites are rating “recruitment target” more than sponsors. This topic should be studied more because the data shows there might be a gap between perceptions of sponsors and other clinical research professionals about recruitment target. It could happen because sponsor wants to recruit patients as soon as possible, but they might ignore the fact that it can cause conflict of interests. The other factors causing conflict of interest such as academic desire, institutional conflict of interests, personal, ignorance in reporting adverse events, compromise in appointments, favouring other stakeholders are also shown in Table 6. The data shows that industry influence, patent or other commercial benefits are not highly affecting but SMOs/others rated it little high. It could be because very few numbers of participants are from that type of organization. However, we cannot ignore the value, and further research is required for the same. Table 6 gives more detail about the rating for other factors.

DISCUSSION

This study reflects the expressed opinions and attitudes of a sample of clinical research professionals from India and has provided an insight into ethical issues in poor setting. To our knowledge this is the first study of this nature with empirical data from Indian respondents. Over the past few years, pharmaceutical companies have shifted trials to developing countries like India because it is easier, cheaper and oversight is minimal. However, regulatory has not expressed a stand on manner in which the industry is growing in India.

Conflict of interest is “a set of conditions in which professional judgement concerning primary interest such as research, education or patient care tends to be biased or influenced by secondary interest such as financial gain or personal prestige”.²
Sometimes, investigators recruit patients for experiments where patients are even not well informed about the study whether the study is funded by government and investigators have n possibility of financial gain from it. In such cases, the primary motive is academic that desire to gain knowledge. And the secondary motive is to advance career by publishing the result of research and to get grant support, academic currency that buys prestige and promotion. Several studies have shown the financial conflict of interest make doctors to refer patients for particular medication, test, operation or procedure. Conflict of interest have effect on publication too. Sometimes it happens that papers published in journal supplements sponsored by pharmaceutical companies are poor to those in parent journal.

There may even be a conflict where a person is working as a research and physician at the same time, Where investigator have additional interests that may not be relative to their patient’s interest. A secondary interest could be altruistic for example the continued employment of the researcher. A typical example of conflict of interest related to personal gain is physician self-referral. As described in about definition of conflict of interest, the reference to “set of conditions” is important; having a conflict of interest is an objective situation and does not depend on underlying motives. The potential for conflict of interest on the part of the investigator is widely expressed concern. Conflict of interest can lead to bias in design, conduct, analysis, reporting and interpretation and communication of result. Thus, the conflict of interest is generally considered in the financial, but other conflicts such as intellectual may also occur.

Ideally, no investigator would have any interests other than the well-being of the study participants and the generation of new knowledge that will improve clinical care and public health. That is unrealistic, however, given that most investigators receive research funding from government, industry, or others with considerable interest in the outcome of the study.

During past two decades, increasing attention has been paid to financial conflict in clinical research because of relationship between investigators and industry. This relationship causes conflicts in conducting, interpreting and reporting of research. The death in 1999 of subject enrolled in study in which investigator and sponsor had financial interests accelerated efforts to raised concerns for financial conflict of interests. However, the death of other research subject is not only because of financial conflict. Sometimes, the problem include the excessive zeal of an investigator to complete the study, an inadequate literature review on toxicity, the potential vulnerable patients to serve as subject, failure to report adverse events to ethics committees, use of poorly trained personnel to measure dose etc. Deaths and injuries are rare even in research involving volunteers who have no underlying diseases. There is no reason to believe that it occurs in studies in which financial conflict is existing.

The first step in managing financial conflict of interest is for the leader to acknowledge that these conflicts are basic to research, whether or not there is financial conflict of interest. Each institute must promote expectation that each person involved in research will act with that conflict firmly in mind. Institutional policies should address both the financial and nonfinancial conflict of interests. The institutional emphasis on this category of conflict of interest wills ethics
committees in their difficult task of balancing the value of research and safety of patients. The EC members themselves subject to the influence of a nonfinancial conflict of interest as majority of them are researcher, employees and colleagues of investigators. The National Bioethics Advisory Commission has recommended that persons who represent the perspectives of subjects, who are not researchers, and who are not affiliated with the institution should collectively make up at least one quarter of IRB membership. This would be an important step in dealing with nonfinancial conflicts of interest. A second step can be expanding audits of ongoing trials. Analysis of the problems leading to deaths indicates that excessive zeal in trying to complete the trial. Disclosure is the golden rule in managing conflict of interest. To judge whether one is in effect of conflict of interest can be revealing to ask the question: “would I feel comfortable if patient found out about my interest?” when the answer is “no”, at a minimum discloser is sensible. The role of disclosure of financial relationships to participants and others has been reviewed and recommendations proposed. Among these recommendations, it was noted that because many participants may not fully appreciate the impact that financial relationships might have on research design, conduct, and analysis, in addition to requiring disclosure, IRBs and others should “play a significant role in determining the acceptability of these relationships.”

A non-government and non-profit organization the Council for International Organization of Medical Sciences (CIOMS) has been established by World Health Organization (WHO) and United Nations Educational, Scientific and Cultural organization (UNESCO) in 1949. In 1993, the publication by CIOMS mentioned that the product under study should be reasonably available to the community and country that hosted the study, and in case of exception, proper justification and agreement by all concerned should be submitted before start of the study. The sponsor and the investigator shall make every effort to ensure that any intervention or product developed or knowledge generated, is made reasonably available for the benefit of the population or community. The declaration of Helsinki points out that the post trial access is a benefit only to subject, while CIOMS extends to include community and population. The CIOMS proposes that the documentation on post study availability should be incorporated into the Informed consent form, while Declaration of Helsinki demands that it should be documented in protocol.

The universal Declaration on Bioethics and Human Rights (UNESCO, 2005) includes the text: “benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries”. However, the benefits can take many forms, not only post trial access to investigation drug. Unfortunately there is no firm consensus regarding how best to respond because many other difficult questions arise for regulatory and policies with the post trial access of study drug. Should subjects have priority access over others? Do they have any legally or ethically valid claim for continued access of investigation drug? Who will bear costs if there is an obligation to provide subject with post study access, whether sponsor, investigator, CROs, medical centres where the research is conducted? In the ICMR guidelines 2000, there is no separate mention of PTA. However, the principle of non-exploitation deals with the kind of remuneration, care and
compensation in case of study related injury. In the revised guidelines issued in 2006 (Ethical guidelines For Biomedical research On Human participants: ICMR 2006) under the principle of maximization of public interest and distributive justice, states that: “Whereby the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged, and in particular, the participants themselves and or the community from which they are drawn”. It refers to the Helsinki Declaration and quotes the same (2004) on PTA. Study participants who have risked harm or experienced other research related burden for good of clinical trial may highly value continued access to study drug, even if it offers marginal therapeutic improvement.

While investigator may have less regards for participants’ needs and place more value on ensuring that the trial continues to a valid statistical stopping point. Investigator might want to conduct new trial with different subject to reasonable degree of scientific acceptability. The sponsors may have fewer concerns about subjects’ needs for business reasons. Sponsors perspective in providing access enables collection of data that lengthens product's market-life and improves company's public image but also reduces its share-holders’ profits and funding of other projects. The commitment for post trial access reduces the incentives to conduct research due to financial constrains especially for academic projects. Sponsors lack power to make unilateral decisions about PTA, priorities of agencies providing health care in host country may differ from sponsor Meanwhile regulatory may focus regulatory review on whether trial data justifies approving the new drug for marketing.

Few studies have been conducted on post-trial access and related issues and most of them are on HIV/AIDS trials. A qualitative study, carried out through focal groups in Kenya, with 89 subjects (potential patients for HIV/AIDS studies, researchers and administrators) has brought, as conclusion, that it would not be reasonable to discontinue therapy after studies in HIV/AIDS patients, except in fully justified cases. A study carried out through interviews with presidents and members of research ethics committees (RECs), as well as researchers and research participants, evaluated the ethical aspects related to conducting clinical trials outside the United States. Sixty-five of 94 questionnaires sent to members of RECs returned, as well as 117 of 159 sent to researchers and 359 of 510 sent to research participants. Eighty-three percent of research participants (of which 43% were from Latin America, Brazil included), 29% of RECs members and 42% of researchers said the drugs should be provided for all infected people worldwide, if proven beneficial. Most research participants from Europe and Latin America said that the drug should be continued, while those from North America, Australia and Thailand said that the drug should be made available at a price that a middle-class individual could buy.

A systematic review of clinical studies enrolled in international registries, from 2004 to 2007, was carried out by Cohen et al. involving HIV/AIDS, malaria and tuberculosis. Of the 312 studies that were included, the majority in developed countries (56%), with 28% being sponsored by pharmaceutical companies, only 4 (1.3%) mentioned post-study provisions: one mentioned the post-study drug would be provided by the governments of the respective countries; another,
that the participants who became infected with HIV during the study would receive counselling and education about the infection/disease and access to necessary healthcare, including free-of-charge antiretroviral drugs, if indicated. Sofaer et al.\textsuperscript{20} described the opinion of 93 individuals who participated in clinical trials in chronic diseases in the United States. In this study, patients were divided into 10 focal groups. Many participants felt that researchers, sponsors and insurance companies should share the post-trial obligations. Others commented that no care or drug should be necessary after the research, but there was an almost general agreement that patients should receive information about the study and its results. The authors conclude by suggesting that the debate on post-trial obligations must go beyond the issue of the test drug. Reviewers and commentators have worried about the possibility of undue inducement from continued provision of treatment. If continued access to treatment is guaranteed, the treatment access may be so attractive that an individual might be unable to refuse participation even if he or she wanted to.\textsuperscript{21}

Even if the rationale for assuring continued treatment is compelling, the question of who should be responsible for assuring this and how it should be accomplished remains. It has been argued that if pharmaceutical companies and sponsors are made solely responsible for assuring continued access to beneficial treatment, this requirement could serve as a major disincentive for companies to engage in certain kinds of research.\textsuperscript{22} This could also jeopardize the future of research in places with limited healthcare access, especially for diseases that might require chronic or expensive treatment.\textsuperscript{23} Commentators worry about the possibility of dampening research in developing countries where new treatments are needed the most.\textsuperscript{24}

However, Post trial access to participants of phase II trial is unarmed where the benefit of the investigational product is still at risk. The benefit of drug is always a relative term in many clinical trials, and it often difficult to quantify the benefit of study drug compared to the standard treatment which forms the basis to advocate it during the post trial periods.\textsuperscript{25} Phase I to III trials do not provide proof of safety but evidence. It is observed many a times that after the drug introduced in larger population, the rare adverse effects are made known. In such case, it is not ethical to prolong exposure of investigational medicine, when standard treatment is available. Again what if drug is not approved? It is ethically not acceptable to expose participants to ineffective drug for extended duration. Clinically the claim for post trial access is more valid when no alternative effective and safe treatment is available. The extension of benefits leads undue inducement and participants joining the trial to obtain access to medication.\textsuperscript{25}

Subsidized access to drug that have been proven successful might be the best alternative to benefit to the host community and it can reduce inequalities between resource poor and rich countries. It can ensure faire division of burden and benefits between host countries and that sponsor the trial. Sometimes more than the benefits to participants, the community may be given benefits in an indirect way such as clinics and giving education on maintain good health practices, improving their living conditions etc.\textsuperscript{26}
In last few years, use of placebo in clinical trial has been criticized a lot and many authors have argued that placebo controlled trials are unethical when known therapy is available, not considering the consequences or the condition of deferring treatment. Some have emphasized that the comparison of new treatment with old treatment is sufficient and disputed the value of placebo controlled trials.

If we take the requirement of Declaration of Helsinki literally that all patients should receive best proven therapeutic method, it will bar all clinical trials, including historically controlled trials, because when effective treatment exists the patients taking study drug are not receiving best proven treatment. According to Temple and Ellenberg, many classes of drugs considered as effective cannot be demonstrated to be superior to placebo in 30 to 50% of studies. The problem could be the small response that varies among population, study samples that improve spontaneously, unresponsive to drug, insufficient compliance or concomitant medications or any other reasons. In such circumstances, they believe that apparent equivalence of a new drug to a standard medication may not imply that the new drug is effective, because there is doubt whether standard treatment is effective, where placebo controlled trials are needed to demonstrate new medications safety and efficacy profile.

Patient willing to participate in placebo controlled trial must provide fully informed consent, and patient must be informed of existence therapy and must be able to understand the possible side effects of new therapy with camper to available one. These concerns apply as much to the patient’s decision to forgo known effective treatment and risk exposure to a potentially ineffective or even harmful new agent in an active-control trial as to a decision to accept possible persistence of symptoms in a placebo-controlled trial. So, the problem is not unique to placebo controlled trial. Although in many cases application of this standard will be fairly straightforward, in others it will not and there may be debate about the consequences of deferring treatment. For these reasons, placebo controlled trials may be conducted ethically even when effective treatment is available, as patient will be adequately informed about alternative therapies and will not be harmed by participation. On other hand, the ability to conduct placebo controlled trial in given situation does not mean that placebo controlled trial should be carried out over when effective therapy exists. Researchers might prefer active treatment to be given to every participant. Now here the question is why placebo controlled trial are needed and often cannot be replaced by active control trials. The limitations of active-control equivalence trials that are intended to show the effectiveness of a new drug have long been recognized and are well described, but are perhaps not as widely appreciated as they should be. A recent proposed international guideline on choice of control group addresses this issue in detail.

In placebo controlled trials patient s are not untreated all the time. Sometimes investigational drug can be assessed by using add-on study design, where all patients will be given standard therapy and will be randomly assigned to placebo or new drug. Such design can be use for the indications where standard therapy cannot be omitted ethically, for example cancer, epilepsy, heart failure etc. ‘Randomized withdrawal’ and ‘early escape’ study designs limit the duration of
placebo exposure without compromising the rigidity of study. In a randomized withdrawal study, apparently responsive patients are given an investigational therapy for a period and are randomly assigned to receive placebo or to continue active therapy. In an “early escape” study, patients are randomly assigned to receive new drug or placebo, but a well defined treatment failure end point is used as the basis for changing therapy in patients who are not benefiting from their initially assigned treatment. This design was initially proposed by Amery\textsuperscript{33} as a way of avoiding extended placebo treatment of patients with angina pectoris. A particular value of the randomized withdrawal study is that it demonstrates a persistent effect for durations that would be difficult to study in placebo-controlled trials.

The another argument in favour of conducting a PCT is based on a principle of ethics, that of utility, which is to always produce the maximal balance of “positive value” over negative value. PCTs provide quicker and more reliable answers to scientific questions. However, using a utilitarian calculation to justify placebo use in conditions that result in morbidity, and/or mortality, violates the principle of beneficence, even if consent is obtained.\textsuperscript{34} Ethical principles sometimes conflict with the scientific rigour of the trial: this argument was based on the assumption that PCTs are methodologically superior and hence beneficence and informed consent may be trumped by “scientific rigour, justice and social utility.”\textsuperscript{35}

**CONCLUSION**

In research context of the primary interest is scientific knowledge where as in clinical practice the primary obligation of physicians is to their patient. A secondary interest may be financial, also consist personal prestige and academic promotion and recognition. The research interests, although often is concordance with patient’ interests, are secondary to clinical care and may conflict with it. Many concerns exists the ability of clinical investigator to provide the information to patient regarding participation in trial in such a way that he/she to recognize the distinction between therapy and research.

The decision on providing access to investigational drug after completion of clinical trial should be based on two dimension, SAFETY and EFFICACY assessment. All clinical trials have its own assessment based on disease and study populating as per their specific needs. Therefore, the post trial obligation cannot be generalized and be considered the same in all trials. Nonetheless, it should be assured that relationship between patient and physicians during study must be always terminated with the respect and responsibilities.

Placebo controlled trials are very important where used ethically, and if they are scientifically desirable they should only be conducted if they are ethically acceptable, no matter where they are conducted. Historical controls are not useful for current studies as diagnostic and efficacy criteria, and concept of disorder has changed for certain diseases. To avoid unnecessary risks, placebo controlled trials should be conducted in highly controlled setting with adequate follow
up and well defined stopping rules. With all these safeguards, the use of placebo will generally benefits and override any ethical uncertainties in short term studies.

LIMITATION

The main limitation of this study is a small sample size and respondents are from the industry. A large survey with adequate sample size including patients group required to validate the survey findings.

CONFLICTS OF INTEREST

We certify that there is no conflict of interest.

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PERCEPTION OF CLINICAL RESEARCH AMONGST CLINICAL INVESTIGATORS IN SAUDI ARABIA

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ABSTRACT

BACKGROUND

Promoting clinical research is important, considering the shortage of clinical investigators and the increasing need for large number of multicenter studies. Participation of clinical Investigators in research is crucial to achieve this goal. Saudi Arabian provinces have infrastructure to promote the research activities. But that is not the case, as the growth of the clinical industry is sluggish as compared with the other MENA region. The objective of this study was to explore attitudes of clinical investigators towards the conducting of clinical trials in Saudi Arabia and the barriers faced by them.

METHODS

A questionnaire based survey was administered to 100 Clinical researchers from different therapeutic background that has clinical research experience at least one or above. The survey was carried out in various hospitals from different province Saudi Arabia. It consisted of questions/ statements on previous research experience, interests and barriers. Responses were either Yes/No answers or graded according to the 5-point Likert scale.

CONCLUSIONS

The majority of Clinical Researchers working at therapeutic department of various academic hospitals were interested in conducting research. But the lack of time, financial compensation and encouragement were perceived as significant barriers.

KEYWORDS

Saudi Arabia, Perception, Barrier, Financial compensation
INTRODUCTION

In recent years, clinical research has now become globalised phenomenon. Many of the pharmaceuticals companies are looking beyond USA and UK for conducting of clinical trials. Thus, there is a need for expanding the clinical research in developing countries, whose contribution to clinical research has remained low in proportion to their population.

Cardiovascular disease, diabetes, cancer and chronic respiratory illness, metabolic disorder, thalassaemia and sickle cell disease are widely prevalent in the MENA region.

Even though Saudi Arabia provinces have good health care infrastructure with well qualified physicians, the clinical industry is growing at very slow rate. The purpose of this thesis is to analysis the reason behind the sluggish growth of the clinical research in the Kingdom of Saudi Arabia.

Through this study we will attempt to understand the perspective of the clinical research professionals towards the research activities in their hospitals.

METHODOLOGY

A questionnaires based survey was followed for acquiring the information from the Clinical Researchers from different therapeutic background having more than 1 year of experiences in their therapeutic department. The use of questionnaires based methodology facilitates to acquire the objectives of the study without any bias. The questionnaires were designed in such a way that the maximum information is directly obtained from the medical professionals involved in the study. The survey was carried out in various hospitals from different provinces of Saudi Arabia.

All the prepared questionnaires for Clinical Research professionals contained closed ended. The responses were recorded either Yes/No answers or graded according to the 5-point Likert scale.

The questionnaires designed for the study includes the demographic data of the professionals and the barriers faced by the professionals’ i.e. ethical barriers, administrative barriers and cultural barriers.

A survey was carried out from March 2014 to September 2014. Around 110 clinical research professional gave consent to be part of this survey based study but only 96 gave their response. The questionnaires were prepared in English language. The various professionals participated in the survey were prior inform that the study is carried out, purely for academic purposes and full confidentiality of the data given by the participants will be maintained. The participants were asked to rate their knowledge. The respondents were even asked to register their names if they were willing to participate in conducting of ethical clinical trials in their department.

The survey was carried out in a very flexible manner, those who were unable to give their opinion during the face to face meeting on the paper; their opinion was recorded through phone
and mail. Before initiation of the telephonic recorded of the survey, a copy of the questionnaires was mailed to them in order to get their consent for the participation.

Frequent reminder mails were sent to all the participants so that the survey is completed within the time limit.

The data acquired from the questionnaires base survey was statistic analysis through help of Microsoft Office Excel. Charts, graphs and table were used for interpretation of the acquired data from survey form.

Since, no personal data of the participants were recorded in this study, thus need for an approval from the Institutional Review Board was not necessary.

RESULTS

Around 110 clinical researchers were asked to give their views but we received only 96 responses from the clinical Investigators of Saudi Arabia.

A. CHARACTERISTICS OF INVESTIGATORS

As an introductory question, the clinical Investigators were asked upon the demographic question which includes age, sex and knowledge about the clinical research field. More number of males than females participated in the studies this may be due to the law where it constraints the women to work in the male dominating society. The age of the participations was of mid-age range which shows that they were highly experienced and qualified in their therapeutic areas. When they were questioned on the certification in Clinical Research, mixed response was received. Still there is need of education for most of the clinical Investigators in the clinical research field. The result is tabulated below.

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<th>Characters</th>
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<tr>
<td>Age</td>
<td>44±9</td>
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<tr>
<td>No. of Participants</td>
<td>Male = 72; Female = 24</td>
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*Figure 1: Demographic Characteristic of Investigators*
Further the questionnaires were divided into three sections in order to know the perspective of the clinical researchers towards the clinical research.

The three sections were ethical barrier, research barrier and cultural barrier. The results for each section are explained further.

B. ETHICAL BARRIER

Ethics forms back bone of the clinical research. Institutional Review Board (IRB) and Ethics
Committee (EC) approval and Saudi Food Drug and Administration (SFDA) approval are mandatory to conduct clinical research. But at the same time they can be major hurdle in smooth conduction of clinical trials because of the long approval timeline. In order to understand the role of IRB/EC and regulating agency, a question were asked to the professionals stating that whether these two regulating bodies are creating barrier in conduction of the clinical trials in MENA region. 69.79% of the clinical research staff felt that long approval timeline from the SFDA is the major barrier for conducting the clinical trials in Saudi Arabia. Surprisingly, 82.29% of the clinical research professionals said that Hospitals in Saudi Arabia have an IRB/EC and also 67.70% said that the approval timeline is not long. These indicate towards the positive future of the clinical research industry in Saudi Arabian Provinces.

C. ADMINISTRATIVE BARRIERS

![Figure 4: Factors contributing as Administrative Barrier](image)

Administrative plays an important role in smooth and proper conduct of the clinical trials. A question was asked in order to evaluate the components responsible for creating barrier in smooth conduction of clinical trials in the administrative part. The result received state that 53.12% and 59.37% of the responded felt that shortage of human resource and lack of the hospital and institutional support are the major barriers in conduction of the clinical trials. All
RTs, 62.6% of nurses and 30.8% of physicians thought that lack of encouragement was also an important factor (p <0.001 among the three groups). Other barriers stated by respondents included lack of training in research and presence of only one biostatistician in the department. These also stated that if proper education, support is provided to the Clinical Investigator than there are chances of growth of industry in the Saudi Arabian region.

The result also demonstrated that Saudi Arabian provinces have scope of expanding the clinical research activities in their region. Most of the clinical research professionals feels that region has enough patient pool and good infrastructure. These eventually state that the region can support the demand of the research activities in the future.

D. CULTURAL BARRIER

![Figure 4: Factors contributing as Cultural Barrier](image)

The literacy rate in Saudi Arabian region is increasing year after year. In spite of progressing literacy rate, advances in the infrastructure development in the region, Arab population is unaware of the newer developments in the scientific field. This may be due to various factors. To understand whether the cultural background is creating a hindrance in the growth of the research activity a question was put forward to the participants. 85.41% of the responders said that lack of awareness amongst the research professionals and general public is causing difficulties in the growth of the industry. The other significant contributing factors are long vacations and holiday
on special occasion. Nearly 76.04% and 62.50% of the responders gave their opinion that special occasion holidays and long vacation respectively are preventing the research activity.

Being a Muslim dominating country Saudi Arabia government declares long holidays during Ramadan and Hajj month.

From the result it can be seen that cultural factors is one of the major barrier for the growth of clinical research field in Saudi Arabia region.

**DISCUSSION**

This study evaluated the research experience, interest and barriers faced by the clinical researchers working in the Therapeutic Department of various hospitals in Saudi Arabia. From the demographic result, it was observed that most of the participants were in average age of 44±9 which showed that they were experienced in their therapeutic area. From the survey it was observed that a very few of physician, nursing and respiratory care staff had prior research experience while the majority of staff in these three disciplines showed high interest in participating in research in the future. In addition, these healthcare providers also indicated that they needed education on various research areas.

This survey was conducted in preparation for a departmental research course and aimed at identifying clinical researchers who were interested in clinical research and the research areas they would like to learn about.

During the survey it was found a high interest in performing research among clinical therapeutic staff primarily hired to perform clinical work. This was likely, at least in part, due to the belief that it would enhance their future career. In a view that research accomplishments and publications can be frequently used to gain promotion in the professional and shall improve academic status.

In this survey, significant number of clinical researchers alleged adequate knowledge in many research areas. Surprisingly, more than 50% of respondents reported adequate or more than adequate knowledge in many research skills. Around 52% of the respondents specified that they possess clinical research certification whereas the other 48% are not certified by clinical research institute. This study survey did not specifically address the knowledge issue, but it was believe that in the current study clinical Investigators might have overestimated their ability to perform certain research activities and that their responses reflected their perceptions and attitudes about clinical research.

Though the interest level was very high amongst the professional, the growth of the industry was sluggish. The obstruction in the growth of clinical research industry in Saudi Arabia was studied with three factors ethical barrier, administrative barrier and cultural barrier.

To facilitate participation of Clinical Investigator in research, barriers should be identified and
addressed. The result received from the survey was very surprising and even interesting.

Long approval timeline for the clinical study from IRB/EC and SFDA was found to be major obstacles in the clinical research activities. An average IR/EC required approximate 6 months in the approval of the clinical trials. SFDA required 180 days for approval of the international study which is not approved by any of the international regulatory bodies i.e. FDA, MHRA etc... If the clinical trial is approved by any of the renowned international regulatory bodies, then SFDA takes 30 days for the approval. Thus, long approval timings had formed major obstacles in the growth. On the other hand, it was surprisingly to observe that Saudi Arabian region have well established IRBs/ECs in their region. This point towards the bright future of clinical research in the region.

Promoting clinical research is important even in developed countries especially with the existence of worldwide shortage in clinical investigators and clinician scientists. When the participants were questioned on the administrative barrier, the same problem of human resource shortage was observed thus making the expansion of researchers’ pool more urgent in the Saudi Arabia too. Although 33.6% of the Clinical Investigator participated in research, only 11.2% presented their research at national or international meetings, suggesting that the number of principal investigators was modest.

To solve the problem of clinical investigator shortage, western countries resorted to multifaceted approach. Research was promoted by the foundation of MD/ PhD dual degrees, research fellowships and various clinician-investigator programs and by the incorporation of research in specialty and subspecialty residency programs. Short and focused research courses can also boost research knowledge and experience. Sherman et al. found that pediatric residents who participated in a formal education process on the topic of informed consent in their residency education program positively affected residents’ knowledge and attitudes about the processes and issues involving informed consent. In a controlled before-and-after study. Löwe et al. investigated the effectiveness of a one-year resident clinical research training program that included a weekly class in clinical research methods, completion of a research project and mentorship found that those who went through the training program had better methodological knowledge and that higher proportion of them were writing journal articles (87% vs. 36%) than those who did not.

From the survey it was found that most of the Investigators believed that lack of financial support and the closely linked lack of time were important factors that hindered participation in clinical research. Many institutions in Saudi Arabia had recently gained ground in organizing and supporting clinical research. Previously, research projects were the results of individual efforts. Moreover recently many of the research had received additional support from King Abdulaziz City for Science and Technology (KACST)by providing research grants, statistical support and research coordination, thus eliminating many of the barriers that were present before.
The result from the survey also demonstrated that Saudi Arabia have potentials to be call as “Hub for Clinical Research field”. The positive prospect of this study is that clinical Investigators stated that they have enough patient pool for the participation in the clinical trials. Additionally, the region also have infrastructure that are capable to support the clinical trials in the future.

Saudi Arabian region is Muslim dominating country where most of the Arabs are followers of Islam. Ramadan and Hajj are the two most important festivals for the Islam followers. Thus, during this period government of Saudi Arabia declares long vacation. This have direct effect on the research activities in the region. During the long vacation the administrative activities comes to a standstill. Thus, no work during the holiday time and research activities is stopped. Also another factors come into sight was the lack of awareness; this may be due to the fact that most of the people are unaware about the new emerging concept of clinical research.

To summarize the result obtained from the study, clinical professional are holding a positive attitude towards the research in the region. The major barrier faced by the professional are lack of encouragement, clinical research knowledge, long approval timelines from regulatory authorities, lack of compensation and many other as mentioned in this section.

The current study has several limitations. These are primarily related to the survey methodology, specifically sampling and measurement. Not all staff responded, which may have led to the overrepresentation of those who had strong opinions about clinical research. However, the relatively high response rate probably reduced this voluntary response bias. The staff knowledge that participation in the survey was voluntary and had no effect on their evaluation should have reduced socially desirable responses.

**CONCLUSION**

Clinical research is a globalised phenomenon where many of the pharmaceuticals companies are in need for expanding the clinical research in developing countries, whose contribution to clinical research has remains low in proportion to their population. Cardiovascular disease, diabetes, cancer and chronic respiratory illness, metabolic disorder, thalassaemia and sickle cell disease are widely prevalent in the MENA region. Thus, in recent years there has been increased in conducting of clinical trials in MENA Region. But the growth is not as per the expectation. Saudi Arabia province have all the facilities to attract the sponsor but unable to do so. This study exploited the barrier faced by the clinical Investigators for conducting the clinical studies.

A survey based methodology was adopted in order to achieve the objective of the study. The participants were asked to fill the questionnaires in face to face interaction. Those participants unable to give response in personal, their response were recorded through means of email and telephone. The statistic analysis of the result were carried with the help of Microsoft excel 2007.

The result from the study found that the vast majority of Clinical Investigator from multiple
disciplines working at the therapeutic department of various academic hospitals in Saudi Arabia were interested in conducting research and identified research areas that they need more education. These findings could result in targeted tutoring and training. Moreover, the lacks of time, of encouragement and of financial compensation were perceived as significant barriers to participation in clinical research. Finding the appropriate incentives and addressing perceived barriers are crucial to the success and maintenance of any research program.

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BLENDED LEARNING OPPORTUNITIES AND CHALLENGES IN MATHEMATICS EDUCATION: PERSPECTIVE IN HIGHER EDUCATION

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ABSTRACT

Blended learning (face-to-face plus online learning) is now part of the learning landscape in Higher Education, not just for campus-based courses but also for courses designed for students studying at a distance (Distance Education). This paper focuses on exploring blended learning as an approach to the teaching and learning of mathematics in Higher Education. Its provide insight and understanding of current and future trends regarding how conventional face-to-face instruction in mathematics is influenced by web-based/computer-supported learning. Practical pedagogical issues related to mathematics and blended learning in Higher Education are also discussed. The researcher recommends that higher institutions could utilize blended learning environment such as WebCT in the teaching and learning of mathematics in Higher Education.

KEYWORDS

Blended learning environment, Higher education, Mathematics, WebCT.

INTRODUCTION

The rapid development of information and communication technology (ICT) and the move toward a robust knowledge-intensive and globalized society have created new challenges and opportunities in instructional design model and pedagogical approaches in the tertiary institutions (UNESCO, 2003; Tella, 2014). The use of ICT in the academic landscape has removed time and place constraints in the teaching and learning of mathematics. These explorations of ICT in the teaching and learning of mathematics is facilitated through the use of web-based and computer-supported technologies in both synchronous and asynchronous dimensions, commonly known as virtual learning environment (VLE). VLE can be defined as a self-paced computer-based (web) environment enabling interaction between lecturers and students where various tools are provided for the students to facilitate their learning experience (Chin, 2003). Some VLEs require specific software to be installed on the users’ computer, but most VLEs operate across the World Wide Web, so learners often need Internet connectivity to
access a VLE. Access to online courses is granted with a password available only to students enrolled in the official institutional courses by the lecturers (Torrieco & Scancarello, 2009). Downes (2010) noted that the web is shifting from being a medium in which information is transmitted and consumed to a platform, in which content is created, shared, repurposed, and passed along as connective knowledge in networks. Course materials are produced and altered by students, sometimes in collaboration, with lecturers, who takes the role of mediators in the process of teaching of the subject matter using web-based approaches (Komlenov, Budimac, Putnik & Ivanovic, 2013). Thus, knowledge only resides not only in the mind of an instructor or individuals, but also in a distributed manner across a network, and learning is the act of recognizing patterns shaped by these complex networks (Siemens, 2003). The main feature of distributed knowledge is that the learning environment is designed to accommodate the fact that students have different learning styles, needs and preferences.

Meta-analyses have shown that the growing number of students in Higher Education have problems understanding the course content in mathematics, because of their poor knowledge of the subject matter attributed to instructional approaches and learners’ perceptions of the learning environment (Lizzio, Wilson & Simons, 2002). It is well-known that mathematics examinations are a major obstacle for students taking mathematical science-related course in higher institution. They have the highest failure rate, many dropouts and lead to considerable delays in completing university degrees. Some may lack interest, motivation, and positive attitude, and some are not interested in specializing in mathematics (Abramovitz, Berezina, Bereman, Shvartsman, 2012). Thus, they pay little or no attention to understanding basic mathematical concepts. Therefore, supplementing conventional face-to-face learning in the classroom with technological-based tools could stimulate learners’ interest and gives learners control of their learning task and may also increase the number of students taking mathematics courses. This blended learning approach could influence students’ perceptions of the learning environment, their learning approaches, and learning outcomes in the subject matter. This article provides insight into current and future trends regarding how conventional face-to-face instruction is facilitated and influence by web-based/computer-supported learning and other emerging technologies. Practical pedagogical issues related to mathematics blended learning in higher institutions are also discussed.

**PERSPECTIVE OF BLENDED LEARNING IN HIGHER EDUCATION**

There is no agreed definition of blended learning, but there has been a common theme presented in many discussions in the literature; the recognition of some combination of virtual learning and the physical environment. Blended learning is a mixture of conventional face-to-face learning and online learning (virtual learning), adopted to foster active learning, interactivity, and collaborative learning experience as learners’ strive to understand, develop knowledge, and creativity in the learning process. According to Singh (2003) blended comprises various event-based activities including face-to-face learning in the classroom, live e-learning (online) and self-pace learning. This pedagogical model encourages students to learn in an interactive and
collaborative environment at their own pace and in their own time. Oliver and Trigwell (2005) summarize the concept of blended learning as follows:

- Combining or mixing web-based technology to accomplish an educational goal.
- Combining learning theories (e.g., constructivism, behaviourism, cognitivism, and connectivism) to produce an optimal learning outcome with or without instructional technology.
- Combining any form of instructional technology with face-to-face instruction-led training and
- Incorporating instructional technology with the design model of an instructional program of study.

BLENDING LEARNING TOOLS IN MATHEMATICS EDUCATION

The mathematics/computer laboratory is considered to be suitable environment for the adoption and implementation of a blended learning approach. The mathematics/computer laboratory could also facilitate the growth of blended learning, if the required software, hardware and Internet facilities are created to optimize its functionality. Basically, blended learning tools that facilitate mathematics instruction are computer-assisted instructions such as MATLAB/SIMULINK software, Modular Arithmetic Software (MAR), Home Work System (HWS), Microsoft MathType Software (MMS), and SPSS. Technology-enhanced tools such as; e-forum/e-mail platforms, Video on Demand, Animated Video Delivery System, and power point presentation facilitate blended learning in mathematics instruction when moderated by lecturers on various courses in higher institutions.

Nevertheless, sophisticated web-based or VLEs have emerged such as; The Modular Object Oriented Dynamic Learning Environment (MOODLE) platform, Blackboard Learning Management System, e-converge pedagogical model, WebCT, MUMIE online resources, WebALT, web2.0, and other open courseware (Albano, 2012; Albano & Maresca, 2010). VLEs can supplement traditional face-to-face teaching methods, but there are a number of challenges in Higher Education where; for example, increased students’ number, automated assessment, increased participation, and improved access to limited resources.

These tools are designed with features that blend with the conventional face-to-face classroom and the goals of the courses, as well as, facilitating intensive learning opportunities for the learners. Chin (2003) suggested that the fundamental tools offered by any VLEs to complement conventional face-to-face classroom should including the following:

- **Communication tools:** The basic feature of any VLE that can supplement conventional face-to-face classroom learning is any form of synchronous or asynchronous
communication tools. It should allow forwarding of mails to regular Internet e-mail addresses. Students are encouraged to use the e-mail feature and communicate with lecturers and with fellow students/colleagues. It provides a more convenient method of filing correspondence relative to the course. Another fundamental communication tool is the discussion board; an electronic board works in much the same way as a physical notice board, by allowing students to post messages for others to read and post replies. This tool helps to compile comprehensive class activities and quiz schedules for the online study sessions, and other relevant information pertaining to the course. A live chat or discussion forum is another synchronous communication tools integrated into VLEs. One benefit of this tool is that it can enable student-student, and student-lecturer communication at different locations. Interactive whiteboard are used in VLEs to help students and lecturers to compose material interactively in a synchronous way so that everyone can see the work of another and contribute.

- **Content delivery tools:** A core function of a VLE is the ability to deliver content in a variety of formats. This tool allows the instructor/course designer to submit/upload files (e-book, e-journal), deliver lecture support notes, and image, audio, or video presentation files, as well as interactive animations.

- **Assessment tools:** This tool enables students to view their quiz grades and examination results. Its enables instant marking, quick data analysis and quick feedback for students. The results can be used with other features within the system by the lecturers.

- **Content exchange and group work tools:** These tools allow staff and students to provide and share files with one another. This means that students can share work in an online environment rather having to meet face-to-face. Students can use this tool to make group presentations.

**BENEFIT OF BLENDED LEARNING IN HIGHER EDUCATION**

- Studies have shown that courses using blended learning delivery method contribute to improved learning outcomes for the students (Boyle, Brandley, Chalk, Jones & Picard, 2003; Groen and Carmody, 2005; Iozzi & Osimio, 2012). Twisg (2003) reported that courses redesigned to include blended learning resulted in students achieving higher grades, greater knowledge, and understanding of course concepts. This could lead to a reduction in the student dropout rate in higher institutions.

- Another benefit of blended learning is the increased flexibility of access to learning which facilitates review and learners’ control of the learning environment. The Internet provides flexibility and efficiency in teaching and learning activities. Teaching sessions can be conducted via video or teleconference links so that learners can attend classes online. Study materials are readily available over the Web. Applications provided over
the Internet such as e-libraries, e-books, e-resources provide opportunities for learners and instructors. The blended learning approaches allow learners who lives some distance away from the institution to enroll in a program, and the online component allows them to work whenever and wherever they prefer because they can access the Internet without making the journey to campus (Tam, 2000).

- Garrison and Kanuka (2004) explored how blended learning can offer transformational potentials to higher institutions. Higher institutions could harness innovative technologies in teaching and learning program by redesigning the curriculum to enhance a community of enquiry, supporting active and meaningful learning. Blended learning also foster professional leaning community, improves institutional reputation, and allows the development of social cohesion due to the inclusion of the face-to-face component (Owston, Wideman, Murphy & Lupshenyuk, 2008).

- Blended learning is cost and resource effective. Institutional costs are reduce because the materials can be placed online and re-used at convenience (Vaughan, 2007; Holland, 2012). The size of the student cohort can increase and the number of classrooms decreases. The use of blended learning can help to reduce staff numbers and student classroom contact time, and consequently save staffing costs.

- Blended learning also promotes student interest, perceptions and satisfaction in the learning environment. It enables students to be more motivated and more involved in the learning process, thereby enhancing their commitment and perseverance. Dziuban, Hartman, Juge, Moskal, Sorg (2006) reported that students satisfaction is higher with blended learning courses compared with purely face-to-face courses.

In addition, Azizan (2010) envisaged that blended learning in Higher Educational Institution

- Offer an efficient and effective approach
- Provide more choice of learning to learners
- Increase learning resources
- Encourage independence and conviviality.

**CHALLENGES OF BLENDED LEARNING IN HIGHER EDUCATION**

Despite the opportunities provided by blended learning, the students, instructors and institutions face some challenges with its implementation. These include the following:

- Studies have shown that students enrolled in blended courses can sometimes have unrealistic expectations. The students in blended learning programmes assumed that fewer classes meant less work, inadequate time management skills were inadequate, and
they experienced problems with accepting responsibility for personal learning (Vaughan, 2007)

- Students in such courses have also reported feeling isolated due to the reduced opportunities for social interaction in a face-to-face classroom environment.

- Having difficulty with more sophisticated technologies is another challenge when implementing blended learning. For example, students may have to rely on slow (e.g., dialup) Internet connections. Poor Internet connectivity has been reported to inhibit students' ability to engage in online discussions, which could lead to considerable frustration and have a negative impact on learning.

- The challenge for implementation of blended learning in higher institutions is time commitment. Johnson (2002) estimates that planning and developing a blended learning course for large numbers usually takes two to three times the amount of time required to develop a similar course in a traditional format.

- Funds are insufficient for the development of a Learning Management System (LMS), which is required to enhance blended learning in higher institutions.

- Technical support for course design may be lacking. This results from insufficient interrelation between the ICT experts and faculty members offering blended learning courses. In order to ensure a successful blended learning experience for students; there should be university support for course redesign, which may involve deciding what course objectives can best be achieved through online learning activities, what parts of the course can best be accomplished in the classroom, and how to integrate these two learning environments.

PROPOSED BLENDED LEARNING MODEL FOR HIGHER EDUCATION

Khan, as cited in Singh (2003), proposed a blended learning model. The framework has eight dimensions: institutional, pedagogical, technological, interface design, evaluation, management, resource support, and ethical (Figure 1). Each dimension in the framework represents a category of issues that need to be addressed. These issues help to organize thinking, and ensure that the resulting learning program creates a meaningful learning experience.
Figure 1. Khan’s Octagonal Blended Learning Model

- **Pedagogical**: This dimension is concerned with the combination and selection of the learning contents to be delivered online and to be delivered offline (face-to-face). It also analyzes the learners’ learning style, objective of the contents, and evaluates students learning outcomes.

- **Technological**: This dimension examines the availability, accessibility and usability of the LMS to enable the synchronicity of blended learning. The technological component also requires the services of technical experts to support the system.

- **Management**: This component deals with issues related to quality control, availability of technical experts, upgrading of infrastructures for multiple deliveries and improvement facilities.

- **Interface design**: This addresses issues related to the user interface of each element in the blended learning environment.

- **Evaluation**: This assesses the capability and effectiveness of the blended learning environment and examines the functionality and improvements of a specific LMS.

- **Resource support**: This deals with making different type of interactive resources (online and offline) available for learners.

- **Ethical**: The ethical dimension identifies the ethical issues that need to be addressed when developing a blended learning program, for example, equal opportunity, cultural, diversity, and nationality.
CONCLUSION

The emergence of computer and technologies has made teaching and learning of mathematics a dynamic process. Blended learning courses are being offered at different higher institutions through the use of LMS. This study has outlined the concept of the blended learning approach from the perspective of mathematics in Higher Education. Moreover, the different blended learning tools that can enhance teaching and learning in mathematics education are discussed. The benefits of blended learning as well as challenges during implementation are also discussed. This study proposes a blended learning model that can foster best practices in blended learning (i.e., Khan’s octagonal model). The study can be considered as a proactive prospect for higher institutions aiming to adopt a blended learning approach, in order to harness the diverse learning opportunities that technology can provide. It may also enable faculty members to select a suitable blended learning environment for teaching and learning program in mathematics.

RECOMMENDATION/FURTHER STUDY

Higher institutions could adopt Khan’s model to design and implement a blended learning environment using a specific LMS such as WebCT. International consortium could be established with other universities to foster and develop blended learning approaches for different programs. Blended learning project should be properly funded, so as to address issues beyond the proposed Khan’s model. Further studies should be carried out using WebCT as a blended learning platform to ascertain its effectiveness and efficiency in mathematics course delivery.

REFERENCE


FRAMEWORK IMPLEMENTATION FOR OWASP TESTING GUIDE

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ABSTRACT

This paper intends to give an introduction how to test vulnerabilities. This is based on the OWASP testing guide or an audit approach and concepts used by penetration testers testing in a web environment. Our main disciplines automating a simple guide testing algorithms were developed. Each corresponds to two methods of algorithms of this guide, the algorithms were run on a non-automated process. So, with this work we want to give facilities present or also give more tools for complex tests. Tests were performed in a prepared with errors, such as broken OWASP Web Application Project environment.

KEYWORDS

OWASP, Test Guide, Pentester, XSS, IT Security

INTRODUCTION

The main objectives in this work are to develop algorithms that automate testing more simple guide teste of OWASP. It will be a framework that called him desired algorithm. And in each one we will look at these methods OWASP guide automated. These were typed on a non-automated process. the framework will be developed based on testing OWASP Testing Guide, this visa provide some more simple tests for beginners pentesters, this also tip the most advanced tools for more complex as tests then functionality testing framework on OWASP Broken Web will Applications Project, a VM (Virtual Machine) having weaknesses tools for testing.

BASIC SECURITY CONCEPTS

The integrity of information means that your content remains unchanged unless it is changed by authorized personnel, and this modification is recorded for subsequent inspections or audits [35][36]. Failure Integrity can be generated by anomalies in the hardware, software, virus computer or modification by people who access the authorized system or no [36].

Availability is the ability of the right information is always available to be processed by authorized persons. privacy is the necessity of the information is known and accessed only by the
authorized persons [35][36]. Authentication allows you to define which information is valid and usable. This property also ensures the origin of information [35][36]. And finally Audit: is defined as the ability to determine what actions or processes are conducted in the system, who carries them and when[35][36].

**THREATS**

We can define a computer threat, as any element compromise system security. Threats may be referred to temporarily: Before the attack, during and after. Prevention (before the attack): These are mechanisms that maintain security system during normal operation. As encryption information for further transmission. Detection (during the attack) is of mechanisms to discover security breaches. For example, audit programs [35].

The recovery (after the attack): these methods are applied when the violation of the system has already taken effect, to return the system to normal operation. We can put here the recovery backups[36]. There is also the intruder. An attacker (intruder) is a person who tries to access to a system without a valid authorization, whether for intentional or not. This can make passive or active attacks.

**OWASP AND OWASP TESTING GUIDE**

Security problems are perhaps the most important technical challenges of our time [22]. You cannot build a secure application, without the security of the test. The set of OWASP guidelines are a good start for building and maintaining secure applications.

There are many different ways to test for security flaws and OWASP Testing Guide that has the knowledge of the leading experts on how to perform a quick test, accurately and efficiently [22]. This guide is very important to be available completely free and open. The result of this project is a complete testing framework.

**WHY OWASP**

Creating a guide like this is a big challenge, which is the experience of hundreds of people around the world. There are many ways different to test for security flaws and OWASP Testing Guide captures the consensus of the leading experts on how to do this rapid test, accurately and efficiently [22]. OWASP Testing Guide is very important to be available completely free of charge and open. Security must not be a black art that only a few can practice. Much of the available safety guidelines are just enough detailed for people concerned about the problem.

OWASP Testing Guide should make its way into the hands of developers and software testers. There is hardly sufficient security experts applications in the world to make a significant reduction in the problem. The initial responsibility for application security must fall on developers. Keeping this information is a critical aspect of this draft guide. By adopting the wiki
approach, the OWASP community can evolve and expand information on OWASP Testing Guide to keep pace with the rapid implementation of mobile security threat landscape[22].

**ROLE OF EACH SPECIALIST**

Guides OWASP testing should be adopted by each organization. May be necessary to adjust the data to match technology organization. There are several different functions that can be used if OWASP Testing Guide [22].

1. Developers should use to ensure that they are producing secure code.

2. Testers must use the software to expand the set of test cases that apply.

3. Security experts should be used in combination with other techniques.

**TESTS PRINCIPLES**

While it is tempting to think that such a scanner or firewall or security will solve the problem, not really, because you will always provide a multitude of defenses or identify a myriad of problems. To avoid security problems that occur is essential to build security in the SDLC with the development of standards, policies and guidelines that fit and work on developing a methodology[37][19]. A good tool is the use of use cases that test the application’s behavior. But a good test security requires thinking like an attacker, for example, in cases of misuse[19]. Here creativity helps determine which data can cause an application crash [22]. It is important to say that if the source code of the application is available, should be given to security personnel for evaluation [22]. Many serious vulnerabilities cannot be detected with any other form of examination or testing [22][19].

**PENETRATION TESTING**

Penetration testing is a technique used to test the security of the network is used for many years. Also known as black-box testing or ethical hacking. Normally, application equipment penetration of user access. These tests may be quicker and therefore cheaper. Check the part of the code is actually very expository. But are the SDLC and has only one frontal impact, i.e., specific to a particular defect.

**INTRUSION TESTINGS**

**TESTING: SPIDERS, ROBOTS AND CRAWLERS (OWASP-IG-001) - DISCOVERY AND RECOGNITION OF A SEARCH ENGINE (OWASP-IG-002)**

Spiders, crawlers and robots (crawlers) used on the web and can recursively retrieve a web page using hyperlinks that make us this other pages referenced to recover, and tends more like the behavior of the robot is specified by the "Robots Exclusion Protocol "written in the robots.txt file
in the root directory [31][16].

**IDENTIFICATION OF INPUT PARAMETERS OF APPLICATION STARTS (OWASP-IG-003)**

Walking through the application, you must pay special attention to all HTTP requests (GET and POST) and all parameters and form fields to pass backend. Also, be careful when using GET and POST requests when used in parameter passing. The most useful is the use of a proxy that intercepts and a worksheet for this stage of the test.

**APPLICATION FINGERPRINT TEST (OWASP-IG-004)**

Web server fingerprinting is a critical task for penetration testing. Knowing the type and version of the current web server allows testers to identify vulnerabilities and suitable for use during the test exploits. Rarely, however, also react to different versions all HTTP commands. The simplest and most basic of identifying a server is to look at the Server field in the HTTP response header. To sos experiences can use netcat[22].

**APPLICATIONS DISCOVERY (OWASP-IG-005)**

It is a process to identify web applications contained in server infrastructure [22]. The server is typically specified as a set of IP addresses, may consist of a set of DNS symbolic name or a mixture of the two. But there is no way to fully determine the existence of non-standard web application with the name. Firstly, if the web server is disconfigured and allows directory browsing, it may be possible to detect these applications. Secondly, these applications can refer to other sites [22].

**ANALYSIS OF ERROR CODE (OWASP-IG-006)**

Often during a penetration test, we find error messages. It is possible that these errors are displayed with a special request. These codes are very useful for testing, because they reveal a lot of information about the DBS, insects and other components [22] application. A common mistake that can be HTTP 404. Often, this code provides useful information about the server and associated components. An example:

Not Found The requested URL/page.html was not found on this server. Apache/2.2.3(Unix) mod_ssl/2.2.3 OpenSSL/0.9.7g DAV/2 PHP/5.1.2 Server at localhost Port 80

This error message can be generated for a nonexistent URL request. After the common message queue displays a page with information about the server version [22].

**SSL/TLS TESTINGS (OWASP-CM-001)**

The plaintext http protocol is typically secured through an SSL or TLS tunnel, resulting in
HTTPS traffic. HTTPS also allows identification of servers and clients using digital certificates (RFC2817, 2013) (RFC3546, 2013). For such communications must pass a series of checks on the certificates, which guarantee encrypted.

**DATA BASE (DB) LISTEN TESTS (OWASP-CM-002)**

The watch receiver is the entry point for remote connections to a database. Connection requests then the deal will be heard. This test is possible if the tester can access this service -should be tested from the Intranet (DBMSs do not expose this great service to the external network). The driver, by default, listens on a port without SSL or SSL [22].

**INFRASTRUCTURE MANAGEMENT CONFIGURATIONS TESTS (OWASP-CM-003)**

For detection of a reverse proxy in a web server we need to do the analysis of web server banner, which could directly reveal the existence of a proxy. We can also determine the HTTP requests and responses between the client and server. If the server response back with a standard 404 message to request unavailable, and returns a different error message, then it is an indication of the reverse proxy. Proxies can also be reverse-proxy caches that accelerate the performance of back-end code [22].

**APPLICATIONS MANAGEMENT CONFIGURATIONS TESTS (OWASP-CM-004)**

Scanners CGIs include a list of known files and directories, and are a quick way to determine the files are present on websites or servers. However, the only way to be sure is by reviewing the contents of the servers and determines if they are even related to his application or not (Microsoft URLScan, 2013).

**FILES EXTENSIONS TESTS (OWASP-CM-005)**

File extensions are commonly used in web servers to easily determine which technologies should be used to comply with the web application. Although this behavior to be consistent with RFC and web standards, using extensions pen tester provides useful information about the underlying technologies used in a web application and simplifies the task of determining the possibility of an attack to be used in technologies [22].

**OLD SECURITY FILES AND WITHOUT REFERENCE (OWASP-CM-006)**

Not uncommon and forgotten files without reference that are used to obtain information about the infrastructure or credentials. Common scenarios include the presence of old versions of modified, renamed or backups, even as archive files. These can allow access to a pen tester rear ports, administrative interfaces, or a DB credentials [22].
ADMINISTRATIONS INTERFACES OF THE INFRAESTRUCTURE AND OF THE APPLICATIONS (OWASP-CM-007)

The test aims to discover these interfaces and access to administrator functionality for users with privileges. These techniques can also be used in other tests, including privilege escalation [22]. Here you can see some techniques that test:

1. Enumerate Directories and Files
2. The comments in source code
3. Documentation Review and server applications
4. Alternative server port

HTTP AND XST TEST METHODS (OWASP-CM-008)

HTTP offers a number of methods you can use to perform actions on the web server. Many methods have been designed to help developers they prove HTTP applications. Cross Site such Tracing (XST) is a form of XSS TRACE method using HTTP. This technique was discovered by Jeremiah Grossman in 2003 in an attempt to circumvent the notice HTTP. Only IE 6 SP1 which should protect access cookies JavaScript [22]. By this one of the most recurrent patterns in Cross Site Scripting attacks is to access the document. Cookie object and send it to an attacker-controlled so that he can hijack the victim’s session server[6].

TRANSPORT TEST CREDENTIALS IN AN ENCRYPTED CHANNEL (OWASP-AT-001)

Test to verify the credentials transportation means that user authentication data is transferred via an encrypted to avoid being intercepted by malicious users channel. The analysis focuses on understanding whether the data travels unencrypted from the browser to the server, or the web application takes appropriate security measures using a protocol such as HTTPS [22].

USER ENUMERATION TEST (OWASP-AT-002) -DEFAULT USER ACCOUNTS OR ADIVINABAIS (OWASP-AT-003)

The objective of this test is to verify whether it is possible to collect a set of valid user-names by interacting with an authentication mechanism. This test will be useful for testing brute force. Overall applications reveal when a valid user exists in the system [22]. The majority of hardware devices such as routers and servers, databases, have another weakness, if these are not set correctly configurations offer standards, it would be a vulnerability [22].
**TEST OF BRUTE FORCE (OWASP-AT-004)**

Brute force is to test all possible candidates for the solution and checking whether each one meets the problem. In web testing, the problem to be solved with brute force logins are therefore going to check the types of authentication schemes and the effectiveness of different brute force attacks [22]. Actually, there are several methods for authenticating users, such as certificates, biometric devices, OTP (One Time Password), cookies, and finally the combination of user ID and password [22].

**TEST BYPASSING AUTHENTICATION SCHEME (OWASP-AT-005)**

Neglect, ignorance or underestimation of threats often result in authentication schemes that can be bypassed by simply skipping the login page and call directly to an internal page that is supposed to only be accessed after performing authentication [22].

**TEST PASSWORD RESET VULNERABILITY (OWASP-AT-006)**

Most web applications allow users to reset their password if they have forgotten, as sending an e-mail password reset or answering security questions. This test should verify that this function is carried out correctly and not create any default authentication. It also checks whether the application stores the password in the browser [22].

**TEST MANAGEMENT LOGOUT AND BROWSER CACHE (OWASP-AT-007)**

At this stage, you should check that the function logout (logout) succeeds, and that it is not possible to reuse yours after closed. You should also check that the application is automatically disconnected when the user is idle for some time, and that no sensitive data continues in the browser cache [22].

**CAPTCHA TEST (OWASP-AT-008)**

CAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) is a type of challenge-response test used by web applications to ensure that the process is done by a computer. CAPTCHA implementations are often vulnerable to various kinds of attacks, even if the generated CAPTCHA is unbreakable[13][27].

**AUTHENTICATIONS TEST STAGES WITH MULTIPLE FRAMES (OWASP-AT-009)**

Assessing the strength of a MFAS (Multiple Factors Authentication System) is a critical task for the penetration test. A major responsibility of penetration testing is to recognize if the MFAS adopted are able to defend the property of the organization of threats. In general, the goal of an authentication system in two stages is to improve the strength of the process [34].
TESTING CONCURRENT CONDITIONS (OWASP-AT-010)

A condition of concurrency is a defect that produces an unexpected result when the timing of actions impact other actions. An example can be seen in a multithreaded application where actions are performed on the same data. The conditions of competition can occur when a process depends critically or unexpected sequence of events or times [22].

TEST SESSION MANAGEMENT SCHEME (OWASP-SM-001) -TEST COOKIE ATTRIBUTES (OWASP-SM-002) -TEST OF SESSION FIXATION (OWASP-SM-003) - TEST SESSION VARIABLES EXPOSED (OWASP-SM-004)

In order to avoid continuous authentication of each page or service, web applications implement various mechanisms to store and validate credentials in a predetermined time interval. These mechanisms are known as session management and are implemented through the use of cookies [22][8]. In this test, you want to check that cookies are created in a secure way, so that an attacker will not be able to pose forge a cookie, hijack legitimate can be sessions [22]. Because when an application does not remove the cookie after authentication, it is possible to find session fixation vulnerabilities in that case, an attacker could steal the user’s session[8]. And exposing parts of the cookie, you can allow access to the application illegitimately. As such, it is important that information protected this sniffing, particularly in traffic between the browser and server. This test verifies also how transport security applies to the transfer of sensitive data through cookies [22].

CSRF (CROSS SITE REQUEST FORGERY) TEST (OWASP-SM-005)

CSRF is an attack which forces an end user to execute unwanted actions on a web application in which it is authenticated actions. With a little help of social engineering, an attacker can force users of an application to execute actions of the attacker’s choice.

TRY TO JUMP DIRECTORIES (OWASP-AZ-001)

A directory path (or route traveled) is the exploitation of insufficient security validation of input file names, so those users traverse to the next through the OS API directory.

TEST USING BYPASSING AUTHORIZATION SCHEMA (OWASP-AZ-002)

This type of testing focuses on verifying how the licensing scheme has been applied for each role and privilege to access functions and reserved resources [22].

TEST PRIVILEGE ESCALATION (OWASP-AZ-003)

In this section the problem of escalating privileges from one stage to another is described. During this phase, the auditor should verify that it is not possible for a user to modify their privileges or
roles within the application in ways that could allow such attacks [22].

**TESTING THE BUSINESS LOGIC (OWASP-BL-001)**

If the authentication mechanism for an application is developed with the intention to perform more than one step, what happens if you go directly from step 1 to step 3? The application provides open access, denied access, or simply return an error (type 500)? This type of vulnerability cannot be detected by a vulnerability scanner and builds on the skills and creativity of the penetration tester[9].

**TEST OF DATA VALIDATION; XSS TEST (CROSS SITE SCRIPTING) REFLECTED (OWASP - DV-001) - XSS STORED TEST (PERSISTENT)(OWASP-DV-002) - XSS TESTS BASED IN DOM (OWASP-DV-003) - CROSS SITE FLASHING TEST (OWASP-DV-004)**

The security weakness in most common web applications is the failure to properly validate input coming from the client or environment before using it. This weakness leads to almost all of the major web application vulnerabilities such as XSS, SQL injection, local attacks, attacks and file system buffer overflow [1][2][22]. Data from a foreign entity or client should never be trusted, because it can be arbitrarily manipulated by an attacker. "All input is evil," said Michael Howard, in his famous book "Writing Secure Code". That’s rule number one. Unfortunately, complex applications often have a large number of input points, which makes it difficult for a developer to enforce this rule[4][22].

**RESULTS AND CONCLUSIONS**

For verification test was used a virtual machine networking. OWASP Broken Web Applications Project (BWA) is a virtual machine with a variety of applications with known vulnerabilities for those interested in:

- learn about web application security
- technical manuals assessment tests
- automated testing tools
- test tools source code analysis
- WAFs tests and technologies similar code
- observation of web attacks

So people interested in learning or testing they will not have the problem to compile, configure and categorize all applications, usually involved. The BWA project is a collection of
compromised Web applications that are distributed in a VMware virtual machine without cost and in a format compatible with VMware Player and VMware vSphere Hypervisor (ESXi) and compatible with this format. This project includes open source applications of various types. Applications designed for learning that guide the user specific, intentional vulnerabilities. The tool used for this platform was WebGoat described below. OWASP WebGoat SVN version 5.4 (Java) and OWASP WebGoat.NET in GIT version 2012-07-05. WebGoat is a deliberately insecure web application maintained by OWASP designed to teach lessons web application security. It can be installed on any J2EE or ASP.NET. This is for users demonstrate their understanding of a security issue by exploiting a real vulnerability. For example, in one of the lessons the user must use SQL injection to steal credit card numbers (false). The application is realistic, providing users with a code to further explain the lesson. All testing tools are developed in the framework. Such a framework was developed in Python, some of the tools are in Python, Ruby and other shell scripting.

**TESTING : SPIDERS, ROBOTS AND CRAWLERS (OWASP-IG-001)**

Here is a script that reads the robots.txt file domain and verifies few directories are desabilitados (Disallow) and may not be assigned by the robots and spiders developed. This script is used for a survey of the number of directories, supposedly the administrator does not want to be indexed by search engines in their results for searches on the site. The dangers here are the existence of services or directories that contain important information, which are mapped by the search engines. In this script filters could be types of directories for fencing more useful information is better.

**DISCOVERY AND RECOGNITION OF A SEARCH ENGINE (OWASP-IG-002)**

In this script two options of google searches, "site" and "cache" is used. The site will return all references (in google servers) domain as a last parameter. And "cache" sample site (chosen reference) that is stored on Google servers. These searches were performed via the HTTP POST method, any API was used. Therefore, limitations, and the inability to clear the cache automatically a web or references to files and directories that are no longer used site has.

**FINGERPRINT TEST A WEB APPLICATION (OWASP-IG-004)**

This was proved by using a web service. The goal would be to run the browser in a setting of text, but was unsuccessful because the site uses JavaScript. It was used an API specified for navigation. As I expected the script worked well and the information is displayed in a web browser window. It is a powerful tool that returns a score for every possible application that is on the server. In the figure below you can see the scores of each, and the maximum is 130 for Apache/2.0.x. The script developed using more suitable parameters.
APPLICATIONS DISCOVERY (OWASP-IG-005)

With the proper setup script for a list of open ports use. It was scanning port 0 to the result of getting the 30,000 figure above.

- Reverse DNS and Zones de DNS

![Figure 1: Using httprint to fingerprint a server](image)

The security problem with the DNS zone transfer is that they can be used to de-crypt the network topology. Specifically a company when a user is trying to perform a zone transfer and sends a DNS query to a list of DNS and name servers, host names, MX and CNAME records, serial number area, records Time to Live, etc. Therefore the amount of information you can get no DNS zone transfer can be easily found in in current days.

PRUEBAS SSL/TLS (OWASP-CM-001)

- Simple verification using SSL or TLS

Here we develop a filter for the execution of nmap command, this command will only bring services to their ports. After this filter is applied to summarize only the services that have SSL or TLS. Such an algorithm is experimental and is based on search of expressions in the texts.

- Levels of SSL and TLS ciphers script with nmap

Here you can check the level of the figures. In the figure below we see that the figures are effective when used (strong), but this would not mean they are not breakable. In this algorithm is verified more fully the existence of SSL or TLS services. Although pruned be hidden, it would be a problem.
TEST FILE MANAGEMENT WITH COMMON EXTENSIONS (OWASP-CM-005)

- Download of a complete site
- Folders standards with Nikto

This script will drop an entire site with its subdirectories and files. It was tested at moments, it should not be expected to do the full download.

Figure 2: Quality figures of the SSL and TLS

Nikto is a comprehensive tool among other things it checks for directories standards. In the figure 3 you can see what the scanner report done your IP 192.168.56.102 and starting with "/".
Figure 3: Review of standards directories in "/"

OLD FILES, SAFELY AND WITHOUT REFERENCE (OWASP-CM-006)

Using those script can check for a specific directory, in this case we should be suspicious of his existence. ”Moved Permanently” gives an indication that the directory exists. That script was developed in shell scripting.

HTTP TEST METHODS AND XST (OWASP-CM-008)

• Checking the HTTP/1.1 methods in a domain

The HTTP protocol has 8 methods, here this script is used to check which can be used. The figure shows the possible use of GET, HEAD, POST, OPTIONS and TRACE.

• Check existence of a directory using HEAD

Using the HEAD method sends some requests are received and will be the directory exists or not. Figure message ”Moved permanently” as in the other case is, this mean that the board is present. Suspecting existence of directories you can make a list of them.

PROOF BRUTE FORCE (OWASP-AT-004)

• Using SSH Hydra

Here is a program that tested the Hydra among other functions, to break what test service login SSH brute force. Can be seen in the figure below the Underway process.

• Test of CAPTCHA

This test has been used only direct use shell program without developing a script filter. First step was to test the CAPTCHA code below without success, then you have done a workout in use OCR technology to identify each letter of the CAPTCHA.

... 

48. =*=*=*=*=*=*

49. OCR processing...

50. =*=*=*=*=*=*

51. Training Results:

52. =*=*=*=*=*=*

53. Number of ’words ’ extracted: 4
Now, move each image to the correct folder on your dictionary: '/iconset/'

With training got good results. Then used the "crack" option has succeeded in breaking the CAPTCHA.

...
In the event you can see the result "p36w".

**Figure 4:** *Forza Gross Hydra against a SSH service*

**SCHEMA MANAGEMENT FOR TESTING SESSION (OWASP-SM-001)**

This test has been used only direct use shell program without developing a script filter. First step
was to test the CAPTCHA Figure above without success, then you have done a workout in use OCR technology to identify each letter of the CAPTCHA.

**Figure 5:** Interception of the cookie, webpage, HEAD, and more information

4.11. Path change test (OWASP-AZ-001) - Test bypassing authorization schema (OWASP-AZ-002) In the figure below attempts acezar the main.jsp file using WebScarab as intercepting proxy. By intercepting the POST request a file in the directory "/var/lib/tomcat6/webapps/WebGoat/lesson_plans/English" WebScarab used to replace the value of the variable "File" for ".../main.jsp" (as shown) knowing that such a file exists. As a result we have the content of that file.
**Figure 6:** Interception of a request and change the desired file

**EVIDENCE OF INCREASED PRIVILEGES, OR CONTROL ACCESS BASED ON ROLES (OWASP-AZ-003)**

This test is done at login with the user "tom" with employee id = 105 as shown in the figure below, and replaced it with the employee id = 102 but the action will equal action Delete Profile view profile and not more, as can be seen in Figure later. This makes the user tom has no privileges to delete other user (pertains only to admin) poses delete user id 102.

**Figure 7:** Original function to be executed is viewprofile
Figure 8: The function to be executed, will now be DeleteProfile

TESTS OF REFLECTED XSS (OWASP-DV-001); PRUEBA DE STORED XSS (OWASP-DV-002); PRUEBA BASADA EN DOM XSS (OWASP-DV-003)

• XSS persistent and no persistent

Here is a XSS tried it with javascript "<img src = x onerror =; alert ('XSS') />" inserted into a textbox, and this tax could reach the JavaScript in a DB (persistent XSS) if there was not a check against XSS. A good solution is to not interpret the HTML characters, so the injection is passed as clear text, you can see an example below: This code is weak, where the data come in”name” is interpreted.

function displayGreeting (name)
{
    if (name != ' ')
    {
        document.getElementById("greeting").innerHTML="Hello , " + name + "!";
    }
}

You should make a small modification so, and it has the most correct code:

function displayGreeting (name)
{

if (name != ' ')
{
    document.getElementById("greeting").innerHTML="Hello , " + escapeHTML(name); + "!";
}

And with escapeHtml method entry and all plaintext is interpreted. For example, if the application has a string "<script>" and wants the browser interprets it as "<script>" (not as plaintext), encoded in the HTML form as "&lt;script&gt;" before including it in the web page that is sent to the browser.

- Test of XML Injection

In this window you can see the options available Rating and entering with his ID account you can earn points. However for the ID 836239 there are limited options in the system. This availability can be changed by intercepting a proxy (here will BurpProxy)

![Interception of response](image)

**Figure 9:** New bloco XML data interception to BurpProxy

Here is the interception of the response and replaced the original xml displayed in this figure. And finally in the image above the choice all the scores available it is found, and as the last sentence is saying "The following items will deliver in his direction". If was a site of true (non-trial) unpaid items are received, and nobody knew. The only way to solve this problem would be by-one analysis of the bank received orders, finding is that such user had never made the
payment. XML injection can be prevented in a similar manner SQL injection. The best way is carefully user input filter. The data received from a user should be considered insecure. The elimination of all single and double quotes should eliminate most types of this kind of attack. Note that the elimination of contributions can have side effects, such as user names can contain valid quotes.

- Phishing with XSS

Example: The user should be able to add a form that asks for the user name and password. By submitting the entry must be sent to

http://localhost/WebGoat/catcher?PROPERTY=yes&user=catchedUserName&password=catchedPasswordName

Development example: With XSS is possible to add more elements to an existing page. This solution consists of two parts that have to be combined: One way the victim has to fill a script that reads the form and send the information gathered by the attacker. A form with username and password could look like this:

<form name="phish"><br><br><HR><H3>This feature requires account login:</H3><br><br>Enter Username:<br><input type="text" name="user"><br>Enter Password:<br><input type="password" name = "pass"><br></form><br><br><HR>

Search this term and will be a form is added to the page from the search field accepts HTML. The initial </form> is to complete the original query form. Now you need a script:

<script>function hack(){ XSSImage=new Image; XSSImage.src="http://localhost/WebGoat/catcher?PROPERTY=yes&user ="+document.phish. user.value+"&password ="+document.phish.pass.value + "; alert ("Had this been a real attack . . . Your credentials were just stolen. User Name = "+document.phish.user.value + "Password = "+document.phish.pass.value);} </script>

This script will read the input from the form and send it to the receiver Web Goat. The local host should be the target address. If you are using the ports and / or Web Scarab, may be different. The last step is to put things together. Add a button to the form required by the script. You can reach this with on click = "myFunction()" handler:

<input type="submit" name="login" value="login" onclick="hack()">

The final string looks like this:

</form><script>function hack(){ XSSImage=new Image; XSSImage.src=" http:/
localhost/WebGoat/catcher?PROPERTY=yes&user ="+ document. phish.user.value + 
"&password =" + document.phish.pass.value + "); alert ("Had this been a real attack . . .
Your credentials were just stolen. User Name = " + document.phish.user.value +
Look for this series and see a requesting your username and password below. Complete these fields and click the login button, which completes the lesson.

- **Sniffing with Wireshark**

Sensitive data should never be sent in plain text. Often, applications are changed to a secure connection after authorization. An attacker could just smell the login and use the information collected to enter an account. The objectives of this test are to understand the advantages of encrypting data access. This test has two stages. In the first step we try to sniff a password that is sent in plain text. In the second stage the same is attempted but a secure connection.

Using is the packet filter, all packets of HTTP request is set and will be a unique package POST method as illustrated above. After duplo-clicking on the line this package POST and property "Line-based text data ....." can see "clear_user=Jack" and "clear_pass=sniffy" fields that are the user and password respectively. Now the test is HTTPS.

**Figure 10:** Wireshark window in the POST request packet showing the user and password in clear text
Figure 11: POST Package with crypted fields with SSL/TLS

Now you have to switch to a secure connection. This would be like changing the URL from http:// to https://. Sniff traffic again as it has done in Step 1. As you can see no password is sent in plain text. The server communicates with the application through a secure layer called Transport Layer Security (TLS), also called Secure Socket Layer (SSL). TLS as seen is a hybrid encryption protocol. It is built to communicate a secret key. This secret key using SHA-1 and MD5. All traffic between the server and the client is encrypted by this key. And as you can see in the figure where before the login data now appear in plain text is not any.

FUTURE PROJECTS

The development of this work will not get to do all tests OWASP Testing Guide. Future projects would be interesting in relation to the development of the remainder of the tests, as well as update installer and automated framework. For good existing evidence would collect more tools of the same purposes as those already present, as well as tools for testing unimplemented. It would also be necessary to conduct further testing and implementation of simple scripts, but help to collect important information.

Also improve these scripts so that they present a more accurate information and have more options. The intention is to have only free software tools that can be open source (or not), but do not pay. For the paid tools can be integrated in the framework-it with both a free version (with or without limitations). The framework was hosted at the Source Forge project site, so you will have a space designed for storage and dissemination. Since we need more people to help keep SourceForge is a good choice. It can be downloaded via the command: get clone get:  
//git.code.sf.net/p/frameworkowasp/testingguide/code/frameworkowasp/testingguide-code/ You must have already installed the github. On source-forge you also have the bog with some information on the address listed below: https://sourceforge.net/p/frameworkowasp/testingguide/blog/
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MERGERS AND ACQUISITION AND BANK PERFORMANCE: EVIDENCE FROM THE GHANA STOCK EXCHANGE

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ABSTRACT

Growth of firms, their improvement, efficiency and profitability are cardinal benefits expected from mergers and acquisitions (M&A). This research is an attempt to seek for the effects of mergers and acquisitions on the performance of firms in the Ghanaian Stock Market from 2002 to 2012. The study was accounting based and used univariate analysis with t-testing as well as panel data methodology for the analysis. The univariate analysis revealed dwindling profitability after the merger for all the firms with the t-test showing significant difference in profitability before and after merger. The evidence from panel methodology indicates that M&A has significant negative effect on the profitability of firms. It is therefore imperative that M&As are properly planned, executed and evaluated. Specifically, efforts should be made to attract and retain key personnel of the merged firms through performance contracts or bonuses, proper conflict resolution measures should be put in place and conscious effort made to reap the expected returns of the merger. This is because gains from mergers and acquisitions do not just occur. Additionally, our results indicate that risk and firm size have a considerable effect on profitability of firms while debt capital and firm growth enhance firm profitability.

KEYWORDS

Merger and Acquisition, Profitability, Ghana

INTRODUCTION

Achieving corporate growth can occur through internal or external means. Langford and Male (2001) identified three means of achieving corporate growth and development: internally, where the firm invests its own capital to set-up and operates a new venture. This option is often the primary vehicle of growth; externally through mergers and acquisition (M&A) which is often used where speed is the essence and a combination of internal and external development through contractual agreements. At the corporate level M&A has been identified by most
companies as the most favoured non-organic strategy for achieving their growth objectives. Choi and Russel (2004) reinforced the principle that modern businesses seek to grow in order to survive in competitive markets using M&A and it has been identified as one of the most important events in corporate finance, for firms as well as the economy (Fuller, Netter and Stegemoller 2002).

To a large extent firms engage in M&A for gains that can accrue through expenses reduction, increase market power, reduced earnings volatility and scale and scope economies. However a number of studies in many countries have shown inconsistent results. Whilst some have concluded that M&A have synergistic effect, others paradoxically have reported negative effect with others showing mixed or insignificant results.

In Ghana studies on the M&A have been limited and the existing studies such as Gatsi and Agbenu (2006), Gatsi and Nyarkotey (2010), Seidu, (2011) either focused on one company merger deal or based on shorter time-frame or both. The use of a case study reflects only a particular event and the shorter time frame on the other hand undermines the process.

The researcher seeks to provide further evidence on the impact of M&A on firms’ performance in a developing economy thus Ghana. The study seeks to add to existing research on M&A and test the existing empirical evidence in the Ghanaian market using merger deals in the Ghana Stock Exchange. Given the size of the emerging Ghanaian market, the results could be at variance with evidence in other countries. The paper is sequentially organized as follows: section two has to do with literature review; section three discusses the methodology of the study whiles section four deals with the empirical results and section five concludes the study.

THEORETICAL AND EMPIRICAL LITERATURE

Merger is defined as an arrangement whereby the asset of two companies become vested in or under the control of one company (which may or may not be one of the original two companies), which has all or substantially all, the shareholders of the two companies (Weinberg and Blank 1979). Gaughan (2002) opined that merger is a combination of two companies in which only one company survives and the merged company ceases to exist, whereby the acquiring company assumes ownership and for that matter control of assets and liabilities of the merged company.

Companies adopt M&A as growth strategy for different reasons. Hopkins (1999) classified the motives of M&A suggested in prior studies as four different and related motives: strategic, market, economic, and personal motives. Strategic motive is concerned with improving the strength of the firm’s strategy, example, creating synergy, utilizing a firm’s core competence, increasing market power, providing the firm with complementary resources, products and strengths. Market motive aims at entering new markets in new areas or countries by acquiring already established firms as the fastest way, or as a way to gain entry without adding additional
capacity. Establishing economics of scale is included in economic motive; the agency problem and management hubris are included in personal motives.

Two main theories underpin the various reasons for M&A: value creation theories and redistribution theories (Berkovitch and Narayanan 1993, Frederikslust et al. 2000, and Vijgen 2007). Value Creation theory postulates that managers look after the interest of the shareholders since they strive to create surplus value. From an economical point of view, M&A makes sense when there is synergy; the value of the merged part is greater than the sum of the target and bidder alone (Vijgen, 2007). Redistribution theories of Merger comprise the hubris and the agency theories. The hubris theory supposes that managers are overconfident in their own ability of running a firm. Although they pursue synergy in order to maximize the shareholder value of the firm, the synergy value is not as high as they expect because they suffer from an inflated ego (Frederikslust et al., 2005).

Roll (1986), stated that M&A driven by hubris, in most of the cases, have a surplus value but that this value is lower than the takeover premium. The agency theory assumes that managers and shareholders have different interests because management and control of a company are separated. Therefore, managers will not always try to maximize shareholder value but act in their self-interest; pursue private benefits. According to Mueller (1989), empire building is a reason for conducting M&A. A big company gives a manager more status and his salary will also increase hence, managers do not strive to maximize the shareholder value of the company but pursue their own goal. Another reason for undertaking M&A is free cash flow. This money could be paid out as dividend to shareholders. However, in the agency theory this money will be used to acquire a company to satisfy the desire of managers.

Many studies have empirically examined the impact of M&A on corporate financial performance. Studies based on analysis of accounting data have attempted to assess the economic impact of M&A by testing for changes in the profitability of the merged firms (Altiok-Yilmaz 2011) and the results are inconsistent.

Some studies reported improved performance after merger event. For example, Ismail et al. (2010) found that some measures of corporate performance, such as profitability, suggest statistical significant gains in the years following M&A. Studies conducted by Lau et al. (2008) which compared pre-merger performance with the post-merger provided some evidence that mergers improve the post-merger operating performance. Ramaswamy and Waeglelein (2003) tested the long-term post-merger financial performance of merged companies in Hong Kong and concluded that there is a positive significant improvement in the post-merger performance.

Gugler et al. (2003) examined and analyzed the effects of mergers and found that profitability is positive in all five years after mergers and is significant in every year at 10% level. On country level, the results suggest that the U.S., the United Kingdom, Continental Europe,
Australia, New Zealand and Canada have the same pattern regarding the increase in profits and decrease in sales. In Japan, the results were somewhat different as three of the five profit comparisons were negative, while sales were greater than projected in two of the five post-merger years.

In contrast to the above, some studies have reported losses after merger event which connote negative effect of merger on performance. Such studies include: Pazarskis et al (2006) reported a decreased profitability of firms due to M&A; Yeh and Hoshino (2002) found insignificant negative change in productivity, significant downward trend in profitability, significant negative effect on the sales growth rate, and downsize in the workforce after mergers and generally concluded that mergers have a negative impact on firm performance; Altiol-Yilmaz (2011) confirming negative impact of mergers on performance found that Return on Asset, Return on Equity and Return on Sales values are significantly lower than pre-acquisition value. Studies such as Hogarty (1978), Ravenscraft and Scherer (1987) and Tambi (2005) also report negative impact of M&A on performance.

Other empirical studies have found mixed results. Kumar (2009) concluded that the post-merger profitability, assets turnover and solvency of the acquiring companies, on average, show no improvement when compared with premerger values. King et al. (2004) showed that M&A do not lead to superior financial performance. They argued that M&A has a modest negative effect on long-term financial performance of acquiring firms. Cabanda and Pajara-Pascual, (2007) reported that pre-and post-merger values obtained mixed results. Some measures of corporate performance such as total assets turnover, which measures firms’ efficiency, suggest statistically significant gains in the long-run analysis, following M&A. Other performance variables such as net income return on asset (ROA), return on sales (ROS), capital expenditure, capital expenditure/sales (CESA) and capital expenditure/total asset (CETA) did not show significant gains after merger in the short run analysis and thus concluded that merger does not lead to all improved corporate performance both in short- run and long-run period.

This study therefore hopes to determine the effect of M&A on the performance of companies in the Ghana Stock exchange.

**METHODOLOGY**

The study was based on listed firms in Ghana. The use of listed firms is primarily due to data availability and reliability. There are five listed companies (Guiness Ghana Brewery limited, Total Petroleum Ghana Limited, AngloGold Ashanti Ghana Limited, SG-SSB Ghana Limited and UT Bank Limited) which underwent Merger or acquisition during the period from 1999 to 2010. Two of these companies (SG-SSB Ghana Limited and UT Bank Limited) are financial institutions. The details of the sample companies, (Acquirer and Target), along with the date of the merger and the name of the companies after merger are provided in table 1. To examine the
effect of mergers on performance of listed firms in Ghana, the following hypothesis was tested using both the univariate approach and the panel data methodology.

H01: There is no significant effect of mergers and acquisition on the performance of listed firms in Ghana.

**USING UNIVARIATE APPROACH**

Financial information for each firm was grouped into Pre-merger and Post-merger periods and coded as 0 and 1 respectively. To examine the difference in the pre and post-merger financial performance, the study derived descriptive statistics for the individual firms and the group before and after the merger from general model (univariate). Independent sample T-testing was used in comparing statistically the pre and post-merger performance.

**USING PANEL DATA APPROACH**

Panel data methodology allows for the study of cross section data over several time periods. The combination of time series with cross-sections can enhance the quality and quantity of data in ways that would be impossible using only one of these two dimensions (Gujarati, 2004)

**The Model**

The basic model is written as

\[ Y_{it} = \alpha + \beta X_{it} + \epsilon_{it} \] (1)

Where \( Y_{it} \) is the dependent variable (Return on Equity), \( \alpha \) is the intercept, \( \beta \) is the slope whiles \( X_{it} \) is the independent variable (Merger). The study also controlled for the effect of the following factors on the performance of companies; capital structure, size, growth and risk. Specifically, the actual effect of M&A on performance and the degree to which merger explains the changes in the financial companies included in the study were determined using regression model below:

\[ ROE_{i,t} = \alpha_0 + \beta_1 MGR_{i,t} + \beta_2 TDA_{i,t} + \beta_3 SIZE_{i,t} + \beta_4 GRO_{i,t} + \beta_5 RISK_{i,t} + \epsilon_{it} \] (2)

The variables are defined in Table 2 together with expected signs for the independent and control variables. The study used Statistical Package for Social Sciences (SPSS) and STATA for the data analysis.
DISCUSSION OF RESULTS

UNIVARIATE ANALYSIS

Tables 3 and 4 show the averages of ROA and ROE of the individual firms before and after the merger event with their respective standard deviations. The results showed that all the companies that were involved in merger on the Ghana Stock Exchange from 1999 to 2010 experienced deterioration in profitability. The average returns on assets and return on equity of all the merged firms reduced with AngloGold obtaining a negative ROA and ROE after the merger event representing operational loss. These results suggest that merger and acquisition is harmful to firm performance.

INDEPENDENT SAMPLE TEST RESULTS

The results from the evaluation of the relative change in the performance indices of the companies are examined and the results are presented in table 5. The profitability position of firms measured by Return on Asset (ROA) and Return on Equity (ROE) show significant decrease and is significantly different from the pre-merger values. ROA and ROE revealed T-Value of 3.315 (P-Value of .002) and 3.880 (P- Value=.000) respectively. Based on the above, the null hypothesis of no significant difference was rejected at a 95% confidence interval. It is evidenced that pre-merger profitability was significantly higher than the post-merger. These results confirmed the findings from Pazarskis et al (2006), Altiol-Yilmaz (2011), Yeh and Hoshino (2002), Hogarty (1978), Ravenscraft and Scherer (1987) and Tambi (2005) which concluded decreased profitability after merger but however run contrary to findings in Ismail et al. (2010), Ramaswamy and Waegelein (2003), Gugler et al (2003) and Lau et al. (2008) which reported improved performance after merger and acquisition.

EVIDENCE FROM PANEL DATA METHODOLOGY

DESCRIPTIVE STATISTICS

Table 6 captures the descriptive statistics of the variables used to examine whether M&As have any effect on the profitability of listed firms. Over the 10-year study period the five companies under study recorded an average return on equity of about 22% even though it is apparent that some recorded very huge negative returns. Meanwhile the average risk associated with getting this return was 11.57%. Debt capital covered a greater proportion (about 71%) of the means of financing company assets confirming earlier empirical evidence that most listed firms in Ghana use more debt as their main source of funding (Abor 2005, Agyei 2011). The average log of total sales was 8.27 while firm growth rate averaged at 32.32% (although, apparently, not all firms under study achieved this height as some recorded as low as -22.59% growth rate).
**CORRELATION AND VARIANCE INFLATION ANALYSIS**

The low levels of pair correlation among the variables explain that the problem of multicollinearity was not significant. This is corroborated by the results of the variance inflation test (1.23). These results have been shown in table 7A and 7B.

**REGRESSION RESULTS**

This study sought to evaluate the relationship between M&As and the performance of firms on the Ghana Stock Exchange. Our results do not deviate from previous empirical findings which have concluded that M&As have negative effect on the performance of firms but does not offer any support for the fact that M&A increase firm profitability. Our results suggest strongly that M&A’s harm the return on equity of the merged firm. Among some of the likely reasons that could account for this include lost of experienced top (middle and lower) executives through voluntary redundancy schemes, lack of proper road map scheme to ensure the effective implementation of the merger or acquisition strategy, inability to cash in fully on the synergies that the M&As bring and improper handling of post merger board room conflicts.

Consequently it is imperative for managers of merged or acquired firms to make conscious efforts to reap the benefits of M&As because these benefits do not just occur. Our results also show that M&A is not the only factor that harm merged firm profitability but also firm risk and surprisingly firm size (as measured by the log of total assets). This seems to suggest improper management of firm risk and inefficient use of firm resources. It is not clear as to whether these abysmal performances were influenced by the merger or acquisition as some other studies showed otherwise. These notwithstanding, debt capital and growth of firms are seen as major catalyst for the profitability of merged firms listed on the Ghana Stock Exchange. The heightened discipline of debt use and the additional benefits of sales expansion are beneficial to firms. The results therefore offer support for the capital structure relevance theory.

**CONCLUSION**

Several benefits are sought from mergers and acquisitions. Prominent of them is an improvement in firm performance. Even though some studies have been done in developed economies same cannot be said of developing countries like Ghana. In Ghana, for instance, M&As have been few just like its studies. No empirical evidence exists on the effect of M&As on the performance of listed merged firms, an objective this study sought to achieve. The univariate analysis revealed dwindling profitability after the merger for all the firms with the t-test showing significant difference in profitability before and after merger. The evidence from panel methodology indicates that M&A has significant negative effect on the profitability of firms. This study therefore does not support the value creation theories of mergers and acquisition. However, firms go into mergers and acquisition for numerous reasons some of which are qualitative. Again, a merger may be effective to deliver the immediate objective but
may fail to deliver all the theoretically defined benefits. In effect it would be fallacious to assume, on the basis of this study, that, merger activities are completely detrimental to companies. It is imperative that M&As are properly planned, executed and evaluated. Specifically, efforts should be made to attract and retain key personnel of the merged firms through performance contracts or bonuses, proper conflict resolution measures should be put in place and conscious effort made to reap the expected benefits of the merger. This is because gains from mergers and acquisitions do not just occur. Additionally, our results indicate that risk and firm size have significantly negative relationship with firm profitability while debt capital and firm growth enhance firm profitability.

REFERENCES


48. Vijgen, D., (2007). *Shareholders wealth effects on mergers and acquisition in the Western part of Continental Europe*, University of Maastricht


Table 1: List of Merged Firm

<table>
<thead>
<tr>
<th>NO</th>
<th>ACQUIRER COMPANY</th>
<th>TARGET COMPANY</th>
<th>YEAR MGR</th>
<th>NAME AFTER MERGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Total Petroleum Ghana</td>
<td>Total Ghana Ltd</td>
<td>2006</td>
<td>Total Petroleum Ghana</td>
</tr>
<tr>
<td>3.</td>
<td>AngloGold</td>
<td>Ashanti Goldfield</td>
<td>2004</td>
<td>AngloGold Ashanti</td>
</tr>
<tr>
<td>5.</td>
<td>UT Holdings Ltd</td>
<td>BPI Bank</td>
<td>2008</td>
<td>UT Bank</td>
</tr>
</tbody>
</table>

Source: Ghana Stock Exchange

Table 2: Definition of variable and their Expected Signs

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
<th>Expected sign</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROE</td>
<td>Return on Equity (Dependent Variable) = Ratio of Net Profit after tax and Preference Dividend to Equity Fund for firm ( i ) in time ( t )</td>
<td></td>
</tr>
<tr>
<td>ROA</td>
<td>Return on Asset= The ratio of Net Profit after tax to Total Assets of Firm ( i ) in time ( t )</td>
<td></td>
</tr>
<tr>
<td>MGR</td>
<td>Independent Variable: Merger = Dummy variable. 1 for Post-merger otherwise 0 for Firm ( i ) in time ( t )</td>
<td>Negative/Positive</td>
</tr>
<tr>
<td>TDA</td>
<td>Control Variable: Leverage = the ratio of Total Debt to Total Net Assets for firm ( i ) in time ( t )</td>
<td>Positive</td>
</tr>
<tr>
<td>SIZE</td>
<td>Control Variable: Firm Size = The log of Total Assets for firm ( i ) in time ( t )</td>
<td>Positive</td>
</tr>
<tr>
<td>GRO</td>
<td>Control Variable: Growth= Year on Year change in turnover for firm ( i ) in time ( t )</td>
<td>Positive</td>
</tr>
<tr>
<td>RISK</td>
<td>Control Variable: Firm Risk=the standard</td>
<td>Positive</td>
</tr>
</tbody>
</table>
deviation of ROE for firm \( i \) in time \( t \)

\[ E \]

The error term

Positive

### Table 3: Descriptive Statistics on ROA

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>MGR</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>GGBL</td>
<td>Pre-merger</td>
<td>.215682</td>
<td>.0852147</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.153152</td>
<td>.0333069</td>
<td>6</td>
</tr>
<tr>
<td>TPL</td>
<td>Pre-merger</td>
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<td>.1042602</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.102215</td>
<td>.0400303</td>
<td>5</td>
</tr>
<tr>
<td>UTBL</td>
<td>Pre-merger</td>
<td>.057948</td>
<td>.0255944</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.042799</td>
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<td>3</td>
</tr>
<tr>
<td>SG-SSB</td>
<td>Pre-merger</td>
<td>.094149</td>
<td>.0182744</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.049836</td>
<td>.0102709</td>
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</tr>
<tr>
<td>AGAL</td>
<td>Pre-merger</td>
<td>.120889</td>
<td>.0364041</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>-.020165</td>
<td>.0676483</td>
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</table>

Source: SPSS General model (Univariate) Output

### Table 4: Descriptive Statistics on ROE

<table>
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<th>CODE</th>
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<th>Std. Deviation</th>
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<tr>
<td>GGBL</td>
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<td>.1233149</td>
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<tr>
<td></td>
<td>Post-merger</td>
<td>.187722</td>
<td>.1469829</td>
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</tr>
<tr>
<td>TPL</td>
<td>Pre-merger</td>
<td>.250562</td>
<td>.2334915</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.176259</td>
<td>.0965570</td>
<td>5</td>
</tr>
<tr>
<td>UTBL</td>
<td>Pre-merger</td>
<td>.399139</td>
<td>.1778140</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Post-merger</td>
<td>.281830</td>
<td>.0770652</td>
<td>3</td>
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<tr>
<td>SG-SSB</td>
<td>Pre-merger</td>
<td>.369075</td>
<td>.0828328</td>
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<td></td>
<td>Post-merger</td>
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<tr>
<td>AGAL</td>
<td>Pre-merger</td>
<td>.197200</td>
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<td>5</td>
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<tr>
<td></td>
<td>Post-merger</td>
<td>-.115915</td>
<td>.1819686</td>
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</tbody>
</table>

Source: SPSS General model (Univariate) Output
Table 5: T-Statistics (Two-Tail) of Financial Indices

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>MGR</th>
<th>N</th>
<th>MEAN</th>
<th>STD. DEVIATION</th>
<th>T-VALUES</th>
<th>P-VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROA</td>
<td>Pre-2</td>
<td>.1322</td>
<td>.0851817</td>
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<tr>
<td></td>
<td>Post-2</td>
<td>.0626</td>
<td>.0727697</td>
<td>3.315</td>
<td>.002</td>
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</tr>
<tr>
<td>ROE</td>
<td>Pre-2</td>
<td>.3122</td>
<td>.1668916</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>Post-2</td>
<td>.1313</td>
<td>.1848423</td>
<td>3.880</td>
<td>.000</td>
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</tr>
</tbody>
</table>

Source: SPSS independent sample test output. (Level of significant at 5% level)

Table 6: Descriptive Statistics of Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Obs</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>roe</td>
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<td>.1970674</td>
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<tr>
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<td>0</td>
<td>1</td>
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<tr>
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<td>.1156796</td>
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</table>

Table: 7A: Correlation Matrix

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<tr>
<th></th>
<th>roe</th>
<th>mgr</th>
<th>tdass</th>
<th>logasset</th>
<th>sagrow</th>
<th>riskroe</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1.0000</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>mgr</td>
<td>-0.4629</td>
<td>1.0000</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>0.0003</td>
<td></td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.1194</td>
<td>0.0396</td>
<td>0.7697</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.3761</td>
<td>0.5152</td>
<td>-0.0302</td>
<td>1.0000</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-0.5960</td>
<td>0.0300</td>
<td>0.8233</td>
<td></td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.3335</td>
<td>-0.1983</td>
<td>-0.0153</td>
<td>-0.2453</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.0157</td>
<td>0.1588</td>
<td>0.9145</td>
<td>0.0796</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-0.2856</td>
<td>-0.2464</td>
<td>0.0564</td>
<td>0.0233</td>
<td>-0.0094</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.0313</td>
<td>0.0647</td>
<td>0.6769</td>
<td>0.8635</td>
<td>0.9474</td>
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</table>
Table 7B: Variance Inflation Test

<table>
<thead>
<tr>
<th>Variable</th>
<th>VIF</th>
<th>1/VIF</th>
</tr>
</thead>
<tbody>
<tr>
<td>mgr logasset</td>
<td>1.47</td>
<td>0.678260</td>
</tr>
<tr>
<td>riskroe sagrow tdass</td>
<td>1.45</td>
<td>0.688897</td>
</tr>
<tr>
<td></td>
<td>1.12</td>
<td>0.896813</td>
</tr>
<tr>
<td>Mean VIF</td>
<td>1.23</td>
<td></td>
</tr>
</tbody>
</table>

Table 8: Regression Results

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>Number of</th>
<th>F(5,52)</th>
<th>Prob &gt; F</th>
<th>R-squared</th>
<th>Adj R-</th>
<th>Root MSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>1.23920756</td>
<td>5</td>
<td>.247841513</td>
<td>52</td>
<td>14.10</td>
<td>0.0000</td>
<td>0.6051</td>
<td>0.5622</td>
<td>.1326</td>
</tr>
<tr>
<td>Residual</td>
<td>.808804347</td>
<td>4</td>
<td>.017582703</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2.04801191</td>
<td>51</td>
<td>.040157096</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Variable       | Coef.       | Std. Err. | t     | P>|t| | [95% Conf. Interval] |
|----------------|-------------|------------|-------|------|---------------------|
| mgr            | -.1276947   | .0449556   | -2.84 | 0.007 | -.2181856 to -.0372038 |
| tdass          | .3227501    | .1389024   | 2.32  | 0.025 | .0431542 to .6023461 |
| logasset       | -.0819017   | .0248139   | -3.30 | 0.002 | -.1318494 to -.0319539 |
| sagrow         | .12133      | .0649398   | 1.87  | 0.068 | -.009387 to .252047 |
| riskroe        | -.717075    | .180731    | -3.97 | 0.000 | -.1.080868 to -.3532824 |
| _cons          | .7739504    | .2283124   | 3.39  | 0.001 | .3143814 to 1.233519  |
ORGANIZATIONAL ROLE STRESS AND JOB SATISFACTION IN PUBLIC AND PRIVATE BANK EMPLOYEES OF PAKISTAN

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Institute of Applied Psychology, University of the Punjab, Lahore, Pakistan
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ABSTRACT

The aim of the study was to see the relationship between organizational role stress and job satisfaction in public and private bank employees. It was hypothesized there would be a relationship between organizational role stress and job satisfaction in public and private bank employees. The sample comprised of 150 managers, operation managers and cashiers (M age=33.9, SD=6.15) selected from different public and private banks of Lahore. Perceived Stress Scale (Cohen, Mermelstein & Kamarck, 1983) and Job Satisfaction Survey (Spector, 1994) were used to measure role stress and job satisfaction. Results demonstrated a significant negative relationship between organization role stress and job satisfaction. The results of the current study will help in diminishing stress related to role (job) of bankers and promoting job satisfaction in them which would increase their productivity.

KEYWORDS

Role stress, Job Satisfaction, Employees of banking sector

INTRODUCTION

The purpose of present study is to investigate the relationship between organizational role stress and job satisfaction in public and private bank employees. In an organization, an individual's role stress refers to the stress formed by the combined expectations of an individual's behavior from all circles. While facing role stress, an individual may produce unfavourable behavior to an organization, such as performance reduction, job burnout, and resignation, which deserve to be taken seriously. In regard to the relationship between role stress and job satisfaction, found that the tension at work caused by role ambiguity, role conflict, and role overload has a significant negative correlation with job satisfaction (Waters & Ussery, 2007).
The term stress was first used by Selye describing stress as the force, pressure, or strain exerted upon a material object or person which resist these forces and attempt to maintain its original state. Role stress is a stress, people experienced within their role (job) in an organization, is a condition which happens when one realizes the pressure on them or requirements of situation are wider than they can handle, and if these requirements are huge and continue for a long period of time without any interval, mental, physical or behavioral problems may occur (Waters & Ussery, 2007).

Stress is dynamic state whereby the masses are faced with an opportunity, obstacle, constraints or demand regarding what one desires and the implication of which is considered to be uncertain, negative, terrifying and important (Robbins, 2004). Behr and Newman define role stress as a situation arising from the reaction of people towards their tasks and results in changes that compel individuals to cope and adjust and disrupt their normal performance. (Pfeffer, 1992). When a person is confronted with a situation which poses a threat, and perceives that she or he does not have the capability or resources to handle the stressors, the imbalance that results at that point in time is termed as stress (Luthan, 2005).

Psychologists, sociologists and empirical researchers have conceptualized role stress from different perspectives (Kahn, Lazarus, Hardy & Conway, 2008). Hardy and Conway (1999) classified the dimensions of role stress specifically for healthcare professionals. These dimensions are role conflict, role ambiguity, role overload, role incompetence or over-qualification and role incongruity. Role conflict is defined in terms of the dimensions of compatibility-incompatibility in the requirements of the role (job) and employee’s capability. Role ambiguity is the predictability of the outcome to one’s behaviour and the existence or clarity of behavioural requirements, often in terms of inputs from the environment, which would serve to guide behaviour and provide knowledge that the behaviour is appropriate (Rizzo et al., 2002). Role conflict and ambiguity are significantly related to job stress, organizational commitment, job satisfaction and intentions to leave profession (Rosse & Rosse, 2008).

Job satisfaction is a measure of the degree to which the employee is satisfied and happy with the job. Job satisfaction is higher when a person feels that he or she has control over the way a given task is accomplished. It is a most frequently studied variable in organizational behaviour research, and also a central variable in both research and theory of organizational phenomena ranging from job design to supervision (Spector, 1997). Job satisfaction may be defined as ‘the pleasurable emotional state resulting from the appraisal of one's job as achieving or facilitating the achievement of one's job values’. It is considered as a multidimensional construct involving for example, perceptions about work content, relationships with co-workers and supervisors, job control, job security, rewards, career opportunities, promotion and advancement, physical work environment, customers and feelings such as self accomplishment and self-advancement.

Sjogren (2005) found that working circumstances (working schedule, management and relationships with co-workers), salary and professional development were the overriding reasons
both for leaving and considering a return. Earnings, working hours, working atmosphere, workplace socialization, independence, organizational control, and participation in training schemes are all work-related factors shown to be affecting job satisfaction (Agho, Mueller, & Price, 1993; Arthur, Edens, Bell, & Bennett, 2003; Georgellis & Lange, 2007).

In giving watchful thought to the relationship between role stress and job satisfaction, found that the stress at work brought on by role conflict, role ambiguity and work overload has a noteworthy negative relationship with job satisfaction. Holdsworth and Cartwright (2003) stated in a recent study on Empowerment, stress and job satisfaction they concluded that job satisfaction is one of the job sources. According to the study, if an individual is frustrated with the penning of the affiliation, this frustration completes in one of the wellsprings of job satisfaction. As per a few studies illustrated that there is a strong negative connection between occupational stress and job satisfaction (Sweeney, 2009).

Beehr and Newman (2004) in their study Organizational role stress characterize the unsafe physical and passionate reactions that emerge when the trouble of work don't match the labourer’s capabilities, assets, or needs.

Nadia and Ayub (2011) in a study described relationship between work motivation and job satisfaction explored numerous factors related to job satisfaction among bank managers. The findings of the study proposed that there was a positive correlation between work motivation and job satisfaction. Furthermore, there was a significant gender difference on the variable of work motivation and job satisfaction.

In two qualitative studies carried out in Taiwan by demonstrated role ambiguity and role conflict developed as normal encounters throughout the first year of practice as a medical attendant authority. Review studies found that the more work-related stressors were under-planning contradicting cravings from therapeutic and nursing divisions (Wu, 2002).

According to some other studies (Johnson, Cooper, Cartwright, Donald, Taylor & Millet, 2005; & Munro; 2006) employees with low occupational stress have more job satisfaction than employees with high work-related stress.

Based on above literature review, the primary aims of the current study are twofold. One, the study attempts to explore the relationship between organizational role stress and job satisfaction in public and private bank employees. Two, the study also looks at public and private bank employees’ differences, in terms of organizational role stress and job satisfaction. And discuss the determinants of role stress and assess how they can reduce among public and private employees. Coming to the rationale of this study requires investigating role stress that promotes dissatisfaction in public and private employees of banking sector.
OBJECTIVES

The objectives of the current study are:

- To explore the relationship of organizational role stress and job satisfaction in public and private organizations.
- To discover differences in the level of role stress and job satisfaction between the workers of Public and Private Sector Banks.
- To find out the factors triggering organizational role stress in public and private banking sector employees

HYPOTHESES

Following are the hypotheses of the study

1. There is likely to be relationship between organizational role stress and job satisfaction.
2. There are likely to be differences in role stress among employees of public and private banks.
3. There are likely to be differences in job satisfaction among employees of public and private banks
4. Bank employees differ significantly in role stress and job satisfaction with respect to their designations.
5. Bankers with more work experience are likely to be more stressed with their role (job).
6. Bankers with more work experience are likely to be more satisfied with their jobs.

METHOD

SAMPLE

Between group research design was used to compare the difference in the level of organizational role stress and job satisfaction among the employees of public and private banks. The sample comprised of 150 managers, operational managers and cashiers with the age range of (25-45). Sample was collected from different public and private banks of Lahore e.g. National bank, The bank of Punjab, Habib bank, Meezan bank, Silk bank, Bank Alfalah following the non probability purposive sampling technique. While taking sample the following criteria were kept in consideration. The age ranged between 25-45 years with the qualification of masters. Below the age of 25 year, above 45 years and physically handicapped participants were excluded.
### Table 1: Descriptive of Demographic Variables (N=150)

<table>
<thead>
<tr>
<th>Variables</th>
<th>M (SD)</th>
<th>f (%)</th>
</tr>
</thead>
<tbody>
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<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
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<td></td>
</tr>
<tr>
<td>MA</td>
<td></td>
<td>62(41.3)</td>
</tr>
<tr>
<td>MBA</td>
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<tr>
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</tr>
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<td>Joint</td>
<td></td>
<td>102(68.0)</td>
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<td>Managers</td>
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<td>Cashiers</td>
<td></td>
<td>3(25.3)</td>
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<td><strong>Banks</strong></td>
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<td></td>
</tr>
<tr>
<td>Public</td>
<td></td>
<td>81(54.0)</td>
</tr>
<tr>
<td>Private</td>
<td></td>
<td>69(46.0)</td>
</tr>
<tr>
<td><strong>Work Experience</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-5 years</td>
<td></td>
<td>33(22.0)</td>
</tr>
<tr>
<td>6-10 years</td>
<td></td>
<td>64(51.9)</td>
</tr>
<tr>
<td>11-15 years</td>
<td></td>
<td>39(26.0)</td>
</tr>
</tbody>
</table>
ASSESSMENT MEASURES

Demographic Information Questionnaire. Demographic information questionnaire was used to get information about age, designation, family system, marital status, education and work experience.

Perceived Stress Scale. The Perceived Stress Scale, PSS is a 10-item self report measure that measures persons' assessment of the unpleasantness of the circumstances in the previous month of their lives (Cohen, 1983). Response categories are 0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often. Things 4, 5, 7, and 8 are the decidedly expressed items. Scores extended from 0 to 40, with higher scores appearing stress. Alpha coefficient for this scale was .78.

Job Satisfaction Survey. The Job Satisfaction Survey, JSS is a 36, nine subscales to assess worker disposition about the occupation and parts of the job. Each subscale is assessed with four items, and a total score is computed from all items. The nine subscales are Pay, Supervision, Contingent Rewards (performance based rewards), Co-workers, Promotion, Fringe Benefits, Communication, Nature of Work, and Operating Procedures (required rules and procedures). Response categories are 1= Disagree very much, 2= Disagree moderately, 3= Disagree slightly, 4= Agree slightly, 5= Agree moderately, 6= Agree very much. The internal consistency of Job Satisfaction Survey assessed by Cronbach alpha was .91.

ETHICAL CONSIDERATIONS

To initiate the study, prior permission for the tool was taken from the author via e-mail; permission letter was signed by the supervisor to collect the data. Accurate information was provided to the organization to obtain organizational approval. Participants were fully informed about the purpose of the research, the procedure, their right to decline to participate and to withdraw from the research once participation has began. Rights of individuals to privacy, confidentiality and self-determination were facilitated.

PROCEDURE

Formal permission was taken from banking sector to collect data. Participants were informed about the nature and purpose of the study and were ensured of privacy regarding their identity. A selection criterion was identified with the help of bank manager. Participants were explained the purpose of the research, their concerns were answered. They were also informed about their right of withdrawal from the study. Informed consent was distributed among the participants and they were given the questionnaire to fill it up. Participants were given instructions to fill the questionnaire. The data was collected in banking settings. None of the participant declined to complete the questionnaire. The participants needed half an hour to complete the questionnaire. All of the 150 participants of different public and private banks completed their questionnaire.
RESULTS

Pearson product moment correlation was used to assess relationship of role stress and job satisfaction. The sample comprised of 150 managers, operational managers and cashiers with the age range of (25-45).

Table 2: Table showing correlation between role stress and job satisfaction (N=150)

<table>
<thead>
<tr>
<th>Role Stress</th>
<th>M</th>
<th>S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Satisfaction</td>
<td>-.18*</td>
<td>3.66</td>
</tr>
<tr>
<td>M</td>
<td>1.81</td>
<td></td>
</tr>
<tr>
<td>S.D</td>
<td>0.37</td>
<td></td>
</tr>
</tbody>
</table>

Note.*p<.05

Table 2 demonstrated results there was significant negative relationship between role stress and job satisfaction. Higher level of role stress will decrease the level of job satisfaction of the bank employees.

Table 3: Independent sample t-test for public and private banks differences in role stress and job satisfaction (N=150)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Public banks</th>
<th>Private banks</th>
<th>95% CI</th>
<th>Cohen’s d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M  SD</td>
<td>M  SD</td>
<td>t</td>
<td>P   LL</td>
</tr>
<tr>
<td>Role Stress</td>
<td>1.81 .32</td>
<td>1.80 .42</td>
<td>.81</td>
<td>.85 -.11</td>
</tr>
<tr>
<td>Job Satisfaction</td>
<td>3.60 .32</td>
<td>3.74 .43</td>
<td>-.2.12</td>
<td>.03 .26</td>
</tr>
</tbody>
</table>

Note. p<.01

Results in Table 3 revealed that no significant difference was found regarding role stress in public and private sector banks which indicates that employees of both public and private banks feel same level of role stress in their organization. Significant difference existed between employees of public sectors banks and private sector banks regarding job satisfaction. The workers of private banks are more satisfied to their employments as contrasted with public sector banks.
Table 4: Table showing ANOVA among sample (managers, operation managers and cashiers) on the basis of role stress (N=150)

<table>
<thead>
<tr>
<th>Role Stress</th>
<th>M</th>
<th>S.D</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers</td>
<td>1.81</td>
<td>0.41</td>
<td>0.31</td>
<td>0.73</td>
</tr>
<tr>
<td>Operation Managers</td>
<td>1.79</td>
<td>0.31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cashiers</td>
<td>1.85</td>
<td>0.45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. M=Mean, S.D= Standard deviation*

Results in Table 4 showed there was no significant difference among managers, operation managers and cashiers regarding role stress, which demonstrated that employees of both public and private banking sector with different designations experience equal level of stress.

Table 5: Table showing ANOVA among sample (managers, operation managers and cashiers) on the basis of Job satisfaction (N=150)

<table>
<thead>
<tr>
<th>Job Satisfaction</th>
<th>M</th>
<th>S.D</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers</td>
<td>3.72</td>
<td>0.44</td>
<td>3.58</td>
<td>0.03</td>
</tr>
<tr>
<td>Operation Managers</td>
<td>3.59</td>
<td>0.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cashiers</td>
<td>3.77</td>
<td>0.38</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. M=Mean, S.D= Standard deviation*

Results in Table 5 showed that the level of job satisfaction was significant among managers, operation managers and cashiers, which showed bank employees with different designations experience different level of job satisfaction.

Table 6: Comparison among three designations of bank employees on job satisfaction (N=150)

<table>
<thead>
<tr>
<th>(I) Designation</th>
<th>(J) Designation</th>
<th>Mean Difference(I-J)</th>
<th>SE</th>
<th>p</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>95% Confidence Interval</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Post-hoc was applied and the analysis revealed that mean differences were statistically significant. Job satisfaction was significantly different among cashiers than other groups.

**Table 7: Table showing ANOVA on work experience of managers, operation managers and cashiers on the basis of role stress (N=150)**

<table>
<thead>
<tr>
<th>Role Stress</th>
<th>M</th>
<th>S.D</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work experience (1-5 years)</td>
<td>1.79</td>
<td>0.42</td>
<td>0.33</td>
<td>0.72</td>
</tr>
<tr>
<td>(6-10 years)</td>
<td>1.84</td>
<td>0.33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(11-15 years)</td>
<td>1.78</td>
<td>0.39</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. M=Mean, S.D= Standard deviation*

Results in Table 7 showed there was no significant difference among work experience of bank employees regarding role stress.

**Table 8: Table showing ANOVA on work experience of managers, operation managers and cashiers on the basis of Job satisfaction (N=150)**

<table>
<thead>
<tr>
<th>Job Satisfaction</th>
<th>M</th>
<th>S.D</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work experience (1-5 years)</td>
<td>3.63</td>
<td>0.29</td>
<td>29.22</td>
<td>.001</td>
</tr>
<tr>
<td>(6-10 years)</td>
<td>3.57</td>
<td>0.26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(11-15 years)</td>
<td>4.26</td>
<td>0.61</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. M=Mean, S.D= Standard deviation*

Results in Table 8 revealed that the level of job satisfaction was significant among bank employees with more work experience. Means differences showed in the post hoc table.
Table 9: Comparison among work experience of bank employees on job satisfaction (N=150)

<table>
<thead>
<tr>
<th>(I) Work experience</th>
<th>(J) Work experience</th>
<th>Mean Difference (I-J)</th>
<th>SE</th>
<th>p</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>-.04</td>
<td>.06</td>
<td>.76</td>
<td>-.20</td>
<td>.10</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>.06</td>
<td>.10</td>
<td>.81</td>
<td>-.18</td>
<td>.31</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>-.01</td>
<td>.10</td>
<td>.48</td>
<td>-.26</td>
<td>.23</td>
</tr>
</tbody>
</table>

Note. S.E= Standard Error, Work experience 1 = (1-5 years), 2 = (6-10 years), 3 = (11-15)

Post-hoc was applied and the analysis revealed that mean differences were statistically significant. Findings revealed that bank employees with more work experience were more satisfied with their job.

**DISCUSSION**

The present study was conducted to find out relationship between organizational role stress and job satisfaction in public and private bank employees. It was hypothesized that there is likely to be a relationship between role stress and job satisfaction. There are likely to be differences in regards to role stress and job satisfaction among employees of public and private banks.

The findings of the present study supported the hypothesis as negative relationship was found between role stress and job satisfaction. Findings are consistent to the study of (Blegen, 2008), who found that role conflict and role stress were negatively related to job satisfaction. As there are various basics inside the work environment that may be assigned stressors. Excessive workload, unhealthy working environment, insufficient resources, conflict between home and work demands, lack of professional respect, lack of promotion chances, inadequate pay and benefits, domestic problems, and marital problems are the major causes of role stress (Cooper, 2001).

The findings can also be supported by one described by Robbins (2004) inverse relationship exists between role stress and job satisfaction. The impact of stress on job satisfaction is far most straight forward. Job related stress tends to decrease general job satisfaction (Brown, 2001).
Researchers found that bring down the stress it expands the job’s satisfaction so both these are contrarily corresponding one another as to the results both role stress and Job satisfaction is adversely related (Ivancevich & Donnelly, 2002).

Individuals under excessive stress tend to find their jobs less satisfying. Some of their intrinsic or extrinsic needs may be let down or not met sufficiently. As per many studies in the literature (Caplan 2001; Keller, 2009), the findings of the present study also reveal the same. These subjects with lower job satisfaction were found to experience more stress in the form workload, role conflict and physical environment compared to those with higher job satisfaction. Due to the intense competition in telecom industry, organizations are exerting more and more pressure on employees in order to compete each other and contradicting demands, excessive workload and physical working conditions causes role stress that decreases employee’s job satisfaction.

Rose (2003) contemplated that the stress in work environment diminishes the suggestion of workers to perform better in jobs with the growing level of stress the specialists instinct unsettle and his inclination to work well likewise diminishes. In banks there is no time bind so employees need to work for more hours as contrasted with different a employment which is additionally a reason of concern. Stress identifying with the employees’ role in the affiliation consolidates commitment in regards to lives, role conflict, and role ambiguity (Sutherland & Cooper, 2000). Different sources may create from relationship with co-conspirators or supervision, disillusionment with profession improvement open doors, and an absence of employer strength (Parker & Decotiis, 1999). The structure of the affiliation itself can in like manner be a wellspring of stress for specialists.

The present research found no significant differences on role stress among employees of public and private banks which indicated they experience same level of stress regarding their jobs. The main reason of the present findings is that both public and private bank employees have equal number of tasks to perform. Findings revealed significant differences among employees of public and private banks. The workers of private banks are more satisfied to their occupations/jobs as contrasted with public banks. Findings were consistent to the study of (Kahn, 2008) which showed that private sector employees have high level of job satisfaction as compared to private sector employees. There could be many reasons of the present finding private sector employees are profoundly paid as compared to public sector employees. They are provided with a lot of health safety facilities, fringe benefits and bonuses over the period of time.

The present research found no significant difference in role stress with respect to designation and working experience of the employees working in banking sector. While significant differences were found in job satisfaction among bankers with different designations, cashiers were found to be more satisfied with their job than bankers with other designations. The research findings were inconsistent with that of Golding, Resnik and Croby (2001).There could be several reasons for the present study with respect to cashier’s satisfaction. Managers and operation managers are less satisfied to their role (job) because they have to perform lot of duties than cashiers. Several
researches described further reasons of their dissatisfaction are: disagreement with administration, constrained open doors for progression, absence of distinguishment, deficient compensation and profits, exhausted with their employment. Managers face many stresses in their jobs. They are the front line and are expected to get it done at whatever cost. These stresses, as well as the dysfunction prevalent in many organizations (poor communication, inadequate resources and conflicting agendas) are key contributors to manager dissatisfaction.

Results of the present study revealed that employees of banking sector with more working experience were satisfied to their organization. These findings are consistent with those obtained by Hussain (2007) reflected the importance of education and experience as the determinant of job satisfaction. The important findings of this research were persons with more experience in the profession were more satisfied. This research also indicated that employees were overall satisfied with their jobs.

It is generally observed that there is not much available in literature regarding relationship of role stress and job satisfaction. Expectedly only significant relationship was found between role stress and job satisfaction in public and private banks. It is concluded public and private bank employees have same level of stress regarding their (roles). While private banks’ employees have high level of job satisfaction as compared to public banks. No significant differences were found on role stress regarding designations and work experience of bank employees. While employees with more work experiences have high level of job satisfaction. Bank is essential organization of every state. It is also the backbone of economy. In terms of amounts and working conditions, banks are comparatively better than any other organization. The results of the current study will help in diminishing stress related to role (job) of bankers and promoting job satisfaction in them which would increase their productivity.

REFERENCES


KNOWLEDGE ATTITUDE AND PRACTICE TOWARDS PRE-MARRITAL/PRENATAL GENETIC TESTING AMONG YOUNG PEOPLE (15-45) YEARS OF AGE IN SAPELE LOCAL GOVERNMENT AREA, DELTA STATE. NIGERIA

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ABSTRACT

This study investigated knowledge, attitude and practice toward premarital/prenatal genetic testing among young people of 15-45 years of age in Sapele Local Government Area in Delta State Nigeria. Descriptive survey research design was used. The population of the study consisted of the members of four major communities (Amukpe, Amuogoddo, Okirighwe and Uguanja). The respondents were selected by simple random sampling method. The research instrument was a self-constructed questionnaire. A total of 50 respondents were selected. A total 50 questionnaire were distributed and same retrieved. The objectives of the study were to determine level of knowledge of premarital/prenatal genetic testing among young people, to assess the level of practice and to identify factors influencing their attitude towards premarital/prenatal genetic testing. The rational is to enhance young people’s knowledge about premarital/prenatal genetic testing, encourage premarital/prenatal genetic screening and also reduces some of the factors influencing attitudes of young people towards premarital/prenatal genetic testing. Data collected were analyzed using frequency and percentages and were presented using tables and graphs. The study shows that 30% of the respondent level of knowledge of premarital/prenatal genetic testing is of high level, 70% of the respondents have low level of knowledge and the source of information was through media (20%), health personnel (40%), friends (6%) etc. The study also showed that the level of practice is low as 80% of the respondent does not practice premarital/prenatal genetic testing, only 20% practiced it. it also shows that there are some factors influencing their attitudes towards premarital/prenatal genetic testing which include lack of knowledge (66%), non affordability (20%), non Accessibility (55) and also as a result of non availabilities of centers (15%) where premarital/prenatal genetic testing should be carried out. In conclusion, lack of basic knowledge, negative attitude and practice has a negative impact on the young people, their family, their community and the society as a whole. It is therefore recommended that effort should be made
by government, parents, and health personnel to improve knowledge, attitude and practice towards premarital/prenatal genetic testing thereby reducing the incidence rate of having children with genetic defect.

INTRODUCTION

Genetic testing is not a single technology rather; it refers to a broad range of methods for ganging the presence, absence or activity of genes in cells. At the relatively low tech, researcher can count the chromosomes in a patient’s cells or measures the amount of cells tale proteins in his or her blood. At the most sophisticated level, researchers assay a cell DNA with molecular probes that can find a specific genetic sequence among the three billion base pairs that make up human DNA. Genetic testing cost less than I 500 for a simple blood screening for sickle cell or cost in the 1,500 range for a complicated pre implantation genetic test for Tay sacks disease. There are two extremes of genetic tests with ranging costs (Abuelo, 2005).

Genetic screening has great potential for our society. It has the capability of improving and lengthening human life. If used in an ethical manner, genetic testing can eliminate unforeseen suffering and distress. But, issues such as privacy, absent, discrimination, equity and social engineering are potential barriers that many individuals have confronted already. Both legal and personal, family conflicts may arise because of testing of individuals or immediate relatives (Bahado-S. 2008).

Genetic screening uses a variety of laboratory procedures to find out if a person has a genetic condition or disorder or is likely to develop a disease based on his or her genetic makeup. Individuals may be tested if the family shows a history of one specific disease such as hunting’s disease or cancer, if the family shows symptoms of a genetic disorder which could be improved by early diagnosis, or if they are planning possibility of passing on a genetic strait to their offspring. This last type of screening can look at the parent’s genotype or look at the genotype of the fetus or newborn. This type of screening can also look for a specific disorder or can be done as a general test for common disorder as in prenatal testing or more commonly newborn screening. (Filly. R. 2000).

Genetic tests use techniques to examine genes markers near the genes. Direct testing for diseases such as down syndrome, sickle cell anemia & thalassaemia come from an analysis of an individual’s specific genes. A technique called linkage analysis, or indirect testing, is used when the gene cannot be directly identified but can be located within a specific region of a chromosome. This testing requires additional DNA from an affected family member for comparison because each person’s DNA is unique except for identical twins. Genetic tests also can be used for individual identification (DNA finger printing). This technique is often used in forensic work, the sample from a crime scene such as blood or semen could be used as indiscriminating or acquitting evidence. (Dweyer 2013).
Carrier identification includes genetic tests used by married people whose families have a history of recessive genetic disorder and who are considering having children. Three common tests include those for cystic fibrosis, anondroplasia, and sickle cell trait. More tests are common on the market at a very high rate. Norman frost of the University of Wisconsin Madison medical school says, “Potential new genetic tests roll off the conveyor belt of the human genome, project almost once a week” (Bahadon S. 2008).

Pre-implantation Genetic Diagnosis (PGD) combines recent advances in genetics with the well-established techniques of in utero fertilization (IUF). In IUF, a woman’s monthly reproductive cycle is manipulated. She is given hormones that stimulate her ovaries so that many eggs mature at the same time. The eggs are surgically collected and fertilized with her partner’s sperm in a lab dish. The resulting embryos are then transferred to the woman’s uterus and if all goes well, pregnancy begins. (Lapham E, 2006).

Mass population testing is a large-scale testing usually of a particular ethnic group that shows high rates of specific genetic disorders. This type of testing has been both successful and unsuccessful. A voluntary genetic screening program was set up in the early 1970s for Tay-Sachs disease. It has been a huge success. More than a million Jews throughout the world, which Tay-Sachs predominantly affects, have volunteered to be tested to see if they were carriers of this genetic disorder. A carrier is not affected because to develop the disease symptoms, a person must carry two recessive alleles, one from each parent (Armitage P. 2008).

Before the people were tested, they were educated as to what the test would mean and what they could do with the information from the test. Once they were tested, genetic counseling was available to answer any questions about the implications of the tests. The mass genetic testing was a huge success, especially for Jews because it gives the individual and the need to plan their family future. (Dweyer J. 2003) This study therefore investigates the knowledge, attitude, and practice of young people of age 15-45 years towards premarital/prenatal genetic testing. This is important because of the relevance of the genetic test to the family, the community, and the society as a whole. There is also a limited study in this area in Nigeria.

**STATEMENT OF PROBLEM**

Knowledge, attitude, and practice toward premarital/prenatal genetic testing among young people has become a matter of concern worldwide.

Premarital/prenatal genetic testing is one of the ways of combating chromosomal abnormalities in our society today. It has helped in reducing the rate of chromosomal abnormalities, e.g., sickle cell disease and thus reducing the rate of maternal and infant mortality.

Information about premarital genetic testing have been disseminated through media, seminars, couple counseling, etc., by health personnel.
World Health Organization (WHO), Governmental and Non-Government organizations have also help in disseminating the benefits of premarital genetic testing because of the alarming rate of death from genetic defect. Despite these advantages, benefits and importance of premarital/prenatal genetic testing, the alarming rate of genetic defect is still on the increase. Nigeria is facing a critical problem of children with genetic defects. A survey by the African network for prevention and protection against child deformity and neglect, which was set up in 1988 by some African countries including Nigeria, shows that majority of children having genetic defect is due to” lack of knowledge, and negligence of their parents” This study therefore investigate the knowledge, attitude and practice towards premarital/prenatal genetic testing among young people 15-45 yours of age in Sapele Local Government Area Delta State. This is important because of relevant of the genetic test to the family, the community and the society as a whole. There is also a limited study in this area of Nigeria.

OBJECTIVES/PURPOSE OF THE STUDY

The purpose of this study is to investigate the knowledge, attitude and practice towards premarital/prenatal genetic testing among young people 15-45 yours of age in Sapele Local Government Area Delta State. In line with this, the following objectives will be addressed

1. To determine the level of knowledge among young people. toward premarital/prenatal genetic testing.

2. To assess the level of practices among young people. toward premarital/prenatal genetic testing.

3. To identify factors influencing their attitudes towards premarital/prenatal genetic testing

SIGNIFICANCE OF STUDY

The significant of study is to

1. Enhance people’s knowledge about premarital/prenatal genetic testing.

2. Encourage premarital/prenatal genetic screening.

3. Reduce some of the factors influencing attitudes of young people towards premarital genetic testing by encouraging government to provide genetic screening centers

4. The findings will add to the body of knowledge for future studies

RESEARCH QUESTIONS

The key questions that will be answered in this study are;
1. What is the level of knowledge of young people toward premarital/prenatal genetic testing in Sapele local government area?

2. What is the level of practice of young people towards premarital/prenatal genetic testing?

3. What are the factors influencing the attitude of the people towards premarital/prenatal genetic testing of Sapele local government area?

SCOPE AND DELIMITATION OF STUDY

This study covers the knowledge, attitude and practice towards premarital/prenatal genetic testing among young people in Sapele Local Government Area Delta State. It is restricted to young people between the age of 15—45 years in the (4) four communities (Okingve. Amukpe. Amuogodo & Uganja).

OPERATIONAL DEFINITION OF TERMS

1. Knowledge: this is the information and skill gained through education or experience.

2. Attitude: This is the behaviour towards an action.

3. Practice: This is the actions of doing something rather than the theories about it.


5. Genetic testing: Test done partaking to reproduction or birth or origin.

LITERATURE REVIEW

In this chapter, the literature review would be discussed under the following headings;

- Concept of genetic testing.
- Importance of genetic testing.
- Impact of genetic testing
- Factors affecting genetic testing
- Consequences on non genetic testing
- Knowledge of premarital/prenatal genetic testing
- Attitude toward premarital/prenatal genetic testing
- Practices toward premarital/prenatal genetic testing
CONCEPT OF GENETIC TESTING

A genetic test is the analysis of human Deoxyribonucleic acid (DNA), ribonucleic acid (RNA), chromosomes and proteins to detect heritable disease related genotypes, mutations, phenotypes or karyotypes (standard pictures of the chromosomes in a cell). For the purpose of diagnosis, treatment and other clinical decision making, most genetic testing is performed by drawing a blood sample and extracting deoxyribonucleic acid (DNA) from white blood cells (Bogart Mit 2007).

Genetic test may detect mutations at the chromosomal level, such as additional absent or rearranged chromosomal material, or even subtler abnormalities such as a substitution in one of the bases that make up the DNA. There is a broad range of techniques that can be used for genetic testing. Genetic tests have diverse purposes, including screening for and diagnosis of genetic disease in newborn children and adults. The identification of future health risk, the prediction of drug responses and the assessment of risks to future children. (Abuelo 2001).

There is a difference between genetic tests performed to screen for disease and testing conducted to establish a diagnosis. Diagnostic tests are intended to definitely determine whether a patient has a particular problem. They are generally complex tests and commonly require sophisticated analysis and interpretation. They may be expensive and are generally performed only on people believed to be at risk such as patients who already have symptoms of a specific disease.

Bahado, (2008) stated that genetic screening has great potential for our society. It has the capability of improving and lengthening human life, if used in an ethical manner, genetic testing can culminate unforeseen suffering and distress. But issues such as privacy. Consent, discrimination, equity and social engineering are potential barriers that many individuals have confronted already. Both legal and personal family conflicts may arise because of testing of individuals or immediate relatives.

There are thousands of genetic diseases such as sickle cell, anemia, cystic fibrosis and Tay-sachs disease, that may be passed from one generation to the next. Many tests have been developed to help screen parents at risk of passing on genetic disease to their children as well as to identify embryo, fetuses and newborns who suffer from genetic disease.

Carrier identification is the term for genetic testing to determine whether a healthy individual has a gene that may cause disease it passed on to his or her offspring. It is usually performed on
people considered to be at higher than average risk such as those of Ashkenazi Jewish descent, who have a slim 24 chance of being Tay-sachs. Carriers (in other populations, the risk is 1 out of 250) according to the National Tay-sachs and Allied Diseases Association (2007)

Testing is necessary because many carriers have just one copy of a gene for an autosomal recessive trait and are unaffected by the trait or disorder. Only someone with two copies of the gene will actually have the disorder. So while it is widely assumed that everyone is an unaffected carrier of at least one autosomal recessive, it only presents a problem in terms of inheritance when two parents have the same recessive gene. It only present a problem if both are carriers. In this instance the offspring would each have a one in four chance of receiving a defective copy of the gene from each parents and developing the disorder. Reports that Genetic tests exist for more than 1,600 conditions and that the national institutes of registry to share information about Genetic testing.

Despite improvements in medical technology, surgically invasive techniques to test for conditions like down syndrome still cause approximately 1 percent of mother receiving the tests to miscarry, reports (the Gucudian, 2011).

Today, the U.S department of Health and Human services (HHS) reports that there are over 4,000 genetic diseases that can be passed down from generation to generation within a family.

As of 2011, fetal sex can be determined by a Non-invasive genetic test as early as seven weeks into the pregnancy, allowing for less use of invasive test to determine sex-specific genetic disorders. The tests were, on average, 95.4 percent successful at identifying a male fetus and 98.6 percent successful at identifying a female fetus.

Prenatal Genetic testing reported by CNN highlights the ongoing political controversies of prenatal genetic with candidates in the 2012 presidential election claiming that such testing encouraged more abortions. Studies conducted between the late 1990s and 2005 found that a majority of women would consider terminating their pregnancies- If tests indicated that the child would have a condition like Down syndrome.

**IMPORTANT OF GENETIC TESTING**

A genetic test is the analysis of human Deoxyribonucleic acid (DNA), ribonucleic acid (RNA), chromosomes and proteins to detect heritable disease — related genotypes, mutations, phenotypes or karyotypes.

Genetic testing, examines the genetic information contained inside a person’s cells called DNA, to determine if the person has or will develop a certain disease or could pass a disease to his or her offspring.

Genetic tests also determine whether or not couples are at a higher risk than the general population for having a child affected with a genetic disorder.
IMPORTANCE OF TESTING FOR GENETIC DISORDERS

Genetic disorders can easily be prevented by genetic testing. Genetic testing can thereby control the occurrence of genetic diseases. Genetic tests can screen fetuses for possible genetic diseases. Genetic testing can help in conception and pregnancy. Read on to know more about the importance of genetic testing.

The importance of genetic testing is magnanimous. There are a lot of diseases that have their roots hidden in our genes. Once we get to know them, the doctors will be better equipped to prescribe an effective cure and even prevent them. Timely precautionary measures play a great role in maintaining the well-being of an individual. The main purpose of the genetic tests is to search for possible genetic disorders. There are almost over nine hundred varieties of genetic tests that are prescribed by doctors to determine the condition of their patients. Genetic tests are carried out on blood or any other tissue samples.

CONDITIONS FOR GENETIC TESTING

Given below are some of the common conditions where doctors suggest a genetic test:

- In order to find out whether the unborn baby has any possibility of contracting a genetic disease
- In order to find whether the individual is a carrier of a disease and thereby determine whether or not he or she can pass on the said genetic disease to their offspring
- Genetic tests are suggested for screening the fetuses for any possible disease
- There are a number of diseases that are present in our system but their symptoms are hidden as they don’t get manifested. Through a genetic test, the presence of the same can be determined and a course of treatment can be charted out before it is too late.
- Genetic tests are also suggested to confirm a disease. Doctors presume the disease after studying the symptoms but when there is any element of doubt due to various other associated complications, a genetic test always clears the doubts.

WHY IS GENETIC TESTING IMPORTANT?

It is the prerogative of the doctor to decide and conclude on whether a particular genetic disease can be prevented or treated after coming across a gene alteration in the genetic tests. It all depends on the final and latest research condition regarding the treatment of the disease along with the status of the patient when the results were obtained. There can well be no treatment for certain diseases.
The importance of genetic testing lies in the fact that the person finds himself equipped to take certain vital life decisions. This can pertain to opting for an immediate insurance coverage, making a career choice or go for family planning. A genetic counselor is the best person to help you make an informed decision after adequately understanding the results and ramifications of the genetic tests.

**SIGNIFICANCE OF GENETIC TESTING**

The importance of genetic testing is defined by the following conditions:

**Diagnostic Testing** – Certain symptoms of diseases have their roots in genetic alterations. The suspected disorder can be correctly determined only through genetic testing. For example, a genetic testing can confirm diseases like polycystic kidney disease or the Chariot-Marie-Tooth disease.

**Presymptomatic Testing** – Also known as predictive testing, the members of the direct family tree are tested in order to ascertain whether a certain suspected genes runs in the family or not. That way the doctors can plan out the treatment even prior to the appearance of the symptoms.

**Carrier Testing** – Genetic testing is important here when you plan to start a family. When you and your partner get tested before conception, you can ascertain whether any of are a carrier to a genetic condition that is liable to be passed on to your child. It is vital to note here that you or your partner may not contract the said disease, but your carrying the altered genes can pose a threat to the unborn child.

**Prenatal Screening** – Genetic conditions like Spinal bifida and Down’s syndrome can be detected through this genetic tests conducted on the genes of the fetus.

**Pharmacokinetics** – When an individual is already suffering from a certain disease, this type of genetic testing helps the doctor to determine the exact type of medicine and dosage that will yield the best results. This is a sort of customized treatment that guarantees effectiveness.

Carrier testing is offered to individuals who have family members with a genetic condition, people with family members who are identified carriers and members of racial and ethnic groups known to be at high risk. Figure 6.2 shows how carrier testing would be used for a family affected by cystic fibrosis and among African-Americans who may carry the gene for sickle cell anemia.

**PRE IMPLANTATION GENETIC DIAGNOSIS**

Pre implantation diagnosis is a newer genetic test that enables parents undergoing in vitro. Fertilization (fertilization that takes place outside the body) to screen an embryo for specific genetic mutation when it is no larger than six or eight cells and before it is implanted in the uterus to grow and develop. Figures 6.3 show how pre implantation genetic diagnosis performed.
PRIMARITAL/PRENATAL TESTING

Premarital genetic testing enables physicians to diagnose disease in the individual. Most genetic tests examine blood or other tissue to detect abnormalities. An example of a blood test is the triple marker screen. This test measures levels of Alpha Feta Protein (AFP). Human chorionic gonadotropin identifies some birth defects such as Down syndrome and neutral tube defects. (Two of the most common neutral tube defects are an encephala-absence of most of the brain -of the back and spine). The fetal yolk sac and the fetal Liver make AFP, which is continuously processed by the fetus and excreted into the amniotic fluid. A small amount crosses the placenta and cab be found in maternal blood. Maternal screening for AFP levels is based on maternal age, fetal gestation, and the number of fetuses the mother is carrying elevated levels of AFP arc associated with conditions such as spinal bifida and low levels are found with down syndrome. Because AFP levels alone may not always adequately detect disorders, two other blood serum tests have been developed. Human chorionic gonadotropin is a glycoprotein produced by the placenta. Normally HCG is elevated at the time of implantation. hut decrease at about eight weeks of gestation, and then drops again a approximately twelve weeks of gestation. Elevated level of HCG is found with ‘DOWN SYNDROME” The placenta also produces unconjugugated estriol. As with AFP, lower unconjugated estriol maternal serum levels are also found with down syndrome. Triple marker screen results are usually available within several days and women with abnormal results are often advised to undergo additional diagnosis testing such as chorionic villous sampling (CVS) amniocentesis. or percutaneous umbilical blood sampling (withdrawing blood from the umbilical cord).

Chromosome 21 is the genetic disease most often identified using this technique. Down syndrome is rarely inherited; most cases result from an error in the formation of the ovum (egg) or sperm, leading to the inclusion of an extra chromosome 21 at conception. As with prenatal diagnosis for most in limited genetic disease, this use of genetic testing is focused on reproductive decision making.

The most invasive prenatal procedure for genetic testing is periumbilical blood sampling. Table 6.1 describes the technique periumbilical blood sampling poses the greatest risk to the unborn child, one in fifty miscarriages occurs as a result of this procedure. It is used where a diagnosis must be mad quickly. For example, when an expectant mother is exposed to an infection agent with the potential to produce birth defects, it may be used to examine fetal blood for the presence of infection.

Until 2006 it was thought that women undergoing CVS were more likely to have miscarriage than those who had AMNIOCENTESIS. However Aaron, Cagney, Linda, Hopkins, and Norton, in “c1orionic Villous sampling compared with amniocentesis and the difference in the rate of pregnancy loss (Ostetrics and Gynecology. September 2006) refute this notion. Caugey, Hopkins, and Norton analyzed the outcomes of nearly 10,000 CVS and 32,000 amniocentesis procedures and found that CVS was no more likely than amniocentesis to lead to pregnancy loss.
They attribute previously reported higher rates of miscarriage resulting from most genetic disorders are treated using more than one type of treatment, in keeping with their complex and varied symptoms. For example, children with cystic fibrosis usually take pancreatic enzymes to help digest food and inhale the main aim of prenatal genetic testing is to prevent fetal abnormality and death.

**STEPS TO PREVENT BIRTH DEFECT**

Awareness and education are the steps to preventing birth defects. The immediate step following awareness and education is taking action.

There are a number of things you can do to increase the probability of having pregnancy and a healthy baby. Some are more challenging than others because they require that you break habits, but it is worth your effort.

Here are a variety of tips you can use to prevent birth defects as you contemplate adding to your family.

- **TIP 1**: The first and foremost tip is maintaining preconception health, eating well balanced and nutritional meals and taking a multivitamin daily that includes the recommended 400mcg of folic acid and other essential B vitamin.
- **TIP 2**: If you are sexually active and pregnancy is a possibility, make since you take a multivitamin daily which includes the recommended 400mcg of folic acid and other essential B vitamins.
- **TIP 3**: Avoid all activities that could potentially lead to birth defects including alcohol, tobacco, illicit drugs and caffeine.
- **TIP 4**: Seek an annual gynecological and wellness exam.
- **TIP 5**: Obtain genetic counseling and birth defect screening particularly if you are 35 years of age or older
- **TIP 6**: Help your family or friends who might be considering parenthood by informing them that January is Birth defects prevention mouth

Other birth defects preventing tip include setting up a birth defects prevention campaign in your company, preimplantation genetic diagnosis.

**THE IMPACT OF PRENATAL GENETIC TESTING ON FAMILY PLANNING SERVICES**

At the same time that legislatures around the country are planning and establishing programs to enable women through genetic screening and prenatal diagnosis to avoid conceiving or bearing
affecting children a trend toward restricting a woman’s right to decide to abort an affected fetus is evident. It seems likely, in view of recent Supreme Court decisions, that individual state legislatures will have increasing power to define the circumstances under which abortion will be legally available. If access to abortion is significantly, one really must ask just what kind of choices prenatal genetic testing offers. How much benefit is knowledge in the absence of meaningful options?

Although many are currently optimistic that abortion will remain a legal option in this country, women are still faced with significant limitations on the accessibility of abortion services both in financial terms and in terms of the number and geographical distribution of facilities offering abortion procedures. Women facing the termination of a desired pregnancy based on an abnormal result from prenatal testing may have even more difficulty because they must locate facilities that offer termination of second-trimester pregnancies.

THE IMPACT OF PREMARITAL/ PRENATAL GENETIC TESTING ON A WOMAN’S RELATIONSHIPS WITH FAMILY AND WITH HER FUTURE CHILD

The decisions a woman is required to make regarding prenatal genetic testing can be very stressful ones for her and for her partner. For many couples, the stress comes at a time when their relationship is already being redefined by the expectation of a child. The woman’s partner may want prenatal diagnosis more than she does, and may be less anxious about it (Keenan, Basso, Goldkrand, & Butler, 2001) potentially leading the woman to experience a sense that “he’ll blame me if the child has diagnosable abnormality that we don’t find out about,” or he’ll blame me if we have an amniocentesis complication.’ If the fetus is affected by a genetic disorder, the woman and her partner may also feel different about the prospect of abortion. Those differences may impact a couple’s relationship far into the future. Regardless of the decision they ultimately make. The disagreement may furthermore affect their relationship with the child, if the pregnancy is continued. The integrity of these relationships is clearly important to women’s overall health. Little work has been done in terms of delineating the effects of decisions about prenatal diagnosis on a woman’s family relationships. It will be important to clarify such ramifications before widespread testing is initiated.

Taken as a whole, investigation of amniocentesis’s impact suggests that anticipation of the procedure and its results may lead to disruption of an otherwise normal adjustment to pregnancy. Studies have revealed that women undergoing amniocentesis may experience a “suspension of commitment to pregnancy” while awaiting test results (Beeson & Golbus, 2009); Spencer and Cox 2008) Beesen and Goibus (200 observed that this was reflected both in social spheres, such as in not telling others about the pregnancy, and in personal domains, such as in avoiding thinking about the pregnancy. Runthman (2006 noted a greater frequency of women not feeling movement until after the 18 week among those undergoing aminocentesis. In contrast. Dixson
(2001) could demonstrate no significant differences between amniocentesis and non-amniocentesis groups in the timing of selecting names or in willingness to talk about the pregnancy. Furthermore, (Phipps & Zinn 2006) found that amniocentesis patients in a United States sample showed a greater increase in fetal attachment over the course of pregnancy than did non-tested controls. (Caccia, 2001) demonstrated that maternal-fetal attachment increased significantly for amniocentesis and CVS patients once normal results were received. No non-tested controls were included. It has also been noted that attachment may be enhanced by viewing the fetus on ultrasound, a technology used in conjunction with amniocentesis (Fletcher, 2003). If suspension of commitment does occur for some women during the early months of pregnancy and if it does testing benefit women? It involves decreased compliance with suggested regimes such as good nutrition and abstaining from alcohol use, long-term adverse effects might result. Further investigation could clarify which women are at risk for this type of response to prenatal testing and could lead to meaningful interventions.

Jeffrey Botkin (2000) states that “a fundamental aspect of parenting is the recognition of the unique and independent nature of our children’s personalities and lives. Try as we might, they rarely fit the molds that we design for them. Knowledge that our intrinsic personal characteristics were the intentional product of our parents’ designs would have a profound influence on the parent-child relationships”. Abby Lippman (2001) points out that ‘prenatal diagnosis does approach children as consumer objects subject to quality control’ Those observations will be important to consider as the use of prenatal genetic testing expands. It will be important to clarify our understanding of women’s expectations in relation to their children, as they depart from the illusion that they actually have some control over the ‘equality’ of the infants they bear.

FACTORS AFFECTING PREMARITAL/PRENATAL GENETIC TESTING

Abuelo, (2001) maintains that several factors such as:

1. Need for more scientific information. 2. Positive attitudes toward genetic testing, 3. Non-affordability of the cost of the conducting the test. 4. Non-accessibility of medical facilities in health centre’s, 5. Non-availability of screen centers and 6. Lack of knowledge of the relevance of undergoing genetic testing. These factors influence their willingness to embark on such all important exercise.

Consequently, Burton (2008) in agreement with Abuelo (2001) believes that non-affordability of the enormous cost of undergoing genetic testing is yet a major factor influencing its access by many pregnant women in Nigeria and the world over. This implies that the provision of medical facilities in health centre’s across the country is a necessary measure that must be taken towards improving the health services delivery in Nigeria. It must be emphasized that the Nigeria as at now lacks adequate medical centers for effective genetic testing.

In the same vein, Croyle (2005) stated that poor attitudes of pregnant lades in our society today tend to impact negatively on their consistent access o i7t51 genetic testing in Nigeria. According
to Croyle, unless this disorder attitude of our expectant mothers is corrected via adequate information on the relevance of this test this wrong notion will continue to affect their behaviour towards carrying this test.

In addition, Bogart (2007) argues that it is being quite amazing today that the level at which medical practitioners neglect the issue of genetic testing to the detriment of the timid pregnant women is dangerous to the actualization of quality health for all in the year 2021) according to the World Health Organization (WHO 2001). Bogart (2007) therefore opines that doctors, and nurses must ass a matter of priority devout much of their time and energy toward the conduct of prenatal genetic testing for the common good of both the expectant mother and their child.

Evans (2008) has continually argued that our society today is characterized with falsehood and the spread of unverified information by the media which no doubt hinder that understanding of the need for prenatal genetic test. According to Evans, accurate and up-to-date information on how to obtain genetic testing should be channeled to health personnel such as nurses & doctors rather than relying on information being peddled around by uninformed individuals in the medical field.

Palomaki, (2006) maintain that inadequate level of knowledge by pregnant women goes a long way to affect their access to genetic testing in health centre’s across the country Nigeria. According to Palomaki, (2006) less rigorous pregnant women tended to be mere in favour of prenatal tests as a result of their interest and up-to-date knowledge on prenatal genetic test and how to undertake such tests. This preliminary study provides genetic counselor and policy makers with a clearer picture of their clients motives and attitudes behind the decision - making process of prenatal genetic testing, contributing to improving both the communication process between counselors and their clients and the organization of genetic services.

Several other factors that seem to influence genetic testing by pregnant women are:

(1) Population-Based Risk - A young, healthy woman may believe that because her population-based risk for chromosome abnormalities is small that she is not at any risk for an abnormality. Women over age 35 may look to screening as a way to avoid the risks of invasive testing. This is the age group most likely to refuse amniocentesis after a positive serum screening test fails to remove them from the at-risk category (Fitzgerald, Streets, & Priest, 2002). The nurse can help the family explore the potential outcome of the decision to accept or decline screening.

(2) Effects of Exposures to Medications- Concern about any harmful effects of exposures to medications or environmental agents may lead some women to accept screening. It is important to clarify what is known about specific agents so that the testing is not being accepted hoping to gain information that screening cannot provide. There are resources that help the practitioner provide this information but it may be necessary to refer some families to specialists for adequate evaluation and counseling.
Specific Family History Factors- For specific family history factors, it may be more appropriate to forego screening and refer the woman for more in-depth evaluation and consideration of diagnostic testing. It is optimal to assess family and personal health before pregnancy so that appropriate diagnostic tests and complex evaluations can be completed. This is not always possible, as some women do not address these risk factors until they are pregnant. Early prenatal visits for review of history and health problems may prevent missed opportunities for early screening or diagnosis. It also gives the woman time to discuss testing with her partner and others who may be important in the decision to accept screening

CONSEQUENCES ON GENETIC TEST

POSITIVE AND NEGATIVE ASPECTS OF GENETIC TESTING

POTENTIAL BENEFITS

There are many potential benefits which can arise as a result of genetic testing. Individuals identified as carrying potentially harmful genetic alterations can receive regular medical check-ups and be eligible for screening to enable early detection of cancer (although these options are also available to individuals who have not been tested but who do have a strong family history of cancer); they may also choose to undergo preventative surgery. This can potentially lead to a reduction in cancer incidence and mortality.

Individuals who are found not to carry a harmful gene alteration which is known to run in their family may feel that they are less anxious and have a better quality of life; they may also benefit from the knowledge that they have not passed a gene alteration on to their children. Also, because such individuals do not require the same regular checkups as do people who carry the gene, resources can be targeted to benefit those people who do have a higher risk of developing cancer.

Despite the significant advantages of genetic testing, there are also, however, several disadvantages which any individual considering undergoing testing should be aware of (these include the limitations of the genetic testing technique which were discussed in the previous section.)

POTENTIAL DISADVANTAGES

Because genetic alterations generally need to be identified in a family member who has already developed cancer this can lead to distress and difficult family relations, for example if there are no surviving family members who are able to undergo diagnostic genetic testing, or if an individual is reluctant to undergo testing he/she may be subject to pressure from other family members. A positive genetic test can also lead to an increased level of anxiety and individuals
may feel guilty for having potentially passed a gene alteration on to their children. There may also be issues for individuals wishing to obtain health and life insurance.

Receiving a negative genetic test can also affect family relations, with many individuals feeling ‘survivor guilt’, for example if they have a brother or sister who has been shown to carry that gene alteration, they may feel guilty at having escaped the increased cancer risk, while their sibling is still at risk.

Some people with a strong family history of cancer believe they would find it too difficult to receive a positive genetic test result. They may feel that knowing they are definitely a carrier of a harmful alteration will lead to increased levels of anxiety throughout their life. They choose, instead, to undergo regular medical check-ups, and screening, to enable early detection of cancer without ever having to know their genetic status.

**ADDITIONAL INFORMATION**

It is very important that genetic testing is always accompanied by pre- and post-test counselling so that individuals are able to make an informed choice about whether or not to undergo testing, and have access to extra support if needed. Below we have provided a few links to UK-based websites which can provide further information on the issues discussed in the Genetics and Cancer and Genetic Testing sections:

- Cancerbackup (www.cancerbackup.org.uk) is Europe's leading cancer information charity, and has over 4,500 pages of up-to-date cancer information. They have a comprehensive section on genetics and cancer, and provide advice for individuals who are worried about cancers running in families.

- In the UK there is currently a voluntary ban which prevents companies who are members of the Association of British Insurers from being able to access the results of genetic tests (apart from those for Huntington’s disease). This ban is due to be reviewed in 2014. For more information please refer to the Association of British Insurers’ (ABI) leaflet ‘Insurance and Genetic Tests: What you need to know’ which can be accessed through the ABI's website.

**ATTITUDE, KNOWLEDGE PRATICE TOWARD GENE TESTING**

Attitude is a psychological construct which expresses one’s disposition towards an issue. One’s behavior can be inferred from his or her disposition to situations. In other words, knowledge about an issue determines attitude towards it which in turn influence the behavior. Al Sulaiman. (2008) found that there was positive attitude of Saudi population towards pre-marital screening and the majority of participants agreed that the program should apply to all couples in all regions of Saudi Arabia.
Best practice guidelines for genetic testing are recommendations describing techniques or methods to perform a specific test in the best way possible. It provides professionals with a standard to perform the tests. This promotes uniformity in testing and results in a higher quality in terms of accuracy of results and interpretation.

These guidelines are usually drafted after best practice meetings with experts from the field. EuroGentest has actively participated in and organized many of these meetings in molecular genetics, biochemical genetics and (molecular) cytogenetics- (EuroGentest 2014)

EMPIRICAL REVIEW

The following two empirical studies illustrate how nurses can provide care for prenatal patients undergoing screening Each empirical study will be followed by a discussion.

EMPIRICAL STUDY 1

An empirical survey conducted by Mennuti (2006) in UI3TH Benin city titled ‘Neural tube defects: issues in prenatal diagnosis and counseling’ the genetic unit distributed 120 questionnaires to some randomly selected patients. Mean maternal age was 36 +/- 4 years. The study revealed that access to prenatal genetic counseling was mainly patient’s own initiative, or ‘self-referral’. Most self-referred patients (87%) considered that ‘receiving accurate information’ was the main issue. Eighty-one percent of all couples contacted knew that TOP because of fetal anomalies was not legal. In case of a serious anomaly, 68.2% of patients would contemplate TOP, in spite of the risk of being exposed to an unsafe abortion.

A similar empirical survey conducted by Bahado-Singh, Ozgur, Oz. Tan, Hunter,, Copel, & Mahoney (2008) selecting 40 patients in 3 local health centers Jos. The study showed that in many countries, prenatal genetic testing is offered, but TOP is not available. The study showed that Mary V. is a 38 year old woman who begins prenatal care early in the first trimester of her second pregnancy. Her first pregnancy ended at 8 weeks with a spontaneous abortion. After several years of trying to conceive, Mr. and Mrs. V. sought infertility treatments and have achieved a pregnancy after In Vitro fertilization. The treatments cost over $10,000 and the couple comment on more than one occasion that after spending so much money to conceive they will not subject the pregnancy to avoidable risk. They feel certain that they would not terminate a pregnancy because of Down syndrome but remain concerned about the risks of other fetal chromosome abnormalities related to maternal age. They also desire to experience a pregnancy that is as normal as possible and want to deliver in their local community.

Their primary care provider is knowledgeable about the risk for chromosome problems related to maternal age and about the common methods of prenatal diagnosis. The information about some of the newer screening tests for chromosome abnormalities is not a familiar and the patient is referred to a prenatal center with expertise in pregnancy screening and diagnosis. The V’s elect to have n nuclear translucency measurement at 11 weeks. The measurement is not increased and
the risk for Down syndrome is determined to be less than the patient’s age-related risk. She chooses to forgo invasive testing at this time but elects to have second trimester serum screening to further evaluate risk.

Although the Quad test is only available in a few selected areas of the country, a laboratory is located and blood is sent for evaluation. The result of this test is reported as screen positive with a risk for Down syndrome of 1/148 that is still less than her age related risk of 1/99 Mrs. V. again declines invasive testing. After discussion with the consultants an ultrasound evaluation of the fetal heart and other organs is scheduled as a final evaluation. When this exam is normal the V.’s continue the pregnancy without further evaluation and deliver a healthy baby at term.

**DISCUSSION OF EMPIRICAL STUDY 1**

This family demonstrates the approach and attitude of many women who are looking to screening to avoid the risks of invasive diagnostic testing. The only birth defects that increase in incidence with maternal age are chromosome abnormalities. If a woman is otherwise healthy and does not have medical conditions such as hypertension or diabetes, the pregnancy is likely to progress normally. There is a decline in fertility in this age group and many women seek evaluation and treatment from infertility specialists in order to conceive. It is not uncommon for couples in this situation to be very well informed about the newest and latest modalities for testing and screening.

The nurse may learn about how these tests perform through this special group of patients. Insurance coverage may also become an issue, as newer tests may not be covered under every benefit package. During the pregnancy, the nurse in the primary care center can provide support for Mrs. V. and her husband as the couple goes through the screening process.

**EMPIRICAL STUDY 2**

In 2001, the American College of Obstetricians and Gynecologists and the American College of Medical Genetics introduced guidelines for prenatal and preconception carrier screening for cystic fibrosis. The American College of Obstetricians and Gynecologists’ Committee on Genetics has updated current guidelines for cystic fibrosis screening practices among obstetrician-gynecologists.

Cystic fibrosis (CF) is the most common life-threatening autosomal recessive condition in the non-Hispanic white population. It is a progressive, multisystem disease that primarily affects the pulmonary, pancreatic, and gastrointestinal systems but does not affect intelligence. The current median survival is approximately 37 years, with respiratory failure as the most common cause of death. Approximately 15% of individuals with CF have a mild form of the disease with a median survival of 56 years (1). More than 95% of males with CF have primary infertility with obstructive azoospermia secondary to congenital bilateral absence of the vas deferens. Cystic
fibrosis is caused by mutation in this gene cause CF. the disease incidence is 1 in 2,500 individuals in the non-Hispanic white population and considerably less in other ethnic groups

Prenatal and preconception carrier screening for CF was introduced into routine obstetric practice in 2001 (2). The goal of CF carrier screening is to identify couples at risk of having a child with classic CF, which is defined by significant pulmonary disease and pancreatic insufficiency. Cystic fibrosis is more common among the non-Hispanic white population compared with other racial and ethnic populations; however, it is becoming increasingly difficult to assign a single ethnicity to affected individuals. It is reasonable, therefore, to offer CF carrier screening to all patients. The sensitivity of the screening test varies among different ethnic groups, ranging from less than 50% in those of Asian ancestry to 94% in the Askkenazi Jewish population (3). Therefore, screening is most efficacious in non-Hispanic white and Ashkenazi Jewish populations. Because testing is offered for only the most common mutations, a negative screening test result reduces, but does not eliminate, the chance of being a CF carrier and having an affected offspring. Therefore, if a patient is screened for CF and has a negative test result, she still has a residual risk of being a carrier.

Preconception carrier screening allows couples to consider the most complete range of reproductive options. Knowledge of the risk of having an affected child may influence a couple’s decision to conceive or to consider preimplantation genetic diagnosis, prenatal genetic testing or the use of donor gametes. Generally, it is more cost effective and practical to perform initial carrier screening for the patient only.

The study shows that Cheryl M. a 19-year-old early in her first pregnancy. She is single, lives at home and is engaged to the father of the baby. The pregnancy is unplanned but both she and her boyfriend are happy. She lives in a small town and is seen for her pregnancy at a clinic established for low-income woman. An ultrasound is done around 10 weeks gestation because of an episode of vaginal bleeding. The ultrasound establishes her due date but offers no explanation for the bleeding. The bleeding continues off and on for the next two weeks and Cheryl is concerned that it may indicate a problem with the baby.

She accepts screening hoping that the test will provide reassurance that all is well with the baby. The initial blood test comes back with a striking elevation of APP and she is referred to a prenatal center for evaluation. The ultrasound at the center shows a fetus with an abdominal wall defect called gastroschisis. Cheryl is counseled about the condition and additional appointments are made with pediatric surgeons who will repair the defect when the baby is born. Delivery at the tertiary center is recommended because of the need for immediate treatment when the baby is delivered. Cheryl will continue her care in her local area and will return for ultrasounds and additional visits to the prenatal center as the time for delivery is near.
DISCUSSION OF EMPIRICAL STUDY 2

Gastrosehisis is an explanation for an elevated maternal serum AFP. This is a repairable defect that will most often have a rood outcome. This problem is seen more often in younger women (Rankin, Dillon. &. Wright, 2009). It is not yet clear what factors may explain the increased incidence in this age group. The infant will, however, require major surgery and high risk care in the neonatal period. Much of the prenatal care can be provided in the local community with some visits to a medical center where the delivery will be planned. The visits often include referrals to the pediatric specialists who will care for the baby after birth. Parents often tour the pediatric units as well as the delivery room to prepare themselves and their family for the birth.

“Genetics is becoming central to the delivery of health care and preventive services. Changes are occurring in the delivery of genetic services, with a gradual move from university-based genetics clinics to satellite genetics clinics and primary care settings. As these services move beyond specialized roles and settings, nurses in a variety of general practice areas have already or soon will confront the implications of the current advances in genetic science and technology” (p. 9). The importance of genetics in nursing practice and the desire for information about evolving genetic screening and technology makes accurate information necessary for nurses in many practice settings. Nurses who understand the screening process can help women make informed decisions about participating in screening. They can provide appropriate information and support throughout the testing process and help to interpret results. When results are abnormal or confusing the nurse can clarify when possible and identify resources to manage the stress and anxiety. Marteau, et al. said it best, “One of the greatest challenges for those involved in the screening process is to inform people of low probability but serious events without alarming them unduly or reassuring them falsely” (2002, p. 13). This skill will be increasingly important as additional screening tests are developed and introduced into practice.

In the present study, although most of the couples who decided to undergo prenatal genetic testing were aware of this, they still chose to perform prenatal diagnosis. The main reason given was to obtain reliable information about fetal condition. Finally, if a fetal chromosomal abnormality were detected, most of them would consider TOP.

Among the ethical issues confronting maternal-child nurses are questions surrounding genetic testing, contraception and sterilization, infertility/assisted reproductive technology, and equality in balancing maternal-fetal needs. This article explores these issues, reviews the literature currently available, and discusses nursing clinical implications for each as well as representative case studies.

The types of support needed by childbearing families who are facing ethical issues require emotional and physical support. Informational support and advocacy support. The role of the nurse in educating women about the ethical implications of their choices cannot be overestimated. When women have been educated about the implications of their decisions and
are therefore empowered to make informed decisions about their lives and their pregnancies, clinical nurses who practice ethically respect those decisions and support the women in their choices. Nurses support childbearing families in the face of multiple ethical issues, and are called upon to provide emotional and physical support, informational support, and advocacy support.

**THEORETICAL FRAMEWORK**

The theoretical orientation of this study is the theory of knowledge by (Karl Marx 2009). Structural equation modeling was used to describe the dynamic interplay between knowledge, beliefs, attitudes and health — related behaviour such as prenatal genetic testing. Following the Theory of reasoned action, three dimensions predict the intention to undergo prenatal genetic testing: the need for more scientific information a positive attitude towards genetic testing and the inclination to terminate pregnancy after receiving a positive test result.

This theory is built on the premise that since this study involves knowledge and practice of prenatal genetic testing therefore tends to depend on knowledge of the individual adolescent as regards what abortion is all about. The theory of knowledge is a theory of social or existential determination of knowledge thought and the social structure in which they emerged. The theory explains why there are variations in thought and perception from one place to another.

The theory of knowledge is a theory of social or existential determination thinking. It also concerns with the procedure by which the socio-historical selection of ideational contents is to be studied. It is being understood, that the contents themselves are independent of socio-historical causation and thus inaccessible to sociological analysis. According to (Mannheim, 2003) all knowledge is bound to a location within the social process. Also, Mannerism believed that different social groups vary greatly in their capacity thus to transcend their own narrow position. At a particular time, a particular group can have filler access to the understanding of a social phenomenon than other groups, but no group can claim to have a total access to it.

Thought is therefore, culturally relative and time specific. Thus, it can be very interesting to want to know the views attitudes and implication of these adults or the youth will be in another environment and at a later date and time may be next century. But this is not provided for in this research work.

Karl Marx (2009) attempted in his early writings to establish a connection between philosophic and the social structures in which they emerged and more specifically, he was concerned with analyzing the ways in which systems of ideas appeared to be dependent on the social position, more particularly the clap position of their proponent. Marx thus attempted to functionalize ideas of individuals to their social roles and to the class position they occupy in society. To him, it is not the consciousness of men that determine their existence but on the contrary the social existence determines their consciousness. Man’s thought is concerned with human activity consequent upon this submission the attitudes and believes of an adult Doctor/Nurse may tend to oppose an abortion as practice but the attitude of a rural farmer ma support it since they might
not be aware of the dangers of abortion and are only thinking of the impact the unwanted pregnancy can have on their image if not terminated especially as unwanted pregnancy before marriage is more often than not the reason for abortion. These variations are as a result of the type of Social roles they play within the structure.

Wright maintains that less religious women tend to be more in favour of prenatal tests and in undertaking such tests. This preliminary study provides genetic counselor and policy makers with a clearer picture of their clients motives and attitudes behind the decision-making process of prenatal genetic testing, contributing to improving both the communication process between counselors and their clients and the organization of genetic services.

In the general practice of medicine, it is important to consider not only therapeutic results, but also the no clinical implications of what is done to or for patients. This is particularly imperative when one considers prenatal genetic screening and testing and its application to broad populations of women. A few basic questions need to be asked: Do we know whether prenatal genetic testing is a good thing for women, children, or society? Does prenatal genetic testing go beyond merely providing more information about a woman’s pregnancy to actually improving her health? The term health is used broadly in this context, a 183184 ELENA A. GATES described by Dorland’s illustrated Medical Dictionary (2008) as a “state of optimal physical, mental, and social well-being, not merely as the absence of disease and infirmity.”

While it is clear that prenatal genetic testing is very useful for identifying a particular chromosomal or genetic abnormality in a fetus, and that it can offer meaningful choices to families at risk for specific genetic disorders, less evidence exists to indicate whether the widespread application of testing to pregnant women will succeed in achieving the broader goal of improving the health and well-being of obstetric patients. Indeed, several goals can be postulated for a broadly applied program of prenatal genetic testing.

The notion that individual women should be offered or encouraged to undergo prenatal genetic testing in order to spare society the expense of coping with diseased or disabled offspring has been put forward (Shaw, 2004). Viewed in terms of medical economics, the burden of genetic diseases on society is significant. “Genetic disorders account for about 20 percent of pediatric hospital admissions and for an even higher percentage of long term admissions” (Simpson, 2006). Widespread application of prenatal genetic testing, if accompanied by treatment or by termination of pregnancy, would decrease the social burden of genetic disease, at least in economic terms. Currently, however, most diagnosable conditions are not treatable prenatally. Furthermore, access to abortion, even for diagnosed genetic conditions, may be limited, either legally, and deformity and these are likes which are inherent and not extern and again those which are caused by external fortune as sovereignty, nobility, obscure, birth, riches, want, magistracy, prosperity adversity and the life (Bncen, 2002).
This shows that an individual is affected in the way he sees things in the society. This might be due to a number of reasons including environmental influences, personality make-up and societal values. This theory of knowledge therefore concerns itself with the social construction or reality. It concerns itself with everything that pauses for “knowledge in the society”. The attitudes and believes of an individual about anything at all, especially the issue of abortion will largely depends on his socio-economic status. There are things that will guide the adults in building an attitude or having a belief about abortion. To some, the fear of death may influence their lack of support for it or it might even be ignorant about the hazard involved in abortion that will determine other attitudes.

**METHODOLOGY**

This chapter deals with and gives light into the research method and procedures used for this project. And it was discussed under the following sub-headings;

- Research design.
- Research setting
- Target population
- Sample /Sampling Technique
- Instrument for data collection.
- Validation of Research instrument
- Reliability of Data collection
- Method of Data Analysis.
- Ethical consideration.

**DESIGN OF STUDY** The researcher adopted descriptive survey method. This design was used because the study deals with analysis of information that will enable the researcher to investigate knowledge, attitude and practice towards premarital/prenatal genetic testing among young people in Sapele local government area of delta state.

**SETTING OF STUDY**

The study was carried out in Sapele Local Government Area of Delta State. The local government is made up of four communities which include:

- Okirighiwe
- Amuogodo
The people of Sapele local government area are fishermen, traders, civil servant and students, they have a formal education while some informal education. Their main language is Urhobo and Itsekiri. Most of them are Christians though some are pagans.

Sapele local Government Area have good roads, 13 government owned primary health centers. 7 government primary and secondary schools, one general hospital (referral centers) and some private hospitals (one man enterprise) Sapele Local Government are have one government company and 3 non-governmental company, one school of midwifery. The local government area is about 60 kilometer to Warri school of Nursing.

**TARGET POPULATION**

The target population consists of young people of age 15-45 years.

**THE ACCESSIBLE POPULATION**

The accessible population for this study is 100 young people in Sapele in the following proportions.

- Okirighiwe -20 young people.
- Amuogodo-36 young people.
- Amiikpe -14 young people.
- Uguanja -30 young people.

**SAMPLE**

The sample was obtained from 50% of the population of each of the community as follows:

1. Okirighiwe

   \[
   \frac{50}{100} \times \frac{20}{1} = 10
   \]

2. Amuogodo

   \[
   \frac{50}{100} \times \frac{36}{1} = 10
   \]
3. Amukpe

\[
\frac{50 \times 14}{100 \times 1} = 10
\]

4. Uguanja

\[
\frac{50 \times 30}{100 \times 1} = 10
\]

Total = 50 young people

**SAMPLING TECHNIQUE**

A probability sampling method was used where simple random sampling method were used for the selection of subject, because the method ensure that every element of the population has an equal opportunity of being selected, following method was used to get the sample in order to prevent falsification.

**INSTRUMENT FOR DATA COLLECTION**

The data was collated through the use of questionnaires designed by the researcher to elicit the responses on knowledge attitude and practice toward premarital/prenatal genetic testing among young people in Sapele Local Government Area. The questionnaire was given out by the researcher to the respondents to answer while those of low educational level were guided by researcher’s assistant.

The questionnaire has four Sections. section A was on socio demographic data, section B on knowledge of premarital/prenatal genetic testing, section C on the practice of premarital/prenatal genetic testing and section D on the factors that influences young people’s attitudes towards premarital/prenatal genetic testing and it is consist of open ended and close ended questions.

**VALIDITY OF INSTRUMENT**

The self structured questionnaire was submitted to the supervisor with three other professional in the field health science for content and face validation they all critically and constructively examined the items on the questionnaire, based on their recommendations necessary corrections were effected on the instrument. The instrument was constructed in such a way that if administered by another individual given the same condition the finding will remain constant.
RELIABILITY OF INSTRUMENT

Pilot study was carried out by choosing is respondents outside the sample and offered questionnaire which they answered, returned and data analyzed and found to answer the research question based on that the instrument was found to be reliable.

PRE-TEST/PILOT STUDY

Before proceeding to the field to administer the research questionnaire to the sample subjects consisting of 50 young people with genetic defect in Sapele LGA. The researcher embarked on a pre-test exercise/pilot test using 40 young people with genetic defect in Sapele LGA in the following proportions. Okirigwe-10 young people with genetic defect, Amuogodo-10 young people with genetic defect, Arnukpe-10 young people with genetic defect and Uguanja -10 young people with genetic defect.

These persons were not part and parcel of the actual sample elements. This was done in order to further determine the reliability or otherwise of the research instrument. Analysis of the result of the pilot test was done using Pearson Moment Correlation Co-efficient. The result of the reliability test yielded 0.75 which signifies a positive outcome indicating that the pilot test or the research instrument was reliable.

METHOD OF DATA COLLECTION

50 Young people were randomly selected (50%) from the four communities (Amukpe, Amuogodo, Okirighiwe and Uguanja of Sapele local government area (LGA). Questionnaires were distributed to them and their co-operation solicited. Those of low educational level was guided on how to fill the questionnaire, in the language they understand. The questionnaires were all retrieved and thoroughly examined to ensure that none of them were improperly filled.

METHOD OF DATA ANALYSIS

The data collected from the survey was analyzed using simple percentage and histogram after presenting them on frequency distribution table. The respondents were given options to participate on their own accord without force after through explanation of what the research is all about. The percentage reveals the different opinion of respondents.

ETHICAL CONSIDERATIONS

The respondents were assured of confidentiality of information given and that such will be strictly used for academic purpose. The researcher also ensured that the respondents participate voluntarily without coercion.

The information in this was genuinely obtained from the respondents. Is meant to protect the research subjects from any physical, mental or social harm and this maintain their integrity.
DATA ANALYSIS

This chapter deals with the analysis of data based on the result of questionnaire and interview conducted in 4 communities (Aukpe, Amuiogodo, Okirighiwe and Ugunja) of Sapele Local Government Area of Delta State.

PRESENTATION OF RESULT / FINDINGS

Analysis is done using simple percentile table, bar charts and histogram

**Table 1: socio-demographic data**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-25</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>26-35</td>
<td>25</td>
<td>50%</td>
</tr>
<tr>
<td>36-45</td>
<td>15</td>
<td>30%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>35</td>
<td>70%</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>30%</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>30</td>
<td>60%</td>
</tr>
<tr>
<td>Single</td>
<td>15</td>
<td>30%</td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
<td>10%</td>
</tr>
<tr>
<td>Ethnic group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itsekiri</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>Urhobo</td>
<td>22</td>
<td>44%</td>
</tr>
<tr>
<td>Ijaw</td>
<td>8</td>
<td>16%</td>
</tr>
<tr>
<td>Igbo</td>
<td>7</td>
<td>14%</td>
</tr>
<tr>
<td>Others</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Educational status</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results: from the table above majority (50%) of the respondents are aged 26-35 while the least (20%) are within the range 15-25. Concerning sex: majority of the respondents are male (70%) while (30% female).

Concerning marital status: majority (63%) are married while the least is 10%. Concerning ethnic group: Majority of the respondents (44%) are Urhobo while the least 6%). Concerning educational status: majority (70%) have had formal, education while the least (30%) have no formal education.

Concerning occupational status: Majority (24%) are fisher men while the least (19%). Concerning religion: majority of the respondents (80%) are Christians while the least (4%) pagan.

Table 2: to showing the level of knowledge of prenatal/pemarital genetic testing among young people.
Table 2: frequency distribution on the level of knowledge of prenatal genetic testing.

<table>
<thead>
<tr>
<th>Level of knowledge</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>15</td>
<td>30%</td>
</tr>
<tr>
<td>No</td>
<td>35</td>
<td>70%</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

The table 2 above shows that 30% of the respondents level of knowledge of premarital genetics testing is positive while 70% of the respondent have a negative level of knowledge.

Table 3: frequency distribution on the source of information

<table>
<thead>
<tr>
<th>Source of information</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>Health personnel</td>
<td>20</td>
<td>40%</td>
</tr>
<tr>
<td>Friends</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Journals</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>Others</td>
<td>7</td>
<td>14%</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

From table 3 above, it is seen that 20% of the respondents got their information through the media, 20% health personnel, 40% through friends, 6% through journals and 14% others.

Figure 1: Sources of Information
The graph above shows that 20% of the respondents got their information from the media, 40% health personnel, 6% friends, 20% journals and others 14%.

**Table 4: frequency distribution on the level of practice of premarital genetic testing**

<table>
<thead>
<tr>
<th>Level of knowledge</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>No</td>
<td>40</td>
<td>80%</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

The table 4 above shows that 20% of the respondents practiced premarital/prenatal genetic testing while 80% did not.

**Figure 2: Practice of premarital/prenatal genetic testing**

The above graph shows that 20% of the respondents, practice premarital/prenatal genetic testing while 80% do not practiced it.

**Table 5: Frequency distribution on factors influencing young people’s attitudes towards premarital genetic testing.**

<table>
<thead>
<tr>
<th>Factors influencing their attitude</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of knowledge</td>
<td>24</td>
<td>60%</td>
</tr>
<tr>
<td>Non affordability</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>Non accessibility</td>
<td>2</td>
<td>5%</td>
</tr>
</tbody>
</table>
The table 5 above shows that 60% of the respondent are as a result of lack of knowledge 20% due to non affordability, 5% non accessibility and 15% as a result of non availability of centre’s where prenatal genetic testing is been carried out.

This can also be represented with the use of histogram

![Histogram](image)

**Figure 3: Factors influencing their attitude**
The histogram above shows that (24) 60% of the respondents are as a result of lack of knowledge, (8) 20% due to non affordability, (2) 5% non accessibility and (6) 15% due to non availability of centers where pre marital genetic testing is done.

**Table 6: Frequency distribution on when prenatal genetic testing should be done**

<table>
<thead>
<tr>
<th>When it should be done</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before marriage</td>
<td>14</td>
<td>28%</td>
</tr>
<tr>
<td>Before pregnancy</td>
<td>6</td>
<td>12%</td>
</tr>
<tr>
<td>During pregnancy</td>
<td>28</td>
<td>56%</td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

From table 6 above, it shows that 28% of the respondents say before marriage 12% before pregnancy, 56% during pregnancy while others 4%.
ANSWERING OF RESEARCH QUESTIONS

According to table 2 which shows that 70% of the respondents does not have positive knowledge of premarital/prenatal. Genetic testing and 30% of the respondents have positive knowledge of prenatal genetic testing. This therefore shows that majority of the respondent are not aware of prenatal genetic testing. This answer research question 1.

According to table 4 which show that 20% of the respondents do practice premarital genetic test and 80% do not practice it as it is seen in figure 2. It therefore seen that young people of Sapele local government area, level of practice of premarital/prenatal genetic testing is very low. This therefore answered research question 2.

According to table 5, 60% of the respondents lack of knowledge, influences their attitude towards premarital/prenatal genetic testing, 20% due to non affordability, 5% non accessibility and 15% due to non availability of centers where prenatal genital testing is earned out.

As it is seen in figure 3 which reveals 60% of the respondents is due to lack of knowledge, 20% non affordability, 5% non accessibility and 15% due to non availability of centers.

According to statistics, it shows that young people in Sapele local government area of delta state have limited knowledge negative attitude and low level practice of premarital/prenatal genetic testing. It is also discovered that lack of knowledge, non affordability, non accessibility and non availability of centers influences their attitudes towards premarital genetic testing. It is a multi- multi furious problem that requires multi-sect oral approach.

DISCUSSION OF FINDINGS

This chapter deals with discussion of major findings of the study / relationship with other related findings conclusion, summary implications for nursing, limitation of the study, recommendation and suggestion for further studies.

DISCUSSION OF FINDINGS RELATIONSHIP WITH OTHER RELATED FINDINGS

Objective 1: to determine the level of knowledge towards premarital/premarital genetic testing among young people. Question 1 table 2: Frequency distribution on the level of knowledge of premarital genetic testing. The results shows that 30% of the respondents have adequate level of knowledge of premarital/premarital genetic testing while 70% of the respondents have no knowledge of premarital genetic testing.

It could be seen that a greater number of the people are not aware of premarital/prenatal genetic testing.
Results of similar study conducted by Palornaki. (2006) shows that inadequate level of knowledge by pregnant women goes a long way to affect their access to genetic testing in health centers across the country Nigeria. According to Palomaki, (2006) less religious pregnant women tended to be more in favor of premarital/prenatal genetic tests as a result of their interest and up-to-date knowledge on premarital genetic test and how to undertake such tests. This preliminary study provides genetic counselor and policy makers with a clearer picture of their clients motives and attitudes behind the decision-making process of premarital/prenatal genetic testing, contributing to improving both the communication process between Question 2.

Table 3: Frequency distribution on the source of information.

The table shows 20% of young people who have adequate knowledge of premarital genetic testing heard about it through the media, 40% through health personnel. 6% through friends, 20% from the journals while 14% others. This correspondent with the study conducted (Evans 2008) have continually argued that our society today is characterized with falsehood and the spread of unverified information by the media which no doubt hinder that understanding of the need for prenatal genetic test. According to Evans, accurate and up-to-date information on how to obtain genetic testing should be channeled to health personnel such as nurses & doctors rather than relying on information being peddled around by uninformed individuals in the medical field.

**OBJECTIVE 2: TO ASSESS THE LEVEL OF PRACTICE OF PREMARITAL/PRENATAL GENETIC TESTING.**

Table 4: Frequency distribution on the level of practice of premarital/prenatal genetic testing. This reveals that 20% of the respondents practiced premarital genetic testing while 80% of the respondent do not.

This falls in line with the survey on the need to boast medical practices on genetic test in Nigeria conducted by Bogart (2007) who argues that it is being quite amazing today that the level at which medical practitioners neglect the issue of genetic testing to the detriment of the timid pregnant women is dangerous to the actualization of quality health for all in the year 2020 according to the World Health Organization (WHO 2001). Bogart (2007) therefore opines that doctors, and nurses must assess a matter of priority devout much of their time and energy toward the conduct of prenatal genetic testing for the common good of both the expectant mother and their child.

**OBJECTIVE 3: TO IDENTIFY FACTOR INFLUENCING THEIR ATTITUDE TOWARDS PREMARITAL GENETIC TESTING.**

Table 5: Frequency distribution on factors influencing young people’s attitudes towards premarital/prenatal genetic testing.
This shows that 60% is due to lack of knowledge/need for more scientific information as well as a positive attitude towards genetic testing, 20% non affordability, 5% non accessibility and 15% as a result of non availability of centers. This finding is in line with a study conducted by Green, (2000) who stated that three dimensions predict the intention to undergo prenatal genetic testing: the need for more scientific information, a positive attitude towards genetic testing And the inclination to terminate pregnancy after receiving a positive test result. This implies that despite the increase in popularity of premarital/prenatal genetic testing relatively little is known about the role psychological factors play in the decision — making process. This correspondent with study conducted by Croyle (2005) who stated that poor attitudes of pregnant ladies in our society today tend to impact negatively on their consistent access to premarital genetic testing in Nigeria. According to Croyle, unless this disorder attitude of our young people is corrected via adequate information on the relevance of this test this wrong notion will continue to affect their behaviour towards the test.

CONCLUSION

From the analysis of the result it could be established that young people have limited knowledge of premarital/prenatal genetic testing and negative attitude and practice towards the premarital genetic testing as a result of lack of knowledge non affordability, non accessibility and non availability of health centers with premarital genetic testing equipment.

The study has shown that despite the increase in popularity of premarital/prenatal genetic testing relatively little is known about the role psychological factors play in the decision — making process.

IMPLICATION FOR NURSING

The knowledge gained from this research work will help the Nurse to know the different types of genetic abnormalities.

It also create an avenue for nurses to health educate the young people on what remarital/prenatal genetic testing is all about, and how to prevent it, what to do and how to do it, and how to avoid member of the community from being affected.

Further, the research work serves as an eye opener for members of the community on the different genetic abnormalities and what to do to prevent it.

LIMITATIONS OF THE STUDY

The extent of this research is constraint by a number of factors. This includes:

1. Time constraint: Time factor was a limitation the researcher would have loved to cover other area of the community but could not because the time allocated to the work was short.
2. Respondents: Due to inability of some of the respondents to read & write, the researcher spent time and energy explaining to them and getting them to fill the questionnaire correctly.

RECOMMENDATIONS

Based on the findings on the research work, it is noted that the knowledge, attitude and practice toward premarital genetic testing among young people in Sapele local government, among the selected community is low, so with this result, the research recommends that;

1. Government should provide screening centers among the people

2. Young people should be encouraged to be involved in premarital/prenatal genetic testing to prevent congenital abnormalities of their offspring.

3. Every January, the community members in Sapele Local Government should go for genetic testing, and counseling.

4. Women of reproductive age especially the pregnant one’s should be encouraged to be involved in prenatal genetic testing to prevent congenital abnormalities.

5. For couples in which both partner are carriers, genetic counseling is recommended to review prenatal testing and reproductive options.

6. Every unmarried young people should assess their genetic status before marriage

7. Efforts should be made by government and health workers to improve their knowledge, attitude and practice toward genetic testing and its abnormalities, thus reducing genetic disorder in the society.

SUGGESTIONS FOR FURTHER STUDIES


2. The effect of prenatal genetic testing on young people in Nigeria.

3. Implication and cost benefit analysis of prenatal genetic testing among couples.

REFERENCES


21. Genes on the Line (http://www.geiieticailiation.org)


PERCEIVED EFFECTS OF PREGNANCY ON THE ACADEMIC PERFORMANCES OF FEMALE NURSING STUDENTS IN IMO STATE UNIVERSITY OWERRI. NIGERIA

Article Review by Ezenwuba Clementina O, Nigeria
(MSN, Texila American University)
Email: - mentieze2@gmail.com

ABSTRACT

This study was on perceived effects of pregnancy on the academic performances of female nursing students in Imo State University, Owerri, Imo State. Nigeria. The objectives of this study was to determine the level of awareness of challenges of pregnancy on the academic performance of nursing students, types of academic challenges due to pregnancy and the effects of pregnancy on the academic performance of nursing students in IMSU. Three research questions were formulated to guide the work. Literature was reviewed based on the objectives. A descriptive survey design was used in which 62 respondents were selected using census survey. Questionnaire was used to collect data that was analyzed using frequency, percentages and charts. Pilot study was conducted and reliability coefficient of 0.8 was obtained. The study revealed that 50 (80.6%) of the pregnant nursing students are aware of the challenges of pregnancy on academic, the students experience challenges such as physical discomfort in 24(38.7%), reduced concentration span in 17(17.7%) and missing of lectures in 53 (85.5%). These affect their academics as they result in (30.6%) absenteeism, (27.4%) low academic performance, (24.2%) difficulty adjusting to motherhood as pregnant students and (17.7%) rewriting of courses.

Conclusion was drawn based on the findings. Recommendations and suggestions were made for further studies were made.

INTRODUCTION

BACKGROUND TO THE STUDY

Education is a lifelong process that enables the continuous development of a person’s capability as an individual and as a member of the society (Effle, 2011). It is central to the development of young people as it prepares them for the world of work and life (Sibeko, 2012).
Academic performance is the outcome of education simply meaning the extent to which a student, teacher or institution has achieved their educational goal.

In educational institutions, success is measured by academic performance or how well a student meets standards set by the institution. Sophie, Benedikt and Tomas (2011) stated that “students with higher mental ability as demonstrated by IQ tests tends to achieve highly in academic settings” thus, academic performance is how students deal with their studies and how they cope with or accomplish different tasks given to them by their teachers.

As career competition grows more fierce in the working world, the importance of students doing well in school has caught the attention of parents, legislators and government education departments alike. It has become imperative that areas of achievement and failure in student’s academic career be evaluated to foster improvement and make full use of learning process.

Performance in school is evaluated in a number of ways such as written and oral tests, presentations, homework’s and participating in class activities and discussions.

Pregnancy is a condition when a child bearing mother is having a developing fetus or embryo inside her. Mfuh, Umma and Sunday (2013) described this as: “the most rewarding experience of a woman’s life which can also be a tremendous challenge. This is a period a woman undergoes several hormonal changes accomplished by discomfort, distraction and physiological transformation which may interfere with her studies in conjunction with her responsibilities at home as a wife for the married. Recent research in South Africa discovered that more than thirty percent (31.5%) of girl at age 18 have given birth at least once (Karra and Lee, 2012). This statistics according to them shows that pregnancy especially that of the teenager is becoming more and more a barrier to girls education. Marteletto, Lam and Ranchord (2008) continued to note that school girls pregnancy has been one of the major hindrances to the educational success of women. To which Changach (2012) concluded that this imposes long term consequences on the career development of these young mothers and hence is likely to lead to transmission of poverty from generation to generation.

Kanku and Mash (2010) also affirmed that falling pregnant while still at school happen at the wrong time for a girl as it affect very much their education and often ends up ruining their future.

According to Lynch and Ghosh (2008), “cultural norms prescribes different role for mothers (pregnant or nursing women) in all societies irrespective of their age, so as to be able to perform their varied care taking role in the family. With these responsibilities and the need to meet up the expectations from the academic field so as to fulfill ones career and destiny, Mngoma (2010) said that most pregnant students drop out of school or had to repeat grades several times. They may also not be socially and personally mature enough to assume the new role of parenthood (Boltin in Sibeko, 2012) together with being a student at same time. Also the emotional impact of the crisis of pregnancy which may in some instance end in the termination of the pregnancy could also result in the student experiencing post- abortion stress symptoms. These might have a
detrimental effect on the student’s bio-psychosocial well-being, relationships and ultimately affect her academic performance.

In Nigeria universities the increase rate of students involving in prenatal sex has predisposed the student to unwanted pregnancies either by their fiance or boy friend as is rampant in the various institutions Pandy, Makiwane, Ranched and Letsoalo (2009) opined that as young people spend longer periods in education, as part of the natural course of development, sexual experimentation and maturity is increasingly coinciding with them. More so, the number of years spent by the nursing student in the institution seems to trigger the inability to control their urges for marriage until after graduating as registered nurses (RN).

As the pregnant student are also expected to meet a minimum rate of academic progress which means passing 50% of the credit units for the subjects enrolled over the duration of the course, this paper therefore, proposes to explore how pregnancy affects the academic progression of nursing student in lmo state university.

STATEMENT OF THE PROBLEM

US department of education (2013) reported that pregnancy is consistently the most common reason given by female student for dropping out of school. Data collected by the National centre for education statistics in (2004), showed that 27.8% of the female students in 2002 and subsequently dropped out due to pregnancy. Similarly, a 2006 report found that, of 467 survey respondents age 16 through 25 who dropped out of public high schools in 25 different locations across the country, 26% of young men and young women combined, one—third of young women said that becoming a parent was a major factor in their decision to leave school to which they reported doing reasonably well in school before becoming pregnant.

Being a student nurse requires high academic effort with utmost attention to meet with the high expectation of the student. This is time consuming and life exhausting in itself talk more combining it with the demand of pregnancy. Before now, every student nurse is restricted from furthering her course at least for one session after her 6months puerperium to enable her take care of her baby, recover fully and set properly to face her academic squarely, meaning that the student misses one whole year and join the junior class.

The knowledge of family planning exposed through the course offered within the institution, the fact that information about sexuality issues and contraceptive methods are widely available provides all that every married or single female student nurse can apply to hold pregnancy from occurring until when ready.

The threat and trauma of stepping down starring the nursing students on the face each session should be enough to scare every student away from any form of distraction to total devotion to academic work, yet the increase in pregnancy among the nursing students of IMSU keeps booming.
The above observations and considerations have given the researcher concern being a nursing student of the same institution; she deemed it worthy to investigate on the effect of pregnancy on the academic performance of the female nursing students in IMSU to fulfill the following objective.

**PURPOSE / OBJECTIVE OF THE STUDY**

The purpose of this study is to evaluate how pregnancy affects the academic performance of the nursing student in IMSU. In line with this, the following objectives will be addressed;

1. To determine the level of awareness of challenges of pregnancy on academic performance among nursing students in IMSU.

2. To ascertain the types of academic challenges due to pregnancy faced by nursing students in IMSU.

3. To determine the effects of pregnancy on the academic performance of nursing students in IMSU.

**SIGNIFICANCE OF THE STUDY**

This study will reveal the impact pregnancy have on the academic performance among the selected pregnant nursing students.

This result obtained will be useful in helping the other female students in choice of marriage and prevention of pregnancies while in school to avoid disruption or distraction in academic progression.

This study will also help the nursing profession and administration to see the need for a counselor and offering of counseling services to the nursing students and the need for more emphasis on how to avoid pregnancy and family planning. This study will help reduce the frustration of students and families experiencing emotional stress and academic struggles as a result of unwanted pregnancy among student mothers.

The finding will help the nursing profession in reducing of occurrences of student pregnancy which will invariably promote a complete devotion to academic requirement and production of responsible graduate nurses who will represent the profession anywhere in the world.

This finding also, will add to existing sparse literature surrounding the academic performance of pregnant nursing students.

**RESEARCH QUESTION(S)**

The key questions that will be answered in this study are;
1. What is the level of awareness of challenges of pregnancy among the pregnant nursing students in IMSU?

2. What are the types of academic challenges due to pregnancy faced by the nursing students in IMSU?

3. What are the effects of pregnancy on the academic performance of nursing students in IMSU?

**SCOPE OF THE STUDY**

The scope of this study is all female students of nursing science in Imo State University (IMSU) who are pregnant or have been pregnant during the course of their study. The study is also delimited to their academic performance and how it is affected by pregnancy.

**OPERATIONAL DEFINITION OF TERMS**

**Pregnancy:** This is a condition when a woman is carrying a child in her womb.

**Academic Performance:** This is how student deal with their studies and how they cope or accomplish different tasks given to them by their teacher.

**Effect:** The way an action or a condition makes impact in ones life either positive or negative.

**Female Nursing Student:** This is an individual who has applied to be trained in the school of nursing so as to obtain the certificate to practice.

**LITERATURE REVIEW**

In this chapter, the literature review would be discussed under the following headings;

- Concepts of studentship and motherhood.
- Academic challenges of faced by pregnant nursing students.
- Effects of pregnancy on the academic performance of nursing students.
- Empirical Review
- Theoretical Framework.

**CONCEPTS OF STUDENTSHIP AND MOTHERHOOD**

Studentship entails studying at a tertiary institution in order to attain a degree or a diploma. It involves a transition from high school to college life. Thus, students have to adjust to college life
in order to appropriately fit into the new situation and experience (Education Encyclopedia in Mamhute, 2011).

Roxburgh et al in Mamhute (2011) described motherhood as central to a woman’s life while Magwaza in same write up referred mothering as a gendered practice and a woman’s prerogative. The society expect mother to be gentle, loving and caring enough to devote all their life fulfilling her role in the family. But Luttrel in Mamhute (2011) refutes the idea of the “Myth of maternal omnipotence”. According to her, mothers do not sorely exist to gratify their children’s needs. In fact, they may have wishes, needs and desire contrary to their children’s needs.

Collage life make new academic demands such as lengthier assignment, more frequent written work and higher standards. Gushing in Mamhute (2011) asserted that in spite of these requirements, the student must exert herself so as to achieve the required levels in order to pass.

Motherhood as an institution is fraught with challenges such as anxiety, stress, indecision, frustration and fear such challenges are compounded by educational challenges in instances where the mother is a student.

Schreiner (n.d) opined that Nursing student learn a plethora of medical information requiring a well developed study skill to make learning and retention of information easier. He further stated that these students have to balance a hectic course schedule while training (P.2). Additionally, in many nursing programs timeliness is required and students can be expelled for accruing an excessive number of absence. Further more, success in nursing school requires dedication to course of study and individuals who have numerous family commitments will likely struggle to keep up on their classes. According to him, even the best intentioned nursing student can struggle with balancing their school work and their current responsibilities (including pregnancy demand).

Luttrell had this to say in Mamhute (2011) “when a female learner becomes pregnant she bids farewell to youth and has to contend with realities and responsibilities of adulthood. She also adds the status of mother to her academic role”. Yet more often than not, the demand of motherhood and studentship are incompatible. The pregnant student has to put effort in balancing the two roles. In her struggle to serve two “masters”, the student may fail to satisfy both said Mamhute (2011).

**ACADEMIC CHALLENGES FACED BY PREGNANT NURSING STUDENTS**

Merill asserted in Mamhute (2011) that pregnant and nursing learners experience challenges due to the competing and conflicting demands of their mothering roles and studentship. According to her, these challenges can be physical, social or administrative. Sekgobela (2008) added that these challenges have a negative effect on academic progress and achievement (Mamhute, 2011) also
affirmed that some challenges are peculiar to pregnant students. These challenges relating to their academics could be physical, social and administrative peculiar to pregnant students.

“When a female student becomes pregnant, her physical and mental states might adversely affect her studies” opined Sekgobela (2008). Luttrell also recognized that pregnancy is a unique condition in that it is the only state which affords two people to line under one skin. This two-in-one state affects the physical well-being of the mother. Some of the physical problems cited by Sekgobela (2008) include; nausea, vomiting, bleeding, dizziness, tiredness, cephalo-pelvic disproportions, preeclampsia toxemia etc.

Canterbury Christ Church University (2010) views pregnant learners as at risk students who should not be exposed to “significant physical activities….chemicals, paints and radiation. Thus, pregnancy curtails students’ working capabilities thereby affecting their self esteem. Study by Luttrell in Mamhute (2011) also showed an expressed sentiment by pregnant girls indicating that school life was a struggle. However, pregnant students experience their pregnancy differently. While some find it easy to study, others find it almost impossible to study while pregnant (Pankhurst, 2010). According to the study by Sekgobela (2008). The pregnant nurses confirmed that the physical, social and academic challenges they faced made it difficult for them to study. Netshikweta in Mamhute (2011) opined that although some pregnant student have positive attitude towards their pregnancies, they acknowledged experiencing physical discomfort. In her study, Netshikweta also noted that 89% of her respondents experienced physical discomfort. For Luttrell, she stated that during pregnancy the body undergoes changes and sends signals which the student must pay attention to. Some such signals are backache, morning sickness, muscle cramps, heart bum and hypertension.

Physical discomfort tends to negatively affect academic performances. Academic progress is held back as coping strategies and attention spans reduces. Netshikweta in Mamhute (2011) in agreement with the above sentiments stated that working abilities of students are affected by pregnancy. Luttrel further affirmed that one of the reasons pregnant students in the USA were expelled from school in the early century was that they were not able to function in an academic situation. Besides, the physical demands placed upon the student can cause stress which also has a detrimental effect in their studies. (Adam in Mamhute, 2011). It is in the light of such challenges that Canterbury Christ Church University (2010) advised the pregnant students to communicate with their programme directors so that they can get the necessary assistance.

Similarly, emotional dispositions impact negatively on pregnant student’s academic progress. Roxburgh et al in Manhute (2011) also echoed same sentiments contending that the mismatch between what is expected in parenthood and the actual reality of parenthood combined with student ship can cause stress as the new parent tries to adjust.

Also, society seems to view pregnant learners negatively. Teacher sentiments indicate that for pregnant learners, education is a responsibility and not a right (Lultrel in Manhute, 2011).
Differential attitudes towards pregnant learners protected by different members of the society tend to affect their self-esteem (Sweetman in Mamhute, 2011). Most participants felt that their lecturers made life difficult for them. Lecturers failed to offer appropriate guidance and support, thereby negatively impacting in these students endeavor to achieve their intended goals. (Van den Berg and Mamhute, 2013). They also reported that lecturers often intimidated, ridiculed and belittled these students through their comments and actions. This did not contribute to creating a positive self-concept in the students. (Crous et al in Van den Berg & Mamhute, 2013). It is believed that pregnant students’ chances of success could be enhanced if lecturers showed care and concern for them. Positive comments could assist the development of self-confidence, self-respect and feelings of adequacy.

Even when provision is made for these learners to study separately from the non-pregnant, they become apprehensive. In the USA, the establishment of the prenunt programme for pregnant teens (PPPT) was seen by the pregnant girls as segregatory rather than an act of goodwill. Society’s refusal to treat such learners with dignity and the concomitant inability to assist them causes anxiety. Anxiety, according to Hybels and Weaver (2004) can create psychological disturbances of the mind leading to confusion. This is a barrier to communication and consequently to academic achievement.

Brook field in Mamhute (2011) indicated that mutual respect among learner is one of the conditions for successful learning. Disrespecting and embarrassing pregnant learners negatively affects their learning.

The realization of these effects has led the Zimbabwe community to expect female learners to complete high school and tertiary education before starting a family. (The Saturday Herald, 2010).

Kambanji (2010) opined that the psycho-social issues that mothering learners have to deal with make it undesirable for girls to fall pregnant while studying.

The realization of the incompatibility of parenting and study has in some instances forced governments, schools or colleges to formulate policies or regulation that would cater for the welfare of mothering students (Mamhute, 2011). Though a gesture of goodwill, the policies in most cases, lack clear guidance or how student mothers should be treated, they instead offer guidelines.

In America, according to Washington D.C (2013), Title IX of Education Amendment of 1972 sanctioned the inclusion of all female learners, including school aged mothers to equal education opportunities however. As late as the 21st century, New York City schools experienced 70% teenage-mother drop out partly due to stigmatization and inadequate support within and outside their schools. (Hearing Testimony, 2010).
Lack of viability and commitment by the authorities to ensure that policies are implemented led to the closure of some schools established for pregnant and nursing learners in New York (Hearing Testimony, 2010).

In Australia, the women’s employment, Education and Training project (WEETAG) found out that social stigmatization of young women can result in negative self images which tend to limit their future options. (Bullen, Kenway and Hay in Mamhute, 2013). This realization they said has led the British Social Exclusion Unit (SEU) to recommend the consideration of the particular needs of teenage parents in the study programme and attendance requirement. Similarly, policy makers should consult pregnant and nursing students so that policy supports can upholds the development of positive image. Though, according to Kambanji (2010), policy targets can achieve the opposite if not well defined. Hence, polices can act as barriers to self — actualization for the student mothers. Over the year, policies have been set by college principals and responsible authority to expel pregnant students. Such student has to rejoin college after wearing their babies. However, the advent of a new policy that allows pregnant learners to go on maternity leave for three moths ushers in an era of hope for pre and nursing adult learners (Murape, 2010). The study on social — education challenges of pregnant student revealed that the college administration did very little in terms of supporting them. The entire participant in the study felt that although the administration was aware of pregnant students among its student population, they refused to give them the necessary support.

**EFFECTS OF PREGNANCY ON THE ACADEMIC PERFORMANCE OF THE NURSING STUDENT**

According to Gaant and Hallman (2006), although, pregnancy and motherhood do not always interrupt school girls education they can introduce a new set of circumstances that influence future decision related to the girls education. For Pandy, Makiware, Ranchod and Letsoala (2009), school girls pregnancy can have a profound impact in the mother and child by placing limits on her education achievement and economic stability as well as predisposing her to single parent hood. Duncan (2011) on the National campaign to prevent teen and unplanned pregnancy asserted that “whether the opportunity for education is lost or delayed, unplanned pregnancy often makes life harder for those trying to achieve the “dream” of a collage education”. She further stated that there are a wide of serious consequences for the young men and women especially those who are unmarried who experience an unplanned pregnancy, as well as for children born as a result of such pregnancies. From the stand point, the consequence may be especially compelling because they can distract, delay or derail student from reaching their education goals. (Duncan 2011)

Kara and Lee (2012), also pointed that pregnancy places a student at an educational and economic disadvantage. She may take longer to complete her studies.
Pregnant students are also known to be often absent from school for a variety of reasons related to their pregnancy (Rangiah, 2013).

Mamhute (2012) affirmed that pregnancy is a unique condition as it is the only state affording two people to live under one skin which invariably affect the physical well being of the mother. To her, some of the most common physical problems associated with pregnancy are nausea and vomiting, dizziness, tiredness and edema which may prevent the girl from going to school.

A pregnant school may miss some classes during the day when she is not feeling well. School days are missed when the pregnant school girl has to visit a clinic or doctor and during the final stage of her pregnancy, delivery and after the birth of the baby. (Bezuidenhout, 2013).

In their opinion Chigona and Chetty (2007) opined that being frequently absent from school results in pregnant students missing a lot of school work (Lectures, Assignment, Tests etc) Beesham in Sibeko (2012) asserted that educators reported a decrease in academic performance during and after pregnancy when compared to the performance of the student before pregnant. Changach (2012) also noted the various research studies confirmed that due to their pregnancy, students are often absent from school because they dot feel well or had to visit the clinic or the doctor. Being absent causes the pregnant student to miss school work such as lesson, test and assignments and most of the time, she falls behind in their school work.

Van den Berg and Mamhute (2013) also articulated that “over the years, large numbers of pregnant students have failed to write their examination because they gave birth during examination period and had to take their examinations the following year.” To drive their point further, they reported that in November 2010, a pregnant student failed to do a music practical examination because she gave birth in the eve of the examination day and no arrangement were made to enable her to take her examination after giving birth. We have had cases where the pregnant students start experiencing labor in the midst of hospital final examination. Another student was not allowed to write professional Council examination after qualifying in the pre-council examination because she delivered a night to the first paper and was not able to leave the hospital ward for the examination hail.

Kramer and Lancaster (2010) in agreement with Lynch (2008) opined that in most Africa cultures, women are expected to subordinate their needs and desire to those of their children and families. Thus, students with infant have to grapple with the role of motherhood and studentship. As a student mother, the student blends two identities the role of which conflicts. To be a good student, one needs to be fully committed to the academic demands.

**EMPIRICAL REVIEW**

A study on “Effect of educational challenge on academic performance of pregnant learners” carried out by Mamhute (2011) in South Africa with 6 participants reported that the interview
with the pregnant students showed that they missed a number of lectures. Even though they collected note from their classmates, most of these lecture notes were incomprehensible as students were fond of using short hand, reported participant y3 and y1. Participant y3 openly admitted that her academic performance was deteriorating which she felt was due to the varied effects of her pregnant state. It was now and rarely before that did she fail most of the course work assignment. In her study one of the participants confessed that “I feel my pregnancy is responsible. Had it not been for it, I would have put more effort and I would not have failed. Apart from failing assignments, these participants were no longer active in class. Participant y2 summed their predicament when she said “…pregnancy slackens my learning pace even participation in lecture, I just sit and try to listen”.

In a research carried out by Bhana, Morrel, Shefer and Ngabaza (2010), it was discovered that the presence of a pregnant girl in a classroom is not only a threat to their own academic achievement but also to the collective academic performance of the class as well as the classroom harmony. Further more, most pregnant school girl are not able to cope with the schools academic demands

Also in a research carried out on “Challenge of pregnant students Van den Berg and Mamhute (2013) reported a particular commentary stating “because I am pregnant, I have so many rewrites”

Another research by Sibeko (2012) on the “Effect of pregnancy on a school girls education” reported that more than ninety percent (92%) of the participant in the research acknowledged that pregnant students are frequently absent from school. Majority of the respondents (88%) agreed that pregnant student perform poorly in school. A large percentage (98%) of the respondents said that pregnant student have to repeat courses.

THEORETICAL FRAME WORK

In this study, Maslow’s hierarchy of need is considered to help us ascertain the reason for students’ pregnancy and how the need can be met without or limited occurrence of pregnancy within the period of schooling to avoid the negative impact on they sort to meet their needs.

Based on Maslow’s hierarchy of needs, Maslow identified that sex is one of the basic physiological need that takes precedence over higher level need. This need is usually expressed directly or indirectly which is manifested in the incidence of pregnancy while still in school such as in the current study. As one of the essential need of human, student tends to exploit sex to satisfy this need which if not met according to Maslow, can lead to pervasion like excessive sexual language, masturbation, exposure of sexual organs etc. Also, others flirt or redirect sexual need to physical exercise, over eating or over-working. This exploit and need to satisfy the sexual need result to engagement in risk lifestyles such as partying, indiscriminate sexual relationship as well as early marriage or negligence to family planning or use of contraceptive that result to pregnancy while in school. In as much as sex is a basic need, if not handled
appropriately, it could bring about unplanned pregnancy with its implications to the student academic welfare as she struggles to combine pregnancy with academics.

Maslow also recognized the need for love and belonging. This being the third level in the hierarchy indicated that people generally need to feel that they are loved by family and are accepted by friend and other citizen of their society. As long as the need for security and safety is ensured, an individual would be in willing to socialize to satisfy the need for love and belonging. Thus, when a student is connected or meets an opposite sex who can offer the love and belonging, sexual involvement which can lead to pregnancy ensures. However, when a student becomes pregnant, due to wrong timing, she can experience isolation as she is excused from so many social activities with course mates.

In self esteem, Sibeko (2013) noted that an adult learners self-concept should be congruent to her potential in order to actualize it. Hybels and Weaver (2014) defined self-concept as how one thinks and feels about oneself which could be enhanced by the learning environment that enable the student to be conscious and accept their feeling and experience. (Sibeko, 2013) further cited Crouse et al, stating that “one requires positive regard from others to reaffirm ones self-esteem. Care and appreciation as well as respect and approval from others are essential in the development of a good self-esteem. Ones self-esteem if positive enhances her chances to function as a self-directed learner.(Bruggerman, 2005). Consequently, ones chances to succeed in attaining a career are increased. On the contrary, when a student gets pregnant in the course of studies and is predispose to the struggle of meeting both needs of academic and pregnancy, she is bound to have set a back which plays a trick on her self esteem as people begin to view her as a failure in the area of academics. She also could start undermining her abilities which could have negative impact on her self-worth as the struggle continues. This of course, hinders the realization of other needs such as self actualization since one cannot claim to have actualized her life dream and satisfaction when she has not been able to complete an attempt in acquiring a degree. However, building students self-esteem would enable them note how important their career or academic achievement is and the need to acquire it first before venturing into pregnancy. Or at least learn to place priorities according to their conceived needs. It would help them discover their self importance independently without falling into the prey of men who would implicate their further by impregnating them.

**RESEARCH METHODOLOGY**

This chapter deals with the methods used by the researcher in carrying on the study.

**RESEARCH DESIGN**

The research design has been defined by Marshall and Rossman (2006) as “a plan for undertaking a systematic exploration of the phenomenon of interest”. All the decision made by the researcher in planning the study constitutes the design of the research (Mamhute, 2011). For
Chinweuba, Iheanacho and Agbapuonwu (2014) it entails the steps used in generating data and converting such data into meaningful forms.

The researcher adopted descriptive survey method. This design was used because the study deals with analysis of information that will enable the researcher to describe the effect of pregnancy on the academic performance of female nursing students in Imo State University, Owerri, Imo State.

RESEARCH SETTING

This study was conducted in Imo State University. The school comprises of two campuses. One in Owerri and the other in Umuna Community, Orlu L. G. A. in Imo State.

The Owerri campus is located in the heart land (Central Zone) of Owerri. A common road (Orji) that leads from Douglas where the largest market (Ekeonunwa) is situated towards Okigwe road. At the school Junction Commonly called IMSU junction, is a fly-over beside which a round-about is situated. This junction leads towards the main campus into the Faculty of health sciences where the nursing students have their lectures.

TARGET POPULATION

The population of the study was the female nursing students who were pregnant at the time of study or who have been pregnant within the course of their study as nursing student in Imo State University Owerri.

SAMPLING AND SAMPLING TECHNIQUES

Chinweuba, Iheanacho and Agbapuonwu (2014) affirmed that when the population size is small and accessible to the researcher, he may decide to use all members as subjects for that study. This they further explained is known as census survey.

The researcher therefore, used the total population of 62 female nursing students who were pregnant at the time of their study as nursing students. The researcher identified students who were visibly pregnant. For those students who have delivered and those whose pregnancy was not visible, the researcher asked the visibly pregnant students to identify them.

However, the 100 level class was not included. This is because they have not really come into the department as nursing students.

INSTRUMENT FOR DATA COLLECTION

The instrument the researcher used was questionnaire which was constructed by the researcher and structured so as to ascertain the effect of pregnancy on academic performance of female nursing students. This consists of total number of 16 items, which were made up of close ended questions.
The questionnaire consists of two (2) sections:

Section A tried to elicit information on the demographic data of the respondents

Section B elicited information on Challenges of pregnancy and Effects of pregnancy on academic performance.

**VALIDITY OF INSTRUMENT**

Validity of the instrument was ascertained by giving the instrument to expert who went through it and certified that it is suitable for the study

**RELIABILITY OF INSTRUMENT**

The reliability of the instrument was tested using test-retest method. A pilot study was conducted among 10 students from mid-wifery class. These students did not participate in the actual study. This group of respondents has similar characteristics with the population of this study. The answers from the first test were collected and after ten days, the same instrument was re-administered to the same respondents. The instrument reliability co-efficient was calculated using Pearson’s product moment correlated coefficient. The reliability coefficient was 0.8 which was highly reliable. The test confirmed that the instrument was suitable for the study.

**METHOD OF DATA COLLECTION**

A letter of approval was received from the school (I-lead of the Department). A letter of consent was also written to the respondents to obtain their consent after some explanations about the nature and purpose of the study. The researcher administered the questionnaires to the respondents in their various classes the first day. Second, third and fourth visits were made within the month for greater coverage of the study populations in each class. The researchers administered a total of 62 questionnaires to the pregnant students and those who have been pregnant during their course of study that were present in school as at that time of study. The questionnaires were administered directly and all the completed questionnaires were collected.

**METHOD OF DATA ANALYSIS**

Data were collected and analyzed using descriptive statistics in form of frequency, percentage. Data were presented using tables, pie chart, bar charts and histogram.

**ETHICAL CONSIDERATION**

During the course of this study, the researcher took into consideration the entire ethical principles governing the conduct of a research. The researcher took permission from the Head of Department of Nursing Science and a written consent was attached to the questionnaire with
reasons, and the procedures explained to the respondents. All the information gathered was treated with utmost confidentiality and anonymity maintained during the course of this work.

The researcher tried her best not to subject the respondents to any harm, both physically and psychologically.

The respondents were free to withdraw from the research at any point in time. In the questionnaire, the researcher ensured that only relevant questions were asked, and confidentially of the response assured and their privacy strictly maintained by using the information obtained only for the purpose of the study.

**DATA PRESENTATION AND ANALYSIS**

This chapter discussed in detail the data collected using questionnaire from the respondents. Each item contained in the questionnaire was critically analyzed using frequencies, percentage, and were presented using tables and charts.

**SECTION A**

**Table 1: Demographic Data**

<table>
<thead>
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<th>Age Range</th>
<th>Frequency</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>18-25</td>
<td>19</td>
<td>30.6</td>
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<tr>
<td>26-33</td>
<td>35</td>
<td>56.5</td>
</tr>
<tr>
<td>34-41</td>
<td>8</td>
<td>12.9</td>
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<td>42-49</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>62</strong></td>
<td><strong>100</strong></td>
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<thead>
<tr>
<th>Marital Status</th>
<th>Frequency</th>
<th>Percentage</th>
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<td>11.3</td>
</tr>
<tr>
<td>Married</td>
<td>55</td>
<td>88.7</td>
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<tr>
<td>Separated</td>
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<tr>
<td>Divorced</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>62</strong></td>
<td><strong>100</strong></td>
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<thead>
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<th>Religion</th>
<th>Frequency</th>
<th>Percentage</th>
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RESULT

Table I shows that 19 (30.6%) of the respondents were between 18-25 years, 35 (56.5%) between 26-33 years, 8 (12.9%) between 34-41 years while 0 (0%) was between 42-49 years. 7 (11.3%) of the respondents were single while 55 (88.7%) were married. All the students 62 (100%) were Christian. 11 (17.7%) of the respondents were in 200 level, 5 (8.1%) were in 300 level, 12 (19.4%) were in 400 level while 34 (54.8%) were in 500 level.

SECTION B

AWARENESS OF CHALLENGES OF PREGNANCY AND EFFECTS OF PREGNANCY ON ACADEMICS

Research Question One: What is the level of awareness of challenges of pregnancy on academic performance among the pregnant nursing students in IMSU?

Table 2: Showing students affirmation that pregnancy has effect on academics.

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>50</td>
<td>80.6</td>
</tr>
<tr>
<td>No</td>
<td>12</td>
<td>19.4</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>
RESULT

From the above, 50 (80.6%) of the respondents agreed that pregnancy has effect on their academics while 12 (19.4%) do not agree.

![Diagram showing areas where students experience effects of pregnancy on academics]

**Fig I:** Showing areas where students experience effects of pregnancy on academics

RESULT

The above figure shows that 24(38.7%) of the students experience the effects of pregnancy on the area of lecture attendance, 16(20.8%) in hospital ward procedures, 13 (20%) in meeting up with assignment, while 9(14.5%) experience it in the area of studying for test or examination.

**Table 3: Showing how often the students meet up with class lecturer before pregnant**

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Not Often</td>
<td>3</td>
<td>4.8</td>
</tr>
<tr>
<td>Quite often</td>
<td>17</td>
<td>27.4</td>
</tr>
<tr>
<td>Very often</td>
<td>42</td>
<td>67.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>62</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

RESULT

From the above, 3 (4.8%) do not often meet up with class lectures before pregnancy, 17 (27.4%) were quite often in class while 42 (67.7%) meet up with their class very often.

**Table 4: Showing how often the students meet up with class lectures when pregnant**
<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Often</td>
<td>31</td>
<td>50</td>
</tr>
<tr>
<td>Quite often</td>
<td>24</td>
<td>38.7</td>
</tr>
<tr>
<td>Very often</td>
<td>7</td>
<td>11.3</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>

**RESULT**

The above shows that when pregnant, 31 (50%) respondents do not often meet up with their classes, 24 (38.7%) quite often meeting while 7 (11.3%) very often meet up with their classes.

Table 5: Showing students affirmation of missing lectures because of antenatal visits or other pregnancy demand.

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>53</td>
<td>85.5</td>
</tr>
<tr>
<td>No</td>
<td>9</td>
<td>14.5</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>

**RESULT**

The above table shows that 53 (85.5%) miss lectures sometimes for antenatal visit or other pregnancy demanded while 9 (14.5%) do not.

Research question Two: What are the types of academic challenges due to during pregnancy faced by the nursing students in IMSU?

Table 6: Showing students affirmation of having academic challenges during pregnancy

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>51</td>
<td>82.3</td>
</tr>
<tr>
<td>No</td>
<td>11</td>
<td>17.7</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>
RESULT

From the above, 51 (82.3%) agrees to have academic challenge during pregnancy as a student while 11 (17.7%) do not.

![Diagram showing the challenges students face while pregnant]

**Fig II: Showing the challenges students nurses face while pregnant**

RESULT

The figure above shows that 24 (38.7%) had physical discomfort as a challenge while pregnant, 19 (30.6%) missed lectures, 11 (17.7%) had reduced concentration span, 5 (8.1%) lacked support while 3 (4.8%) had social challenges.

**Research Question Three:** What are the effects of pregnancy on the academic performance of nursing students in IMSU?

**Table 7: Showing students’ affirmation that missing lectures affects academic performance.**

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>51</td>
<td>82.3%</td>
</tr>
</tbody>
</table>
RESULT

From the table above, 51 (82.3%) agrees that missing lectures affects their performance academically, while 11 (17.7%) did not agree.

Table 8: Showing students affirmation that pregnancy affects their studying pattern.

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>48</td>
<td>77.4</td>
</tr>
<tr>
<td>No</td>
<td>14</td>
<td>22.6</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>

RESULT

The above table shows 48 (77.4) of the respondents agree that pregnancy affects their study while 14 (22.6%) did not agree.
RESULT

The figure above shows that 19(30.6%) experiences low performance, 15(24.2%) difficulty adjusting to motherhood as a pregnant student while 11(17.7%) rewriting of some courses due to the fact they were pregnant.

Table 9: Showing rewrites of assignment or examination as a result of pregnancy.

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>30</td>
<td>48.4</td>
</tr>
<tr>
<td>No</td>
<td>32</td>
<td>51.6</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>
RESULT

From the above table, 30 (48.4%) had to rewrite an assignment or examination as a result of pregnancy while 32 (51.6%) did not.

Table 10: Showing the frequency of those who would take the chance of another pregnancy while in school.

<table>
<thead>
<tr>
<th>Options</th>
<th>No of Respondent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>24</td>
<td>38.7</td>
</tr>
<tr>
<td>No</td>
<td>38</td>
<td>61.3</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100</td>
</tr>
</tbody>
</table>

RESULT

From the table above, 24(38.7%) indicated to take another chance of pregnancy in school while 38 (61.3) would not.

DISCUSSION OF FINDINGS

This chapter deals with the discussion of major findings, implications of the study, Conclusion and recommendations. Discussion of the findings of this study was discussed according to the research questions.

Research Question One: What is the level of awareness of challenges of pregnancy on academic performance among the pregnant nursing students in IMSU?

Table 2,3,4,5 and Fig I answers the above question.

The result shows that 50 (80.6%) recognized that pregnancy has effect on their academic while 12(19.4%) did not. Among those who recognized these challenges, 24(38.7%) saw the effect in the area of studying for test or examination, 16(25.8%) in the area of lecture attendance, 13(20.6%) in hospital/ward procedure, while a smaller number 9(42.5%) in meeting up with assignment. Also, most of the respondents 42(67.7%) who were very often in meeting up with lecture before pregnancy decreased to 7(11.3%) when pregnant. While 3(4.8%) who were not often meeting up with class before pregnancy increased to 31(50%) when pregnant. 53 (85.5%) agreed that they sometimes misses lectures due to antenatal visits or other pregnancy demand.

From the above, it could be inferred that majority of the respondents recognizes that pregnancy has challenges on academics which is seen mostly in area of preparing for a test or examination
and reduction in meeting up with lecture as the need for antenatal and other pregnancy demand arises.

This findings corresponds with the result gotten from a study carried out by Sibeko (2012) on “Effect of pregnancy on a school girls education”, 92% of the respondents in the research sample agreed that pregnant students are frequently absent from school in order to visit the clinic or doctor, when not feeling well and for the birth of the baby. Mamhute (2012) also reported that the pregnant students in her study showed that they missed a number of lectures to which they admitted that their academic performance was deteriorating. Zwolak (2008) pointed out that pregnant students felt they could not cope with the demand of pregnancy. Pregnant student nurses find it difficult to care for their patients. (Netshikweta in Sekgobela, 2008)

Research Question Two: What are the types of academic challenges due to pregnancy faced by nursing students in IMSU?

Table 6 and Fig II answers the above question.

The result of the findings shows that majority 51(82.3%) of the respondents admitted have academic challenges due to pregnancy. These challenges include physical discomfort experienced by 24(38.7%), missing of lectures in 19 (30.6%) respondents and reduced concentration span in 11(17.9%), The findings shows that most of the pregnant students undergo certain challenges such as physical discomforts of pregnancy which makes studying difficult and unavoidably missing some lectures which exposes then to failure. This finding corresponds with the result gotten from a study carried out by Mamhute (2011) with 6 pregnant nursing students which inferred that physical discomforts of pregnancy were obstacles which impacted negatively on their studies. Participant y3 openly admitted that the varied effects of her pregnant state affected her academic performance. This student declared that her pregnancy slackens her learning pace. While Sekgobela (2008) affirmed that pregnancy can cause undue tiredness and reduce the student’s concentration span. Sibeko (2012) in his study also affirmed that it has been found that during pregnancy, school girls were often absent because they felt sick as proved by 92% of respondents agreeing to be frequently absent from school as a result of pregnancy. According to Lynch (2008), pregnant students experience challenges due to the competing and conflicting demands of their mothering roles and studentship. The challenges can be physical, social, financial and administrative.

Research Question Three: What are the perceived effects of pregnancy on the academic performance of Nursing Students in IMSU?

Table 7, 8, 9, 10 and Fig III answers the above question.

The result of the findings shows that majority, 51(82.3%) agreed that missing lectures affects their performance academically and most 48(77.4%) acknowledged that pregnancy affects their studying pattern. Their experiences showed that pregnancy leads to low performance in 19
(30.6%), increases absenteeism in 19 (30.6%), makes it difficult adjusting to motherhood as a pregnant student in 15 (24.2%) and brings about rewriting of some courses in 11(17.7%). 32(51.6%) did not rewrite any assignment as a result of pregnancy while 30 (48.4%) did. On weather they would take another chance of pregnancy while in school, 38 (61.3) would not while 24(38.7%) would do so.

The above result shows that pregnancy has a profound effect on academic performance. As these students miss lectures, experience challenges in study pattern and try to struggle with adjusting to motherhood as a pregnant students. Most begin to experience rewrites of courses and assignments and low performance in their academics. Even though many agreed on taking another chance of pregnancy in school which may be related to the fear of their age at school and fear of reaching menopause before graduating, as one indicated that she would have to struggle, most would not give it another chance. This finding supported Mamhute (2011) who wrote that as a result of challenges of pregnancy; most of the participant’s experienced low academic performance. And all the 3 pregnant participants felt that studying while pregnant was not only difficult, but a never to be repeated experience. In agreement, Sibeko (2012) reported that the majority of the respondents (88%) agreed that pregnant students perform poorly in schoolwork. While large percentage (93%) said that pregnant students have to repeat grades. In Sekgobela (2008) opinion, “the challenges the pregnant students face have a negative effect on academic progress and achievement.”

IMPLICATION FOR NURSING

From the findings made by the researcher in this study, it is the role of the nurses be it in the hospital or in the school to give the students correct information and orientation to help them realize the implication of pregnancy while studying before they actually get into it.

Nurses should organize health education sessions, workshops, seminar and conferences for student nurses to increase the awareness of effect of pregnancy on the student’s performance.

The nursing college administration should further establish an office for proper counseling and support for both non and pregnant students in their academic performance and in choice making.

Nurses should be encouraged to conduct more studies on the effect of pregnancy and child rearing on the academic performance of students.

The finding will serve as a contribution to the existing body of knowledge in this area of study and useful as reference for future researchers in nursing profession.

Nurses should make more emphasis on family planning and appropriate arrangement for sexuality education.

The professional body should set policies that will guide the students in area of pregnancy and studying.
SUGGESTION FOR FURTHER STUDIES

This study is subject to criticism from other researcher to validate its claims.

- Similar studies should be carried out in other universities in Imo State as well as universities in other states of the federation and beyond.
- Research should be carried out on the effects of marriage and pregnancy on the academic performance among nursing students.
- Research should also be done on the academic challenges of pregnant student nurses for broader coverage.

CONCLUSION

Based on the result of this study, the researcher assert that majority of the pregnant nursing students in Imo State University are aware of challenges of pregnancy on academics, the students experience challenges such as; physical discomfort, reduced concentration span and missing some lectures which result in low performance, absenteeism, difficulty adjusting to motherhood as a pregnant student and rewriting of some courses (carry over).

REFERENCES


INNOVATIVE NURSING APPROACHES IN MANAGING LOWER BACK PAIN (LBP) AMONG THE ELDERLY PERSONS. A CASE STUDY IN MARIDI COUNTY, WESTERN EQUATORIAL STATE, SOUTH SUDAN

Article Review by Bakoko Joyce Matua, Uganda
(BSc to RN, Texila American University)
Email: - jbakoko@yahoo.com

LIST OF ABBREVIATIONS

LBP  Lower Back Pain
RN   Registered Nurse

DEFINITION OF KEY TERMS

Pain        UN pleasant feelings expressed by patient can be physical Psychological, or Spiritually.
Suffering A situation of distress due to events that shortens life.
Acute pain sudden unpleasant, physiological response to a stimulus
Chronic Pain Physiological bad responses to a stimulus and it persists
Pain assessment Comprehensive follow up of client patents related to his grief
Chemotherapy Art of relief of pain by use of drugs
Geriatric The aged group

ABSTRACT

The elderly generation, coexists with the rest of the population of the world (Jared T. Scott 2010). They suffer a great deal of several kinds of pain including lower back pain. In most cases this condition in the elderly is not managed by use of nursing interventions rather managed with other medical remedies, and yet the client spend most of their times with nurses, than, other health workers. This case study addressed the gap that could be filled by nurses by using innovative means in nursing to relieve pain of lower back in the elderly by ideal assessment then given specified nursing interventions to a specific individual, so as to avoid disabilities. Sackett et al (2000).

Conclusion: Disabilities in elderly related conditions can be assessed and managed by nursing
Recommendations: Nurses needs to be trained with more contemporary skills in assessing LBP, suggesting that the knowledge of nurse with higher qualification is paramount to meet the fourth coming challenges in the management of the elderly with LBP.

INTRODUCTION

BACKGROUND OF THE CASE STUDY

Most of the population of the world comprises of old human beings (Alan D. Kaye, Amir Baluch, and Jared T. Scott, 2010). Old age is inevitable. It starts from 65 years and above. This is incidentally estimated to be 506 million from 2008 to 2040, further threatening definitely to increase to 1.3 billion, with further expectation to grow more. This therefore means, suffering from aging related syndromes, mostly pain including the lower back pain known as low back pain (LBP) will be numerous due to physiological, psychological, degenerating problems. In Africa, the disease burden for lower back pain (LBP) prevalence is rated at 62% with expectation of rising (Morris L.D, (2007).

BACKGROUND OF THE STUDY AREA

Lower back is a global disease burden; many scholars have forecast that the prevalence of LBP, in Africa is rising with concern because Africa represents 14% of the world’s population and poorest continent contributing to 40% of the global disease burden suggestive of many disabilities in Africa in future (Tropical Doctor, 2004).

In S. Sudan however there is no literature that shows any disease burden but the disease burden can be discussed in relations to the burden reported in various countries in Africa on assumption that they have resemblances in race, economics and culture.

In Maridi, the prevalence of elderly living unattended to in various villages could be escalating. This was confirmed by “ward in charge of medical ward on 17th/10/2014 during a major medical round”.

PROBLEM STATEMENT

Lower back Pain prevalence amongst the aging is almost reported by all the elderly and with different presentations. The degree of the LBP ranges from mild moderate to severe depending on the cause. This in most cases leads to disabilities in the society. But many scholars have noted that it is not well managed; only some have been left to be managed by, surgeons, physiotherapists and other allied medical personnel (African Journal of Physiotherapy 2000)

This limited involvement of the nurses in using nursing interventions to manage LBP in the older person has occurred due to poor assessment of the nurses on LBP, inadequate communication and thus leading to poor management using the nursing interventions.

PURPOSE OF THE CASE STUDY

The main purpose of the study was to assess the nurses’ rating of LBP and use of innovate nursing modalities in management and prevention of LBP.
OBJECTIVES

1. To determine how well the nurses rate LBP using current methods of assessment.

2. To assess the ability of the nurses in using innovative nursing modalities in the management of LBP

3. To evaluate the communication strategies the nurses use to prevent and treat LBP in their geriatric patients

THEORIES

Many theories have been in place for successful management of back pain in other places (Woolf A, Pfleger, 2003) on management of LBP such as

- Relief of pain by use of hot or positioning the pain
- To control on body weight by control of nutrients
- Positive and proper ways on the ascribed roles
- Health education
- Use proper body mechanics
- And increase on physical mobility

RESEARCH QUESTIONS

The study sought to answer the following research questions:

1. How well do the nurses rate LBP using current methods of assessment?

2. Do the nurses have the ability to use innovative nursing modalities in the management of LBP?

3. What communication strategies do the nurses use to prevent and treat LBP in their geriatric patients?

JUSTIFICATION (SIGNIFICANCE OR SCOPE)

- To improve the idea of nurses in proper assessment of LBP.
- Comprehensively use the former and present theories of managing LBP in the elderly.
- To communicate the importance of Geriatric nursing especially in management of LBP.
CONCEPTUAL FRAMEWORK

Figure 1: Conceptual framework for the study about the assessment of LBP by Nurses in Maridi Hospital.

In the conceptual framework the optimum assessment of lower back pain and use of nursing interventions can improve lower back pain and prevent disability among the geriatric.

LITERATURE REVIEW

INTRODUCTION

Low Back Pain is a global challenge, especially now that the number of the elderly is increasing worldwide. This is expressed in the following literature. Sackett et al (2000) reported that Lower back pain can lead to disability; this is majorly due to musculoskeletal disorders such as rheumatoid arthritis osteoporosis low back pain and osteoarthritis. But out of these the most cause of disability is due to LBP.

As a result of musculoskeletal disorders. Many results have shown that at least all Africans have at one moment got an episode of LPB once in life time, which can easily re-occur due to various reasons, which can be economical, or related to many predisposing causes. The unfortunate scenario is that, most of the priorities of resource in Africa are re-allocated to other epidemic diseases. (Walker 2000).

Other literatures shows that, lower back pain is a global health problem but, western world has got ways in place of managing the elderly but in the growing country the facilities and personnel’s are either not enough or not present, to manage the aging.

Besides the above issue, originally elderly management has been more associated to be managed by the physicians; surgeon’s physiotherapist’s using either chemotherapy, osteopathic manipulations’, but not using nursing modalities of modern means such as proper assessment of pain rating from scale of 1-10 and management.

This calls a greater plan for training nurses with specialized skills ready to be able to address these
challenges forth coming. By using very innovative means that can be available and manipulated by either the client, or the attendant depending on where the pain is originated from.

The critical management of aging should vividly kick off with very good, competent assessment of lower back pain, then come up with a proper nursing diagnosis which will lead to elderly oriented nursing plans/interventions to manage so that the aging are relieved only by nursing care that other means such as chemotherapy, radiotherapy, surgery, which has got adverse effects and sometimes costly.

This calls a greater plan for training nurses with specialized skills ready to be able to address these challenges forth coming. By using very innovative means that can be available and manipulated by the either the client or the attendant depending on where the pain is originated from.

METHODOLOGY

INTRODUCTION

The chapter discussed the study design, study setting, study population, sample size determination, sampling procedure, inclusion criteria, variables, research instruments, data management, data analysis, dissemination of results and other procedures that were employed in the proposed study.

STUDY DESIGN

The method used for the study was a descriptive design. The design was most appropriate for the study because it was able to provide information about nurse’s knowledge of assessing lower back pain in the elderly, treat and prevent it to avoid disability.

STUDY SETTING

The study was carried out in Maridi hospital, located in Maridi county Maridi Payam in western Equatorials, Sudan. The town council is being inhabited by many tribes where the majorities are Bakas. All these people get treatment from Maridi Hospital which has many Health services, but lacking geriatric facilities suggesting most of the old are nursed at homes by their relatives; the hospital handles a patient load of 200 per day. Maridi hospital was therefore a suitable setting for the proposed study because it was easier to attain the required sample size of nurses.

STUDY POPULATION

The population targeted by the study consists of nurses, midwives who were currently working or teaching in national health training institute Maridi or had ever worked elsewhere as a registered nurse (RN)/Midwife. This district has not reported anything about the disease burden of the elderly suffering with lower back pain. This population was chosen because in Maridi district, the gap could be identified for the care of elderly.

SAMPLING PROCEDURE

In the study random sampling technique was used in order to attain the required sample of 10 participants. The researcher went on different occasions to the hospital and obtained data from
Nurses/Midwifes found on duty done randomly. Random selection of participants generated a representative sample to provide unbiased results.

**INCLUSION CRITERIA**

The inclusion criteria outlined below was used to select the participants for the study;

1. Must be a nurse with licensed certificate which should be recognised by the S. Sudan Nurses council.
2. Should be a staff of Maridi Hospital.
3. A nurse tutor teaching in national health training institute Maridi

**STUDY VARIABLES**

The proposed study measured two main variables which were; knowledge on assessment of Lower back pain in the elderly, available means nursing modalities of treating the lower back pain.

**STUDY INSTRUMENT**

An interview questionnaire was used for data collection in the study. The questionnaire comprised of three sections. The first section comprised of items on demographic characteristics. The second section comprised of items measuring knowledge of assessment of lower back pain. The thirds was on nursing modalities/intervention/ methods of treatment and prevention of lower back pain. The questionnaire was written in English the official language in S. Sudan. And this was also allowed for self-administering of the questionnaire by literate participants. The questionnaire comprised of both open and close ended questions.

**PRE-TESTING AND RELIABILITY**

The questionnaire was pre-tested using three final student nurses in Maridi Nurses training. The interviewers were trained to harmonize differences prior to data collection and other field work activities. They were trained on how to translate questions, interpret responses and on how to fill questionnaires appropriately. Interviewer’s conducts were emphasized to cultivate discipline while on field work.

**DATA COLLECTION PROCEDURE**

After approval from Texila American University, the researcher sought approval from Maridi Hospital. On obtaining approval from Maridi Hospital then the researcher introduced herself to each in-charge as nurses were approached During working days the researcher explained the purpose and the procedure of the study to participants and those who agreed to participate were taken in a private room to complete the consent form and research questionnaire as part of the data collection. After participants had completed the questionnaires, they were thanked.

**DATA MANAGEMENT**

After the Questionnaires had been filled by participants the researcher checked them for completeness
and missing data. Where possible, the missing data were elicited from the participants before they left the interview room. Questionnaires with raw data were stored in doubled locked cupboards and were only accessible by the researcher. Data was entered in the computer in SPSS software and the files were pass-word locked and only accessible by the researcher. The questionnaires after data analysis were safely kept in a well-protected cupboard for safety.

**DATA ANALYSIS**

Data analysis was performed using SPSS software program. The results of data analysis were presented in varied formats such as frequencies, table.

**ETHICAL CONSIDERATION**

The researcher while conducting the study sought consent from the interviewees and maintained confidentiality at all times. Approval and an introductory letter were obtained by the researcher from the Texila American University, for secondment by the student coordinator nursing officer and the medical superintendent leaders in Maridi Hospital. This built confidence in the respondents and eliminated suspicions about the interviews. Client’s confidentiality, privacy and autonomy were ensured through the consent form and all other activities which were part of the study.

**LIMITATIONS**

The following constraints were anticipated to be encountered and therefore limited the study;

Resource and time were not enough for the researcher to explore the problem to the required depth. And the time available for data collection was interfered with by other school activities.

**DISSEMINATION RESULTS**

The results of the study shall be submitted to, Texila American University, State ministry of Health Yambio and Maridi Hospital. Efforts shall be made to present findings of the study during nursing conferences and other professional meetings.

**DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS:**

The study involved 10 participants who were trained nurses or midwives licensed and working in Maridi hospital or teaching student nurses in a training school in Maridi Health science institute.

<table>
<thead>
<tr>
<th>Table 1: Demographic characteristic</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>GENDER</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>DISCIPLINE</td>
</tr>
</tbody>
</table>
The study involved 10 participants who were trained nurses or midwives licensed and working in Maridi hospital or teaching student nurses in a training school in Maridi Health science institute.

The data was collected from 10 participants who were of both sexes; male constituted 10% and female 90%. Both disciplines were interviewed and the result shows that the nurses constitute 80% and midwifes 20%.

Concerning education level; certificate nurses were 70%, diploma 20% degree 10% and none of them had masters.

Assessment knowledge on lower back pain all had no idea representing 90% which is suggestive that nurses and midwives in south Sudan have little knowledge on assessment of pain as other scholars noted Sackett et al (2000) this has left the elderly in pain and probably many elderly are in pain and heading to disability.

<table>
<thead>
<tr>
<th>LEVEL OF EDUCATION</th>
<th>Midwifes</th>
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<tr>
<td>Certificate</td>
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<td>70</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 1: knowledge or speciality of the respondents in geriatric nursing
Figure 2: Interest of respondents to specialize in the various disciplines of nursing

The study have shown that there is no interest of specialising to manage the elderly, suggesting that elderly are still managed in a tradition way and many could be neglected in this nation. Therefore this call for sensitization of training many discipline especially in geriatric nursing.

During the study, the despondences were asked whether they had ever nursed elderly patients with LBP.

The majority said they had never nursed. This is sworn in the figure 3 below

Figure3: The nurses according to whether they have ever nursed an elderly patient with LBP

This figure shows despondence experience whether they had nursed an elderly with LBP unfortunately 90% never nurse only 10 % had ever nursed suggesting that LBP is not a quick killing disease so in this place people are only brought early in the hospital with fast killing diseases and yet
those with LBP suffer at their home then probably brought with disabilities

**DATA SYNTHESIS**

Sub-theme was derived from transcribed in-depth individual interview discussion data. This focused on

1. Demographic data level of education is still a problem as such, many are under educated and lacked many ideal knowledge about LBP
2. Knowledge of assessment of LPB. It is suggestive that most nurses and midwives are still green on how to assess pain general and particularly LPB
3. By using innovative means of nursing approach of LPB, many acknowledged not to know how to assess LBP.

**DISCUSSION OF RESULTS**

- Elderly Nursing is not practiced commonly in S.Sudan; the study showed that, many nurses did not show an interest of specializing in the discipline
- There is no knowledge of management of pain and specifically in the elderly.
- Many had low standard of education, results showed that many remained in certificate level and it is possible that their curriculum is not updated with the contemporary knowledge.
- The few nurses are relying on surgeons and other means of treatment of LBP but not using innovative nursing measures.

**CONCLUSION**

This study has shown poor level of knowledge of nurses in the followings

1. Assessment of pain in the LBP
2. No innovative use of nursing knowledge in management, and prevention of lower back pain in the elderly
3. Low standard of nursing education in this country

**RECOMMENDATIONS**

1. Nurses should be done refresher courses frequently on vital nursing procedures such as health assessment especially in pain assessment so that they can care for all types of pain and care of elderly.
2. Put measures of innovative means of management and prevention of LBP in the elderly
3. Curriculum for nurses be reviewed regularly and in comparison to other developed Countries curriculum so that such gaps are bridged
4. An elderly bed with all its appliances could be invented for management of pain. Besides the other nursing means of managing LBP.

5. Have an exchange visit for nurses to exchange ideas.

**IMPLICATION FOR NURSING PRACTICE**

The current study has strong implications for nursing practice. One of its major findings is about the activities that nurses regularly perform with patient’s i.e. proper assessment, health education. And to be innovative while managing patients

This study highlights the importance of health assessment, and how it is communicated to the clients, so that patient complies with treatment. Therefore nurses have to ensure and understand the process of proper assessment of LBP.

This can improves adherence to instruction given by nurse to patients and outcomes of nursing care. If nurses assess patient well, patients will get better health, stay for fewer days in the hospital and eventually reduce the patient load in the hospital. Hence disability reduced in the elderly.

**LIMITATIONS AFFECTING GENERALIZATION OF FINDINGS**

The major limitation of this study was a small sample size, use of self-report method of measuring level of assessment of pain in the elderly and lack of standardised tool for the study. However the methods for measuring assessment used in this study have also been used in so many other studies worldwide, therefore the result of this study are still very important in the healthcare of geriatric conditions like LBP.

**BIBLIOGRAPHY**


APPENDIX 1: RESEARCH QUESTIONNAIRE

INTRODUCTION AND INSTRUCTIONS

This questionnaire collected data about innovative methods of managing lower back pain in the elderly.

SECTION A: DEMOGRAPHIC CHARACTERISTICS

Q1. Gender: 1 = Male 2 = Female
Q2. Age: ____________________
Q3. Discipline
1 = Nurse 2 = Midwife
Q4. Level of Education
1 = Certificate Nurse 2 = Diploma Nurse 3 = Bachelor’s degree
4 = Postgraduate Nurse
Q5. Do you have any knowledge or speciality in geriatric nursing 1. No 2. Yes
Q6. What would you like to specialize in nursing in future?

SECTION B: KNOWLEDGE ON ASSESSMENT OF LOWER BACK PAIN IN THE ELDERLY

Q7. In your nursing experience have you ever nursed an elderly with a history of lower back pain?
1 = No 2 = Yes
Q8. If No, how old was the patient 1 = Young 2 = Middle aged 3 = Elderly
Q9. What did you do first to the patient with lower back pain? 1 = Ask questions 2 = Examine painful area 3 = Give treatment 4 = Did nothing
Q10. How much pain did you think the patient had?
1 = Mild
2 = Moderate
3 = Severe
4 = I don’t know
Q11. Do you know or have heard any ways of rating pain?
Q12. If yes which one do you know

Q13. Was the method you used taught or learnt by yourself?
1 = taught, 2 = learnt by self, 3 = doesn’t apply.

Q14. Using the provided line below can you use it for rating pain in the elderly

0 __________________________ 5 __________________________ 10

Q15. Have you used five finger digits for rating pain
1 = Yes 2 = No

Q16. If yes how

SECTION C: INNOVATIVE NURSING METHODS TO RELIEVE PAIN IN THE ELDERLY

Q17. In your opinion, do you think nursing interventions can relieve pain adequately?
1 = strongly disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree

Q18. What did you first do to relieve the pain?
1 = advise 2 = treatment nursing measure 3 = I don’t know

Q19. Do you know any nursing means of relieving LBP in the elderly?
1 = NO 2 = Yes

Can you mention some of them?

Q20. In your opinion, do you feel nurses have other means of relieving LBP in elderly?
1 = strongly disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = strongly Agree

If strongly agree which are those means?

Q21. Is there anything else you want to let me know about assessment, and management of lower back in the elderly?

Thank you
MENTAL HEALTH CO-MORBIDITY IN PEOPLE LIVING WITH HIV IN SOUTH AFRICA – STEPS TOWARDS A SYNTHESIS OF INTERVENTIONS AND POLICY ADVANCEMENT

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ABSTRACT

OBJECTIVE

Mental health disorders are prevalent in HIV-infected populations, ranging from 43-56%, compared to about 30% of the general population. This comorbidity may exacerbate the progression to HIV/AIDS by increasing viral load, reducing CD4 count, and reducing adherence to ARVs. Despite the well established relationship between mental health and HIV/AIDS, and the World Health Organization (WHO) recommendation that attention to the psychosocial needs (which includes the prevention and treatment of mental health problems) of people with AIDS should be an integral part of HIV care, mental healthcare is yet to be integrated into primary care HIV treatment programmes in South Africa and other poor resource countries.

DESIGN AND PROCEDURE

The Rorschach inkblot test was conducted on a convenience sample of four South African HIV positive participants. Furthermore, a situational analysis was conducted from 2011-2013 to determine the context of mental health/HIV services in the Tshwane-Metsweding area, South Africa.

RESULTS AND RECOMMENDATIONS

Outcomes suggest that there is a high rate of psychological comorbidty in HIV infected individuals (such as mood disorders, personality disorders etc.), that there is a need to further develop and pilot test appropriate materials and models of delivery of mental healthcare within the parameters of affordability, acceptability and availability, and to advocate for the advancement of mental health and HIV policy integration.
KEY TERMS

HIV, AIDS, mental health, South Africa, Rorschach inkblot test, systems strengthening, policy advancement

INTRODUCTION

Infection with HIV has been consistently linked with poor mental health. The rates of mental disorders in HIV infected populations are in excess of that found in the general adult population. In a case-control study, Adewuya et al. (2007) reported a rate of 59.1% for psychiatric disorders compared to 19.5% in participants without HIV. In South Africa, prevalence of psychiatric disorders in HIV-infected populations range from 43-56% compared to about 30% in the general adult population (Olley et al., 2003; Olley, Seedat & Stein, 2006; Freeman, Nkomo, Kafaar & Kelly, 2007; Stein et al., 2008). In some patients, especially in resource poor settings, psychiatric disorders are the initial presenting clinical manifestation of HIV disease.

BACKGROUND

There is evidence of a high HIV seroprevalence in persons with serious chronic mental illnesses. In South Africa; Collins, Berkman, Mestry and Pillai (2009) found a seroprevalence rate of 26.5% in patients admitted to a public psychiatric hospital, while in Uganda; Maling, Todd, Van der Pool, Grosskurth and Kinyanda (2011) reported a rate of 18.4% amongst first time psychiatric admissions in two national referral hospitals.

Several mechanisms have been implicated in the complex relationship between HIV and mental health. HIV is known to directly infect the central nervous system leading to the neuropsychiatric complications such as minor cognitive and motor disorder, HIV associated dementia and mood disorders. The high prevalence of psychiatric disorders reported in people living with HIV and AIDS (PLWHA) may actually reflect high rates of pre-existing mental and substance use disorders in demographic groups at increased risk for HIV (Burnam et al., 2001). On the other hand, emotional distress, depression and anxiety may be a response to the initial crises of learning about HIV status or to the subsequent development of symptoms and associated disability, or may be related to the unwanted effects of anti-retroviral therapy (Atkinson & Grant, 1994; Owe-Larsson, Sall, Salamon & Allgulander, 2009). Factors that have been associated with increased likelihood of having a psychiatric disorder include the number of HIV related symptoms, viral load, younger age, heavy alcohol use, unemployment and living alone.

Depression is usually the most prevalent psychiatric diagnosis among HIV-infected patients, there is a 2-7 times increased likelihood for a diagnosis of depression in patients with HIV compared to the general population (Owe-Larsson et al., 2009). The prevalence rate ranges between 3%-35% in African studies (Myer et al., 2008; Olley et al., 2006, Marwick & Kaaya, 2010; Maj et al., 1994), the rates reportedly increase with clinical stage or progression of the HIV disease (Maj et al., 1994; Freeman et al., 2007). The diagnosis of depression is sometimes
difficult in patients with HIV due to the overlap in some symptoms for example fatigue, pain, anorexia and insomnia (Dube et al., 2005).

Depression in HIV/AIDS is associated with poor adherence to antiretroviral therapy, reduced quality of life and increased mortality (Mast et al., 2004; Nakimuli-Mpungu, Mutamba, Othengo & Musisi, 2009). Poor adherence to highly active antiretroviral therapy (HAART) has been linked with poor outcomes including increased viral load, viral resistance, clinical progression to AIDS, opportunistic infections and increased hospital admissions. Early detection and appropriate interventions for depression will be important in efforts to achieve optimal adherence to HAART.

Rates of manic illness are increased in HIV/AIDS especially with progression of symptoms. Mania in patients with AIDS is related to cognitive impairment, immunosuppression (indicated by low CD4 cell counts) and is thought to result from direct CNS infection by HIV (Nakimuli-Mpungu, Musisi, Mpungu & Katabira, 2006).

The prevalence rates of anxiety disorders are commonly elevated in patients with HIV infection and are often comorbid with depression. Anxiety syndromes typically manifests as post traumatic stress disorder (PTSD), generalised anxiety disorder (GAD), mixed anxiety and depression and phobias. PTSD has been documented in up to 20% of patients; and it is associated with a greater number of life events (Olley et al., 2006).

There are very few studies that have investigated the occurrence of psychotic symptoms in HIV/AIDS in Africa. The few available studies suggest that the pattern of occurrence is similar to that in other settings. It is a relatively uncommon psychiatric manifestation of HIV and appear more often in later stages of the disease (Säll, Salamon, Allgulander & Owe-Larsson, 2009). Psychosis in HIV infected populations are associated with untreated HIV infection, cognitive impairment, HIV associated dementia and a past history of psychiatric or substance use disorder (Owe-Larsson et al., 2009).

Despite the well established relationship between mental health and HIV/AIDS, and the World Health Organization (WHO) recommendation that attention to the psychosocial needs (which includes prevention and treatment of mental health problems) of people with AIDS should be an integral part of HIV care, mental healthcare is yet to be integrated into HIV treatment programmes in many African and other resource poor countries (Collins, Holman, Freeman & Pattel, 2006). Considering the fact that mental health resources and professionals are lacking across Africa, effective delivery of mental healthcare to persons with mental illness can only be achieved by strengthening the capacity of those working within HIV prevention and treatment programmes to recognise and treat mental health problems.

There is also a need for well-designed studies to increase the evidence base of the interactions between mental illness and HIV/AIDS at various stages of the disease in Africa and other resource poor settings where the disease is most prevalent. It is also important to increase
awareness that mental health constitutes a major barrier to reducing the spread of HIV infection, preventive efforts including the uptake of counselling and testing services and adoption of low risk behaviours, adherence to HAART and ultimately survival (Prince et al., 2007). This can only be achieved when empirical evidence from locally conducted research becomes available to guide the formulation of effective policy and intervention strategies.

RESEARCH OBJECTIVES AND METHODOLOGY

Strategies to address HIV and psychological comorbidity are not well understood, and this impacts on programming and service delivery. Many theorists believe that emphasis on individualisation in treatment is accomplished through making appropriate judgements about psychometric results which yield important information regarding an individual’s psychological experiences and functioning (Butcher, 1997). The study aimed to obtain evidence relating to the psychodynamics in four HIV infected individuals, by means of the Rorschach inkblot test, and to inform the design of clinical programmatic interventions that address the issue of HIV and psychological comorbidity. A convenience sample was obtained, and Rorschach data was subjected to actuarial analysis according to the Exners’ (2003) Comprehensive System by means of the RAP3. A clinical interview was also undertaken, as well as information relating to the medical HIV staging of the participants, however, this information was used as collateral information and did not form part of the actuarial analysis. Furthermore, a situational analysis was conducted from in 2011-2013 by the investigator and other consultants at her former place of employment – the Foundation for Professional Development (FPD), in order to determine the context of mental health in HIV treatment services in the Tshwane-Metsweding district, in facilities supported by FPD. The aim of this endeavour was to develop and implement an intervention to improve the physical and mental status of people with comorbid HIV infection and mental disorders who attend primary care HIV treatment sites. An initial pilot project was initiated in the Tshwane-Metsweding region of Gauteng. The intervention was piloted at 5 sites: Soshanguve 3, Phedisong and Laudium Community Health Centres, Kalafong Hospital and at the free-standing ART site situated on the grounds of Cullinan Care and Rehabilitation Centre. The project used existing staff and services as far as possible. The project consisted of 4 phases: conceptualisation; baseline survey and training; on-site supervision, consultation and monitoring, and evaluation. Ethical approval for the study was obtained from Texila American University in July 2011 and the Foundation for Professional Development in January 2012.

CASE STUDY, SITUATIONAL ANALYSIS AND PILOT PROJECT FINDINGS

Providing an ambiguous stimulus to an individual and allowing him or her to tell the examiner what the stimulus might be and why it might be that is perhaps one of the most ingenious ways to access the person’s inner world of thoughts, feelings, wishes, impulses and ideas (Huprich, 2006). However, it is to be expected that any device, which lays claim to the assessment of
personality, cannot, by virtue of its object, yield completely consistent results. Although mindful of the inherent limitations pertaining to consistency, Rorschach exponents have pointed out that a satisfactory degree of stability is to be found in this case. The outcomes of the study highlight complex psychological dynamics (psychopathology) in the case studies – including signs of mood disorders (inclusive of possible clinical depression and bipolar disorder), potential personality disorders (for example, Narcissistic Personality Disorder) and a degree of reality testing and/or cognitive deterioration in some of the participant protocols. There are indications that the Rorschach can make a meaningful contribution to the complex process of determining whether an individual has, for example, a personality disorder, despite the fact that each DSM 5 personality disorder criterion is not directly represented on the Rorschach inkblot test (American Psychiatric Association, 2013; Huprich, 2006).

The study findings thus suggest the need for further research relating to HIV and mental health comorbidity, and to develop and evaluate psychosocial interventions, which can be integrated into management of communicable and non-communicable diseases such as mental health illness and HIV/AIDS. Healthcare systems should be strengthened to improve delivery of mental healthcare, by focusing on existing programmes and activities, such as those which address the prevention and treatment of HIV, TB, and malaria; gender-based violence; antenatal care; integrated management of childhood illnesses and child nutrition; and innovative management of chronic disease.

An explicit mental health budget needs to be allocated for such activities. Mental health affects progress towards the achievement of several Millennium Development Goals, such as promotion of gender equality and empowerment of women, reduction of child mortality, improvement of maternal health, and reversal of the spread of HIV/AIDS. Mental health awareness needs to be integrated into all aspects of health and social policy, health system planning, and delivery of primary and secondary general healthcare (Prince et al., 2007).

The intervention consisted of training in modules for all levels of staff working in selected HIV treatment services and selected mental health services. This was followed by on-site mentoring and further training. Liaison with health service managers took place throughout to facilitate the project. Various aspects of the intervention were evaluated to determine whether such an intervention could be sustainably implemented in other districts.

Although health information systems did not record important mental health data, a retrospective record review and a patient survey demonstrated that up to 30% of patients have symptoms of possible mental disorder, but less than 4% of records reviewed documented the presence of such symptoms. Approximately 100 staff members in the Tshwane District Health Services (DHS) received training in various aspects of HIV and mental health. These included training in screening for and identifying common mental disorders, HIV dementia and serious mental illness in PLWHA who attended the DHS; training in management of PLWHA with mental disorders; training in management of HIV and tuberculosis (TB) in people with mental illness; training in
basic counselling skills as well as psychotherapeutic interventions for PLWHA and mental disorder. Assessment of knowledge before and after training demonstrated that participants increased their knowledge, and in the case of HIV doctors and nurses retained that knowledge over a six-month period. On-site mentoring was provided to a limited number of participants only. However, there was an improvement in the clinical skills of participants who attended mentoring sessions.

The pilot project identified the following strengths and opportunities: the general structure of HIV services are well organised and run, the staff working in these services are committed and hardworking, there is a mental health service available on site at 4 out of the 5 sites, it appears that good use is made of social workers and psychologists where they are available, and there is already a screening question for mental disorder on first assessment. Furthermore, the political climate in South Africa is in favour of a mental health intervention at this time, managers at all levels are supportive of this intervention, generally a positive attitudes to a mental health intervention from all involved, and this is an opportunity for mental health services to be integrated into primary level services on a broader scale.

Apparent weaknesses and threats include the insufficient information on prevalence of mental disorders at these sites, the lack of indicators in the existing information system in order to monitor the impact of the intervention, staff do not have sufficient knowledge and skills to screen for, identify and manage common mental disorders, and insufficient mental health services or in some cases, poor communication between HIV and mental health services. There is also no formal relationship between the services. The following threats were further discerned: lack of time for training, lack of resources – staff shortages and high turnover of staff, high patient numbers, additional burden on overstretched mental health services as a result of increased identification of mental disorders requiring intervention, and there is very limited psychotropic medication in the ART clinics piloted in – only amitriptyline, a tricyclic antidepressant with significant side-effects and interactions with ARVs.

In summation, there were significant challenges in implementing the intervention. Many of these were health system related or due to the heavy workload and inadequate resources in the DHS. The pilot project outcomes indicate that it is not possible to implement such an intervention in current circumstances without dedicated staff to advocate for such interventions and to provide training and support to staff in the DHS. Furthermore, the need for further studies on the psychodynamics of PLWHA and impact of such combination mental health and HIV/AIDS interventions on PLWHA are necessary.

DISCUSSION AND RECOMMENDATIONS FOR POLICYADVANCEMENT, PRACTICE AND RESEARCH

World Health Organization estimates of the global burden of disease have helped to raise awareness of the enormous effect of mental disorders, both in their own right and relative to
other health conditions such as HIV (World Health Organization, 2009). Much of this effect arises from the commonest disorders, especially depression and alcohol use disorders. However, the Cartesian dualism that is implicit in the methods used to generate these estimates has meant that what began as a blessing is now, in some respects, a bane. In reality, the interactions between mental disorders and HIV/AIDS are widespread and complex.

Mental disorders are risk factors for the development of communicable and non-communicable diseases, and contribute to accidental and non-accidental injuries. For some infectious diseases such as HIV/AIDS, mental disorders in infected persons increase the risk for transmission. Health conditions such as HIV/AIDS increases the risk for mental disorders, and can lengthen episodes of mental illness (Thom, 2008). The resulting comorbidity complicates help seeking, diagnosis, quality of care provided, treatment, and adherence, and affects the outcomes of treatment for physical conditions such as HIV/AIDS, including disease related mortality. For many health conditions such as HIV/AIDS, mental illness makes an independent contribution to disability and quality of life (Chisholm et al., 2007).

Mental health is missing from the policy framework for health improvement within the South African context - and poverty reduction; missing from health and social research; and missing from targets for interventions. Moreover, mental health has not been acknowledged as an obstacle to achievement of several Millennium Development Goals - notably, promotion of gender equality and empowerment of women, reduction of child mortality, improvement of maternal health, and reversal of the spread of HIV/AIDS, malaria, and other diseases. Mental health awareness needs to be integrated into all elements of health and social policy, health system planning, and healthcare delivery. Sophisticated evidence-based arguments to increase resources for mental healthcare should be linked to evidence for its wider importance to public health (Chisholm et al., 2007).

Integrated mental health policies, applied across all disease categories (not only HIV/AIDS), and to different levels of care and types of care setting, will maximise the effectiveness of the small number of mental health professionals available in most low- and middle-income countries (Saxena, Thornicroft, Knapp & Whiteford, 2007). Such policies will also mobilise the forces of public and community health to work for better mental health and reduce redundancies and budgetary and organisational inefficiencies in overstretched health systems. The strengthening of healthcare systems to deliver mental healthcare should focus, where possible, on existing programmes and activities such as HIV prevention, antiretroviral treatment programmes, treatment of multidrug-resistant TB and innovative chronic-disease management (Epping-Jordan, Pruitt, Bengoa & Wagner, 2004).

Mental health needs to be recognised as an integral component of practice in primary and secondary healthcare. Beyond this, primary healthcare workers need to be trained in recognition and evidence based treatment of mental disorders, and given suitable supervision and support, as indicated the outcomes of the FPD situational analysis and pilot project. Furthermore, basic drug
and psychotherapeutic treatments need to be made available at all levels of healthcare (Patel et al., 2007).

Primary and secondary care providers should overcome their reluctance to treat HIV/AIDS patients with severe mental illnesses, and learn effective ways to interact and communicate with these patients. Inequities in access and provision of good quality physical healthcare for HIV positive people with mental disorders must be ended. The need to promote holistic models of care is imperative, which integrates psychosocial assessments and interventions seamlessly and routinely into the management protocols for major communicable and non-communicable diseases and reproductive and childhood disorders, for example, modelling exercises indicate that up to 20% of infant stunting could be averted if maternal depression was treated more effectively, and that up to 15% of suicides could be averted by interventions to treat major depression (Prince et al., 2007).

By the same token, mental health professionals should routinely assess their patients to identify and monitor physical health problems, should encourage them to attend regular checks in primary care, and should generally place a greater emphasis on lifestyle review and management. Current guidelines about the management of patients given antipsychotic drugs should be applied; for example, patients with schizophrenia should be weighed at every visit. Although more mental health specialists are needed, these might never be sufficient to meet the need, especially in low-to middle-income countries such as in South Africa. The marshalling of this scarce resource will demand careful thought and planning, including clear protocols for referral from primary care (Prince et al., 2007).

Evidence for interactions between mental health and other health conditions comes overwhelmingly from the developed world, especially the United States of America. Although 99% of deaths from HIV/AIDS are in low-income and middle-income countries, nearly all research on the interaction between mental disorders and chronic management of HIV infection comes from the United States of America, furthermore, 99% of deaths from malaria are in low-income countries, and 90% of these are in children aged younger than 5 years (Prince et al., 2007). It has been identified that there is an absence of evidence, rather than evidence of absence, for what could be, by analogy with other evidence, important interactions between maternal mental health, adherence to malaria prevention measures, and prompt and appropriate help seeking for childhood infections (Prince et al., 2007).

A priority, therefore, is to increase the evidence base for interactions between mental health and other health conditions such as HIV/AIDS in low- and middle-income countries. Some existing evidence (for example, that which investigates mental disorders as risk factors and prognostic indicators for non-communicable diseases) might be generalisable to less well-developed settings. However, the evidence on maternal depression and infant growth outcomes is reported mainly from low- and middle-income countries. Only research that is conducted locally can be expected to affect awareness and lead to new policy development.
Second, there is a need to understand better the mechanisms that underlie interactions between mental health and health conditions such as HIV/AIDS, if one is to develop effective public health and clinical interventions. We need to learn from the experience that, in many instances, interventions designed to treat common mental disorders are effective for reduction of the frequency of these conditions, but not for improvement of downstream physical health outcomes with which associations had been reported (Rees, Bennett, West, Davey & Ebrahim, 2004; Glassman et al., 2002; Berkman et al., 2003; Katon et al., 2004; Lin et al., 2006; Lustman, Freedland, Griffith & Clouse, 2000; Rabkin, Wagner & Rabkin, 1999; Rabkin, Rabkin, Harrison & Wagner, 1994). Explicit targeting of illness representations and associated behaviours through cognitive behavioural techniques might be effective.

Third, this study, together with other research, indicates that we are as yet at a very early stage in the studying, development and trialing of adjunctive psychosocial, psychological, and mental health interventions. Despite strong evidence for relevance of mental health to HIV/AIDS, well designed trials to investigate effects of mental illness on the important downstream health outcomes are scarce; for example, presentation for HIV counselling and testing (HCT), access to and acceptance into HAART programmes, adherence, adoption of low-risk behaviours, virological and immune status, and survival. Further detailed study could highlight the potential capacity for psychosocial interventions to improve HIV/AIDS physical health outcomes. However, the need also exists to act immediately on the existing robust evidence that treatment of comorbid mental disorder is highly effective for improvement of mental health and quality of life outcomes across a range of disorders including cancer (Osborn & Demoncada, 2006), diabetes (Katon et al., 2004), heart disease (Rees, Bennett, West, Davey & Ebrahim, 2004; Berkman, et al., 2003), and HIV/AIDS (Laperriere et al., 2005; Lechner et al., 2003). The moral and ethical case for redressing the imbalance in provision for people with mental disorders can brook no delay. Practical steps such as those discussed must be accompanied, wherever possible, by high quality assessments of efficacy and cost-effectiveness.

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DONOR DRIVEN HEALTH SYSTEMS: REFLECTIONS ON THE IMPLICATIONS FOR HEALTHCARE DELIVERY IN NIGERIA

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ABSTRACT

Efforts geared towards strengthening health systems and improving health outcomes necessitated the co-operation between developed and developing countries for long term international developmental assistance for the latter. These efforts climaxed with the signing of the United Nations millennium development goals which created a platform for the ‘injection’ of billions of dollars of donor funds, technical assistance, inter alia, into countries with great need. Accordingly, there are reflections of marked achievements towards achieving the envisaged objective(s) in recipient countries such as Nigeria. In fact, the impact of donor support for health system strengthening in Nigeria has being remarkable with funding to combat major health problems reaching unprecedented levels in recent times with improvements on certain fronts. Of such include, decrease in the prevalence of HIV/AIDS, Tuberculosis and the eradication of guinea worm, as well as capacity development and health facility infrastructural upgrades. Nevertheless, these obvious gains have not being without issues of concern hitherto. Cardinal amongst these is that not all the developmental support is reaching communities with the greatest of needs or being delivered in a manner that is proving effective. More so, are the issues of corruption, abdication of co-operate social responsibilities by the government in certain instances to donor partners, as well as the rising ‘ineptitude’ in many of the recipient communities that has fast created a climate were self-reliance is being ebbed into a place called the past. The argument therefore is that the merits and demerits of donor support for health system strengthening in Nigeria has created debates, needing further reflections thereof.

INTRODUCTION

Strengthening health systems and improving health outcomes necessitated the co-operation between developed and developing countries for long term international developmental assistance for the latter. These efforts climaxed with the signing of the United Nations millennium development goals which created a platform for the ‘injection’ of billions of dollars of donor funds, technical assistance, inter alia, into countries with great need globally.¹² Accordingly, the reflections reveal marked achievements towards achieving the envisaged
of health workers, facility and infrastructural upgrades, improving of information systems and supply management chain with better health outcomes to show case.\textsuperscript{3-5} Of note is that donor support for health care delivery in developing countries including Nigeria has being quite remarkable with funding reaching unprecedented levels and improvements on certain fronts.\textsuperscript{4,5} Evidence reveals that these have led to developments within the health sector; in many instances primary health care services have been improved and health systems have been strengthened.\textsuperscript{5-8} The reflections reveals impacts in HIV/AIDS programmes, Tuberculosis control programme, eradication of Guinea worm, and the control of other neglected tropical diseases have so far been driven by international developmental assistance.\textsuperscript{7-9}

In spite of these reports and the increasing volumes of official development assistance being directed particularly at improving health care delivery and overall health systems performance in the country there have been reports of challenges. Of concern is that not all the donor support targeted at improving healthcare delivery is reaching communities with the greatest need or being delivered in a manner that is proving effective.\textsuperscript{5} Chiefly, while aids for HIV/AIDS and health infrastructure have been used to strengthen health systems, and in some cases primary health care services have been improved, overall, there are reports of concerns, too – among them, a temporal association between increasing HIV/AIDS funding and stagnant funding for reproductive health, and accusations that scarce personnel are siphoned off from other health care services by offers of better-paying jobs in HIV/AIDS programs.\textsuperscript{5,6} Regrettably are also the issues of corruption in donor supported health care delivery programmes and concerns that donor expenditures in Nigeria are not only unsustainable but may be considered as inadequate considering the enormous health care burden in the country.\textsuperscript{10,11} Furthermore, there is an increasing controversy about whether the scaled-up investment in programs to strengthen the existing weak health system in the country is producing the ‘required outcomes’ in creating self-reliance in health care delivery.\textsuperscript{12} Some analysts and critics of donor support are of the view that governments at all levels have abdicated some of its primary responsibilities to donor partners.\textsuperscript{12} Accordingly, these gamut of issues as well as the changing geopolitical climate of the recent past decade led to critical questions being asked of the usefulness, impact and effectiveness of donor driven healthcare delivery in Nigeria.\textsuperscript{5} The argument therefore is that the merits and demerits of donor support for health system strengthening in Nigeria has created debates, needing further reflections thereof.

METHODS FOR REVIEW

As literature reviews are summaries of research evidence that address research issues by using explicit methods to identify, select, critically appraise relevant research studies and analyse data from the studies that are included for the review, the authors made this study as inclusive as possible.
SEARCH METHODS

By using key words, the authors involved a broad search of literatures on donor developmental support for health system and health care delivery in Nigeria. Via broad criteria online search engines and databases including Pubmed, Medline, Embase and Google Scholar were searched, websites and online resources of international organisations as well as hand searches of bibliographic records. However, the authors did not contact experts or donor agencies.

SELECTION CRITERIA

To generate evidence for the review, studies between 2000-2013 were considered and findings included were from literature reviews, expert commentaries, cross sectional studies, panel discussions as well as grey literatures that reported an objective measure of at least one of the following outcomes: donor funding for healthcare, healthcare financing in Nigeria, utilization and coverage, health outcomes in health systems, *inter alia*.

DATA COLLECTION AND ANALYSIS

The findings generated from all included studies formed the themes used to critically analyse international developmental support for health system strengthening in Nigeria. There was no detailed data synthesis and quality as the study is not a systematic review.

SUMMARY OF RESULTS

Three main issues that emerged from included studies were: (i) healthcare financing through donor support in Nigeria (ii) impact of donor support on healthcare delivery (iii.) sustainability and a future road map for healthcare delivery in the country. The findings revealed discernible evidence of the impact of donor support for health system strengthening in Nigeria, while at the same time suggesting the need for robust polices towards self-reliance and self determination.

ISSUES OF CONSIDERATION

There is concern that the country with a population of about 170 million is the most populous country in Africa; sadly, its health sector, a foremost service sector has never really fared well due to a number of factors. Primarily is the perennial underfunding by government – estimated to be a meagre 5% of gross domestic product (GDP) - and having to compete with other important social service sectors such as housing, transportation, environment and security. The starting point here is that funding of health healthcare delivery by the national government has perennially being a huge threat to achieving the health targets of the MDGs. Amongst others, this issues necessitated the perennial injections of billions of dollars of donor funds to accelerate achieving the health targets of the UNMDGs particularly through vertical health programmes. Hitherto, these programmes have had significant strides in improving on health systems performance in many parts of the country. There are reports of improved morbidity and mortality.
indicators and particularly improved the developmental trajectories in the health system in the past few years to just over a decade. However, there are a number of issues bothering on international developmental assistance for health care delivery to health policy makers in Nigeria, donor institutions and governments. These issues are centered on healthcare financing, the impacts of donor support on healthcare delivery, as well as the issues of integration of donor programmes and sustainability.

HEALTHCARE FINANCING THROUGH DONOR SUPPORT IN NIGERIA

The signing of the millennium development goals in the year 2000 paved the way for the ‘injection’ of billions of dollars from donor partners into Nigeria. Evidence reveals that donor grants through the Global Funds for AIDS, Tuberculosis (T.B) and Malaria (GFTAM) amounting to US$1,504,046,273 were provided between 2003 and 2009. A breakdown analysis of the funding reveals that US$ 677,565,797, US$ 147,354,856 and US$ 679,125,620 has so far been spent on HIV/AIDS, tuberculosis and malaria respectively in the country. Also, the President’s emergency programme for AIDS relief (PEPFAR) committed US$488.6million to support comprehensive HIV/AIDS prevention, treatment and care programmes in the country in 2011 alone. Besides the increased funding for major communicable diseases (HIV/AIDS, Tuberculosis and Malaria) in the country, there are also international donations and sometimes grants or loans for other health care challenges.

In recent times, there have being scaling up of funds for neglected tropical diseases in Nigeria particularly through non-governmental organizations (NGOs). Of such is the Carter foundation that has funded the fight against Dracunculiasis (guinea worm infection), trachoma control, river blindness, schistosomiasis control and lymphatic filariasis elimination. Annually, these NGOs fund, mobilize as well as train workers in order to achieve their objectives in the country. Staggered estimates from reports have it that USD$2-3 billion have being earmarked for the control of neglected diseases globally over the next three to five years globally with Sub-saharan Africa expected to gulp the lion’s share. The obvious is that Nigeria stands to benefit largely from these funds. Additionally, there are also anecdotal reports of huge sums injected into the country for research and training, although exact estimates are however difficult to ascertain. These give insights into the enormous amount of funds ‘poured’ into the health system and healthcare delivery in the country. In fact, some analysts argue that annual budgeting and planning for health care delivery in the country relies heavily on international developmental assistance. These funding have had their tolls on healthcare delivery and the health system of the country.

IMPACT OF DONOR SUPPORT ON HEALTHCARE DELIVERY

With the continued support for health systems strengthening in the country by international developmental assistance, the evidence reveals marked impacts on a number of health indicators. For instance, there have been impacts on HIV/AIDS, Tuberculosis and a number of other
diseases. Between 2001 to 2012, HIV/AIDS adult prevalence had dropped significantly from 3.7 to 3.1 per 100,000 of the population\textsuperscript{20}, similarly, the incidence of tuberculosis dropped from 180 to 108 per 100,000 of the population between 2004 and 2012.\textsuperscript{21} These cannot be unconnected to the efforts of PEPFAR, GFTAM and other funding bodies such as the Department for International development (DFID), the United Nations international children’s fund (UNICEF), the World Bank amongst others in combating these in the country. More so, is the impact on Dracunculiasis (Guinea worm) of which Nigeria was declared free in January, 2014.\textsuperscript{9} In fact, the successes against Dracunculiasis and other neglected tropical diseases in the country are not unconnected to international organizations such as the Carter Foundation.\textsuperscript{18} There are also reports of these developmental assistances in wide scale infrastructural upgrade of existing health facilities as well as the provision of technical expertise in healthcare delivery programmes in Nigeria.\textsuperscript{5,6} Nevertheless, there are concerns about international developmental support towards health system strengthening and health care delivery in the country. While these funding may be channelled for the their ‘primary objectives’, aids in many instances are allocated only to disease specific projects (termed “vertical programming”) rather than to broad based investments in health infrastructure, human resources, and community oriented primary healthcare services (“horizontal programming”).\textsuperscript{22} In fact, the ‘monopoly’ of funding of these programmes in the country may result in ‘monopoly’ of decision and ‘reduced’ regulation in accordance with national health policy. Accordingly, the concerns have been with the integration of some of these programmes into the national health policy (albeit the primary and comprehensive health care programme). These have often times resulted in poor coordination between donor agencies and the ministry of health as well as the results of poor collaboration between TB and HIV programmes and their co-morbidities. Furthermore, with similar situations to some other sub-Saharan African countries, such as Zambia, donor support through vertical health programmes for HIV/AIDS and Tuberculosis are such that the salaries of healthcare providers working for donor funded programmes are often more than double those of equally trained government workers in the fragile public health sector.\textsuperscript{23} The import is that it lures highly skilled government workers to the higher paying donor driven programmes and creates an internal ‘brain drain’. This creates dire circumstances for the underfunded primary care clinics and health centres that care for all diseases, including common illnesses such as diarrhoea, poor nutrition and respiratory tract infections, which take many more lives than HIV/AIDS, tuberculosis, and malaria.\textsuperscript{12} This suggests that donor investments in Nigeria may shift strategies and commitments to manage other disease through the primary health care. It could be argued that donor funding tends to crowd-out attention to other areas of critical need in healthcare delivery in the country. Infact, they could be criticized for their narrow focus on a specific disease, duplication of existing service and their delivery through a parallel structure circumventing the general health system and hence not contributing to the strengthening of the capacity of the public sector.\textsuperscript{24} Nevertheless, advocates and experts may posit that these have had other contributions to the health system that impacts indirectly on other health needs of the population. Chiefly is the case with skills acquisition and capacity
development, upgrade of infrastructure and strengthening of information systems and supply management in the country and other countries of the sub-Saharan African region. These donor programmes are justified for their absorptive capacities which the public health sectors can’t provide in certain instances. It follows that absorptive capacities relates to institutional and administrative issues that concerns staffing- hiring and firing of staff-, rules, regulations as well as motivation of staff. It is possible that the adoption of the concept of strategic purchasing or performance based financing (PBF) improves efficiency in service delivery and improved staff performance as against public driven healthcare delivery. Despite these successes in capacity and health infrastructural development in the country, it is possible that the skills and the technical capacity acquired by workers in these donor supported programmes may be sourced externally and as such negates the principle of essential healthcare based on practical, scientifically sound and socially acceptable methods of technology of the primary healthcare policy in the country. This may also create a situation of decreased self reliance by benefiting communities.

Additionally, there are concerns with misappropriation of donor funds and corruption. Corruption as it were is straightforward and it captures the extent and nature of the actions among officials-including bribes among civil servants, irregularities in public purchasing and oversight. It is the misuse of entrusted power for personal (pecuniary or monetary) gain. This reduces the resources available for health development, lowers the quality of services, compromises effective coverage of health services and inflates the unit costs of services provided. The concern so far in Nigeria is that, even when well-intentioned funding is made available for healthcare delivery, the outcomes may not be as ‘visible’ as expected. In fact, it is well said that “priorities cannot be met if institutions don’t function and scarce resources are wasted”. There are anecdotal reports from the country, where funds for projects were not even used and were ‘siphoned’ into private pockets with little or nothing to show in terms of health outcomes. Some other issues which bother on supply management have emerged with anecdotes suggesting that lack of drugs has been repeatedly shown to discourage utilization of health facilities even when there were donations from international agencies. A common practice in health centre is that drugs tend to be a commonly “leaked” product given that it can fetch a higher price in the private market. These salient actions results in decreased utility (satisfaction) in economic terms and otherwise both to the funding agencies and the benefiting populace. Often times these have triggered remarks from donor countries and bilateral donor organizations to cut or withhold developmental assistance following developments that offends their driving principles as they will want to shield themselves from accusations of excessive meddling and from assuming responsibility for any failures or sub-optimal outcomes. In fact, corruption and mismanagement of funds reduce the impact of donor funding for health system strengthening besides the challenge of vertical programmes being run by many donor agencies.
SUSTAINABILITY AND A FUTURE ROAD MAP

While international developmental assistance is critical to strengthening the fragile health system in Nigeria, sustainability and a future road map for health system strengthening for the country is most needful. Beyond the millennium development goals, the country needs a post-2015 development frame work that will reflect sustainability for strengthening its health system besides donor support. Given the foregoing issues surrounding the outcomes of donor developmental support for health care delivery in the country, it is important that policy makers begin to think of new paradigms for strengthening the health system and achieving significant outcomes in health care delivery in the country. Policies and programmes that will support the principle of self reliance and self determination should be the front line of thought. This necessitates sustainable health policies to decrease over reliance on international developmental assistance and gradual integration of donor driven programmes into routine services which is in line with the principle of self reliance of the World Health Organization.

Workable and sustainable health policies should involve a decrease in economic inefficiencies in health system performance. This will include; reprioritizing public expenditures on health care delivery, increasing additional tax revenues for healthcare financing, increased private sector participation in health development and fighting corruption. Additionally, there is the need for the gradual integration of these donors driven health programmes with horizontal services in the country.

REPRIORITIZING PUBLIC EXPENDITURES AND RAISING TAXES FOR HEALTH

With the current spending of about 85US dollars per capita on health in the country, improving the efficiency of health system performance in the country necessitates policies that will increase government the reprioritizing public expenditures on health care delivery in the country. The import is that it will help in focused spending on diseases of priority while at the same time reducing waste of scarce resources. Allocation of public funding of health care delivery should be channelled towards the common causes of morbidity in Nigeria which are still preventable infectious and avoidable disease; as government should continue to encourage the shift of investment to preventive services from the hitherto high investment on curative services which had often been to the detriment of preventive services. Chiefly is the direct funding by the subsidy reinvestment programmes (SURE-P); a health reform programme by the Federal government. This also calls for sustainability however. More so, producing maximum outputs from health services in the country will require utilizing cost-minimizing production techniques in healthcare delivery. Of note is the fact that there are reports of waste form inefficiencies in some of these programmes such as those funding vertical programmes. Evidence from studies of health facility efficiency in the World Health Organization (WHO) African Region have provided significant scope for increasing provision of health services using their current levels of
resources allocated to hospitals and health centres.\textsuperscript{33} Drawing from this, policies that will entail the leveraging of health promotion strategies to create the demand of underutilized healthcare or transferring specific inputs from over resourced to under resourced health facilities will be needful as it will reduce the inefficiencies in many of the underfunded funded public healthcare delivery programmes.\textsuperscript{35}

More so, are the issues of inefficiencies arising from misallocation of resources such as the choice of a health facility site that is based on political criteria rather than need as well as funding of a programme where investments of the majority of resources are put into tertiary and secondary hospitals instead of in cost-effective primary health care or in situations where donor funds are channelled through vertical programmes instead of through the national health systems.\textsuperscript{36} These will involve making investment decisions based on cost-effectiveness and cost-benefit analysis criteria. Economic monitoring and evaluation through information systems in health systems across the region will also be critical to reduce waste of scare resources.\textsuperscript{37} Furthermore, increasing additional tax revenues for healthcare financing and increased private sector participation in health development are key for achieving self reliance in the country. Notably, the steady economic growth patterns encourage foreign direct investment, which can indirectly contribute to the creation of ‘fiscal space’, thereby generating tax revenue for health. Nevertheless, while these prospects appear to continue in the country, increased budgetary allocation to health service delivery through increased taxation rates will require strengthening the weak tax administration systems and other contextual factors.

\textit{INCREASED PRIVATE SECTOR PARTICIPATION IN HEALTH DEVELOPMENT}

There is already evidence of the financing-gap in the Nigerian health system due to the lean government budgetary allocation.\textsuperscript{13,14} While this continue to bother health policy makers, approaches through internal managerial reforms hitherto have not yielded the needed results as envisaged and effective alternatives are needed. Against this backdrop, policy reforms through public-private partnerships (PPPs) - a promising approach will be of critical consideration, scaling-up private healthcare financing arrangements and community financing. Chiefly is the fact that within the health sector, the aim of PPPs (where private finance and/or provision supersedes that of the public) is to increase funding to the health sector, improve management efficiency and innovation in health care services while it also helps to accelerate the modernization of health systems.\textsuperscript{38} Going by this, PPPs as a measure to address the burgeoning challenges in health system financing in the country will come to bear if a number of issues are critically reflected upon with a view to implementation. Of such will include: autonomous authority and strategic purchasing as well as monitoring of health care services. More so, efforts geared towards scaling-up private health insurance and community financing will necessitate accelerated reforms in these regards.
FIGHTING CORRUPTION

Additionally, achieving self reliance in health care delivery in the country will involve policies aimed at reducing corruption and other sharp practices to the barest minimum. Misappropriation of funds and other corrupt practices in funding, budgeting and expenditure, management of medical supplies and frictions in health worker/patient interaction can be brought to its barest minimum by providing sound institutional and legal frame works, developing of sound budget and expenditure systems and avoiding off-budget activities through effective auditing systems. Educating policy makers on health budgets and involving the mass media and civil society as channels to make information available for public scrutiny and appropriate channelling of all aid flows for health development will be invaluable to tackling the culture of corruption in the country’s health system. There is no other solution besides addressing the systemic inefficiencies, within donor and recipient environments.

INTEGRATION OF SERVICES

There is now the increasing argument in favour of integration of vertical health programmes into routine services. The current line of thinking is that a comprehensive and integrated health system that has adequate capacity to respond efficiently to the health needs of the population should be most considered. As most of the programmes from donor support in the country are vertically driven, vertical and routine health services, don’t have to be mutually exclusive but rather as complementary strategies, thus pointing to the need to discard dichotomy of one versus the other. Although there are current efforts aimed at the integration of donor programmes into routine services in the country, experts often suggest that interventions that require hospital-level facilities should be delivered in an integrated mode due to economies of scope and scale. There is the need for an adaptation to local realities and circumstances which are contextual. This in no doubt strengthens the need for self reliance, while at the same time not de-emphasizing donor support considering the enormous health burden in Nigeria and the lean resources available for health expenditure. In fact, anecdotes and scattered is evidence reveals the integration of some of these services such as the directly observed treat short course (DOTS) for tuberculosis and the voluntary counselling and testing (VCT) for HIV/AIDS. The advantage being that besides being cost effective, the activities of the donor funded programmes will indirectly help in strengthening the health system particularly primary healthcare in the country.

CONCLUSION

Given the capacity constraints and weakness of the Nigerian health system and its existing services, there is the need for consistent strengthening of the health system. The complementary effort of international development assistance has so far produced impacts, with visibility in reducing key disease burden such as those of HIV/AIDS and Tuberculosis. Notwithstanding, as international development towards improving health care delivery in Nigeria continues through partnerships, there is the need to achieve much more if the country is to meet the health targets of
the millennium development goals. Donor support is only a part of the development picture for health system strengthening in Nigeria. Economic growth and social progress as well as sustainable and workable policies for achieving self-reliance is needful.

REFERENCES


COMMUNITY PARTICIPATION IN HEALTH CARE: ISSUES AND CHALLENGES IN NIGERIA

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ABSTRACT

Since the Alma Ata declaration of 1978, Community participation (CP) has been recognized as one of the core strategies of achieving the goals of Health for All (HFA). The benefits of CP are numerous to the communities, the health systems and Governments. This review article described the nature and dimensions of Community Participation (CP) and its role and scope in successful implementation of different components of Primary Health Care. With the near collapse of PHC system in Nigeria, health care systems had suffered with most emphasis on curative health care that does not involve inputs from the local communities. Community participation is not without challenges but most are surmountable, thus it is important to appreciate the various levels in Nigeria in order to be able to operationalize CP towards realizing of set goals and objective.

INTRODUCTION

The rationale for community participation in health care delivery, health promotion and interventions has been clearly articulated. According to the national goal of HFA towards building sustainable and formidable health systems for all citizens of the world, a minimum level of health that would permit every citizen to lead an economically productive and socially useful life could be achieved by 2000 AD through Primary Health Care approach. Communities shape behavior through a system of exchange and influence while they themselves may be engaged or mobilized to act as change agents to achieve social and behavioral outcomes. Also, early and sustained participation by community members and leaders is needed to realize community ownership and sustain programs. The general experience of practitioners and limited evidence from participatory evaluations suggest that, when organizers and researchers seek out and involve community members in their efforts, health outcomes are better realized, and maintenance of programs is enhanced.¹

Involving a community is like a process evaluation. This encourages refinement of constructs during implementation and focuses on program operations and how outcomes are achieved, as opposed to outcome evaluation, which studies the program’s influence on health outcomes. Notably, community participation has been measured both as a process (who, how, when, why,
how many, and how much community members participate in an initiative) and as a program outcome.

RATIONAL FOR COMMUNITY PARTICIPATION

Government-community partnerships are central to developing effective, sustainable models of primary health care in low-income countries; however, evidence about the nature of partnerships lacks the perspective of community members. Several factors which have led to community participation include; Recognition of right and duty of people to participate in community affairs, including health. Recognition of inability of health system to provide all health needs. Recognition that planned social change is achievable only through focus on community as locus of attention. Rising health expectations. Diminished confidence in policies enunciated by health experts alone. Concerns about health care costs. Perceived untapped resources at community level. However, different communities, participants had different, albeit complementary, understanding of the term 'Community Involvement in Health'.

WHAT IS COMMUNITY PARTICIPATION?

Although this may appear to be a simple question, there is no single definition of participation by communities because definitions vary mostly by the degree of participation. "Participation" ranges from negligible or "co-opted"—in which community members serve as token representatives with no part in making decisions—to "collective action"—in which local people initiate action, set the agenda, and work towards a commonly defined goal. Youth from Burkina Faso offer a practical definition of community participation. In an example of collective action (see chart below), these youth work with organizations in their communities to improve adolescent reproductive and sexual health. It is one of the principles of primary health care, a way in which members of a community are organized, sensitized and mobilized towards participating in health programmes affecting their health and existence. It is a very important component of the health and development of every community.

FRAMEWORK FOR COMMUNITY PARTICIPATION

The genesis of the idea and its conceptual development are primarily attributed to large multinational organizations particularly the World Health Organization (WHO). This framework integrates models and types of community participation.

<table>
<thead>
<tr>
<th>Mode of Participation</th>
<th>Type of Participation</th>
<th>Outsider Control &amp; Ownership</th>
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<table>
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<tr>
<th></th>
<th>Description</th>
<th>Co-opted</th>
<th>Cooperating</th>
<th>Consulted</th>
<th>Collaborating</th>
<th>Co-learning</th>
<th>Collective Action</th>
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<tbody>
<tr>
<td>Co-opted</td>
<td>Tokenism and/or manipulation; representatives are chosen but have no real power or input.</td>
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<tr>
<td>Cooperating</td>
<td>Tasks are assigned, with incentives. Outsiders decide agenda and direct the process.</td>
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<tr>
<td>Consulted</td>
<td>Local opinions are sought. Outsiders analyze data and decide on course of action.</td>
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<tr>
<td>Collaborating</td>
<td>Local people work together with outsiders to determine priorities. Responsibility remains with outsiders for directing the process.</td>
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<tr>
<td>Co-learning</td>
<td>Local people and outsiders share their knowledge to create new understanding and work together to form action plans with outside facilitation.</td>
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<tr>
<td>Collective Action</td>
<td>Local people set the agenda and mobilize to carry it out, utilizing outsiders, NOT as initiators or facilitators, but as required by local</td>
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Community involvement in health is a contribution of community members to health by fulfilling given responsibilities, which have been broadened or narrowed from a situation to another or from a country to another. In some cases, the community assumes only social responsibilities by setting up structures to support the implementation of health programs. In some others, communities have both social and technical responsibilities\(^2\). Community involvement in health means that communities take responsibility for their own health through:

- Adoption of behavior to prevent and treat diseases
- Effective participation in disease control activities
- Contribution to the design, implementation and monitoring of health programmes
- Provision of resources for health

Community participation thus occurs when a community organizes itself and takes responsibility for managing its problems. Taking responsibility includes identifying the problems, developing actions, putting them into place, and following through those actions

**WHO BENEFITS FROM A COMMUNITY PARTICIPATION APPROACH?**

Community participation has many direct beneficiaries when carried out with a high degree of community input and responsibility. Everyone benefits when participating in the activities. For example, adults and youth might participate in village committees to improve services. Everyone might watch a play or video and learn from presentations about local programs. Youth benefit from improved knowledge about contraception and HIV/AIDS or from increased skill in negotiating condom use, and other community members’ benefit too. A truly participatory program involves and benefits the entire community, including youth, young children, parents, teachers and schools, community leaders, health care providers, local government officials, and agency administrators. Programs also benefit because trends in many nations towards decentralization and democratization also require increased decision making at the community level. Community participation is considered important in primary health care development and there is some evidence to suggest it results in positive health outcomes\(^5\).

**APPLICATION, ROLE AND SCOPE OF COMMUNITY PARTICIPATION**

Community participation is a foundational principle of primary health care, with widely reputed benefits including improved health outcomes, equity, service access, relevance, acceptability, quality and responsiveness.
EDUCATING PEOPLE ABOUT HEALTH MATTERS

Appropriate educational programmes are to be organized for different groups of people. Health education to the community should be a prime function of the health workers and village level functionaries. In this endeavor, functionaries of other sectors such as social and women’s welfare, education, agriculture and animal husbandry, voluntary agencies and youth clubs can contribute very significantly. Health education in schools and adult education sessions should incorporate various health problems. The members of the community, both individually and collectively can play a very important role in the promotion of these activities.

PROMOTING FOOD SUPPLY AND PROPER NUTRITION

The poor nutritional status of the people particularly of the pregnant and nursing mother, and the infants and children can be substantially improved by organizing and conducting nutrition education programmes in the community and in the schools by encouraging people to make kitchen gardens and community gardens, and by educating the people on food hygiene.

Steps also need to be taken to encourage growing locally more foods such as cereals, pulses, vegetables, fruits, milk, fish and poultry products through cooperative and other efforts to make these easily accessible and affordable to the people. Simultaneously, the purchasing capacity of the families might be improved through a variety of income generating schemes. In addition, for the moderately and severely malnourished groups, special nutrition programmes are to be organized.

In these endeavors, functionaries from other sectors such as agriculture, animal husbandry, irrigation, banks and cooperatives, social and women’s welfare, voluntary organizations and other community can play a very significant role.

SUPPLY OF SAFE WATER AND BASIC SANITATION MEASURES

Systematic approach should be made to survey and identify resources of safe water and to carry out analysis of water. Arrangements should be made for regular purification of water through chlorination etc., before using for drinking and other household purpose. People at all levels, including village leaders, women and school children should be educated on continuous basis about the importance of proper maintenance of water and the use of safe water. Observation of personal hygienic practices should be emphasized.

It would be important to organize the people and resources for constructing household and community latrines, and making arrangements for collection and disposal of human and animal waste. Proper and imaginative disposal of waste water is also of human and animal waste. Proper and imaginative disposal of waste water is also very important. Construction of composting facilities, soakage pits and the use of some of the waste resources in kitchen gardens would be
helpful. Proper educational programmes on all these aspects for the children, youths and adults and the mothers should be organized in a systematic manner

In these programmes cooperation of the workers of other sectors such as Irrigation, Engineering Department, Village Industries, Agriculture, Education, Social and Women’s Welfare, and Cooperatives would be most vital. Active community participation in organizing all the above activities and programmes would be the key to success.

**MATERNAL AND CHILD HEALTH CARE**

Maternal care: Systematic efforts are to be made increase progressively with ante-natal registration and care of pregnant women. It is also to be ensured that trained health personnel conduct all deliveries under aseptic conditions.

Pregnant and nursing mothers should get prophylactically two to three doses of tetanus toxoid, iron and folic acid supplement for nutritional anemia. During post-natal check-ups, mothers are to be educated on breast feeding, growth monitoring, proper weaning practice and immunization of the child; and on personal hygiene, proper diet and family planning. For proper implementation of these programmes people are to be educated and utilized for active involvement.

**Infant care;** Effective intervention adopting a high-risk approach by the properly trained health workers and health assistants would be important. Proper facilities for referrals to the secondary and tertiary levels are also to be developed and organized.

People’s awareness and orientation about the problems and their genuine interest and efforts in solving them would go a long way, in improving intent care and in decreasing the mortality and morbidity among the infants.

**Care of Young children;** For curing malnutrition in pre-school children the strategy would be:
(a) To provide nutrition education to mothers
(b) To detect cases of malnutrition and grade them
(c) To rehabilitate grades I and II by supplementary feeding from home resources
(d) Supplementary feeding of grade III case at sub-centers
(e) Referral of grade III cases with diarrhea and infection to the secondary level of care.

For fighting against infant mortality the strategy should be: (a) to educate the mothers on how to prevent and treat diarrheal and respiratory disease; (b) to train the health functionaries about how to recognize and treat these disorders and to judge which patients should be referred to higher levels of health services; (c) to create facilities for secondary level care of referred cases; and (d) to provide drugs ORS and other supportive measures.
All children preferably at the age of under one year must be immunized against tuberculosis, poliomyelitis, diphtheria, whooping cough and measles. For all these activities, the people have to be educated and their involvement in community welfare activities are to be promoted. People must recognize that health programmes are in their own interest and they should take part in the implementation and monitoring of these programmes.

**Family Planning:** The acceptance and continued use of contraceptives are influenced by several factors such as the method of contraception, including its advantages and disadvantages, individual and social acceptability, provider’s knowledge, skill and attitude; effective communication, motivation and counseling the nature and quality of delivery services including supply logistics and follow up care and the cost. Small family norm has to become a way of life; for this purpose, organization of population education in the schools and colleges, for the out-of-school youth and in adult education programmes would be most vital.

There is increasing evidence that programmes based on the participation of the people have drawn much better response. It is evident that people do participate in family planning whenever they are mobilized by an agency or organization close to them. Therefore, there is a need for conscious and deliberate mobilization of the people for promotion of family planning.

**PREVENTION AND CONTROL OF LOCALLY ENDEMIC DISEASES**

Some endemic diseases and disorders in the country are known to have caused major public health problems. With differences in degree of prevalence and geographic distribution, the major disease are tuberculosis, leprosy, malaria, filarial, iodine-deficiency goiter, blindness, diarrheal disease particularly among the infants. Several national programmes are simultaneously in operation for their eradication or control.

The health functionaries are to be trained for their early detection and treatment, and the services and follow-up care are to be organized. People’s participation is to be promoted in implementing measures for prevention, early diagnosis and proper treatment of these diseases.

Diseases like leprosy and tuberculosis continue to be associated with high degree of ignorance, prejudice and social stigma. These can only be removed with proper education of the people and with their full cooperation.

**PROVISION OF ESSENTIAL DRUGS**

Utilization of locally available remedies and use of indigenous systems of medicines should be considered. Considering the financial constraints from the government sources, community’s participation through for example, cooperative funding may be explored.
ORGANIZATION OF REFERRAL SERVICES SUPPORT

For proper implementation of the referral services support programmes, proper orientation, involvement and cooperation of the community would be most vital.

CHALLENGES TO COMMUNITY PARTICIPATION

EVALUATING PARTICIPATION

One challenge for program planners is how to evaluate community participation. In particular, what should be evaluated—health outcomes, participation levels, improved capacities, or some combination of these—and how will they be evaluated? While measuring health outcomes—such as birth rates or sexual health knowledge, attitudes, and behaviors in a particular age group—may be fairly straightforward, it will be important for community participation programs also to identify and measure indicators of participation. One of the goals is to achieve participation. Whether planners want to measure changes in community self-efficacy or changes in local capacity to identify and solve problems, it is important to define these objectives clearly and to develop appropriate tools for measuring progress toward the objectives. Qualitative tools (or some combination of qualitative and quantitative) may be most appropriate to assess the subjective quality of "participation," but the community should define indicators of participation and ways of assessing it, and community members should decide and carry out the evaluation.

SCALING UP PARTICIPATORY MODELS

Increasingly, funding sources express interest in programs that have potential for "scaling up." Community participation programs present some obstacles to "scaling up" due to their deliberately and intensely local nature. As a program develops and matures, program planners may face the challenge of "scaling down" the intensity of community participation in order to "scale up" the project without compromising its participatory nature and results.

DESIRE FOR REMUNERATION

A major hindrance to community participation in developing countries is the desire for remuneration by the lay volunteers. There is evidence to suggest that in the absence of appropriate incentives, attrition rates in lay worker programmes tend to be high after the initial novelty wears off. Whenever incentives are not for the coming, several community members suspends participation, not minding that continuity of services and sustainability of programmes may be hampered.

OPERATIONAL LEVELS OF COMMUNITY PARTICIPATION IN NIGERIA

There are about eight levels of CP in Nigeria.
1. Informing: in which case communities are just informed that a project or programme is ongoing for their utilization

2. Manipulation: Citizens are being manipulated, and not yet in control

3. Tokenism: The community takes token control, implementers are still in full control

4. Delegated powers: in this case, a certain section of decision making about the programme is vested in the community so that they can also take part towards sustainability of the programme and its utilization

5. Citizens’ control: here, the community takes full control of the programme right from planning through implementation to the evaluation stage.

Having become familiar with various aspects of community participation, it would be appropriate to know how to operationalize the participatory approach in the delivery of primary health care Steps towards operational issues would involve the following in Nigeria:

1. Studying the structure and status of health system and the community setting.

2. Sensitizing and reorienting health personnel and functionaries.

3. Sensitizing and orienting the community.

4. Setting the goals and objectives for participatory approach.

5. Mobilization and utilization of resources.

6. Developing a system for implementation, monitoring and evaluation.

CONCLUSION

Designing participation processes cannot be just confined to the health sector. When we think about the social determinants of health, most of them are outside the direct control of the health sector. Participation processes must be multi-sectoral and designed to open up meaningful discussion across a range of sectors.

Quoting from the WHO report on the social determinants of health, ⁴ ‘In countries at all levels of income, health and illness follow a social gradient; the lower the socioeconomic position, the worse the health’. Putting right inequities between and within countries is a matter of social justice, it is an ethical imperative but most importantly, it is all of our responsibility.

Community participation is a vitally important strategy in efforts to work with youth to improve their sexual and reproductive health. Community participation is a strategy that respects the rights and ability of youth and other community members to design and implement programs within their community. Community participation opens the way for community members—
including youth—to act responsibly. Whether a participatory approach is the primary strategy or a complementary one, it will greatly enrich and strengthen programs and help achieve more sustainable, appropriate, and effective programs in the field.

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HEATH-SEEKING BEHAVIOUR OF RIVERINE RESIDENTS OF AROGBO-IJAW ISLAND IN ESE-ODO LOCAL GOVERNMENT AREA OF ONDO STATE, SOUTHWEST NIGERIA

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ABSTRACT

A cross-sectional study using focus group discussions with 3 different categories of key stakeholders at a riverine local government area in southwest Nigeria. The objective was to highlight the factors affecting the health of the residents in this area with the possibility of using this information to improve the health status of the people. Among the factors identified as affecting health seeking behaviour of the residents were inaccessibility either due to lack of health services or poor roads network, illiteracy, poverty and cultural or religious beliefs that are inimical to good health. Suggestion of community based social health insurance program (CBSHIP) as a means of defraying the cost of healthcare was not too acceptable to majority of the dwellers. However, many residents still prefer patronising private hospitals instead of the public health facilities.

KEYWORDS

Riverine, Behaviour, Focus group discussion (FGD), Community based social health insurance programme (CBSHIP)

INTRODUCTION

Health seeking behaviour is a part of a wider concept of health behaviour. The concept of studying health seeking behaviours has evolved with the course of time and has ultimately become a tool for understanding how people utilize health care systems in their respective socio-cultural, economic and demographic circumstances. All these behaviours can be classified at various institutional levels: family, community, health care service s and the state. One of the essential functions of public health is to use the applications of social and behavioural sciences for better understanding of the disease process. Biomedical knowledge alone cannot guarantee better health.
Social determinants of health which refer to the social, economic, and political situations that affect the health of individuals, communities, and populations are among the factors responsible for inequality in health status of people in different or same settings. These determinants act either directly or indirectly through modifying the health-seeking behavior of the people to impact on their health status.(1)

Riverine people especially in the developing nation like Nigeria are known to have very poor health indices as result of their geographical location and health seeking behaviour, which either make some healthcare services unavailable or make them unwilling to access them even when these are present. Also, there are peculiar health challenges in form of water-borne infections and infestations in such areas.(2)

But with over 70% of the earth being covered by water(5), it is safe to assume that a large proportion of the earth 7 billion population actually live by some water body and therefore may be disadvantageous in their accessibility and availability of healthcare service.

To therefore bridge the inequality in the health status of the riverine dwellers compared to the mainland residents, an analysis of the baseline situations including the health seeking behavior of people in this location is needed. This would also enable policy makers and healthcare workers to formulate and implement policies and services that are specific and acceptable to the needs of the people.

This study therefore is to describe the health seeking behaviour and those factors that affect such behavior among the residents of Arogboijaw Island in Ese-Odo local government area of Ondo state, southwest Nigeria, Africa.

The Arogboijaw community in EseOdo local government area of Ondo state in southwest Nigeria comprises of about 20 islands separated by creeks and lagoons. Ese–Odo is located within the low lying coastal zone which extends eastwards from the Niger Delta to the western border between Ondo and Delta States to the Atlantic ocean, while it shares the same boundary with Edo state to the eastern Nigeria. It is one of the two local governments which acts as the principal border settlements between the rest of the Niger–Delta and the south Western Nigeri. It is bounded in the east by Ovia South Local Government of Edo State, in the north by Irele Local Government of Ondo State, in the West by Ilaje Local Government, also of Ondo State as well as Warri South West Local Government of Delta State to the Southern fringe(4).

The Local Government lies between longitudes 2°24 to 3°24 and latitudes 6°22 to 6°42 and it is dominated by a maze of creeks and estuaries, which have played important roles of effectively linking up the different parts of the various communities within the Local Government Area. The population as at 2006 was 154,978(NPC 2006)
It is mostly made up of young people. The major occupation of the dwellers is fishing. And there is very little or no public social amenities and services in the area for example all the over 20 Islands are yet to connected to national public electricity grid and there is no pipe-borne water.

**METHODS**

This is a cross-sectional study based on focus group discussions (FGD) with relevant stakeholders. A brief introduction and the need for the FGD were reviewed with participants and 3 groups were formed. The 3 groups were formed based on the category of participants present at the meeting. The groups of participants include:

Group 1: Community/ward leaders and representatives in EseOdo LGA (A total of 12 persons)

Group 2: Personnel from LGA secretariat including LGA supervisors for Health, works, budgeting, political issues, Program officers from the LGA PHC department comprising of LGA PHC MOH, LACA manager, M&E officer, Reproductive health officer, Immunization officer, Health Education/Community mobilization officer (A total of 14 persons)

Group 3: Officers in Charge of health care facilities in EseOdo LGA (A total of 18 health care workers)

A note taker and a recorder were selected amongst the group members to document for each group discussion. Three EHAI staff served as moderator for each of the groups (Dr Timothy Akinmurele– Group 1; Fadero Tonubari – Group 2; AdebawoDamilare – Group 3) while there was a general observer (Edet-Utan Oluwakemi) ensuring that discussions were kept in perspective in each group.

Discussions on the following topics were held per group and responses outlined by the note taker on flip charts:

The reviewed guide for discussion was handed over to each group moderator. The content of the guide for discussion is as follows:

**A. Factors affecting the health of people in EseOdo Community:**

**B. Discuss about the past and current situation of Health care services in your community.**

**C. Discuss obstacles to health outcomes**

**D. Choice of health care service: what influences people choice of where to receive health care in your community? Where do people prefer to obtain health care services?**
E. Attitude of community members and health care workers towards Community Based Social Health Insurance Program; how to combat poverty.

Each Group presented their discussion in itemized manner for ease in comparison of opinions amongst the 3 groups who discussed on the same sets of topics. In addition to the documented and highlighted points on flip charts by each group, the recording of conversations of participants in each group session was transcribed and analysed.

LIMITATIONS

- Each group did not have enough time to discuss each topic in-depth
- Note takers may be bias in taking down salient points and they may lose track of important opinions in the course of note taking
- This discussions did not capture non-verbal queues that might have been expressed in the course of discussion with participants
- Opinions of moderators for each group may differ on each topic across the 3 different groups
- As a result of the above listed limitations, it may be difficult to generalise findings from this focus group discussions to the general population.

FINDINGS

The FGD proceeding was for a duration of 1 hour and 5 minutes.

Findings for the purpose of this report are presented with relation to the key points of discussion as reflected on the discussion guide. Findings are then presented in such a way that it reflects each group’s opinion about each question/assertion

FACTORS AFFECTING THE HEALTH OF PEOPLE IN ESEODO COMMUNITY

How these factors affect the readiness/willingness of community members in seeking health care services within and outside the community were discussed among the various group member. Though there appear to be differing opinions of each group on this subject matter, there appeared to be some level of agreement amongst discussants.

Responses from group 1: Group one majorly comprised of community leaders and gatekeepers.

Group one members agreed on some major factors affecting the health of people in EseOdo community and were identified as:
a. Inadequate trained health workers for case management of different types of health problems facing the people dwelling at EseOdo.

b. Inability of community members to access health care facilities due to bad roads or no access roads (especially water ways on the Arogbo Island)

c. Many of the community leaders reported and agreed that their community members are often unaware of resources/programs available at their health facilities. They complained that when a health program is going on, health workers do not usually communicate such to the community gatekeepers appropriately while sometimes, no communication at all

d. Another major problem is that there is inadequate funding of healthcare program/provision of healthcare services

e. Illiteracy was also identified to be a major factor affecting the health status of EseOdo dwellers. According to the discussants, many do not have enough knowledge on how to live a healthy life

f. Unfriendly attitude from some health workers also drive people away from utilizing health care services, thereby hindering uptake of available health care services for improving their health status.

g. Inadequate infrastructure of health care facilities in Arogbo Ijaw. Most of their health facilities were said to be dilapidated and not having basic equipments for live saving.

h. Poor hygiene of the community dwellers also affect their health

i. Oil pollution of water and environment from their crude oil natural resource. People rarely have source of clean and portable water, hence, this lack of water pushes some community members to ingest ‘poor water’. In the face of poverty, people cannot afford portable water.

Responses from group 2: Group two majorly comprised of stakeholders at the LGA level as outlined earlier under the methodology section.

Group 2 members identified the following as factors affecting the health of people in Ede Odo LGA.

1. Ignorance on the part of community members on appropriate approaches towards healthy living and how to maintain one’s health

2. Poverty: Discussants claim that majority of EseOdo community dwellers are very poor and most of them who normally earn a living from fishing have now been displaced as the water is now severely polluted with crude oil exploration
3. High level of illiteracy is also one of the factors identified to be affecting the health of community members of EseOdo

4. Accessibility to health facility is a problem as there are no good roads and where there are they are very bad and inaccessible

5. Religion/ culture/ Taboo

6. Inadequate health personnel at health facility really prevents a lot of community members to access quality healthcare

7. Inadequate equipment in health facilities

8. Most communities are ‘hard to reach’ thus people cannot access healthcare and healthcare workers find it difficult to access the people in this area

9. Money to afford good health is a challenge.

10. Transportation Finance/ Logistic problems.

**Group 3** members identified the following as factors affecting the health of people in Ede Odo LGA. Group 3 majorly comprise of health workers from across different healthcare facilities in EseOdo LGA and majorly from Arogbo Ijaw area. They identified the following factors affecting people’s health in EseOdo LGA.

1. Difficult terrain – in the Riverine areas, most communities are separated by creeks

2. Poor accessibility to healthcare

3. Poor economic status of community dwellers

4. Discussants of group 3 who were mainly health workers of various cadre agreed that poor dissemination of health information to community dwellers is one of the factors affecting the health status of the community

5. Ignorance on the part of community dwellers

6. Cultural belief of the community dwellers hinders some community dwellers from accessing orthodox medicines

**DISCUSS ABOUT THE PAST AND CURRENT SITUATION OF HEALTH CARE SERVICES IN YOUR COMMUNITY**

According to group 1 discussants the following past and current situations of health care services in the EseOdo community was described as follows:
i. In the past, there have not been stable health workers in the hospital but it has changed drastically during the tenure of this government (Gov. Mimiko’s Administration).

ii. The turn up of the community in visiting health facilities has improved (as regards the first point).

iii. Improvement on the health workers as capacity of some (though few) health workers have been built regarding certain program areas.

iv. Health workers were once frustrated due to inadequate drugs and other treatment equipments.

v. People who have money prefer to visit private hospitals because they will be properly attended to, though most private health workers are quacks around the area.

Group 2 opinion about the past and present situation of healthcare services differ slightly from that of group one discussants:

1. Previously, In Biagbini, Amatibi and Ipoke communities – some communities on the Island, there was no health facility, no health personne and the people sought/practiced the traditional way of treatment when ill.

2. Presently, there are some form of health care facilities (either using a church, town hall or donated house for facility space) in the earlier stated health care facility.

3. Poor accessibility to health care services; for example Arogbo CHC (on the island), is too far from the community and there is no staff quarters.

4. Arogbo also have problems with sneaks invading the facility to attack patients on admission, so people/staffs are scared of using facility.

5. Very poor infrastructural condition of available health care centers e.g. Opuba BHC presently roof is leaking, due this this, the community is not using the place and health workers do not have some where to stay and attend to patients in the raining season.

6. All health facility lack equipment, drugs and competent/skilled workers/personnels.

7. All facilities have difficulty in transportation especially during the raining season.

Group 3 described the same situation as group 1 and 2 as their past and present status of health care services in the community.

**DISCUSS OBSTACLES TO HEALTH OUTCOMES**

According to group 1, two major obstacles to health outcomes were identified. These include:
People still believe some diseases are not natural and they prefer treating them in a local way.

b. Illiteracy still reflects in the way they view disease occurrence.

Group 2 differed slightly, they have the following identified obstacles to Health outcomes in their community:

1. Lack of skilled health personnel
2. Theft in health care facilities as sneaks enter into the health facilities
3. Refusal of community members to attend health facilities
4. Bad road network during the rainy season

Group 3 identified the following:

a. Ignorance of management of specific ailments by the patient as well as health worker
b. Combinations of alternative medicines and orthodox medicines

**Choice of health care service: what influences people choice of where to receive health care in your community? Where do people prefer to obtain health care services?**

All Groups discussion points on the above subject matter are as follows:

1. Involvement of community leaders in any health program usually propels community members to make up their minds on utilize the health care facility or not.

2. Many community members prefer to initially try self medication (usually herbs and concoctions) then access health care through traditional healers, traditional birth attendants(TBAs), mission homes, or even approach the health issue religiously

3. Attitude of health workers sometimes either drives people away or encourages them to utilize modern health care services

**Attitude of community members and health care workers towards Community Based Social Health Insurance Program. How to combat poverty**

Discussants believe that health should be free to an extent (at least the basic needs). Therefore, only a few community members who are enlightened about health insurance will respond to this because of the level of poverty in the community. The major sources of income of community dwellers used to be fishing, trapping and they are no more in existence due to some factors such
are deforestation, continuous pollution of water ways due to crude oil exploration. Discussants believe that poverty can be eradicated through the following means in the community:

✓ Employment and empowerment of youths especially
✓ Citing of industries in the environment
✓ Maintaining the plantations that are available – oil palm, plaintain, rubber,
✓ Farming
✓ Block industries – since there is access to pure fine sand, water and the area is just developing

CONCLUSION

A. Factors affecting the health of people in EseOdo Community as identified by discussants summarily range from Inadequate trained health workers to inability of community members to access health care facilities due to bad roads, ignorance of resources/programs available at their health facilities, inadequate funding of healthcare program/provision of healthcare services, illiteracy, unfriendly attitude from some health workers, inadequate infrastructure of health care facilities in Arogbo Ijaw, poor hygiene of the community dwellers, oil pollution of water and environment from their crude oil natural resource, poverty, religion and cultural factors, Inadequate equipment in health facilities.

vi. Discuss about the past and current situation of Health care services in your community. The following summarily describes the past and current health care services in Eseodo community: Lack of stable health workers in the health facilities, Health workers were once frustrated due to inadequate drugs and other treatment equipments, there was no health facility, no health personnel and the people sought/practiced the traditional way of treatment when ill, Poor accessibility to health care services (some are still the same),

Currently, the turn out of the community in visiting health facilities has improved (as regards the first point), there is improvement on the health workers as capacity of some (though few) health workers have been built regarding certain program areas.

People who have money prefer to visit private hospitals because they will be properly attended to, though most private health workers are quacks around the area. Some forms of primary level of health care now exist theough situtated either a church, town hall or donated house for facility space. Pilfering, stealing is the order of the day in some facilities. Very poor infrastructural condition of available health care centers. All health
facility lack equipment, drugs and competent/ skilled workers/personnels. All facilities have difficulty in transportation especially during the raining season.

B. Discuss obstacles to health outcomes

Those identified included According to group one, 2 major obstacles to health outcomes were identified. Cultural and religious beliefs, illiteracy, lack of skilled health personnel, theft in health care facilities as sneaks enter into the health facilities, refusal of community members to attend health facilities, bad road network during the rainy season, ignorance of management of specific ailments by the patient as well as health worker, combinations of alternative medicines and orthodox medicines.

C. Choice of health care service: what influences people choice of where to receive health care in your community? Where do people prefer to obtain health care services?

a. Involvement of community leaders in any health program usually propels community members to make up their minds on utilize the health care facility or not.

b. Many community members prefer to initially try self medication (usually herbs and concoctions) then access health care through traditional healers, TBAs, mission homes, or even approach the health issue religiously

c. Attitude of health workers sometimes either drives people away or encourages them to utilize modern health care services

D. Attitude of community members and health care workers towards Community Based Social Health Insurance Program; how to combat poverty.

From the discussions, it was clear that community members may be reluctant in embracing CBSHIP program if it its not near free. Discussants also believe that poverty can be eradicated in their community through the following means:

✔ Employment and empowerment of youths especially
✔ Citing of industries in the environment
✔ Maintaining the plantations that are available – oil palm, plaintain, rubber,
✔ Farming
✔ Block industries – since there is access to pure fine sand, water and the area is just developing
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http://water.usgs.gov/edu/earthhowmuch.html
AWARENESS OF EBOLA VIRUS DISEASE AMONG NON-DOCTOR HOSPITAL STAFF IN BASSA LOCAL GOVERNMENT AREA OF KOGI STATE

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ABSTRACT

The objective of this study was to assess the level of awareness amongst non doctor hospital staff in Bassa L.G.A of Kogi state on the subject of Ebola Virus Disease.

Methodology: A descriptive cross sectional study design was used. A well structured self-administered questionnaire was given to 278 consenting health staff in Bassa L.G.A selected by a multistage sampling technique comprising of clustering and simple random sampling. The results were collated and analyzed manually.

Results: A total of 278 health staff drawn from different departments completed the questionnaire. 58.2% of respondents respectively, were between the ages of 21 and 30 years and first degree holders. All the respondents have heard of Ebola Virus Disease. 83.5% heard of it from electronic media such as radio and television. 74.8% respectively knew that it is caused by Ebola virus, can occur both in the rural and urban areas, putting on protective wears each time one visits an Ebola patient or during routine clinical work can protect one from the virus and that Ebola has no cure. 66.5% knew that everyone is at risk of contracting the disease and that confirmation is by laboratory assays. 91.7% knew that the incubation period is between 2 and 21 days, the same number knew that high fever is an early symptom. 50% of the respondents knew vomiting and bloody diarrhea as late symptoms. None of the respondents knew the location of the laboratories in Nigeria.

Conclusions: the result shows a below average awareness about Ebola virus Disease among these health workers. However, more awareness is needed in certain areas.

KEYWORDS

Ebola virus disease, Awareness.
INTRODUCTION

The world and medical world in general and West African sub region and public health medicine were stunned by the outbreak of Ebola Virus in March 2014 in West Africa mainly with few cases outside the sub region. This outbreak turned out to be the most complex Ebola outbreak since the virus was discovered in 1976.

The recent outbreak had a total case of 17834; laboratory confirmed cases 11214, total deaths 6346 as at 9th December 2014.

Nigeria had a total of 20 cases, 19 laboratory confirmed and 8 total deaths. Health care providers caring for Ebola patients are at highest risk of getting sick because they come in contact with infected blood and body fluids of patients who are very sick with Ebola.(WHO 2014) This necessitated this study which is on assessment of hospital staffs’ preparedness to combat the scourge in Bassa Local Government Area of Kogi State.

METHODOLOGY STUDY AREA

The study area is Bassa Local Government Area Kogi state, Nigeria, located in the North central geopolitical zone of the country. It has a general hospital, a cottage hospital, ninety five primary health care centers, fifty two private clinics most of which are not been manned by doctors, a health staff population of 1453. The area is inhabited by Bassa Komu, Bassa Nge, Igbirra, Igala, Igbo and Yoruba.

STUDY POPULATION

The study design was a descriptive cross sectional one. Consenting hospital staffs were enrolled into the study.

SAMPLING METHOD

A multistage sampling technique was used.

Stage one: formation of clusters; the respondents were clustered into three namely, general hospital staff, PHC staff and Private hospital staffs.

Stage two: Selection of the ninety three staffs from the general hospital and PHC staff respectively and ninety two staff from private clinics by simple random sampling.

Data collection was done using self administered structured health care provider questionnaires; Quantitative data was analyzed manually.

The results are presented in form of tables for easy appreciation.
SAMPLE SIZE AND SAMPLING TECHNIQUE

The sample size was 278. This was determined using the single proportion formula,

\[ n = \frac{z^2 \times P \times q}{d^2} \]

Where \( n \) = calculated sample size, \( z \) = standard normal deviate at 95% confidence interval =1.96, \( P \) = Prevalence (taken as 50% since there is no similar study in the area), \( d \) = marginal error (taken as 5%).

\[ q = 50\% = (1-P = 0.5) \] the proportion of the population that don’t.

\[ d = 0.05 \] (degree of accuracy)

\[ n = \frac{1.96^2 \times 0.5 \times 0.5}{0.05^2} = 384 \]

For population less than 10,000

An adjustment of the estimate of the sample size to cover was made using the correction formula by dividing the sample size calculated with a factor \( f \) that is \( n/f \) where \( f \) is an estimated response rate. \( n_f \) = the desired (corrected) sample size when the population is less than 10,000 \( n = 384 \) i.e. the desired sample size when the population is more than 10,000 \( N = 1000 \), i.e. the estimate of the population size.

\[ n_f = \frac{n}{1 + n/N} \]

\[ n_f = \frac{384}{1 + 384/1000} = 277.5 = 278 \]

The calculated sample size was 278 health staff in Bassa L.GA. A 10% non response rate was assumed and 305 questionnaires were administered.

Pretesting was done at Dekina Local Government amongst similar population.

**Ethical considerations**: Permission to conduct the study was obtained for the study Ministry of Health, and Hospital Management Board of Kogi state at Lokoja and the various hospital heads to satisfy the right to institution. In addition consent was obtained verbally from all the respondents to satisfy right to participants. Confidentiality of participants was ensured throughout the study.
DATA ANALYSIS

All data obtained from the questionnaire forms were entered manually. Descriptive statistics was used to compute percentages.

RESULTS

The results of the study done on the awareness of Ebola virus disease among hospital staff in Bassa L.G.A in Kogi state Nigeria are as shown below.

278 questionnaires were administered and analyzed based on the following parameters, age of respondents, gender, religion, educational qualification, awareness of Ebola virus disease, means of awareness, transmission modes, those at risk, early and late signs and symptoms, protective measures against the disease, knowledge of designated isolation centers and notification process, knowledge of diagnosis and management of cases, awareness of input of the Nigerian government against the spread of the virus. Below are the tables representing the aforementioned parameters.

Table 1. Socio-demography of respondents

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Variables</th>
<th>Number (%) (n= 278)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>162 (58.2)</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>43 (15.5)</td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>46 (16.6)</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>27 (9.7)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>193 (69.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>85  (30.6)</td>
<td></td>
</tr>
<tr>
<td>Highest educational qualification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First degree and above</td>
<td>152 (58.2)</td>
<td></td>
</tr>
<tr>
<td>RN/RM</td>
<td>46 (16.6)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>70 (25.2)</td>
<td></td>
</tr>
<tr>
<td>Religion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christian</td>
<td>146 (52.5)</td>
<td></td>
</tr>
<tr>
<td>Muslim</td>
<td>93  (33.5)</td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td>39  (14)</td>
<td></td>
</tr>
</tbody>
</table>
Table 1 shows the socio-demographical data of respondents namely:

Age distribution: The age group of 21-30 forms bulk of the respondents while the least was age greater than 50.

Gender distribution: shows the males leading 69% while females were 31%.

Highest educational qualification of respondents and it shows that first degree holders were 162 (58.2%) while the least were secondary school certificate holders numbering 46 (16.6%).

Religious caste of respondents which shows that the Christians to be 38(52.7%), Muslim 24 (33.4%). The distribution of respondents by departments with administrative staff having the bulk of the respondents.

Table 2: Knowledge of epidemiology of Ebola.

<table>
<thead>
<tr>
<th>Question/ Answer</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>N=278</td>
</tr>
<tr>
<td>Have you heard of Ebola disease before?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>278(100)</td>
</tr>
<tr>
<td>No</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Through what means? (Multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Media (TV and radio)</td>
<td>232 (83.5)</td>
</tr>
<tr>
<td>Seminars</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>Relatives</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Friends</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Places of worship</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>What is the causative organism of Ebola virus disease?</td>
<td></td>
</tr>
<tr>
<td>Ebola virus</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Ebola bacterium</td>
<td></td>
</tr>
<tr>
<td>Ebola fungus</td>
<td>47 (16.9)</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
</tr>
<tr>
<td>Spiritual attack</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>How is Ebola virus transmitted? (Multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>From animals such as bats, monkeys, gorillas, chimpanzees and antelope</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Touching of dead body of humans and animals infected by Ebola</td>
<td>162 (58.3)</td>
</tr>
<tr>
<td>Contact with infected human urine, blood, sweat, feces and sperm</td>
<td>139 (50)</td>
</tr>
<tr>
<td>By consumption of fruits/ foods left over by animals</td>
<td>93 (33.5)</td>
</tr>
<tr>
<td>From consumption of fish</td>
<td>0</td>
</tr>
<tr>
<td>Where is Ebola transmitted?</td>
<td></td>
</tr>
<tr>
<td>Both rural and urban</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Rural areas only</td>
<td>47 (16.9)</td>
</tr>
<tr>
<td>Urban areas only</td>
<td>0</td>
</tr>
<tr>
<td>No response</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Has there been any case in Nigeria?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>278 (100)</td>
</tr>
</tbody>
</table>
Table 2 shows knowledge of Ebola epidemiology.

The awareness of EVD was 100% as all respondents have heard of Ebola viral disease.

The means of awareness. Mass media ranks first with 232 respondents (83.5%) followed by seminars, 70 (25.2%).

The knowledge of causative organism of Ebola virus disease. 74.8% of the respondents knew it is caused by infection with a virus, 16.9% said bacterium while 8.3% did not know.

Knowledge of modes of transmission of Ebola virus disease. 75% of respondents knew that consumption of infected animals such as monkeys, bats, gorillas, chimpanzees and antelope could cause the disease, 58.3% knew that touching of dead body of humans and animals infected with Ebola, 50% knew that contact with infected human body fluid while 33.3% knew that consumption of food left over by infected animals could all cause Ebola disease. None of the respondents chose consumption of fishes as a mode of transmission.
Knowledge on urban-rural distribution of Ebola. 74.8% of respondents said that both areas can be involved, 16.9% said rural, none of the respondents chose urban areas alone while 8.3% chose none of the options.

Knowledge about cases of Ebola in Nigeria. All the respondents are aware of the cases in Nigeria. Knowledge about those at risk. 66.5% of respondents said everyone is at risk, 33.5% said burial rites can predispose people, 25.2% said health workers caring for patient and also handlers of wild animals such as monkeys and bats, 16.7% mentioned travelers to infected settlements or countries. Incubation period for Ebola 2-21 days was chosen by 91.7% of respondents while 8.3% chose greater than 21 days.

Table 3: Signs and symptoms of Ebola

<table>
<thead>
<tr>
<th>Questions/ answers on signs and symptoms</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=278</td>
<td></td>
</tr>
<tr>
<td>What are the early signs and symptoms of Ebola disease? (Multiple response allowed)</td>
<td></td>
</tr>
<tr>
<td>High fever</td>
<td>255 (91.7)</td>
</tr>
<tr>
<td>Muscle and joint pains</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>Headache</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Sore throat</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Weakness</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>What are the late symptoms of Ebola disease? Multiple responses allowed</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>139 (50)</td>
</tr>
<tr>
<td>Bloody diarrhea</td>
<td>139 (50)</td>
</tr>
<tr>
<td>Bleeding eyes, nose, ears and nose</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Rash</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>Difficulty in breathing</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Confusion and irritability</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>No response</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td></td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Table 3 shows knowledge of signs and symptoms of EVD.

Early symptoms of Ebola virus disease. 91.7% of respondents knew that high fever was an early symptom, 25.2% knew about muscle and joint pains, headache, sore throat and weakness had 16.6% of respondents.

Knowledge of late signs and symptoms of Ebola disease. Vomiting and bloody diarrhea had 50% of respondents, bleeding eyes, nose, ears and nose had 41.3%, rashes 25.2%, difficulty in breathing had 16.6%, confusion and irritability 8.3%, 8.3% did not respond to this question. Stomach and chest pain was not chosen by any of the respondents.

Table 4. Awareness of protective measures against the disease

<table>
<thead>
<tr>
<th>Questions/ Answer.</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can you protect yourself and others? (Multiple responses allowed)</td>
<td>n=278</td>
</tr>
<tr>
<td>Wearing gloves, gowns, facemasks, goggles to visit Ebola patients</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Avoid improperly cooked bush meat</td>
<td>139 (50)</td>
</tr>
<tr>
<td>Clean environment</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Hand washing with soap and clean water always</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Avoid eating fruits left over by animals</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Obtaining clearance from health authority before moving corpses from abroad or one state to another</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Avoiding forest animals that are sick or found dead and their body fluids.</td>
<td></td>
</tr>
<tr>
<td>Avoiding embalmment, washing or touching dead bodies (traditional practices)</td>
<td>93 (33.5)</td>
</tr>
<tr>
<td>Report death of suspected Ebola patients to nearest health facility</td>
<td>70 (25.2)</td>
</tr>
</tbody>
</table>

Table 4 shows knowledge of protective steps against Ebola. Wearing protective covers such as gowns, facemasks etc had 74.8% of respondents, 50% chose avoiding improperly cooked bush
meat, 41.3% respectively chose hand washing, clean environment, avoiding leftover food consumed by animals, 33.5% said obtaining clearance from health authority before moving corpses, 25.2% respectively chose avoiding the bodies and body fluids of forest animals found dead or sick, avoiding harmful traditional practices such as embalmment, washing and touching Ebola dead bodies, and report of the death of suspected Ebola patients will prevent transmission of the disease.

**Table 5: Knowledge of isolation and diagnosis**

<table>
<thead>
<tr>
<th>Questions /Answers</th>
<th>N =278 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you know any Isolation centers?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>185 (66.5)</td>
</tr>
<tr>
<td>No</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>No response</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>If yes how far is it from your location</td>
<td>All respondents said very far</td>
</tr>
<tr>
<td>Do you know Ebola hotline?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>93 (33.5)</td>
</tr>
<tr>
<td>No</td>
<td>162 (58.2)</td>
</tr>
<tr>
<td>No response</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>What will you do if someone exhibits signs and symptoms of Ebola disease? (Multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Inform the nearest isolation center</td>
<td>185 (66.5)</td>
</tr>
<tr>
<td>Tell others not to touch patient</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Call Ebola hot line</td>
<td>93 (33.5)</td>
</tr>
<tr>
<td>Run away from patient</td>
<td>0</td>
</tr>
<tr>
<td>Start treating patient</td>
<td>0</td>
</tr>
</tbody>
</table>
What will you do if you have signs and symptoms?

<table>
<thead>
<tr>
<th>Option</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperate and adhere to government health institutions</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Hide away</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Continue with social activities</td>
<td>0</td>
</tr>
<tr>
<td>No response</td>
<td>47 (16.9)</td>
</tr>
</tbody>
</table>

How are Ebola cases confirmed?

<table>
<thead>
<tr>
<th>Method</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory tests</td>
<td>185 (66.5)</td>
</tr>
<tr>
<td>Clinically</td>
<td>93 (33.5)</td>
</tr>
</tbody>
</table>

How many certified laboratories are there in Nigeria?

<table>
<thead>
<tr>
<th>Number</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two</td>
<td>139 (50)</td>
</tr>
<tr>
<td>Three</td>
<td>47 (16.9)</td>
</tr>
<tr>
<td>Four</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Five</td>
<td>46 (16.6)</td>
</tr>
</tbody>
</table>

Where are the laboratories located?

<table>
<thead>
<tr>
<th>Location</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lagos and Oyo</td>
<td>139 (50)</td>
</tr>
<tr>
<td>Lagos, Port Harcourt and Abuja</td>
<td>47 (16.9)</td>
</tr>
<tr>
<td>Lagos, Aba, Ogun and Oyo</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Abuja, Oyo, Lagos and Ogun</td>
<td>0</td>
</tr>
<tr>
<td>Kaduna, Lagos, Port Harcourt, Aba, Ogun</td>
<td>46 (16.6)</td>
</tr>
</tbody>
</table>

Table 5 shows knowledge of Ebola isolation and diagnosis.

Knowledge of isolation centers. 66.5% of respondents were aware of presence of isolation centers, 25.2% did not know, 8.3% did not respond.

All the respondents knew that the isolation centers were far but none could quantify the distance. Knowledge of Ebola hotline. 58.2% of respondents did not know the Ebola hotline while 33.5% knew it, 8.3% never responded.
Action to be taken by health staff on a suspected Ebola case. 66.5% said they will inform the nearest isolation center, 41.3% said they will inform others not to touch the patients, 33.5% said they will call Ebola hotline, none of the respondents chose to run away from the patient or to start treating the patient.

What the health staff should do when he/she has symptoms and signs of Ebola. 74.8% will cooperate and adhere to government and health institutional directives, 8.3 will hide away, none will continue social activities, 16.9% didn’t respond.

Confirmation of Ebola. 66.5% of respondents knew that confirmation is via laboratory tests while 33.5% said confirmation was clinically using symptoms and signs.

Knowledge of number of laboratories for Ebola tests in Nigeria. 50% of respondents chose 2 labs, 16.9% chose 3 labs while 16.6% chose 4 and 5 labs.

The locations of certified Ebola labs in Nigeria. 50% said Lagos and Oyo, 16.9% chose Lagos, Portharcourt and Abuja, Lagos, 16.6% chose respectively Aba, Ogun and Oyo and Kaduna, Lagos, Portharcourt and Ogun. None of the respondents chose Abuja, Oyo, Lagos and Ogun.

Table 6: Management of Ebola cases

<table>
<thead>
<tr>
<th>Questions/ Answers</th>
<th>N = 278 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How are Ebola cases managed?</td>
<td></td>
</tr>
<tr>
<td>Supportive (symptomatic management)</td>
<td>208 (74.8)</td>
</tr>
<tr>
<td>Ebola has a cure</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>If Ebola has a cure, what is it? N= 70 (multiple responses allowed)</td>
<td></td>
</tr>
<tr>
<td>Zmapp</td>
<td>70 (25.2)</td>
</tr>
<tr>
<td>Vaccines</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Prayers</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Bitter kola</td>
<td>0</td>
</tr>
<tr>
<td>Bathing with salt water</td>
<td>0</td>
</tr>
<tr>
<td>Nanosilver</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 6 shows Management for Ebola. 74.8% knew that Ebola disease is only managed symptomatically (supportive) while 25.2% believes there is a cure.
The cure for Ebola as was believed by some respondents. 25.2% believed Zmapp can cure Ebola, 16.6% believed vaccines and 8.3 believed in prayers as a cure. Bitter cola, nanosilver and bathing with salt water were not seen as cures.

**Table 7. Attempts by Nigerian government to curb the spread (Multiple responses allowed)**

<table>
<thead>
<tr>
<th>Question/ Answers N=278</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massive awareness campaigns in media in Local and English</td>
<td>231 (83.1)</td>
</tr>
<tr>
<td>languages</td>
<td></td>
</tr>
<tr>
<td>Screening of travelers at entry and exit points</td>
<td>115 (41.3)</td>
</tr>
<tr>
<td>Use of churches and mosques</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Seminars</td>
<td>46 (16.6)</td>
</tr>
<tr>
<td>Establishment of emergency operation centers</td>
<td>23 (8.3)</td>
</tr>
<tr>
<td>Intensification of early detection in 36 states and FCT</td>
<td>23 (8.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEASURES</th>
<th>NUMBER</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massive awareness campaigns in media in Local and English languages</td>
<td>231</td>
<td>83.1</td>
</tr>
<tr>
<td>Screening of travelers at entry and exit points</td>
<td>115</td>
<td>41.3</td>
</tr>
<tr>
<td>Use of churches and mosques</td>
<td>46</td>
<td>16.6</td>
</tr>
<tr>
<td>Seminars</td>
<td>46</td>
<td>16.6</td>
</tr>
<tr>
<td>Establishment of emergency operation centers</td>
<td>23</td>
<td>8.3</td>
</tr>
<tr>
<td>Intensification of early detection in 36 states and FCT</td>
<td>23</td>
<td>8.3</td>
</tr>
</tbody>
</table>
Table 7 shows measures undertaken by the Nigerian government to prevent the spread of Ebola disease. 83.1% knew about the use of media houses in diverse languages, 41.3% knew about screening of people at entry and exit points, 16.6% knew of the use of worship centers and also organization of seminars, 8.3% respectively knew about the establishment of emergency operation centers and intensification of early detection in 36 states and Abuja FCT.

DISCUSSIONS

In the present study, the level of awareness of Ebola is low. All the respondents have heard of Ebola virus disease (EVD) through further questioning revealed that such knowledge have not gone further than an in passé hearing of the word Ebola. Majority of the respondents heard of Ebola from the electronic media (TV and radio)(83.5%). The internet which is turning to the major means of conveying information had only 16.6% of respondents having Ebola via it. This may stem from two things namely, internet illiteracy and the poor 3G networks in the areas of study. Although all the respondents know that Ebola virus disease is spread by Ebola virus. This could have been apparent fever from the name of the disease but 16.9% still thought it was a bacterial infection. Commendable, however given the nature of the superstition environment is that none of the respondents thought it is a spiritual attack and several other ailments are thought to be.

On the transmission, 74.8% of respondents knew the animal hosts of the disease namely the bats of the pteropodidae family, monkeys, porcupine, gorillas, chimpanzees and antelopes. Above average knowledge in contact with body fluids and touching dead bodies. However, consumption of fruits left over by animals was only selected by 33.5% meaning that this important means of transmission is still not widely known. None chose fish as a host.

Previously, the attacks were known to occur in rural areas but the present outbreak affected both rural and urban areas and 74.8% knew this new trend while 16.9% still held on to the previously held view that it was a purely rural disease. All the respondents heard about the outbreak in Nigeria. This is due to the wide media coverage given to the disease from the first day. 66.5% knew that everyone is at risk as the disease has no predilection to any age, socioeconomic status, religion, gender or tribe.

91.7% of the respondents knew the correct incubation period of between 2 and 21 days.

On awareness of the early symptoms and signs, the knowledge was very poor as the only above average symptom known is high fever (91.7%), other symptoms such as muscle and joint pains(25.2%), headache, sore throat and weakness(16.6%) were far below average. Awareness about the late symptoms was not good either. Vomiting, bloody diarrhea was chosen by 50% of respondents, 41.3% selected bleeding from the eyes, nose, ears, and mouth. Other symptoms
such as rashes (25.2%), difficulty in breathing and swallowing (16.6%) confusion and irritability were not well known. None of the respondents thought abdominal and chest pain is a late symptom.

The result showed that awareness of protective measures was poor. The option most chosen (74.8%) was wearing protective clothing such as gloves, face mask and goggles in hospital. This is not surprising as this was a hospital/clinic based study and response usually follows practice. Avoiding eating improperly cooked bush meat had 50%. However, personal and environmental hygiene (41.7%), Obtaining clearance from health authority before moving corpses from abroad or one state to another (33.5%), avoiding traditional burial practices such as embalmment, washing or touching dead bodies (25.2%), Reporting death of suspected Ebola patients to nearest health facility (25.2%) were not well known across respondents. Worthy of note is the wide disparity between those who knew that Ebola can be transmitted by consumption of fruits/foods leftover by wild animals (33.5%) and the 4.7% that said avoiding such food in itself is a protective means against the disease.

Awareness of isolation centers was above average 66.7%. The 25% that were unaware is a major problem. The nearest isolation centre is very far (Lagos) according to all the respondents that knew where it was though none attempted distance quantification.

The Federal Ministry of Health Abuja through the Nigerian Centre for Disease Control provided a toll free hotline for Ebola surveillance, 0800EBOLAHELP (0800326524357) which was on 24 hours, 7 days a week. In addition, a website, www.ebolaalert.org, an electronic mail, ebolainfo@health.gov.ng, two twitter handles, @ebolaalert; @ebolainfomohNg and a facebook page, fb.com/ebolaalert to enable communication and adequate notification. 33.5% of respondents knew about the existence of the hotline and also knew the hotline. This is very poor.

66.5% of respondents will rightly inform the nearest designated center and 33.5% consented to calling Ebola hotline. 41.3% will tell others not to touch a suspect which is another important issue. Remarkable here also is that none agreed to start treating the patient or running away from the patient.

74.8% of the respondents will cooperate and adhere to government and health institutions regulations such as quarantine when they exhibit symptoms and signs of Ebola. A dangerous 8.3% confessed they will run away, this group will obviously spread the virus if they succeed.

Diagnostically, Ebola can be definitively isolated in a laboratory through several types of tests namely

- Antibody-capture enzyme linked immunosorbent assay (ELISA)
- Antigen detection tests
- Serum neutralization test
Reverse transcriptase polymerase chain reaction (RT-PCR) assay

Electron microscopy

Virus isolation by cell culture (Medscape 2014)

66.5% knew rightly that the confirmation for Ebola cases is by laboratory tests. Suspects can only be isolated through clinical signs and symptoms but real diagnosis is through the aforementioned tests.

Knowledge about these labs and their locations were nonexistent. The federal Ministry of health identified four laboratories for the testing of suspected Ebola cases as follows.

- Lagos: Central Research Laboratory, College of medicine, Lagos University Teaching Hospital, Ibi Araba.
- Ogun: Redeemer University reference Laboratory, Lagos Ibadan Expressway, Mowe, Ogun State.
- Oyo: Virology Department, University College Hospital, Ibadan.
- FCT: National Influenza Reference Laboratory, Asokoro General Hospital, Abuja. (FMOH, Abuja 2014)

However only 16.6% knew that there are four reference laboratories for Ebola in the country and none of the respondents could mention the location of these laboratories. So even the 16.6% that mentioned four did merely guesswork.

On management of Ebola, 74.8% knew that only supportive management suffices at the moment while 25.2% said Ebola had a treatment. The talk about treatment regimen is another offshoot of misinformation by myths and the media that was awash with several remedies at the peak of the scourge. 25.2% of those who accented to a cure mentioned Zmapp, 16.6% mentioned vaccines, while 8.3% believed that prayers can cure Ebola viral disease. Notably, no one chose consumption of bitter kola or bathing with sodium chloride water which were rumored as cures for Ebola disease.

The Federal Government through the Federal Ministry of health created a lot if awareness to prevent the spread in Nigeria. Most of the respondents however, were not well aware of these measures. The only activity that was well known, which should have been a fulcrum for others but from all indicators did not work well was massive campaigns in radios and televisions in English and Local languages reported by 83.1% of respondents, this was followed by screening of travelers at the points of entry/exit (41.3%). Other areas where the government did pretty well such as use of churches and mosques (16.6%) organization of seminars (16.6%), establishment of emergency operation centre (8.3%), intensification of early detection in 36 states and FCT
were unrecognized. The result of this study may be so since both clinical and non clinical staffs were recruited. A core clinical study may have a different result.

**CONCLUSION**

Ebola virus disease is a rare and deadly viral disease which is reportable worldwide. Early recognition of Ebola is critical for infection control. Health-care providers should be alert for and evaluate any patients suspected of having Ebola.

Having come to the end of this study, the author concludes that the level of awareness on the subject of Ebola Virus Disease is low amongst the health staff in Bassa L.G.A of Kogi state. The study showed the commendable but improvable job that the media is doing and hence since it appears to be the major means of information dissemination amongst inhabitants of the area, more information should be passed to the people over the television and radio. In as much as the WHO has declared Nigeria Ebola free as at October 2014, we have to be on the watch out.

**LIMITATIONS OF STUDY**

The study was not devoid of limitations. Some of these limitations included:

**STUDY DESIGN**

A descriptive study design was used to describe the awareness of non-doctor hospital staff in Bassa Local government of Kogi State on Ebola virus disease. Descriptive designs fail to generalize the findings to the population outside the study participants. Hence, the findings of this study could not be generalized beyond the participants of the study in Bassa Local government Area.

**SAMPLING METHOD**

A multi stage random sampling involving clustering and random sampling were used. Cluster sampling is known to produce lower precision though it is cheaper (Osuala, 2005).

**DATA COLLECTION TOOL**

The use of structured questionnaire to collect data from the study participants was another limitation. This greatly limited the answers the respondents could choose from and did not have the capacity for in depth answers as could have been the case in an interview. This was however reduced by using words that could be understood clearly by the study participants after analyzing the pilot study.
NON RESPONSE

This affected the ability of the author to make inferences from the samples. This was foreseen and allowance was made to that effect by distributing more than 278 questionnaires.

RECOMMENDATIONS

(1) The government and nongovernmental organizations should utilize the media to create more awareness of what have been done, what is being done and what needs to be done.

(2) More seminars especially for health care workers and other hospital staff, who will now step down same to patients and their relatives.

(3) Localizing more of the isolation centers in different parts of the country to ensure proximity to the people.

(4) Network service providers should be pressed to provide 3G browsing services.

(5) More training on universal precautions would facilitate a decrease in spread.

(6) Institution of laws against harmful traditional burial practices should be done.

RECOMMENDATIONS FOR FURTHER STUDIES

Having seen the trend so far, the author wishes to recommend that these studies should be carried out:

(a) Awareness of clinical staffs in Bassa on Ebola virus disease.

(b) Computer and Internet knowledge, attitude and practices amongst health care staff.

(c) Awareness of the Bassa people on Ebola virus disease. This is necessary because, the health staffs that should inform and direct them are themselves not adequately informed about the disease.

(d) A more robust study on attitude and practices on Ebola amongst same study population as the present study concentrated mainly on knowledge.

REFERENCES


WHO/ Ebola virus disease-Fact sheet. Updated September 2014
ACCURACY EVALUATION OF HIV RAPID TESTS RESOLVED BY TIE-BREAKER: A CASE STUDY OF NIGERIAN SERIAL ALGORITHM

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(PhD in Public Health, Texila American University)
Email: aminusule2000@yahoo.com

ABSTRACT

INTRODUCTION

The World Health Organization strongly recommended test algorithm for diagnosis of Human Immunodeficiency Virus (HIV) infection. In either parallel or serial algorithms, discordance is commonly encountered and the final result has to be determined by the use of a tie breaker.

OBJECTIVE

The objective of this study is to evaluate the accuracy of HIV rapid test results resolved by tie breaker in a serial algorithm using Western Blot as gold standard.

METHODOLOGY

A total of 110 remnant samples reactive as positive by Determine but giving discordant result with Unigold were collected and retested by national (serial) algorithm from January 2013 to July 2013. Samples were collected in either plain bottles or EDTA container by staff conducting HIV rapid test and transported/stored at 2-8 degree Celsius. Samples were tested according to manufactures leaflet insert. The final result obtained with the serial algorithm was verified with Western Blot technique.

RESULT

Out of the 10 discordant results, 9 were confirmed HIV positive by serial algorithm but only 8 were confirmed positive by Western Blot technique. Thus, there was 1(11%) false positive obtained with serial algorithm. Samples that were reactive by Determine were 110 (100%), 94(85.5%) reactive for Unigold and 93(85%) reactive results with Stat Pak.

CONCLUSION

One out of every 9 HIV results resolved by tie breaker as positive is false positive. This accounts for 11%. There is need therefore to introduce further means of verifying positive results resolved
by tie breaker to avoid placing patients on anti retro vial drugs wrongly and subjecting people to psychological trauma.

INTRODUCTION AND BACKGROUND

HIV/AIDS infection has been described as the most dangerously serious pandemic infection ever known in the history of mankind. More than 40 million people are presently living with the virus globally; and more than 70% of the victims live in Sub Saharan Africa. People infected with HIV remain asymptomatic for many years until when their body’s immune system is completely weakened and opportunistic infections begin to set in. During the asymptomatic stage, the only way to diagnose the infection is by laboratory test. Unfortunately thousands of people are yet to know their HIV statuses (Heneke, 2009) and many are not yet willing to take the laboratory test because of fear of stigma. There are also allegations that the HIV test is not reliable. The allegations may not be far from the truth especially when the test was conducted with a single rapid test kit which increases the chances of false positives. To improve the quality of HIV diagnosis, the WHO recommended the use of a combination of two or more rapid test kits to diagnose HIV infection. This sequence of tests is called the HIV testing algorithm.

Since 2007, Nigeria has been involved in the development of rapid testing algorithms for diagnosis of Human Immunodeficiency (HIV). The first phase of rapid test kits evaluation called Phase 1, recommended a serial algorithm; which comprised of Determine as screening test, Unigold as confirmatory test as confirmatory, and the use of Stat Pak as tie breaker if discordance exists. However, in 2012 a Phase 2 evaluation was conducted by the Federal Ministry of Health as a result of which the following three algorithms were selected:

<table>
<thead>
<tr>
<th>Possible Choices for Screening Test 1</th>
<th>Possible Choices for Confirmatory Test 2</th>
<th>Possible Choices for Tie-breaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stat-Pak</td>
<td>Uni-Gold</td>
<td>Sure-Check</td>
</tr>
<tr>
<td>Sure-Check</td>
<td>Determine</td>
<td>Stat-Pak</td>
</tr>
<tr>
<td>Determine</td>
<td>Stat-Pak</td>
<td>Sure-Check</td>
</tr>
</tbody>
</table>

However, only 2 algorithms were evaluated in this study because they are most commonly used in Nigeria. There has not been any study conducted in Nigeria to establish or compare the accuracies of any of the testing algorithms against the gold standard of Western blot with a view to determining the reliability of the results confirmed by tie breaker.

RESEARCH QUESTION

Are the results of HIV rapid tests resolved by tie breaker in serial algorithm as accurate as the results of HIV test obtained Western blot confirmation in diagnosis of HIV infection?
RATIONALE AND JUSTIFICATION FOR THE STUDY

Rapid test for HIV is cheap, easy to use and results can be ready within 15 to 30 minutes. With a kit’s sensitivity of 99.9%, there is a chance of misdiagnosing one true HIV positive as HIV negative in every 1000 persons testing positive when such kit is used as first line screening test. The aim of this research therefore is to evaluate the accuracy of HIV rapid test which have been resolved by tie breaker. A primary concern about rapid testing is the poor testing sensitivity and the unacceptably of high rate of false positive results. In the Rakai district of Southwestern Uganda, a region heavily plagued by HIV, trials conducted on the three most commonly used rapid HIV tests in Uganda revealed critical inaccuracies in rapid testing results. When the results of the rapid tests were retested using traditional tests that have been proven to be acceptably reliable, such as the western blot test and an enzyme immunoassay, it was discovered that 129 of the 295 people who were diagnosed as HIV-positive were actually HIV-negative (Gray et al, 2007). Thus, nearly 45% of the patients who received positive results received them in error. Western blot technique will therefore be used as gold standard for confirmation of HIV infection in this study.

OBJECTIVE

The primary objectives of the study are to:

a. To determine the accuracy of final HIV result resolved by tie breaker in Nigerian serial algorithm using western blot as gold standard.

RESEARCH OUTCOMES

The outcome of this research would be useful in selecting the appropriate testing algorithm in Nigeria and whether further confirmatory tests will be necessary after resolution of results by tie breaker for any patient diagnosed as either HIV negative or positive by tie breaker.

LITERATURE SEARCH STRATEGIES

Past literatures and relevant publications were searched on Internet using terms like HIV rapid test, challenges of HIV rapid test, and flaws in HIV test”. Search engines like pubmed, ScienceDirect, and HINARI were also searched.

LITERATURE REVIEW

A primary concern about rapid testing is the poor testing sensitivity and the unacceptably of high rate of false positive results. In the Rakai district of Southwestern Uganda, a region heavily plagued by HIV, trials conducted on the three most commonly used rapid HIV tests in Uganda revealed critical inaccuracies in rapid testing results. When the results of the rapid tests were retested using traditional tests that have been proven to be acceptably reliable, such as the western blot test and an enzyme immunoassay, it was discovered that 129 of the 295 people who were diagnosed as HIV-positive were actually HIV-negative (Gray et al, 2007). Thus, nearly 45% of the patients who received positive results received them in error. Similarly, another study analyzed one
of most popular rapid testing algorithms used in Cameroon, an algorithm which first tests with a rapid test called Determine and then confirms results with another rapid test called Immuno-Comb II. The algorithm demonstrated a sensitivity of 100% but a specificity of only 91.5 %. Therefore, although this rapid testing combination produces virtually no false negatives, it regularly leads to false positive result (Aghoken et al, 2009). A second commonly used testing algorithm employed by the Cameroonian Ministry of Health results in a specificity of 98.8%, which is significantly higher than that of the first testing combination. Yet despite the improvement in specificity, 2 out of every 100 people who are tested with this algorithm are still receiving false positive results. “2% false HIV positive individuals in a high burden country such as South Africa with more than 5 million HIV infections will correspond to about 100,000 people falsely declared HIV positive (ibid). Nigeria has a population of more than 150 million. However, no studies conducted in Nigeria to evaluate the reliability of result obtained by tie breaker as confirmatory of HIV testing, hence the need for this study.

IMPACT OF HV DIVERSITY ON SEROLOGICAL DIAGNOSIS

It has been reported that HIV diversity has an impact on its serological diagnosis (Lihana et al, 2012). And a very heterogenous distribution and dominance of different sub types (including sub types N, O and P) are found in Africa. Nigeria is not an exception. Significant data have reported the circulation of CRF02_AG, sub type G, su-subtype A3, CRF06_cpx, and other recombinants in significant proportion. Peeters. Et al, 2000; McCutchan et al 1999). Since recombination may introduce genetic and biological consequences that are far greater than those resulting from the steady accumulation of single mutations it is therefore essential to continually study the likely influence of these diverisites on serological diagnosis.

DEVELOPMENT OF HIV TESTING ALGORITHM IN NIGERIA

The Government of Nigeria (GON), in collaboration with several development partners, in 2005, established a multi-agency working group charged with the responsibility of evaluating HIV rapid test kits and recommending their appropriate use at points of services in Nigeria.

The working group, using an internationally standardized method, created a set of criteria which guided the selection of nine HIV rapid test kits for evaluation. One major criterion for kit selection was non-reliance on refrigeration. Test performance was assessed in a one week laboratory exercise to determine sensitivity, specificity and operational characteristics of individual tests. A panel of well characterized sera collected from the different geo-political zones in Nigeria was used to assess kit performance.

Based on their characteristics and performance, six of the tests were selected for further evaluation, three test kits were dropped from further consideration due to poor performance, cost or complexity. The remaining six kits (Bundi, Determine, Double Check Gold, StatPak, SureCheck and UniGold) all had 100% sensitivity and high specificity, ranging from 97.9 to 100%.

In practice individual tests are not used for diagnosis of HIV; tests are used in combinations (algorithms) to increase diagnostic accuracy. Since a single specimen panel was used in this
evaluation various algorithms could be proposed and the sensitivity/specificity of these algorithms calculated. Using the six test kits listed above there are 120 possible serial test algorithms. All of these were 100% sensitive, specificity ranged from 99.1 to 100%.

Parallel algorithms were also proposed and when compared to serial algorithm there was no difference in accuracy. There was however, a substantial difference in cost. Serial algorithms, in general, are half the cost.

Based on the outcome of this evaluation the following recommendations were proposed:

1. Serial testing should be adopted for use in Nigeria. In this evaluation it was as accurate as and more cost effective than parallel testing.

2. Three possible serial test algorithms are proposed.

3. These algorithms are built around four tests which performed well in this evaluation, have a proven record of use in Nigeria, satisfy concerns for purchasing locally produced products and make use of kits soon to be available in large supply in Nigeria.

4. All HIV diagnostic testing, especially that using rapid tests, should be linked to a well developed training program and a comprehensive quality assurance system.

5. A formal evaluation of HIV rapid test performance is an ongoing process that begins prior to implementation of testing and continues after testing programs have been scaled-up in the field. The following algorithms have been widely in used based on this work

**SERIAL ALGORITHMS**

<table>
<thead>
<tr>
<th>Screening Test</th>
<th>Confirmation of Positives</th>
<th>Tie-breaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine</td>
<td>StatPak</td>
<td>Bundi</td>
</tr>
<tr>
<td>UniGold</td>
<td>StatPak</td>
<td></td>
</tr>
<tr>
<td>Determine</td>
<td>UniGold</td>
<td>StatPak</td>
</tr>
</tbody>
</table>

However, Bundi and operational challenges and limitations long the line and had to be withdrawn from the market. Therefore this study will evaluate the performance of the only optional algorithm of Determine – Unigold- Stat Pak.

Nigeria is a highly-populated country of 140 million people with an HIV prevalence rate around 5% (Antenatal Clinic [ANC] Survey, 2005). It is a multi-ethnic society with a large proportion of the population living in rural settings (64%).

Traditionally, HIV testing has been the gateway to HIV/AIDS prevention, treatment, care and support. To date, many African countries have evaluated simple, rapid HIV testing as a tool for fighting the HIV epidemic. All of these studies have demonstrated that the use of rapid testing
strategies can be an important part of overall HIV testing in resource-poor settings, where cold storage capacity, reliable power, efficient transportation and sufficient numbers of skilled laboratorians may not be readily available.

The use of HIV rapid testing has also dramatically increased the proportion of tested individuals who receive their results. Prior to the availability of rapid testing, same-day results were not available, and an estimated one-third of those tested did not return to learn their HIV status. The Government of Nigeria (GON) is currently working to expand quality HIV counseling and testing (HCT) services as a prevention intervention, and as an entry to care and treatment. Therefore, the need for well-evaluated, reliable testing products whose performance and use is quality-assured is essential and urgent.

GON health care facilities and non-government organizations (NGOs) in Nigeria are currently providing HIV rapid testing for HCT, prevention of mother-to-child transmission (PMTCT), emergency blood transfusions, and clinical diagnosis. When rapid testing is provided in settings where people learn their status, a multiple test algorithm is used. The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) program supports HIV diagnosis through rapid testing, over the past six months more than 350,000 clients attending HCT sites and nearly 100,000 women attending PMTCT programs across Nigeria. In addition, test kits were provide for emergency HIV screening of 20,000 units of blood in the past year.

Enzyme immunoassays (EIA) and Western Blot (WB) technologies have been available in Nigeria; however cost and the required infrastructure have limited their availability. HIV rapid tests offer a cheaper, simpler and faster alternative. HIV Rapid Test Kits (RTKs) have been used in Nigeria for at least ten years. However, they have not always been used in a systematic or standardized fashion, such as a three-test algorithm as recommended by the World Health Organization (WHO). As of 2003, there was no national HIV rapid testing algorithm in Nigeria (though recommendations did exist in the initial VCT manual). Therefore, PEPFAR adopted the testing algorithm used successfully in past HIV ANC surveys. This was a serial algorithm, using Capillus (for screening) followed by Genie II (for all Capillus positive specimens), and Determine as a tie-breaker (in cases where discordant results were seen between the initial two tests).

The first two tests in this algorithm require refrigeration, and it was apparent that this would hinder expansion of HCT beyond tertiary and secondary healthcare facilities. In early 2006 a temporary move was made toward a non-cold chain dependent testing algorithm. Parallel testing was suggested using any two of the following tests: Determine, StatPak, Bundi, Double Check Gold or Inocheck. None of these tests require refrigeration and have eased the burden of cold chain during transport to and storage at testing sites. These tests are also far easier to run and have allowed Nigeria to move toward the use of trained, non-laboratory staff for HIV diagnostic testing at HCT sites. To resolve discordant results Genie II or Capillus was suggested or clients could be referred to a higher level facility for EIA or WB testing. However, both tie-breaker tests require refrigeration, there were concerns over loss of clients and availability of EIA / WB testing. There still existed a need for a completely non-cold chain dependent algorithm.
No formal evaluation of HIV rapid tests for the development of an algorithm has been conducted in Nigeria. HIV rapid tests have been evaluated individually, but multiple test products have not been evaluated with a single, well-characterized specimen set representative of the entire Country.

**AVAILABILITY OF HIV RAPID TEST KITS IN NIGERIA**

Currently there are dozens of HIV RTKs available commercially, but not all of these are appropriate for use in Nigeria. The following criteria were developed by the evaluation working group established by GON to decide which HIV RTKs should be evaluated. Criteria have been ranked by order of importance. The first five criteria were deemed by the working group to be the most important (presented below in bold text).

1) Stability within the climate in Nigeria, and not dependent on cold chain
2) Ability to test whole blood
3) Easy to perform and interpret
4) Low test price
5) Ability of manufacturers to produce and provide adequate numbers of testing kits to meet the needs of testing programs in Nigeria
6) Prior experience and validation - documented performance in Nigeria and other African countries
7) Ability to detect HIV-1, HIV-2 and HIV-type O subtypes
8) Ability to detect IgG and IgM antibodies to reduce the window period
9) Do not require additional equipment to run tests or read results
10) Packaging of test kits not excessively bulky
11) Long shelf life (at least one year) and robust
12) Test results provided in at least 30 minutes

There were seven HIV rapid tests which met these criteria. Two additional tests were included in this evaluation for the following reasons. OraQuick meets most of the inclusion criteria but is more costly than other tests ($4.00) and has a shorter shelf life (6 months). However, members of the working group expressed interest in evaluating this test since it has the capacity to test oral fluid and could be used in settings where oral testing is the only viable option. Bundi was also included; this is a new product and therefore does not have a documented performance record (criteria 6). The capacity of the manufacturer to produce adequate numbers of tests to meet the needs of programs in Nigeria is not known (criteria 5). Bundi was included in this evaluation since it is a locally assembled test product, an important issue for the GON. All evaluated kits are listed in...
Table 1 along with test characteristics. NAFDAC registration information is also provided for each test.

**PRINCIPLES OF HIV RAPID TEST KITS**

All the tests studied in this evaluation are qualitative tests for the detection of antibodies to HIV-1 and HIV-2. All of these tests, with the exception of InstantChek, use immunochromatographic technology (also described as lateral flow). Recombinant and/or synthetic proteins representing the immunodominant regions of the envelop proteins of HIV-1 and -2 (such as glycoproteins gp41, gp120 and gp36) are immobilized in the test regions of a reaction strip (nitrocellulose). A small volume of sample (whole blood, plasma or serum) is added to the sample pad at one end of this strip. This pad acts as a filter to remove red blood cells or other blood solids (such as fibrin clots) and provides a substrate for reconstitution and mixing of the sample with the colloid-antigen conjugate (including either selenium or gold as a colorimetric agent).

Some kits include a buffer which is added just after the specimen, this facilitates the flow of liquid through the strip. As the specimen and conjugate migrate through the strip to the immobilized recombinant antigens at the detection window, a red/purple line is formed if HIV specific Ab is present. If antibodies to HIV are absent, the antigen-selenium colloid flows past the patient window.

To ensure assay validity, a procedural control bar is incorporated in the assay strip, which provides an indication that a specimen has been added to the strip and that fluid is flowing adequately through the device. Typically, test results are interpreted within 15 – 20 minutes.

Many lateral flow strips (Bundi, DoubleCheck Gold, First Response, Stat-Pak and UniGold) are incorporated into a plastic cassette. This is then sealed in foil package to preserve the test from humidity. These cassettes allow for easier labeling and handling of the reaction strip. The manufacturers of SureCheck HIV have gone one step further and encased the strip into a clear plastic tube with a small capillary at one end for specimen loading. This tube completely encloses the strip, preventing contamination of the strip or exposure of the specimen to the tester, while at the same time allowing for easy viewing of the test results.

While OraQuick can test whole blood, plasma and serum, it was primarily designed to test oral fluid. To facilitate this, a collection pad is attached at one end of the device.

The makers of Determine do not use a cassette; instead test strips are attached to a flexible foil backing sealed with a foil cover. Ten tests are attached to create a card. One hundred tests are packed into a single envelope measuring 15 by 25 centimeters. This type of packaging greatly reduces the size and weight of test packages, which in turn reduces transport/shipping costs.

InstantChek uses a different test principle: it is a ‘flow through’ device. HIV antigens are immobilized on a membrane through which specimens are allowed to flow (on to an absorbent pad). If HIV-specific antibodies are present, they bind to the antigen and the addition of colloidal gold particles results in a red spot. A control spot is also incorporated into the membrane.
Efforts were made to ensure that specimens were contributed from sites in all six of the geo-
political zones in Nigeria.

**METHOD AND STUDY DESIGN**

This is a cross sectional study to determine the accuracy of HIV test results resolved by tie breaker rapid test kits. In Nigeria, Determine rapid test strip is used as first screening for HIV. If Determine reacts negative; the result is declared as negative. If Determine test strip indicates positive, the results has to be confirmed by a second line rapid test kit called Unigold. If the Unigold indicates positive, the test results is concluded as positive and is given to the patients. When the two test results disagree (discordance), then a tie breaker HIV rapid test kit (Stat Pak) is used to resolve the discordance.

All remnant samples of samples whose results were resolved by tie breaker from patients attending 3 hospital laboratories (Defense Headquarter Medical Centre, Abuja, 44 Nigeria Army Reference Hospital Laboratory, and 45 Nigeria Air Force Hospital Laboratory) were collected. A total of 110 remnant samples reacting as positive by Determine but giving a discordance with Unigold were retested collected for this study from January 2013 to July 2013. All the 110 samples were re-tested following serial algorithm and final results confirmed with Western Blot technique. Samples were collected in either plain bottles or EDTA container by staff conducting HIV rapid test and transported/stored at 2-8 degree Celsius. The research was conducted at Defense Reference Laboratory (DRL) using a serial algorithm below:

<table>
<thead>
<tr>
<th>Screening Test 1</th>
<th>Confirmatory Test 2</th>
<th>Tie-breaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine</td>
<td>Unigold</td>
<td>Stat Pak</td>
</tr>
</tbody>
</table>

The results were tabulated and all the samples tested by Western Blot (New Lav Blot1) to confirm the presence or absence of antibodies against HIV in the sample.

**SAMPLE COLLECTION**

Blood samples were collected from patients from ante cubital fossa vein. Plasma or serum samples were used for the tests.

**TESTING PROCEDURE**

After all specimens were initially tested in the selected laboratories and presumptive results were released to patients, the discards specimens were collected and assigned new ID numbers between 1 and 110. Standard Operating Procedures and manufacturers/kit’s insert/instructions for each test were used for each test procedure – Western blot and rapid tests.

**QUALITY ASSURANCE**

To ensure quality is maintained throughout the testing process, a daily Quality Control panel (HIV Sera Care) of positive and negative vial is used before commencing the testing. In
addition, care was taken to ensure that all validation specimens were of high quality. For this reason, all specimens included in this evaluation met the following criteria:

- Properly collected specimens in line with DRL sample collection SOP,
- Properly processed, no obvious signs of hemolysis, fungal or bacterial contamination/growth
- Properly stored, at -20°C
- Freshly collected specimen, not stored for longer than two months at the collection sites
- Clear HIV Enzyme Immunoassay (EIA) sero-status, positive or negative
- Adequate specimen volume, at least 3 ml

DATA COLLECTION AND ANALYSIS

All test results were collected on paper and entered into a spreadsheet database (MS Excel) for analysis. The sensitivity and specificity of each rapid test were calculated by comparing rapid test results with reference results derived from WB testing.

CALCULATION OF SENSITIVITY AND SPECIFICITY

<table>
<thead>
<tr>
<th>Test Positive</th>
<th>WB Gold Standard Positive</th>
<th>WB Gold Standard Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Positive</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Test Negative</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>A + C</td>
<td>B + D</td>
</tr>
</tbody>
</table>

Sensitivity = A/(A+C)

Defined as the ability of an assay being evaluated to correctly detect specimens containing Ab to HIV. In other words, sensitivity is the percentage of true positive HIV specimens identified by the assay under evaluation as positive (A), divided by the number of specimens identified by the reference assays as positive (A+C).

Specificity = D/(B+D)

Defined as the ability of an assay being evaluated to correctly detect specimens that do not contain Ab to HIV. In other words, specificity is the percentage of true negative specimens identified by the assay being evaluated as negative (D), divided by the number of specimens identified by the reference assays as negative (B+D).

In practice, individual tests are not used for the diagnosis of HIV in patients. International recommendations (WHO, Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa, page 4) support the use of multiple tests as part of a testing algorithm to improve the overall accuracy of diagnosis.
DATA ANALYSIS

Sensitivities, specificities, positive predictive values and negative predictive values were calculated as described in the HIV Testing Guidelines (5, 6); see Table 3

Table 3: 2 ×2 Table for data analysis

<table>
<thead>
<tr>
<th>Results of assay pos</th>
<th>Results of assay neg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A True Positives</td>
</tr>
<tr>
<td></td>
<td>C False Negatives</td>
</tr>
<tr>
<td>Being evaluated</td>
<td>A + C</td>
</tr>
</tbody>
</table>

Sensitivity (SENS) = A / A + C

Specificity (SPEC) = D / B + D

Positive Predictive Value (PPV) = A / A + B

Negative Predictive Value (NPV) = D / C + D

In addition, Efficiency (EFF) of the assay, which is the percent of all results that are true results, was calculated as, EFF = A + D / A + B + C + D

Sensitivity, specificity, PPV, NPV and efficiencies for serial test algorithms (combination tests) were calculated using the individual sensitivity and specificity values of the RTK assays applied in sequence at several HIV prevalence rates.

In order to calculate positive and negative predictive values for the RTKs at a range of HIV infection prevalence, we use the sensitivity and specificity values calculated from the study data and adjust for the prevalence of disease. The rarer HIV infection may be in a given population, the surer we are that a negative test result indicates no infection, and the less sure we are that a positive
test result indicates infection. Showing the effect of prevalence on the different RTK predictive values is useful to guide clinical as well as policy decisions as the prevalence of HIV infection in persons being tested often varies from the prevalence in the groups used in a study.

The formulas for calculating predictive values are based on Bayes’ theorem of conditional probability and are shown here.

\[
\text{NPV}_{Pr} = \frac{\text{Prev} \times \text{Se}}{\text{Prev} \times \text{Se} + (1-\text{Prev}) (1-\text{Sp})}
\]

\[
\frac{(1-\text{Prev}) \times \text{Sp}}{(1-\text{Prev}) \times \text{Sp} + \text{Prev} \times (1-\text{Se})}
\]

NPV$_{Pr}$ = where PV$_{Pr}$ = predictive value at a known or set prevalence; Prev = true prevalence or the pre-test probability of disease; Se = sensitivity; Sp = specificity

Using these data, a 3 x 3 table was constructed for each RTK at each calculated prevalence level. An example using a prevalence of 0.1% and an RTK with a stated 100% sensitivity and 99% specificity is shown here.

RESULTS

Determine detected HIV antibodies in all the 110 samples collected, while Unigold detected antibodies in only 94. There was discordance in 10 samples. Out of the 10 discordant results the tie breaker (Stat Pak) did not detect antibodies in one of the 10 specimens; thereby agreeing with the second line test kit in 9 specimens. However, when these 10 specimens were subjected to Western Blot confirmation, only 8 samples were found to have antibodies; thus 2 samples were actually confirmed HIV negative by Western Blot. Thus, there were 2 false negative results by the algorithm. Samples that were reactive by Determine were 104, and only 93 results of Stat Pak were concordant with that of Western Blot. On the other hand only 94 results from Unigold were actually agreeing with the results of Western Blot. The result is tabulated as follows:

<table>
<thead>
<tr>
<th></th>
<th>Determine</th>
<th>Unigold</th>
<th>Stat Pak</th>
<th>Western Blot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>110</td>
<td>94</td>
<td>93</td>
<td>108</td>
</tr>
<tr>
<td>Negative</td>
<td>6</td>
<td>16</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>No. False Negative</td>
<td>2</td>
<td>14</td>
<td>15</td>
<td>N/A</td>
</tr>
<tr>
<td>Total</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td>110</td>
</tr>
</tbody>
</table>

Using the formulae given above, the following performance parameters were calculated for each rapid test kit.
<table>
<thead>
<tr>
<th></th>
<th>Determine</th>
<th>Unigold</th>
<th>Stat Pak</th>
<th>Western Blot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>98.11%</td>
<td>87%</td>
<td>86.11%</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>96</td>
<td>94</td>
<td>99</td>
<td></td>
</tr>
<tr>
<td>Positive Predictive Value (PPV)</td>
<td>97%</td>
<td>98%</td>
<td>99%</td>
<td></td>
</tr>
<tr>
<td>Negative Predictive Value (NPV)</td>
<td>96%</td>
<td>86%</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td>Concordance with Western Blot</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Therefore by national algorithm, only 10 samples require the use of a tie breaker, which is Stat pak. The stat pak reacted with only 9 specimens and resolved as reactive. However, when the 10 discordant samples were tested with western blot, 8 samples were confirmed HIV positive while 2 were negative.

**DISCUSSION**

Human Immunodeficiency Virus (HIV) can lead to Acquired Immune Deficiency Syndrome (AIDS); a condition which renders the immune status of individual severely compromised. It has been estimated that more than 20 million people have died from the disease and more than 40 million people are infected with the virus. The discovery of rapid test kits for HIV have facilitated rapid ways of identifying people infected with the virus faster; cheaper and more accessible especially in low income countries; without the necessarily using sophisticated equipment (Gray, 2007). May publications have revealed the fallacy of using rapid test kits for diagnosis of HIV (Aghokeng, 2009). Thus, the WHO strongly recommended the use of test algorithm to increase test accuracy, where serial or parallel algorithm is used. In Nigeria, serial algorithm is used, where Determine rapid test strip is used as first screening test. If Determine reacts negative; the result is declared as negative. If Determine test strip indicates positive, the results has to be confirmed by a second line rapid test kit called Unigold. If the Unigold indicates positive, the test results is concluded as positive and is given to the patients. When the two test results disagree (discordance), then a tie breaker HIV rapid test kit (Stat Pak) is used to resolve the discordance.

This study discovered that the testing algorithm may still have some short comings compared to Western Blot method of confirming HIV infection. Out of the 10 discordant results subjected to confirmation by tie breaker, 9 were confirmed positive by the tie breaker. However, Western Blot confirmation revealed that only 8 were actually positive. By implication 1 out of every 9 cases resolved by tie breaker will emerge to be a false positive. This accounts for 11% of all HIV test results resolved by tie breaker.

**IMPLICATION OF HIV FALSE POSITIVE RESULTS**

There are many implications of false positive HIV results in public health context. A woman in Democratic Republic of Congo revealed that her husband divorced her after she was told she was HIV positive; but later she was re-tested and confirmed to be HIV negative. She was in the process
of remarrying a HIV positive from peer group when she was re tested. Other implications include loss of jobs, psychological trauma, loss in self dignity and possible placement on anti retro viral drugs.

LIMITATIONS OF THE STUDY

Limitation of this study is lack of large number of samples yielding discordant results in a testing algorithm to compare its performance with Western Blot.

It is important therefore to verify the HIV seropositivity of every sample resolved by tie breaker by Western Blot.

Advanced research in this area is also very important.

REFERENCES


THE PERCEPTION OF NIGERIAN TRADERS ABOUT THE SYMPTOMS AND TRANSMISSION OF EBOLAVIRUS DISEASE

Article Review by Maclawrence Kolapo Famuyiwa, Nigeria
(PhD in Public Health, Texila American University
Email: - maclaw196@gmail.com

ABSTRACT

This is a study carried out to gauge the perception of market men and women about Ebola virus disease and its transmission. It is a cross-sectional questionnaire based study, in which 126 market men and women were involved. This study became imperative going by the fact that Nigeria was just recently let off the hook of the ravages of the virus, and the government of Nigeria pellucid engagement in mass media campaign to enlighten the citizens about the symptoms and various modes of transmission of the disease, because the virus still causes serious devastation in nearby West African countries of Liberia, Sierra Leone, Guinea, and most recently Mali, and as not to make a ludicrous mistake of allowing another Ebola panic in the country.

The analysis of the data was done using IBM SPSS; descriptive statistics to get the general characteristics of the study participants. Chi-square test was used to determine the level of significance of groups of categorical variables. P values < 0.05 were considered significant.

The data analysis showed that 126 out of the 150 respondents returned the questionnaires completely filled, representing 84% of the respondents. The respondents showed a poor knowledge of animal to man mode of transmission, 20.7% of this mode chosen by the respondents is that EVD can be transmitted through the eating of well cooked meat of the known EVD infected animals. 72.3% of the respondent identified at least two man to man modes of transmission and 68.7% of the symptoms of Ebola identified include at least one of the early symptoms of EVD.

The study concluded that the knowledge shown by the respondents is mixed; there was a good knowledge of man to man mode of transmission while the knowledge of the animal to man mode of transmission is poor while that of the symptoms of the disease is average.

KEYWORDS

Ebola Viral Disease, Nigerian traders, Symptoms, Transmission.
INTRODUCTION

The short reign of terror of Ebola in Nigeria, brought with it great panic, it redefined conviviality, even hoi polloi dared not exchange greetings making bodily contacts, a strange modus vivendi in Africa, children’s playtime became a quietude no longer rambunctious, regular hand washings became a norm, obsequies no longer attract multitudes of sympathizers, the entire societal fabric was in a pell-mell. At its quietus, 19 Nigerians were affected by the index case, a Liberian, that travelled by air into Nigeria, out of which 7 Nigerians died with the index case being the 8th, the case fatality of the disease in Nigeria was 36.8% but with the inclusion of the index case it pellucid became 40%, just a bit off the WHO average rate of 50%. (1)

This study therefore, intends to study the knowledge of the symptoms and the various modes of transmission of Ebola virus disease among Nigerian traders. The study is necessary to establish the effectiveness of the educational measures adopted by the government to educate the populace about the disease.

MATERIALS AND METHODS

The study was done using questionnaires and cross sectional. It was carried out among market women and men in a popular open market in Southwest Nigeria. All categories of traders were involved. Ethical approval was obtained before the commencement of the study from the management of the market, who also invited the researcher to many of their weekly market meetings where the traders were intimated about the aims of the study.

DATA ANALYSIS

The analysis of the data was for bio-data, response regarding their response to the mode of transmission of the disease, the symptoms of the disease, how easily they feel the disease can be spread from those that are sick of it and from the animals infected with the Ebola virus disease. IBM SPSS was used in the analysis of the data; descriptive statistics was used to get the general characteristics of the study participants. Chi-square test was used to determine the level of significance of groups of categorical variables. P values < 0.05 were considered significant.

RESULTS

Table 1: Age Distributions

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Number of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
<td>28</td>
<td>22.2</td>
</tr>
<tr>
<td>31-40</td>
<td>46</td>
<td>36.5</td>
</tr>
</tbody>
</table>
Table 1 shows that 36.5% of the respondents are within the 31-40 age range, 23.8% within the age range 41-50 and 22.2% within the age range 21-30. The median age is 38.1 years, the mode is 35.8 years, and the mean is 39.9 years.

**Table 2: Education Level**

<table>
<thead>
<tr>
<th>Responses</th>
<th>Number of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Formal Education</td>
<td>12</td>
<td>9.5</td>
</tr>
<tr>
<td>Primary Uncompleted</td>
<td>8</td>
<td>6.3</td>
</tr>
<tr>
<td>Primary Completed</td>
<td>6</td>
<td>4.8</td>
</tr>
<tr>
<td>Secondary Uncompleted</td>
<td>13</td>
<td>10.3</td>
</tr>
<tr>
<td>Secondary Completed</td>
<td>51</td>
<td>40.5</td>
</tr>
<tr>
<td>Post Secondary</td>
<td>36</td>
<td>28.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>126</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Table 2 shows that 40.5% of the respondents completed Secondary School while 28.6% have Post Secondary School education and 10.3% of the respondent started but didn’t complete Secondary School education.

**Table 3: Mode of Transmission of Ebola to Man**

<table>
<thead>
<tr>
<th>Responses</th>
<th>Number of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>By having bodily contacts with sick patients already showing Ebola</td>
<td>124</td>
<td>25.2</td>
</tr>
</tbody>
</table>
symptoms

<table>
<thead>
<tr>
<th>Activity</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>By having bodily contacts with a suspected patients not yet showing Ebola symptoms</td>
<td>56</td>
<td>11.3</td>
</tr>
<tr>
<td>By eating well cooked meat of fruit bats, monkeys and chimpanzees</td>
<td>102</td>
<td>20.7</td>
</tr>
<tr>
<td>By eating poorly cooked or raw meat of fruit bats, monkeys and chimpanzees</td>
<td>30</td>
<td>6.1</td>
</tr>
<tr>
<td>By breathing the air that sick Ebola patients breathe out</td>
<td>78</td>
<td>15.8</td>
</tr>
<tr>
<td>By having bodily contact with the dead bodies of Ebola victims</td>
<td>103</td>
<td>20.9</td>
</tr>
</tbody>
</table>

493 100.0
Table 3 and Figure 1 show that 25.2% of the respondents were aware that Ebola can be transmitted by having bodily contact with patients already showing symptoms of Ebola, 20.9% knew one can contract Ebola by having bodily contact with the corpse of someone that died due to Ebola viral disease. And 20.7% felt that one can be infected with Ebola virus by eating well cooked meat of fruit bats, monkeys and chimpanzees.

Table 4: Symptoms of Ebola

<table>
<thead>
<tr>
<th>Responses</th>
<th>Number of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Headache</td>
<td>536</td>
<td>12.0</td>
</tr>
<tr>
<td>Fever</td>
<td>850</td>
<td>19.0</td>
</tr>
<tr>
<td>Nausea and Vomiting</td>
<td>434</td>
<td>9.7</td>
</tr>
<tr>
<td>Joint muscle ache</td>
<td>324</td>
<td>7.2</td>
</tr>
<tr>
<td>Chills</td>
<td>212</td>
<td>4.7</td>
</tr>
<tr>
<td>Weakness</td>
<td>407</td>
<td>9.1</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>524</td>
<td>11.7</td>
</tr>
</tbody>
</table>
Table 4 and Figure 2 show that the most recognized symptoms of Ebola among the respondents are Fever 19%, severe headache 12%, Diarrhoea 11.7%, Red eyes 10.9%, Nausea and vomiting 9.7%, Weakness 9.1%, and Sore throat 8%.

DISCUSSION

Majority of the respondents (92%) are below 60 years in age, the active working age group; with 36.5% within the 31-40 years age group, 23.8% within the age group 41-50 years, 22.2% within the age group 21-30, and 9.5% within the 51-60 age group. The age distribution of these traders is comparable to the findings in a study done in the same geographical zone of Nigeria with this study, it was shown that 38% were in the age range of 18-30, (34.6%) in 31-40, 41-50 (16.8%) in 41-50 and 8.4% were over 50 years old. (2) The preponderance of people between 21 years and 50 years among the respondents can be explained mainly because of the scarcity of the white collar jobs in Nigeria, and this has driven majority of the people in these active working age group into trading and other small scale businesses, mostly after they had searched in vain to secure for themselves a well paying job. This is further corroborated by the fact that that 38.9%
of the respondents have at least completed their secondary school education with 28.6% having a post secondary education.

Most of the respondents are females (63.6%) while the males are 36.4%, also agreeing with a study done using a sample of the open market traders in the same geographical region, where the finding was that 59.8% were females and the rest were males. (2)

The knowledge shown by the respondents about the animal to man mode of transmission of the virus is extremely poor, since 20.7% of the mode of transmission chosen by the respondent is the belief that one can get infected with Ebola virus by eating well cooked meat of the animals believed to be the reservoirs of the virus, that is, fruit bats, monkeys and chimpanzees, while only 6.1% of the mode of transmission chosen is by eating poorly cooked meat of these animals, this is particularly alarming, because this means that most of the respondents are oblivious of the potentiality of having an animal to man transmission of the disease, through the handling of raw meat of these animals and eating poorly cooked meat of these animals. This is based on the fact that it is scientifically believed that there are unknown physiological and environmental conditions, contacts between the reservoir (potentially certain fruit bat species) and non human primates (monkeys, gorillas and chimpanzees) that can trigger epizootic outbreaks. (3) Human infections may also occur through the handling of animal carcasses, as shown in the 2001 outbreaks in Gabon and Democratic Republic of Congo (4, 5) There is even the suspicion that there may be direct transmission from these animals to humans as was the case in Luebo. (6)

The picture is however, not as gloomy with the knowledge of man to man mode of transmission, since 72.3% of the respondents were able to identify at least two of the man to man mode of transmission. 25.2% of the mode of transmission chosen is that it can be through bodily contacts with Ebola virus disease patients already showing symptoms, and 20.9% of the mode of transmission chosen is by having bodily contacts with dead bodies of people killed by Ebola virus disease. The infection, is believed, to spread by person-to-person contact, through body fluids, medical care and burial practices. (7)

15.8% of the mode chosen is by the inhalation of the air exhaled by the sufferers of the disease, a pathetically similar findings with a study done in Sierra Leone where 30% of the respondents believed that the virus can be transmitted through the air, (8) and 11.3% by having bodily contacts with people suspected of having the disease but not yet showing any symptom of the disease. Meanwhile it is known that transmission relies on direct contact with bodily fluids containing the virus, either through broken-skin or through mucous membranes, and this is possible when they are already symptomatic. Airborne, droplet- aerosol transmission does not seem to be a popular mechanism of spread, though it is possible that this does occur. (9)

The knowledge of the early symptoms of Ebola virus disease is fairly good, since 68.7% of the symptoms of Ebola virus disease chosen by the respondents includes at least one of the early symptoms of the disease: 19% of the symptoms of Ebola virus disease chosen was fever, 12%
was severe headache, weakness 9.1%, sore throat 8%, joint muscle ache 7.2% and chills 4.7%, this knowledge becomes significant because most of the early symptoms of the disease resemble those of malaria which is endemic in Nigeria, but on the whole many of them are still unaware of the plethora of the symptoms that are associated with the disease, only (38.7%) chose correctly more than two or more early symptoms of the disease, this is worrisome, since many may still not able to suspect the disease early enough so as to seek medical intervention.

CONCLUSION

This study, thus, make the following conclusions:

There is a poor knowledge among the respondents about the animal to man transmission of the Ebola virus, the failure of most of them to know that by handling raw meat of the infected animals with bare hands or eating the poorly cooked meat of these animals that are infected with the virus is lugubrious, only 6.1% of the mode of transmission chosen by the respondents was the conviction that the virus can be transmitted through handling of the raw meat of these animal reservoirs.

Most of the respondents (68.7%) were able to identify at least one of the early symptoms of the disease. Though, the knowledge of two or more of the early symptoms of the disease is extremely poor (38.7%). This is despite the aggressive information on identification of early symptoms by various level of government, using different arms of the media.

The knowledge about man to man transmission of the disease was quite impressive, 72.3% of the respondents were able to identify at least two modes of man to man transmission of the disease.

15.8% of the mode of transmission chosen is that people can be infected, when they breathe the air the Ebola virus disease victims exhaled, otherwise, they believe that the virus is airborne.

RECOMMENDATIONS

The content of the campaign strategy being currently used, should be made to contain information on animal to man transmission of the disease. More efforts should also be put into educating the people about the established scientific accepted ways of transmitting the disease, it is out of place that some of the respondents believed the disease is airborne.

Though, the present education campaign on how to prevent EVD, clearly inform the people about the symptoms of the disease, more efforts should be put into the design of the education campaign messages to make them more educative, since the respondents in this study, though were able to identify at least one of the early symptoms, their knowledge of two or more of these symptoms was abysmally low.
REFERENCES


PATIENTS’ SATISFACTION IN PUBLIC AND PRIVATE HOSPITAL OF MORANG DISTRICT NEPAL: A COMPARATIVE CROSS SECTIONAL STUDY

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Email: - aanil.sigdel@gmail.com

ABSTRACT

Patient satisfaction is a multidimensional aspect, represents a vital key marker for the quality of health care. The objective of the study was to compare the level of patients’ satisfaction among public and private hospital. A cross sectional comparative was conducted in two hospitals of Morang District i.e. one public and one private hospital selected purposively. Patients discharged from different wards were selected by consecutive sampling method and exit interview was performed. The sample of study was 220. The written consent was taken before the interview. 5 points Likert scale was used for measuring patients’ satisfaction. Discharged slip was checked for the maintaining validity and Chronbach’s Alfa was calculated for ensuring reliability of tools. Coding, entry and analysis was done in SPSS version 16. A median score of 148 was used as the cutoff point for defining the level of patients’ satisfaction. Patients in public hospital were more satisfied (61.8%) than those of private hospital (37.27%) and the difference in level of satisfaction and type of hospital found to be statistically significant (p<0.001).Moreover, the patients in public hospital were more satisfied with overall cost of health services (OR=30.83, CI 95%:13.014-73.05), laboratory and registration facilities (OR=2.805, CI 95%:1.628-4.833) and other facilities of hospital (OR=8.35, CI 95%:4.31-16.196) compared to private hospitals. Patients in public hospital were more likely to be good satisfied compared to public hospital and the important reasons for this was found to be high cost of health services in private hospitals and lack of health insurance provision.

KEY WORDS

Patients Satisfaction, Comparative, Public, Private, Hospital
INTRODUCTION

Patient satisfaction has become an important indicator to measure the quality of care rendered to the patients while in hospital. Healthcare institutes have often used patients' outcome as measures to evaluate the health care services provided to patients. Patient satisfaction surveys can help identify ways of improving nursing and health care services. Getting views of the patients on the care services is a much realistic tool to evaluate and improve the health care services since it is based on direct experiences of the users. The purpose of the study is to compare the levels of patients’ satisfaction in public and private hospital of Morang district Nepal.

METHODOLOGY

The study was cross-sectional comparative and was conducted in two hospitals i.e. one private and one public hospital of Morang District Nepal. Indoor patients at least staying 2 days and were discharged from the different wards of hospital were regarded as the respondents of study and exit interview was conducted to minimize the victimization of patients by hospital staffs and to enhance the real scenario of the problem. Hospitals were selected purposively and consequentive sampling techniques had been adopted to select the respondents. The sample size was found to be 110 for each hospital and was calculated by using formula

\[ n = \frac{2(Z_\alpha + Z_\beta)^2}{\text{Effect size}^2}; \]  

Where \( n \) = the sample size per group (assumed equal);

\[ Z_\alpha = \text{the } (1-\alpha /2) \text{ percentile of the standard normal distribution for two-sided test}; \ 1-\alpha \text{ percentile for 1-sided test; } \]

\[ Z_\beta = \text{the } (1-\beta) = \text{Power of the study} \]

Face to face interview was used as the method of data collection using pre tested sturctured questionnarie. 5 point likert scale (very satisfied, satisfied, neutral, dissatisfied and very dissatisfied) that had been used in prior study with necessary modification in local context was used to measure the level of patients satisfaction. Patients’ satisfaction had been then classified into two groups namely satisfied versus poorly satisfied using median score as a cutoff point.

The right and confidentiality of the respondent was maintained throughout the research. The written consent was taken before the interview. The Chronbach’s Alfa was calculated for ensuring reliability of tools which was found to be 74.06% and discharged slip was checked for ensuring the validity. The patients discharged from psychiatric ward and patients less than 16 years of age were not included in the study.
RESULTS

Table 1 represents the level of patients’ satisfaction according to the types of hospital and found that nearly two third of the respondents (68.8%) in the public hospital were found to be satisfied as compared to 37.27% in private hospital.

Table No.1: Distribution of level of Patients’ Satisfaction with different types of Hospital, n=220

<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Level of Satisfaction</th>
<th>Total n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Satisfied n (%)</td>
<td>Poorly Satisfied n (%)</td>
</tr>
<tr>
<td>Public</td>
<td>68(61.8)</td>
<td>42(38.2)</td>
</tr>
<tr>
<td>Private</td>
<td>41(37.27)</td>
<td>69(62.73)</td>
</tr>
<tr>
<td>Total</td>
<td>109(49.54)</td>
<td>111(50.45)</td>
</tr>
</tbody>
</table>

Table 2 represents the dimension of patients’ satisfaction in public and private hospital and found that patients were more satisfied with the physician care and physical facilities in the private hospital as compared to public hospital. Similarly in other dimensions of patients satisfaction like cost for health services, registration and laboratory services and other services people were found more satisfied in public hospital as compared to private hospital. There seems no difference in satisfaction level in public and private hospital in contract to nursing care.

Similarly, Table 3 shows a significant association between type of hospital and level of satisfaction. Result shows that patients in the public hospital are nearly 3 times (OR=2.804, CI 95%: 1.628-4.830) more likely to be satisfied compared to the respondents of private hospital.

Table No. 2: Distribution of dimension of patients’ satisfaction in Public and Private Hospital (n=220)

<table>
<thead>
<tr>
<th>Dimension of patients’ satisfaction</th>
<th>Type of Hospital</th>
<th>Level of patients’ satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Satisfied n (%)</td>
</tr>
<tr>
<td>Physician Care</td>
<td>Public</td>
<td>47(42.7)</td>
</tr>
<tr>
<td>Dimension of patients’ satisfaction</td>
<td>Type of Hospital</td>
<td>Level of patients’ satisfaction</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Satisfied n (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n (%)</td>
</tr>
<tr>
<td>Public</td>
<td>Private</td>
<td>58(52.7)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>116(52.7)</td>
</tr>
<tr>
<td>Private</td>
<td>Public</td>
<td>67(60.9)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>40(37)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>107(48.64)</td>
</tr>
<tr>
<td>Private</td>
<td>Public</td>
<td>38(34.54)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>60(54.5)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>98(45.54)</td>
</tr>
<tr>
<td>Public</td>
<td>Public</td>
<td>74(67.28)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>07(6.36)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>81(36.82)</td>
</tr>
<tr>
<td>Private</td>
<td>Public</td>
<td>62(56.36)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>15(13.64)</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>77(35)</td>
</tr>
</tbody>
</table>

** <0.001, Others Facilities\(^a\) includes availability of drugs, courtesy and friendliness of Pharmacist, cost of food, availability of hygenic food, availability of beds and cost of bed and 1-reference category
Table No. 3: Association between Types of Hospital and level of Patients’ Satisfaction (n=220)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Level of Satisfaction</th>
<th>P value</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Poorly Satisfied</td>
<td>Satisfied</td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of Hospital</td>
<td>Private</td>
<td>69(62.73)</td>
<td>41(37.27)</td>
</tr>
<tr>
<td></td>
<td>Public**</td>
<td>42(38.2)</td>
<td>68(61.8)</td>
</tr>
</tbody>
</table>

**<.001 and 1 – reference category

A statistically significant association seems between the laboratory and registration services, cost of health services and other facilities and types of hospital and other dimension of patients’ satisfaction does not seem statistically significant. Patients in the public hospital were more than 2 times (OR= 2.805, CI 95% = 1.628- 4.833) more satisfied with the laboratory and registration services as compared to private hospital. Patients were more than 30 times (OR=30.83, CI 95%=13.014-73.05) more likely to be satisfied with the cost of health service at public hospital compared with private. Similarly Patients in public hospital were more than 8 times (OR=8.35, CI 95%: 4.31-16.196) more satisfied with other services compared with private hospital as shown in table 4.

Table No. 4: Association between dimension of Patients’ Satisfaction and Types of Hospitals (n=220)

<table>
<thead>
<tr>
<th>Dimension of Satisfaction</th>
<th>Types of Hospital</th>
<th>Level of Satisfaction</th>
<th>P value</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Poorly Satisfied</td>
<td>Satisfied</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Care</td>
<td>Private</td>
<td>54(49.1)</td>
<td>56(50.9)</td>
<td>0.277</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>63(57.3)</td>
<td>47(42.7)</td>
<td>1.39(0.817-2.365)</td>
</tr>
<tr>
<td>Nursing Care</td>
<td>Private</td>
<td>58(52.7)</td>
<td>52(47.3)</td>
<td>0.348</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>52(47.3)</td>
<td>58(52.7)</td>
<td>0.804(0.473-1.365)</td>
</tr>
</tbody>
</table>
**DISCUSSION AND CONCLUSION**

An investigation of level of patients’ satisfaction between public and private hospital was conducted where exit interview was conducted to 220 respondents i.e. 110 from each hospital found that patients in the public hospital was nearly 3 times (OR=2.804, CI 95%: 1.628-4.830) more likely to be satisfied than patients in the private hospital. This result contracts with the study conducted in Peshawar Pakistan 2012 ⁵ and a study conducted by Suresh K Sharma and Pawan K. Karma (2013) which found the patients in private hospital were more likely to be satisfied with the services than public hospital.¹ The contradiction might be due to the absence or lack of provision of health insurance and high cost of services at public hospital.

The patients in the public hospital were found to be more than 2 times (OR= 2.805, CI 95% = 1.628- 4.833) more satisfied compared to public hospital which is contradictory to the study conducted by in Turkey but resembles with the result of patients satisfaction regarding physician care and types of hospital.⁶ The patients in the private hospital seems to be more satisfied
(53.6%) with the nursing care than the patients in the public care and the finding were supported by study conducted by Sharma SK and Karma PK in 2013.  

The patients in the public hospital were more 30 times (OR=30.83, CI 95%=13.014-73.05) more likely to be satisfied with the overall cost of health service compared to that of private hospital and this is one of the leading reasons for high percentage of patient satisfaction in public hospital.

The study reveals that the patients in the public hospital were found to be more than 2 times good satisfied than those of patients in private hospital. The main reason behind the patients’ good satisfaction in public hospital compared to private was that more patients in public hospital were found to be good satisfied in term of laboratory services and registration facilities, overall cost of the health service and other facilities of the hospital. However the study follows the consequentive sampling method, many respondents have been left and this may increases the selection biases.

Since the results of the finding was found to be contradictory with the finding of many other study conducted which highlights the need of the new research to find out the reason behind the difference in patients’ satisfaction in public and private hospital.

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ASSESSING BOTSWANA’S PREPAREDNESS IN DEALING WITH NATURAL DISASTERS

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DEFINITIONS

Natural Disaster - Any event or force of nature that has catastrophic consequences (1)

Disaster – Any event that would disrupt the normal pattern of activities in a given area as a result of interaction between hazard and human population. This results in loss of life, injury, economic and social hardships.

Disaster risk – The potential disaster losses in lives, health status, livelihoods, assets and services which could happen in a specified community

Disaster management – An integrated series of activities and strategies (prevention, mitigation, preparedness, response and recovery) implemented within the context of national development

Disaster mitigation – refers to the plans, strategies and actions taken to reduce the vulnerability of a population to a future disaster threat

Disaster preparedness – refers to the plans and actions taken to ensure an effective response to a disaster that may occur in the future

Emergency response – refers to the actual operations and actions that are taken as soon as a disaster strikes. These are aimed at providing assistance and support to the affected population and area.

Recovery – refers to all the actions that are taken to return the affected population to normal life and to phase in mitigation measures to help with better protection in the future.

ABBREVIATIONS/ SYNONYMS

1. NDMO – National Disaster Management office
2. HIV – Human Immuno Virus
3. AIDS – Acquired Immune Deficiency Syndrome
4. HDI – Human Development Index
5. UN – United Nations
6. UNDP – United Nations Development plan
7. UNISDR – United Nations International Strategy for Disaster Reduction
8. ISDR – International Strategy for Disaster Reduction
9. HFA – Hyogo Framework for Action
10. WCNDR – World Conference on National Disaster Reduction
11. USD – United States Dollar
12. CBPP – Contagious Bovine Pleuro – Pneumonia
13. DRR – Disaster Risk Reduction
14. Sms – Short Message Service

ABSTRACT

Natural disasters have affected Botswana with varying regularity and intensity. The United Nations General Assembly of 2005 (WCNDR) called upon all Governments to establish national platforms or focal points for disaster reduction, encouraging Governments to strengthen platforms were they already existed. In Botswana the National Committee on Disaster management and the National Disaster Management Technical Committee acts as the above platform. Disaster management is coordinated by the National Disaster Management Office (NDMO) which is within the President’s Office. At village and district levels, disaster committees report to the NDMO. There is no legal instrument on disaster management in Botswana but the office of the President has overall responsibility for disaster management with disaster committees at all levels. The HFA outlined 5 key priority areas that international countries agreed to adopt to build better resilience of communities to national disasters. The progress reports show that Botswana is doing well with the country’s Disaster management policy providing guidelines for all the sectors and institutional levels to implement disaster preparedness and emergency response. However the lack of budget allocations means that the NDMO is under resourced and lacks the capacity to actively engage private sector community and non – governmental organizations. Where progress has been enormous such as the awareness campaigns and training programmes coordinated by the NDMO throughout the country, there has not been tools and sufficient resources to assess effectiveness. Overall Botswana has built a good foundation that can be continually improved on to build resilience towards natural disasters as well as reducing hazards and vulnerability; ultimately reducing the disaster risks.
INTRODUCTION

Botswana is a land locked country in Southern Africa, sharing borders with South Africa, Zimbabwe, Zambia and Namibia. It is a semi arid country with a sub tropical climate characterized by recurrence of drought and very low rainfalls. Of the land area 0.7% has a tropical wet and dry savanna climate (Northern parts), 98.5 % has a semi arid/steppe climate. The country is relatively flat lying at an average of 900m above sea level. Of the population 99.4% live in a semi arid steppe climate while 0.6% live in arid/ desert climate. Botswana’s population is estimated at 2.1 million with a poverty rate of 20.7%, per capita income of $3 500 and an HDI rank of 119 as at 2013 (2).

Botswana is vulnerable to a range of disasters occurring with varying degrees of intensity and regularity. The disasters encountered are principally droughts, however; there are also veld fires, floods, epidemics, transport and industrial accidents, chemical spills and influx of illegal immigrants (4). The United Nations, in its World Conference on National Disaster Reduction (WCNDR, 2005) reported that the impact of disasters is much more severe on those who are already suffering due to poverty and diseases. This means that African countries, including Botswana, have to channel resources towards building of safer communities and increasing the resilience towards disasters and hence reducing the disaster risk (7).

The level of disaster risk is established by assessing the hazards facing a particular community, in relation to the resilience and vulnerability of those potentially affected. In general, the disaster risk is directly proportional to the hazard and vulnerability, but indirectly proportional to the resilience (see summary in Appendix 1). The planning stage of reducing disaster risk hence works by:

- Reducing the hazard level by either changing its severity or the probability of it ever occurring at all
- Decreasing vulnerability by changing the physical, social, economic or environmental characteristics of the receiving entity
- Building greater resilience against disasters by increasing the capacity of the affected community through increasing physical, social, institutional and economic means as well as collective attributes such as leadership and management (6)

Disasters cause a lot of trauma, sadness, depression and suffering for those who survive them. Not only do people have to deal with losses of the ones they love, but many a times they are displaced from their homes and they lose property. Coupled with the chances that a good number of the survivors do not insure their property, comes the dynamics of some insurance companies not compensating losses due to natural causes, hence the survivors suffer losses that may never or may take long to recover from.
Disaster risk reduction is influenced by a number of factors, such as climate change, economic growth, regional growth and development etc. Botswana realises that a plan to reduce disaster risk cannot be implemented in isolation, hence the National development is carefully designed taking into cognisance international agreements and guidelines. One such agreement is the HYOGO Framework for Action 2005-2015 by the United Nations International Strategy for Disaster Reduction (UNISDR). The UNISDR was established in December 1999 after realising the need that the United Nations (UN) needed to have a department concentrating on reducing disaster risk. In a World Conference on Disaster Reduction that was held on 18 -22 January, 2005 in Kobe, Hyogo, Japan; the Hyogo Framework for Action 2005 – 2015 ISDR was established. This was a 10 year plan explaining, describing and detailing the requirements from different sectors and actors to reduce disaster losses. The goal was to substantially reduce disaster losses by 2015, through building the resilience of Nations and communities to disasters. The five priorities for action are as follows:

- Ensure that disaster risk reduction is a national and a local priority with a strong Institutional basis for implementation
- Identify, assess and monitor disaster risks and enhance early warnings
- Use knowledge, innovation and education to build a culture of safety and resilience at all levels
- Reduce the underlying risk factors
- Strengthen disaster preparedness for effective response at all levels

**DROUGHTS**

Botswana is a land locked semi arid country with a sub tropical climate characterized by recurrence of drought and very low rainfalls. Of the land area 0.7% has a tropical wet and dry savanna climate (Northern parts), 98.5 % has a semi arid/steppe climate. Of the population 99.4% live in a semi arid steppe climate while 0.6% live in arid/ desert climate.

Agriculture wise the country mainly depends on cattle farming, the economy is driven mainly by an international beef market including South Africa and the European markets. There is very little commercial crop production and most crops are produced for subsistence or for sale locally.

Drought inevitably puts a strain on the scarce water resources resulting in loss of lives for cattle and other reared animals as well as human beings. Since 1981, Botswana has been experiencing countrywide droughts. Between 2002 and 2008, almost a billion pula (approximately one million USD) in over six thousand projects to reduce the effects of drought on the affected populations. The programmes covered primary school feeding and vulnerable group feeding with enrolments of more than two hundred and thirty thousand individuals.
Fires

The largest parts of Botswana are covered by the Kalahari desert, however when you take a closer look at the precipitation figures, the area qualifies more as a semi desert changing into a hilly steppe area in the North(5). During the summer months of October to March, temperatures get very high, even up to 40°C, and even during the night time, temperatures may not fall to below 22°C. Vegetation is mainly savanna, grass, shrub, tree, dry deciduous forests, aquatic grassland (especially in the northern parts of the country) and woodland. The country is prone to fires and recent statistics prove that large areas have been burnt; the 2007 - 2008 fires destroyed approximately 14 million hectares of land, with about 12 million hectares in 2010 and 15 million hectares in 2011 destroyed by bush fires causing loss of lives, wild animals and livestock.

About 16% (58 000 hectares) is national parks and forest reserves, thus Bush fires have to be carefully monitored and planned for as the consequences of such are catastrophic. There is also a risk of structural fires, and these occur mainly in the two largest cities, Gaborone and Francistown.

Floods

Due to the relatively poor town planning and drainage, floods occur during the rainy seasons of October to March, however because of a generally low rainfall pattern; these are rarely serious enough to be classified as disasters. However the floods that occurred between 1999 and 2000 are the worst to have occurred in living memory as they affected 23 administrative districts, villages and towns causing loss of life and suffering, and extensive damage to infrastructure. The damaged roads meant that it was difficult to supply food and clean water to affected communities. These floods destroyed five million Pula (more than five hundred thousand United States Dollars) worth of private and public property. Statistics available in the National Disaster Management Office show that thousands of people are affected by storms and floods every year (6).

Animal Diseases

Botswana is bound by South Africa on the South and South east, Zambia on the narrow strip of North, Zimbabwe in the North east and Namibia in the West. Due to borders that did not have clear lines of demarcation and populations with relatives both side of the borders, movement and hence chances of cross infection between countries is a real danger. In 1995, there was an outbreak of the Contagious Bovine Pleuro -Pneumonia (CBPP) in Ngamiland, this resulted in the eradication of more than three hundred thousand cattle at a cost of more than two hundred and seventy million Pula (over twenty seven million USD) (6). Botswana has since put up laws forbidding unregulated importation of meats/ animals between its neighbours.
AIMS/ OBJECTIVES

This project aimed at outlining the nature of disasters that could affect Botswana, highlighting the factors affecting vulnerability.

The project also aimed to show the status of preparedness; highlighting the responsible authorities and measures that are in place to deal with the same.

METHOD

The statistics on natural disasters and their effects were sought for, mainly from the Botswana Central Statistics Office and the National Disaster Management Office.

Information outlining the responsible departments and the strategies they have in place to mitigate and deal with disasters was also obtained.

Progress reports on implementation of the Hyogo Framework for Action were obtained from the United Nations.

RESULTS

In 1993 the Botswana Government established a National Committee on Disaster Preparedness (NCDP). This followed the United Nations International Decade for reduction of natural Disasters. The NCDP had two main mandates, which were increasing coordination and also improving effectiveness of the management of natural disasters as well ensuring effective cost utilization in management of natural disasters.

However in 1996 the Government formulated a National Policy on Disaster management, after realizing that Botswana was vulnerable to other disasters and not just drought alone. Hence there was need to give equal focus to all disaster management elements (that is prevention, mitigation, preparedness, response and recovery). The Objectives of the policy were as follows:

- Establishing and maintaining systems to deal with all (actual and potential) disasters
- Integrating these systems into normal development activities at local and national levels
- Establishing a set of working definitions and outlining disaster management responsibilities
- Creating a framework that facilitates preparation of plans and legislation for effective implementation and legitimacy of the programmes for disaster management

In 1998, the National Disaster Management Office (NDMO) was established; this was put in the Office of the president having the overall responsibility of Managing disasters. Section 17 of the Constitution of Botswana grants the president powers to declare a state of emergency. This is
complemented by the Emergency Powers Act 22:04 which grant the president powers to make regulations, subject to approval by parliament, when a State of Emergency has been declared.

The NDMO ensures a nationwide state of disaster preparedness and capacity to deal with any eventuality. It also facilitates the integration of disaster management into the policies and programmes of different sectors.

Botswana takes the commitment to the HFA: 2005-2015 UNISDR seriously. And the official progress reports are summarised below (9):

**Priority 1 - Ensure that disaster risk reduction is a national and a local priority with a strong Institutional basis for implementation**

Table shows the level of progress achieved outlining the successes and the challenges faced in implementing priority 1

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sector strategies and plans available in the form of the National disaster risk management Plan of 2009</td>
<td>No DRR in development plans and strategies at National level</td>
</tr>
<tr>
<td>780 000 USD allocated to disaster proofing post disaster reconstruction</td>
<td>No common country assessments</td>
</tr>
<tr>
<td></td>
<td>No climate change policy and strategy 0% allocated from National budget and local Governments and also nothing for standalone DRR investments</td>
</tr>
<tr>
<td></td>
<td>No legislation in place</td>
</tr>
</tbody>
</table>

**Priority 2 - Identify, assess and monitor disaster risks and enhance early warnings**

Table shows the level of progress achieved outlining the successes and the challenges faced in implementing priority 2

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of National multi hazard risk assessment to inform planning and development decisions</td>
<td>There are no agreed national standards for multi hazard risk assessments</td>
</tr>
<tr>
<td>Disaster losses are systematically reported, monitored and analysed</td>
<td>There are no programmes and projects addressing trans – boundary issues</td>
</tr>
</tbody>
</table>
Risk prone communities receive timely and understandable warnings of impending hazard events | No action plans addressing trans-boundary issues

Local level preparedness with good communication systems and protocols

Regional and sub – regional strategies and frameworks as well as monitoring and reporting mechanisms

**Priority 3 - Use knowledge, innovation and education to build a culture of safety and resilience at all levels**

**Table shows the level of progress achieved outlining the successes and the challenges faced in implementing priority 3**

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public education campaign on DRR do reach risk prone communities</td>
<td>There is no National disaster information system that is publicly available</td>
</tr>
<tr>
<td>Public education campaigns and availability of information on DRR practices at community level</td>
<td>The DRR is not included in Primary and secondary school curricula, though it does feature in some programmes at University level</td>
</tr>
<tr>
<td>There is no funding, and no research programmes and projects nor studies on economic costs of DRR</td>
<td></td>
</tr>
</tbody>
</table>

**Priority 4 - Reduce the underlying risk factors**

**Table shows the level of progress achieved outlining the successes and the challenges faced in implementing priority 4**

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment in drainage infrastructure in flood prone areas</td>
<td>No investments to reduce the risk of vulnerable urban settlement</td>
</tr>
<tr>
<td>There is provision of safe land for low income households and communities</td>
<td>No slope stabilisation in landslide prone areas</td>
</tr>
</tbody>
</table>
There is assessment of impact projects such as dams, irrigation schemes, highways, mining etc on disaster risk

Priority 5 - Strengthen disaster preparedness for effective response at all levels

Table shows the level of progress achieved outlining the successes and the challenges faced in implementing priority 5

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is training and mock drills in schools and hospitals for emergency preparedness</td>
<td>There are no policies and programmes for school and hospital safety at local and national levels</td>
</tr>
<tr>
<td>There are contingency plans, procedures and resources to deal with major disasters</td>
<td>There are no catastrophe insurance facilities and catastrophe bonds</td>
</tr>
<tr>
<td>There are search and rescue teams as well as stockpiles of relief supplies</td>
<td></td>
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<tr>
<td>There are secure medical facilities with properly outlined triaging criteria</td>
<td></td>
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<tr>
<td>There is availability of trained human resources</td>
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</table>

DISCUSSION

Botswana has managed to lay a solid foundation that can be built upon in a bid to ensure disaster preparedness. Putting the NDMO in the Office of the President means everything can be coordinated by the highest office in the land. Routine progress reports given to show progress in implementing the HFA – UNISDR 2005-2015 show that the country is committed to meeting the requirements and creating a safer and more resilient nation to natural disasters.

The reports show that substantial achievements have been attained, though there are recognized limitations in some key areas most notably financial resources in budget allocations and operational capacities. The NDMO is under resourced and hence lacks the capacity to encourage active participation of other sectors such as the private sector and non – governmental organizations. The other challenge faced is that there is no specific legislation that supports implementation of disaster risk reduction in the country.

In 2008, The Government of Botswana did commission study on hazard vulnerability and risk identification, this went a long way in highlighting the actual and potential disaster threats
throughout the country. However this study only went as far as district and urban levels, and did not incorporate risk data at village and community levels (9).

The NDMO collects data on disaster impacts, with the help of District Management Committees. This data is further analysed by the Central Statistics Organization with the information disseminated throughout the country. However there is still lack of modern data collection and compilation systems

With regards to early warning systems for major disasters, the Meteorological services department works in conjunction with national Disaster Management Office to issue early warnings regularly to the communities. Apart from the main information broadcasters of television, radio and newspapers; mobile phone sms are also used to disseminate early warning information to subscribers of all the three networks (Mascom, Orange and Be-Mobile). The NDMO has also conducted nationwide campaigns on multiple hazards and vulnerability in different communities. District level Officials have also been trained in DRR and Emergency Management planning. However there has been a lack of tools to determine the effectiveness of such awareness campaigns (9).

CONCLUSION

Overall Botswana has built a good foundation that can be continually improved upon to build resilience towards natural disasters as well as reducing hazards and vulnerability; ultimately reducing the disaster risks. A sound post 2015 plan is also needed to consolidate the gains of the past decade, and improvements on funding of the NDMO projects and activities and putting up of legislation to empower and back up their activities will definitely take the country to new heights of disaster preparedness.
APPENDIX

1. Table showing the relationship between disaster risk, hazard, vulnerability and resilience

<table>
<thead>
<tr>
<th>HAZARD</th>
<th>VULNERABILITY</th>
<th>RESILIENCE</th>
<th>RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑</td>
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</tr>
</tbody>
</table>

Risk = [hazard X vulnerability/resilience]
2. Diagram A Showing picture of the performed self plagiarism check with http://smallseotools.com/plagiarism-checker/ and unique content percentage
3. Diagram B Showing picture of the performed self plagiarism check on Abstract
4. Diagram C Showing picture of the performed self plagiarism check on Introduction

![Plagiarism Check Results]

**Check for Plagiarism**

94% Unique Content

Results:
- Zimbabwe in the North East and Namibia
- Namibia in the West. Due to borders that did not have clear lines.
- of the borders, movement and hence chances of cross infection.
- a real danger. In 1995, there was an outbreak of the 
  *Contagious*
- in Namibia, this resulted in the eradication of 
  *tuberculosis.*
- million USD. Botswana has since put up laws.
5. Diagram D Showing picture of the performed self plagiarism check on Discussion
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A WORKSHOP ON LABORATORY QUALITY ASSURANCE – AN EVALUATION OF THE QUALITY OF CLINICAL TESTING USING HIV RAPID TESTING AS THE PORT OF ENTRY IN THREE HEALTH DISTRICTS IN SOUTH WEST REGION OF CAMEROON

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ACRONYMS
AFENET: African Field Epidemiology Network
AIDS: Acquired Immunodeficiency Syndrome
CDC: Centers for Disease Control and Prevention
DTS: Dried tube specimen
EQA: External Quality Assurance
FELTP: Field Epidemiology and Laboratory Training Program
GHSS: Global Health Systems Solutions
HIV: Human Immunodeficiency Virus
IHR: International Health Regulations
ISO: International Organization for Standards
NGO: Non-government organization
PT: Proficiency Testing
QA: Quality Assurance
BACKGROUND

As HIV rapid testing expands to non-laboratory settings, ensuring the quality and accuracy of HIV test results becomes more critical in HIV diagnosis, care and treatment. A number of tools to monitor and improve test accuracy such as hands-on workshop, liquid or dried tube specimen-based proficiency testing programs, retesting strategies, and supervisory visits have been implemented as part of a national quality assurance (QA) program in resource limited settings.

Dried Tube Specimen (DTS) is a QA tool which was developed by GAP/International laboratory Branch at CDC (Centers for Disease Control and Prevention) for monitoring and evaluating the quality of HIV testing in laboratories. It is especially adapted for use in resource limited countries because it is lyophilized and can be stored at room temperature for up to four weeks.

The standardized logbook was developed as an ongoing QA tool to monitor and evaluate the performance of the HIV testing sites, personnel competence, view testing trends and evaluate the different types of tests used. The goal of the logbook database is to capture all data from the monthly summaries and provide a detailed analysis that will identify key areas of improvement at the site, district, or national level.

INTRODUCTION

Quality Assurance involves all steps and procedures taken by the laboratory to ensure the reliability of results and that the results are achieved in a standard, reproducible and traceable manner. These steps are from the preparation and collection of specimens, reviewing transcriptional measures, using the most reliable assays, techniques used and the manipulation procedures, transcription as well as the delivery of test results.

Efficient and reliable laboratory services and networks are essential and fundamental components of effective, well-functioning health systems. High-quality laboratory testing is critical for patient care, prevention, disease surveillance, and outbreak investigations.

In sub-Saharan Africa, laboratory infrastructure and personnel are adversely affected by a lack of resources and prioritization, hampering laboratory systems in efforts to fulfill their important role in the fight against infectious and chronic diseases. As a result, the accessibility of laboratory testing and the quality of available services remains a serious challenge. It is therefore imperative
that laboratory systems be strengthened within broader efforts toward health system strengthening.

In an effort to continue strengthening laboratory systems in Cameroon, CDC/DGHA Cameroon with its implementing partner for laboratory activities, Global Health Systems Solutions (GHSS) intends to rolled out the Quality Assurance (QA) training in all health institutions within the national laboratory tiered system. In April 2009, CDC in collaboration with the Ministry of Public Health launched the Cameroon National External Quality Assessment Scheme (CAMNEQAS) for HIV rapid testing using the DTS method. 28 labs (14 Regional, 2 District, 2 blood banks, 4 private, 5 confessionals and 1 reference lab) are currently enrolled and actively participating in CAMNEQAS. About 300 lab staff had been trained on basic QA elements including the DTS method and use of a standardized logbook for recording HIV test results. It’s worth mentioning that AFENET (African Field Epidemiology Network) Uganda and Global Health Systems Solutions (GHSS) Cameroon are implementing DTS.

In November 2011, CDC in collaboration with GHSS launched CAMNEQAS for HIV rapid testing using the DTS method in the Far Northern region of Cameroon which has not been involved in the program since 2009. While launching CAMNEQAS in the far northern region, CDC and GHSS used the opportunity to roll-out DTS to some districts and integrated health centers in the Adamawa and the Northern region.

Owing to the improvements measured overtime the ministry plans to roll this out to the entire tiered system with support from CDC/GAP Cameroon and this began with labs in the Fako Health District in September 2012 and in June 2013 Kumba, Tombel and Ekondo Titi health district using HIV testing as a port of entry. This training was offered to head of facilities, laboratory personnel, nurses and midwives currently involved in HIV testing as it included; basic concepts of HIV serology, proper recording of results in a logbook and all participating labs were enrolled in the Cameroon National External Quality Assessment Scheme (CAMNEQAS), an HIV serology Proficiency Testing (PT) program that was launched in 2009 together with the use of the logbook as a Quality Assurance monitoring tool.

The training was held in Kumba and the participants from the other health districts had to come to Kumba. The Centers for Disease Control (CDC) through its implementing partner GHSS supported all the logistics for the training. This forum also served as an excellent opportunity for enhancing networking amongst laboratories and learning from each other’s experiences. The training session took place from the 18-20th June, 2012.

Fifty two (52) participants from Forty five (45) health facilities who were either head of facilities, laboratory staff, nurses or midwives participated in the training. For better understanding and support, the Chief Medical Officers or upper management and one or two health personnel involve in HIV rapid testing from each health facility were present to ensure sustainability and continuity.
OBJECTIVES

- To roll out the basic components of quality Assurance within the laboratories through a skill transfer workshop
- To acquire knowledge and skills to perform HIV Rapid Tests accurately, interpret and report results reliably in a safe and professional manner in an era of expanding programs

LITERATURE REVIEW

Laboratory is one of the core capacities that countries must develop for the implementation of the International Health Regulations (IHR [2005]) since laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of events. While developed countries easily adapt their well-organized routine laboratory services, resource-limited countries need considerable capacity building as many gaps still exist.

Sufficient laboratory capacity is essential to effective infectious disease surveillance and control. This is recognized in the current International Health Regulations (IHR), which identify laboratory services as a category of core capacities that all the World Health Organization (WHO) Member States are expected to develop and maintain. IHR Core Capacity 8 requires laboratory services for every phase of real-time event management (i.e. detection, investigation, and response), with sample analysis being performed either domestically or through collaboration centers. Laboratory services are considered a key component of national health systems, with the Integrated Disease Surveillance and Response (IDSR) utilizing the structures, processes and personnel of national clinical laboratory services for disease surveillance. However, laboratory services for both patient care and disease surveillance remain among the most neglected components of the overall health system in resource-poor countries. Challenges include lack of national laboratory policy and strategic planning, insufficient numbers of trained professionals, poor laboratory infrastructures, and absence of quality management systems.

In 2008, WHO and the US Centers for Disease Control and Prevention (CDC), Atlanta, USA, convened in Lyon, France, an international conference on laboratory quality systems. During that meeting, the need for accurate laboratory testing was stressed, with poor quality laboratory services in resource-constrained countries leading to untold misery in human lives and unnecessary expenditures due to inadequate treatment.

Eight key interventions were identified: (i) strengthening laboratory management at all levels; (ii) strengthening infrastructure and support systems; (iii) developing human capacity; (iv) establishing a national laboratory referral network; (v) establishing a national quality assurance program; (vi) developing a comprehensive monitoring system including laboratory information management system; (vii) coordinating government and partner support activities; and (vii) mobilizing resources to finance the strategic plan. The need to integrate networks that already exist – mostly those related to malaria, tuberculosis and HIV/AIDS – was also stressed.
In response to these calls, several international development partners have been implementing capacity building programs that include the training of laboratory personnel in epidemiology, microbiology and quality assurance.

The cost of carrying analytical measurement is high and additional costs may rise from decisions made on the basis of incorrect test results, therefore it is very important to determine the correct test results and to be able to show that they are actually correct. While developed countries have made a significant achievement in laboratory quality system, developing countries like Cameroon are still facing a lot of challenges in this area, as there are a lot of gaps in the whole process of laboratory quality systems. The workshop on basic concepts on quality assurance will assist in addressing these gaps. The aim is to ensure that the laboratories obtain the competence required to produce unquestionable results.

In today’s interconnected world, the risk of international spread of infectious diseases has greatly increased. This was well illustrated by the rapid spread of the recent influenza (H1N1) and severe acute respiratory syndrome (SARS) epidemics, where all continents were quickly threatened by an emergent pathogen in one corner of the world. The purpose of International Health Regulations (IHR [2005]) is to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Core capacity 8 of IHR (2005) obligates World Health Organization (WHO) Member States to establish mechanisms for providing reliable and timely laboratory identification and characterization of infectious agents and other hazards likely to cause public health emergencies of national and international concern, including shipment of specimens to the appropriate laboratories if necessary. Laboratory services therefore play a major role in all the key processes of the IHR, including detection, assessment, response, notification, and monitoring of events. Developed countries with well-organized routine laboratory services can easily meet this core capacity through existing systems. However, resource-limited countries, especially those in sub-Saharan Africa, need considerable capacity building. Attaining adequate capacities will require functional community, sub-national and national systems. Therefore, laboratory capacity building for IHR core capacity 8 must by necessity focus on strengthening the routine systems within which events are detected and reported.

For a long time, laboratory services were not considered a priority for most resource-limited health care systems in Africa, resulting in poor infrastructure, low human resource capacity and inappropriate technologies.

The need for building laboratory diagnostic capacity in Africa has been well articulated over the recent past. Consequently, there have been efforts to enhance laboratory capacity over the past five years in many sub-Saharan countries. These efforts have largely been driven by the need for
improved laboratory support to surveillance and treatment programs for specific diseases such as HIV/ AIDS, malaria, tuberculosis (TB) and avian influenza at national and a few regional centers. Indeed, a recent review by Olmsted et al (2010) suggests a general improvement in infrastructure and service provision. However, more challenges still exist, including the lack of sufficient numbers of well-trained laboratory scientists in public health service and inadequate laboratory management and leadership skills. There is no or limited distribution of available national laboratory guidelines and a lack of internal and external quality assurance systems, which is usually accompanied by low appreciation of quality control. No efforts have been made towards assisting laboratories to attain international standards such as ISO 15189 and hence slow progress to accreditation. Other challenges have been the poor quality, limited analysis and utilization of laboratory data; inconsistent and inadequate reagent supply chains; and lack of equipment maintenance.

The African Field Epidemiology Network (AFENET) is a coalition of Field Epidemiology Training Programs (FETPs) in Africa, initiated in 2005 out of a need to network and facilitate the strengthening of disease surveillance and public health responses to epidemics in the region.

LABORATORY QUALITY ASSURANCE: THE HIV EXTERNAL QUALITY ASSURANCE (EQA) PROGRAM

The unreliability of laboratory results is cited as one of the major limitations to laboratory support for health care in Africa. The utility of laboratory systems in the implementation of the IHR is also greatly dependent on the reliability and quality of laboratory results. However, applicable and cost-effective models for achieving accurate and reliable laboratory results in the low-income African countries have yet to be optimized.

One of the areas where external quality assurance (EQA) is critical is in the monitoring of the routine HIV rapid testing. Most countries in the region depend on re-testing as the primary means of monitoring the quality of HIV serologic testing. This approach is expensive, time-consuming and logistically challenging in decentralized settings. Traditionally, HIV external quality assurance programs use liquid serum or plasma specimens that require special cold storage and transportation conditions. The biohazard risks and costs of this approach have resulted in national quality assurance programs being weak, and consistent quality assurance is generally lacking in lower-tier laboratories.

The DTS is a cost-effective approach and is easy to prepare, stable at high temperatures and can be transported by mail to any part of the country. DTS panels are produced by the CDC reference laboratory assisted by GHSS staff and distributed to these sites on a quarterly basis through the postal services. After testing at the sites, the results are sent back to the reference laboratory for analysis and scoring. Feedback reports are generated and poorly performing sites are provided with support supervision visits and/or retraining. The project supports the mailing costs, data entry and laboratory scientists to provide technical backup.
Common problem areas include failing to follow national testing algorithms, not mastering proper pipetting technique, failing to follow DTS reconstitution procedures, new or untrained testing staff, and clerical errors in recording test results in both registers and PT report forms. Proper corrective actions, including on-site training and demonstrations, are taken.

Where resources are scarce and inequitably distributed, networking may reduce the gaps between different populations. WHO advocates for the establishment of national public health networks to ensure the timely exchange of information and the adequate support of laboratory services at all levels. At both the national and sub-national levels, only a few countries have functional public health laboratory networks in place.

**ACCREDITATION**

Accreditation is a means of certifying the competence of a laboratory to perform specific types of testing and it enhances customer confidence in accepting testing results. Medical laboratories are accredited by attaining requirements for quality and competency based on international standards, namely ISO 15189. Accredited laboratories therefore play a critical role in providing reliable information to inform IHR decision-making and guiding public health response. Currently, there are only 340 accredited laboratories in Africa and most of these belong to private sector or international research organizations. To address the paucity of accredited laboratories in the African region, the WHO Regional Office for Africa (WHO AFRO) established a stepwise approach for laboratories to attain the required standards. This approach supports laboratories at all levels through a series of evaluations using demonstrated improvements, which are recognized and rewarded for the progress.

To support this accreditation process, the Strengthening Laboratory Management Towards Accreditation (SLMTA) program — a training and mentoring toolkit for laboratory improvement and accreditation was developed. The purpose of the SLMTA trainings is to strengthen laboratory management for immediate and measurable laboratory improvement and to accelerate the process toward lab accreditation by WHO AFRO. Laboratory equipment maintenance and calibration is one of the key components of improving the quality of laboratory services, and is also critical in moving laboratories towards the stepwise WHO AFRO accreditation scheme. Additionally, quality equipment is essential to produce the valid and reliable laboratory results needed to inform decision-making in outbreak situations. The lack of working equipment has affected the effective delivery of health care in resource-poor settings. Often, laboratory equipment does not function properly because regular maintenance services are unavailable, particularly for ancillary equipment. AFENET, in collaboration with CDC and other partners such as Global Health Systems Solutions (GHSS), has organized training sessions to create a pool of local and regional biomedical engineers and equipment technicians able to meet the demands of laboratory equipment maintenance and calibration on a regular basis. This training creates regional capacity that reduces the costs of having the laboratory equipment serviced and calibrated.
Efforts to strengthen laboratory systems in the African region have received increased attention in recent years. In the 2008–2009 period, 6 landmark events were of particular significance for national health laboratory services. These events are described below:

1. January 2008 (Maputo, Mozambique): Thirty-three (33) countries—together with the World Health Organization (WHO), the World Bank, and the Global Fund for AIDS, Tuberculosis and Malaria—issued the Maputo Declaration to strengthen laboratory systems in developing countries. Meeting participants called on national governments to develop national laboratory policies and to provide laboratory support for diseases of public health importance; and they called on donors and development partners to commit to work collaboratively with each other and with coordination from national governments to strengthen laboratory systems.

2. April 2008 (Lyon, France): WHO and the US Centers for Disease Control and Prevention (CDC) issued a statement regarding laboratory quality systems, calling for countries with limited resources to consider a staged approach toward laboratory accreditation. It was suggested that national laboratory standards establish minimum requirements for all laboratories, although national reference laboratories were encouraged to meet international standards, such as ISO 15189.

3. September 2008 (Yaounde, Cameroon): During the 58th session of the Regional Committee, member states adopted the resolution AFR/RC58/R2, strengthening public health laboratories in the WHO African region, emphasizing the urgency to strengthen public health laboratories at all levels of the health care system in addition to requesting that the WHO Regional Office for Africa (AFRO) support member states to mobilize, access, and sustain resources to strengthen laboratory services.

4. September 2008 (Dakar, Senegal): At the fifth meeting of the Regional HIV/AIDS Network for Public Health Laboratories, it was agreed that the network should broaden its scope beyond HIV/AIDS and HIV/AIDS-associated diseases to become an integrated network encompassing all laboratories, without the limitation of a disease specific designation.

5. July 2009 (Kigali, Rwanda): WHO AFRO, in collaboration with the CDC, the Clinton Health Access Initiative, the American Society for Clinical Pathology, and other partners, launched a stepwise laboratory accreditation process in the presence of government health officials from 13 African countries. The WHO-AFRO accreditation process will recognize and encourage year-over-year progress toward fulfillment of the requirements of ISO 15189.

6. September 2009 (Kigali, Rwanda): During the 59th session of the Regional Committee, member states adopted the following resolutions: AFR/RC59/R2, drug resistance related to AIDS, tuberculosis, and malaria: issues, challenges, and the way forward; and AFR/RC59/WP/3, policy orientations on the establishment of centers of excellence for disease surveillance, public health laboratories, food, and medicines regulation. These
resolutions call for the strengthening of public health laboratories and other centers of excellence to improve disease prevention and control.

These meetings built consensus and focused critical attention on the call for systematic and standardized approaches for strengthening the African region’s national health laboratory systems and the attendant need for national and regional efforts to implement laboratory quality standards.

METHODS

The training workshop was scheduled for three days and the activities carried out are as described below.

Upon arrival at the training hall, there was the registration of the participants and a welcome address from the Hospital Directors. Participants were congratulated for honoring the invitation for the training and encouraged to concentrate and understand well the lessons, because they are going to help improve their services. This was then followed by an introduction of the participants and trainers, and later group photos. Next were the discussion of the goals and the objectives of the training workshop followed by a pre-training assessment.

An overview of assuring the quality of HIV testing and the key elements in quality assurance and the national algorithm was introduced, followed by an introduction to the logbook. The participants were given some exercises on rapid HIV testing for better understanding.

The following day, a summary of the previous day’s activities was given by one of the participants and clarification by the trainer where the participants had doubts followed by activities on how to enter data into logbook and a presentation on stock management and inventory. The DTS panels and its use in proficiency program were introduced to the participants and practical sessions followed thereafter characterized by reconstitution of the panels. Shipment forms were explained.

Day 3 started with a review of the previous day’s work. Next was the hands-on practical by testing the panels following the national algorithm with Determine for first line test and Immunocomb for second line test. The QA implementation and rollout plans were discussed. The training was conducted by GHSS staff. The training ended with a post training assessment, participants signed an engagement form to participate in EQA programs and filled feedbacks from the participants. The training ended at 2.pm with lunch. The questions of the pre/post tests are discussed by the trainer and participants.

RESULTS AND DISCUSSION

There were twenty five (25) questions in all and each scored one mark.
Table 1 Pre and post test performance scores of the Quality Assurance Training Workshop

<table>
<thead>
<tr>
<th>Participant Code</th>
<th>Pre-test Score</th>
<th>Post-test score</th>
<th>Score Increase</th>
<th>Participant Code</th>
<th>Pre-test Score</th>
<th>Post-test score</th>
<th>Score Increase</th>
</tr>
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<tbody>
<tr>
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<td>18</td>
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<td>18</td>
<td>19</td>
<td>1</td>
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</table>
Figure 1 Bar Chart comparing the pre and post test for participants A-Z

Figure 2 Bar Chart comparing the pre and post test for participants A1-Z1
Figure 3 A line graph showing increase score of participants A-Z

Figure 4 A line graph showing increase score for participants A1-Z1

From the bar chart above, for the pre test 35 (67.31%) participants had pass scores of 13 and above, 17 (32.69%) participants failed with scores below 13 and just 1 (1.92%) participant scored 20.

There was general improvement in the post test score with 47 (90.38%) participants having a pass mark of above 13, 20 (38.46%) participant scored 20 and above and 5 (9.62%) participants had a fail mark of 12 and below. 3 (5.77%) participants dropped in the post test from what they scored in the pre test.
With the general improvement in the post test, I can say that most of the participants actually understood the concept of Quality Assurance.

RECOMMENDATIONS

1. Follow-up and supervisory site visits should be conducted to the various health facilities to make sure what was learned during the training is being implemented.

2. Corrective actions for gaps that are noticed during supervisory visits should be discussed with the staff of the health facilities and give them a timeline to implement.

3. Make sure those sites that finally attain the desired quality outcome should be able to sustain it.

CONCLUSION

Detection, response, notification and monitoring of PHEICs are the key components of the IHR and all require robust laboratory support. Therefore, capacity building for the IHR must by necessity also focus on strengthening the routine laboratory systems within which events are detected and reported. GHSS is purposefully building capacity that runs through the entire laboratory structure from the lowest level to referral facilities by leveraging on the network approach. We believe this approach will build laboratory capacity at lower levels where these events usually occur, and thus ensure timely and adequate laboratory support. With adequate support, GHSS’s approach provides a logical, sustainable and strategic model with a multiplicative effect that can enable Cameroon a resource limited country attain and sustain the IHR laboratory capacity (core capacity 8).

If a test cannot be trusted then it has little value. Customers expect to trust the results reported, thus laboratory staff have a clear responsibility to justify the customer’s trust by providing the right answer which fits for purpose. For an analytical result to be fit for its intended purpose it must be sufficiently reliable that any decision based on it can be taken with confidence.

This training was timely for the rollout to the district level considering the non-conformances realized in conducting HIV testing in these health areas. If fully acceptable, then the logbook will be an effective QA tool to monitor and evaluate the quality of HIV testing in our laboratories. Participants must pass knowledge learned during training to their colleagues. Certificates will only be awarded to those who will put into practice what they learned during the training in their various health facilities.

Training fulfills requirements and supports the laboratory’s role in the provision of high quality health care services. Effective training ensures consistent and predictable staff performance which is fundamental to the delivery of quality laboratory services and optimal patient outcomes.
There is therefore the need for more Quality Assurance training for all health facilities in Cameroon.

PHOTOS

| Participants during the practical session at the training site | HIV Rapid Testing Logbook |

REFERENCES


THE MAGNITUDE AND FACTORS ASSOCIATED WITH ANTIRETROVIRAL THERAPY DEFAULTING IN MABUTSANE DISTRICT

Article Review by Ngeleza kasongo, Botswana
(Master in Public Health, Texila American University)
Email: - kasongomatthieu@gmail.com

ABSTRACT

BACKGROUND
This study sought to analyse the magnitude and factors associated with antiretroviral therapy defaulting using the patient electronic medical record system in Mabutsane health district.

OBJECTIVES
Objectives of the study are: to establish the factors associated with defaulting ARV and to analyse the outcomes of ARV defaulter.

METHODOLOGY
A retrospective cross-sectional survey was conducted. The target population for this research is adult clients on antiretroviral therapy registered in Mabutsane between December 2011 and December 2013. Descriptive statistics, x2 test and cross tabulation was used to analyse data.

RESULTS
Mabutsane clinic has a defaulter rate of 11.3%. More males (64.3%) defaulted treatment than females (35.7%). Majority 13 clients (92.9%) were on treatment for more than 1 year before defaulting.

Reasons for defaulting ART are as follow: Substances abused 42.9%, side effect of drugs 21.4%, Transport 14.3%, Work 14.3% and Religion 7.1%. Mortality rate among defaulter stand at 21.4%.

No significant statistic relation between social economic variables (sex, substances abused, marriage status, and employment status) and variable defaulter was found in our study.
CONCLUSIONS

Mabutsane health district has a lower defaulter rate as compared to most of the African countries; however this rate is above the Botswana one in 2013.

No significant association between social economic variables and defaulter was found.

Factors such as substances abused, work, transport etc…have been mentioned as reasons for defaulting.

Case fatality rate among defaulters was low than what was observed in most of the Sub Saharan Africa countries.

KEY WORDS

Mabutsane has a low defaulter rate.

INTRODUCTION

The study aims to inform the district of factors associated with patients defaulting ART in order to help improve systems and maintain patients in care for maximum benefit from the therapy.

THE SPECIFIC OBJECTIVES OF THE STUDY ARE

- To analyse ARV defaulter surveillance database in Mabutsane health district to identify the magnitude of ART defaulting between 2011 and 2013.
- To identify the factors associated with ART defaulting in the district
- To assess the outcomes of ART defaulting in the district
- To formulate recommendations to improve the situation in the district.

METHODOLOGY

RESEARCH DESIGN

A retrospective approach will be used to collect data on the rates of ART defaulters and factors associated with defaulting in Mabutsane health district over a two year period.

POPULATION

The target population for this research was the clients on HAART registered at Mabutsane clinic from December 2011 to December 2013.
RESEARCH SETTING

The study was be conducted at Mabutsane Infectious Disease Care Clinic (IDCC), which is an HIV clinic in a health district in Botswana. The clinic has both adults and paediatrics patients on treatment. Mabutsane, a health district in Botswana is one of the 27 health districts situated on the Kalahari basin and has a total population of 13,689 individuals according to 2011 census. The HIV prevalence in the district was 16.1% in 2009(1) (45) Mabutsane is a rural district that has 9 clinics and the main Mabutsane clinic started offering ART in 2007 before rolling out to the rest of the district. The district managed to roll out successfully ART to all clinics in the district. Many of the patients under Mabutsane Infectious Disease Control Clinic (IDCC) were transfers from the referral hospital which means many of them may have been on treatment from as early as the start of the national program in 2002. Unemployment rate in the district is very high and farming is the major activity for the local population. Alcohol intoxication is one of the biggest challenges in the district (46)

The Mabutsane IDCC operational since 2007 uses an electronic medical record system called PIMS (Patient Information Management System) and the data base has been operational since then. The electronic medical system allows clinicians to utilize it during consultation, lab requisitions, dispensing ART as well as scheduling. This means that the data base has all patient statistics as well as flagging those missing their follow ups, refills or those being lost to follow up.

SAMPLE AND SAMPLING TECHNIQUES

A simple random sample of patients will be selected from all adults (aged 18+ years) registered at the clinic between December 2011 and December 2013. The population is that of HIV positive individuals ever been on ART between the study periods at Mabutsane IDCC.

Clients will have an equal chance of being selected for the study.

There is a total of 853 who have ever been registered in the electronic data base. Currently there are 617 active patients on ART and the 19 are lost to care.

Using margin error (e) of 0.07, z score of 1.645(90%) and σ standard deviation of 0.5 our sample size will be: Sample size (n) = \( \frac{(Z\sigma)^2}{\text{error}^2} \) This gives n = \( \frac{(1.645*0.5)^2}{0.07^2} \) 3.7 = 124 patients (20% of the population)

DATA COLLECTION

The researcher will collect data from the PIMS data base for Mabutsane Health District and from patient personal file at Mabutsane IDCC.

A questionnaire will be used to collect data with the following data points
• Age and sex of the clients
• Employment status
• Level of education
• ART start date
• Time on HAART before defaulting
• Reasons of defaulting HAART
• Outcome of defaulter clients
• The data will be entered into an excel data base for analysis

DATA ANALYSIS AND INTERPRETATION

Descriptive statistics were used to describe the demographic situation and frequencies were also calculated for some variables.

Cross-tabulations and chi-squared test will be used at a significance level of 0.05 to test if there were any significant relation between social economic situation and defaulting HAART drugs. Excel and SPSS Statistical Packages for Social Science will be used to analyse data

ETHICAL CONSIDERATIONS

This study will be bound by all principles of ethics and will be approved by Texila America University Ethical Committee. Approval will be sort from the Human Research and Development Committee (HRDC) in the Ministry of Health of Botswana. Permission will also be sort from the District Health Management Team of Mabutsane health District to conduct the study.

There will be no direct contact with patients/study participants during the conduct of the study. De-identifiable information will be extracted from PIMS and patients personal files for the randomly selected sample. A master copy linking the PIMS identity and the study identity will be kept, password protected by the Investigator. The study data base (excel) will utilize only the study identifiers and no other person identifiers will be used. A waiver of consent will be sort from the HRDC in order to analyse de-identifiable data from patients registered at the clinic between 2011 and 2013.

CONFIDENTIALITY

Data will be collected using an anonymous questionnaire. No identifiers will be used which have a risk of linking the respondent
RESULTS

SOCIO-DEMOGRAPHIC AND SOCIO ECONOMIC CHARACTERISTICS

CLIENTS

<table>
<thead>
<tr>
<th>Variables</th>
<th>Category</th>
<th>Number of clients(n=124)</th>
<th>Percentages</th>
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<td>AGE</td>
<td>18-27</td>
<td>14</td>
<td>(11.2%)</td>
</tr>
<tr>
<td></td>
<td>28-37</td>
<td>42</td>
<td>(33.8%)</td>
</tr>
<tr>
<td></td>
<td>38-47</td>
<td>35</td>
<td>(28.2%)</td>
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<tr>
<td></td>
<td>48-57</td>
<td>23</td>
<td>(18.5%)</td>
</tr>
<tr>
<td></td>
<td>58-67</td>
<td>6</td>
<td>(4.8%)</td>
</tr>
<tr>
<td></td>
<td>&gt;67</td>
<td>4</td>
<td>(3.2%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>124</td>
<td></td>
</tr>
<tr>
<td>MEAN AGE</td>
<td></td>
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<tr>
<td>SEX</td>
<td>MALE</td>
<td>49</td>
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<td></td>
<td>FEMALE</td>
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<tr>
<td></td>
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<td>60</td>
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<tr>
<td>MARITAL STATUS</td>
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<td>57</td>
<td>46%</td>
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A total of 124 clients files reviewed for the study, the majority were females 75( 60.5%) and males 49(39.5%), On education status 50(40%) reached secondary school, and 33(26.6%) primary school. 46% of our clients were single and only 13.8% were formally married.

**CLINICAL AND BIOLOGICAL CHARACTERISTICS OF CLIENTS**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Category</th>
<th>Number of clients(n=124)</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 AT THE START OF HAART</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;200</td>
<td>57</td>
<td></td>
<td>46%</td>
</tr>
<tr>
<td>200-350</td>
<td>45</td>
<td></td>
<td>36.3%</td>
</tr>
<tr>
<td>350-500</td>
<td>8</td>
<td></td>
<td>6.5%</td>
</tr>
</tbody>
</table>
46% of clients had CD4 < 200 at the beginning of treatment and 3.2% had a CD4 > 500. Tuberculosis infection was the commonest opportunistic infection associated with HIV 8.9%, follows by herpes zoster and Pneumonia. Only 1 defaulter client had Tuberculosis.

**TIME ON ART BEFORE DEFAULTING TREATMENT**

13 clients (92.9%) were on treatment for more than 1 year before defaulting and only 1 (7.1%) client defaulted before 1 year of treatment.

**REASONS FOR DEFAULTING ART**

<table>
<thead>
<tr>
<th>REASONS</th>
<th>NUMBER</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Religion</td>
<td>1</td>
<td>7.1%</td>
</tr>
<tr>
<td>Substances abuse(alcohol and drugs)</td>
<td>6</td>
<td>42.9%</td>
</tr>
<tr>
<td>Transport</td>
<td>2</td>
<td>14.3%</td>
</tr>
<tr>
<td>Work</td>
<td>2</td>
<td>14.3%</td>
</tr>
<tr>
<td>side effect of drugs</td>
<td>3</td>
<td>21.4%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>
### MARITAL STATUS VS DEFAULTER

**DEFAULTER (ART ACCESS) * MARITAL STATUS CROSS TABULATION**

<table>
<thead>
<tr>
<th></th>
<th>Marital Status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single</td>
<td>Married</td>
</tr>
<tr>
<td><strong>Count</strong></td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td><strong>Expected Count</strong></td>
<td>12.1</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>95</td>
<td>15</td>
</tr>
<tr>
<td><strong>Expected Count</strong></td>
<td>94.9</td>
<td>15.1</td>
</tr>
<tr>
<td><strong>Count</strong></td>
<td>107</td>
<td>17</td>
</tr>
<tr>
<td><strong>Expected Count</strong></td>
<td>107.0</td>
<td>17.0</td>
</tr>
</tbody>
</table>

**CHI-SQUARE TESTS**

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Df</th>
<th>Asymp. Sig. (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
<th>Exact Sig. (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>.004a</td>
<td>1</td>
<td>.947</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity Correction</td>
<td>.000</td>
<td>1</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td>.004</td>
<td>1</td>
<td>.947</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fisher's Exact Test</td>
<td></td>
<td></td>
<td></td>
<td>1.000</td>
<td>.605</td>
</tr>
<tr>
<td>Linear-by-Linear Association</td>
<td>.004</td>
<td>1</td>
<td>.947</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
N of Valid Cases | 124

Marital Status

- Single: 66.7%
- Married: 13.3%

Cases weighted by Freq

Defaulter (ART Access)

- Yes: 31.3%
- No: 68.7%

Cases weighted by Freq
In the Marital Status variable, 86.3% were Single compared with 13.7% Married. Considering the Defaulter variable of the population under study, 76.6% of the Single category were non-defaulters, with 9.7% defaulters and 12.1% of the Married being non-defaulters with only 1.6% Defaulters, giving total defaulters of 11.3%. The data was analysed using the Chi-Square goodness of fit test. Since the difference was not significant ($\chi^2=0.004$, df=1, p=1.000), the null hypothesis was accepted.

**DISTANCE VS DEFAULTER**

**DEFAULTER (ART ACCESS) * DISTANCE CROSS TABULATION**

<table>
<thead>
<tr>
<th>Defaulter (ART Access)</th>
<th>Distance</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;=5km</td>
<td>&gt;5km</td>
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<tr>
<td>Yes</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td>Count</td>
<td>13.3</td>
<td>.7</td>
</tr>
<tr>
<td>Expected Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>105</td>
<td>5</td>
</tr>
<tr>
<td>Count</td>
<td>104.7</td>
<td>5.3</td>
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<tr>
<td>Expected Count</td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>118</td>
<td>6</td>
</tr>
</tbody>
</table>
### CHI-SQUARE TESTS

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymp. Sig. (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
<th>Exact Sig. (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>.182a</td>
<td>1</td>
<td>.670</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity Correction</td>
<td>.000</td>
<td>1</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td>.163</td>
<td>1</td>
<td>.687</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fisher's Exact Test</td>
<td>.163</td>
<td>1</td>
<td>.687</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linear-by-Linear</td>
<td>.180</td>
<td>1</td>
<td>.671</td>
<td></td>
<td>.520</td>
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<td>Association</td>
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<td>.520</td>
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<td>N of Valid Cases</td>
<td>124</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Distance**

- `<5km`
- `>5km`
Considering the variable Distance, 95.2% were within a distance of less than or equal to 5km compared with 4.8% who were more than 5km. The variable Defaulter (ART access) in the population under study showed that 10.5% were defaulters who were within 5km compared with 0.8% defaulters more than 5km, giving a total of 11.3% defaulters. The data was analysed using the Chi-Square goodness of fit test. Since the difference was not significant ($\chi^2=0.182$, df=1, $p=1.000$), the null hypothesis was accepted.

**GENDER VS DEFAULTER**

**DEFAULTER (ART ACCESS) * GENDER CROSS TABULATION**

<table>
<thead>
<tr>
<th></th>
<th>Gender</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Defaulter (ART Access)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Expected Count</td>
<td>5.5</td>
<td>8.5</td>
</tr>
<tr>
<td>No</td>
<td>40</td>
<td>70</td>
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</tbody>
</table>
### CHI-SQUARE TESTS

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymp. Sig. (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
<th>Exact Sig. (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>4.051a</td>
<td>1</td>
<td>.044</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity Correctionb</td>
<td>2.967</td>
<td>1</td>
<td>.085</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td>3.953</td>
<td>1</td>
<td>.047</td>
<td></td>
<td>.078</td>
</tr>
<tr>
<td>Fisher's Exact Test</td>
<td>3.953</td>
<td>1</td>
<td>.047</td>
<td></td>
<td>.044</td>
</tr>
<tr>
<td>Linear-by-Linear Association</td>
<td>4.018</td>
<td>1</td>
<td>.045</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N of Valid Cases</td>
<td>124</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5.53.
- b. Computed only for a 2x2 table
Considering the variable Gender, 60.5% were Female compared with 39.5% Male. The variable Defaulter (ART access) in the population under study showed that 7.3% were Male defaulters compared with 4.0% Female defaulters, giving a total of 11.3% defaulters. The data was analysed using the Chi-Square goodness of fit test. Since the difference was not significant ($\chi^2=4.051$, df=1, p=0.085), the null hypothesis was accepted.

**EMPLOYMENT STATUS VS DEFAULTER**

**DEFAULTER (ART ACCESS) * EMPLOYMENT CROSS TABULATION**

<table>
<thead>
<tr>
<th></th>
<th>Employment</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Employed</td>
<td>Non Employed</td>
</tr>
<tr>
<td>Defaulter (ART Access)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Count</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>7.2</td>
</tr>
<tr>
<td>No</td>
<td>Count</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>56.8</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>64</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>64.0</td>
</tr>
</tbody>
</table>

**CHI-SQUARE TESTS**

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>df</th>
<th>Asymp. Sig. (2-sided)</th>
<th>Exact Sig. (2-sided)</th>
<th>Exact Sig. (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Chi-Square</td>
<td>.193a</td>
<td>1</td>
<td>.660</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity Correction</td>
<td>.024</td>
<td>1</td>
<td>.876</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td>.194</td>
<td>1</td>
<td>.660</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fisher's Exact Test</td>
<td></td>
<td></td>
<td></td>
<td>.779</td>
<td>.439</td>
</tr>
</tbody>
</table>
Linear-by-Linear Association | .192 | 1 | .662
N of Valid Cases | 124

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.77.
b. Computed only for a 2x2 table
Considering the variable Employment, 51.6% were Employed compared with 48.4% Non-Employed. The variable Defaulter (ART access) in the population under study showed that 6.5% defaulters were employed compared with 4.8% Non-employed defaulters, giving a total of 11.3% defaulters. The data was analysed using the Chi-Square goodness of fit test. Since the difference was not significant ($\chi^2=0.193, df=1, p=0.876$), the null hypothesis was accepted.

**Substance Abuse Status vs Defaulter**

\[
\text{DEFAULTER (ART ACCESS) * SUBSTANCE_ABUSE CROSS TABULATION}
\]

<table>
<thead>
<tr>
<th></th>
<th>Substance_Abuse</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Defaulter (ART Access)</strong></td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Expected Count</td>
<td>6.1</td>
<td>7.9</td>
</tr>
<tr>
<td>No</td>
<td>48</td>
<td>62</td>
</tr>
<tr>
<td>Expected Count</td>
<td>47.9</td>
<td>62.1</td>
</tr>
</tbody>
</table>
### CHI-SQUARE TESTS

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Expected Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>54</td>
<td>70</td>
</tr>
</tbody>
</table>

**Substance Abuse**

- Yes: 56.5%
- No: 43.5%

**Defaulter (ART Access)**

- Yes: 11.3%
- No: 88.7%

Cases weighted by Freq
Considering the variable Substance Abuse, 56.5% were Non Abusers compared with 43.5% Abusers. The variable Defaulter (ART access) in the population under study showed that 6.5% defaulters were do not abuse substance compared with 4.8% Substance Abusers who are defaulters, giving a total of 11.3% defaulters. The data was analysed using the Chi-Square goodness of fit test. Since the difference was not significant ($\chi^2=0.003$, df=1, p=1.000), the null hypothesis was accepted.

**GENDER VS AGE BAR GRAPH (FREQ. DISTRIBUTION)**
More females than males are on ART treatment and females enrolled at early age than males and the picked of age is between 28-47 years

**GENDER VS AGE BAR GRAPH (% DISTRIBUTION)**

![Gender vs Age Bar Graph](image)

**DEFAULTER OUTCOMES GRAPH**

![Defaulter Outcomes Graph](image)
After follow up 71.4% clients were restarted on ART and 21.4% died.

**DISCUSSION**

Adherence to ART is the key for a successful treatment and survival of HIV patients on treatment.

Mabutsane ART clinic has a defaulter rate of 11.3% which is lower than what was recorded in Ethiopia 21.4 % (34).

A Nigeria study showed 36% of the study population defaulted treatment. (19)

However this rate is higher as compared to the Botswana national defaulter rate 7.345% (17)

Lower defaulter rate in our study in comparison to other studies conducted in Africa may be justified by the provision of antiretroviral treatment free through the public health service (14) and easy accessibility to ART services as all health facilities in this district are providing ART services.

More females than males were on ART treatment in our study and females started ART treatment at an early age as compared to males., but more males (64.3%) defaulted treatment than females (35.7%) this difference was not significant in our study.

This finding is in consistence with what was observed in Ethiopia, (56%) men and (44%) women respectively defaulted treatment.(34). And no association was observed between gender and adherence in Botswana study. (18)

The Majority 13 clients (92.9%) were on treatment for more than 1 year before defaulting this differed from the Ethiopian study where Akula addis found that for all lost to follow-ups the median time between start of ART and date of default was three months (34)

46% of client had a low starting CD4, bellow 200, and the mean cd4 was 206 this is high than what was found in Ethiopia.(34)

Tuberculosis was the most common opportunistic infection associated with HIV in our cohort but only 1 client out of 14 defaulters had Opportunistic infection; however these findings were inconsistence with findings in Cameroon. CDC stage B patients and specially CDC stage C patients had higher risk of pharmacy non-adherence than asymptomatic patients (36).

Reasons for defaulting ART in Mabutsane are as follow: Substances abused (alcohol and drugs) 42.9%, side effect of drugs 21.4%, Transport 14.3%, Work 14.3% and Religion 7.1%

But in the Nigeria study Major reasons for default includes: opting for spiritual/faith/alternative healing (8%), loss of interest in the programme/financial (7%), movement to home town of
origin (6%), changed address(5%), untraceable home address or name (5%), side effects of ART (2%), widowhood rites (1%).(19)

Joyce Kgatlwane et al ,2004 in semi- urban villages in Botswana reported that the most common reasons cited for missing medication were: forgetfulness (18%),costs and logistics (13%), work and home duties (12%), stigma (7%), lack of support (4%), lack of food (2%) and alcohol abuse (2%)(18)

The differences on the reasons for poor adherence with our study may be due to the fact that our work was done in a rural area with high unemployment rate were alcohol is the major entertainment.

The major activity here is farming; men have to migrate for work reason in hard to reach area.

13.7% of our clients were officially married other were either single or in a non-formal relationship, there was no significant association between marital status and ART defaulter in our study, this is in consistence with study in Ethiopia where 38% of clients were married but there was no significant relation between marital status and ART defaulter. (34)

Considering the variable Distance, 95.2% were within a distance of less than or equal to 5km compared with 4.8% who were more than 5km, but clients living near health facility defaulted more than those who are fare, the difference was not significant.

These findings are in consistence with the Ethiopian study of which 71.5% were within ≥5 km radius but the was no significant relation between variable distance and defaulter rate. (34)Distance to facility, and cost of transport do not have significant association with adherence(18)

51.6% were Employed as compared to with 48.4% Non-Employed and more defaulter observed among the employed as compared to the non-employed but the difference was not significant. These may be explained by the low level of education of most of employed clients which is also most comparable to the level of education of non-employed clients.

But Botswana study in 2004 found a significant association between employment status and adherence, suggesting that people who are employed are more likely to adhere to treatment.(18)

The mortality rate among defaulter clients in our study stand at 21.4%, and 71.4% were successfully traced and restarted on ART, In Nigeria, the study showed that18% had died while 46% were alive and well. A study from Malawi also demonstrated that 50% of the patients who had been lost had died. (19)

The difference with the Malawi study may be due to the fact that most our client started HAART with a high cd4 and took long on treatment before defaulting. (32)
CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Mabutsane health district has a lower defaulter rate as compared to most of the African countries; however this rate is above the Botswana one in 2013.

Increased access by scaling up ART services in the district has helped to improve the retention rate among client on ART in Mabutsane.

Despite increasing access defaulter phenomena remains a threat for the ART Program in Mabutsane and Botswana in general as it is associated with increased treatment failure, increased mortality etc.

No significant association between social economic variables and defaulter was found in our study due probably to small sample size of our population.

Factors such as substances abused, work, transport etc…have been mentioned as reasons for defaulting and might have a big impact on ART adherence in this district.

Most of defaulter successful restarted treatment, and case fatality rate among defaulters in our study was low than what was observed in most of the Sub Saharan Africa countries.

Improving living conditions in this district may help to reduced defaulter rate.

Addressing the major concerns of patients on treatment as well as effective patient tracing mechanisms to truck those defaulters constitute among the major intervention needs.

RECOMMENDATIONS

1. Improved follow up of patients on HAART by regular home visit and close monitoring of clients with poor adherence.

2. Improved record keeping by regular update of the register and regular feeding the computer system (PIMS ) with information.

3. Intensify anti-alcohol campaigns in the district through talk shows, mass education etc..

4. Government to improve living conditions in the district by creation of more jobs in partnership with the private sector.

5. Conducted another study with larger sample size, triangulation of data collection methods to improve the quality of data and comparison with an urban setting.
LIMITATIONS OF THE RESEARCH

This study was conducted in just one health district in Botswana which has a rural background. The sample size was small and no significant statistical association was found between variables. Limited data collected due to poor record keeping.

No qualitative analysis was done for this research due to limited data.

This research utilized one data collection approach and richer data could be obtained by triangulation of data collection methods.

REFERENCES

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9. DHAPC (Department of HIV/AIDS Prevention and Care) 2013

11. Etienne M et al. Effect of varying models of adherence support on lost to follow up rates; findings from 34 treatment facilities in eight resource limited countries. 4th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, abstract WEPEB101, Sydney, 2007.


16. Joyce Kgatwane et al. (2004). Factors that facilitate or constrain adherence to antiretroviral therapy among adults at four public health facilities in Botswana: a pre-intervention study


28. Predictors of adherence to antiretroviral therapy among people living with HIV/AIDS in resource-limited setting of southwest Ethiopia Ayele Tiyou1, Tefera Belachew2, Fisehaye Alemseged3 and Sibhatu Biadgilign3*

29. Patients Rougemont M, Stoll BE, Elia N, Ngang P: Antiretroviral treatment adherence and its determinants in Sub-Saharan Africa: a prospective study at Yaounde Central Hospital, Cameroon.AIDSResTher 2009, 6:21


34. (UNAIDS, 2009, NACA Botswana 2007,)

35. (UNAIDS, 2012, NACA Botswana 2010,)


38. WHO (2006, August) 'HIV treatment access reaches over 1 million in sub-Saharan Africa, WHO reports'


DIETARY DIVERSITY AND ITS EFFECT ON ANAEMIA PREVALENCE AMONGST TEA TRIBE ADOLESCENT GIRLS IN DIBRUGARH DISTRICT OF ASSAM, INDIA

Article Review by Tulika Goswami Mahanta, Bhupendra Narayan Mahanta, Pronab Gogoi, Jenita Baruah
Department of Community Medicine, Assam Medical College, Dibrugarh
Email: - drbnmahanta@gmail.com

ABSTRACT

OBJECTIVE

Effect of Dietary diversity and other intervention in prevalence and determinants of anaemia amongst tea tribe adolescent girls.

DESIGN

A community based before after intervention study was conducted covering 16 tea estates of Dibrugarh District, Assam.

PROCEDURE

Variables includes socio-demographic, environmental, anthropometry, history of present and past illness, clinical examination and laboratory investigation including haemoglobin, serum ferritin, haemoglobin typing and routine stool examination and dietary survey using 24 hour recall method and food frequency questionnaire. Interventions given were dietary diversification, health promotion by monthly NHED, cooking demonstration, cooking competition and kitchen garden promotion and counselling to improve IFA compliance and remove barriers and directly observed weekly IFA supplementation. SPSS and EpiInfo software, used to calculate of rates, ratios, chi-square test, Fisher Exact test and multiple logistic regression analysis.
RESULTS

Enrolments were 802, with mean age, 14.8 years. Anaemia prevalence was 96.3% with median serum ferritin, 22.9 ng/ml. Prevalence of Sickle cell anaemia was 12% and helminthiasis 84.20%, night blindness (5.6%), weakness (62.1%), loss of appetite (37.5%), gum bleeding (23.6%), loose motion (13%), loss of weight (9.9%), menstrual problem (19.3%) was common. Following intervention mean haemoglobin difference was 1.48 gm/dl with 13.5% difference in prevalence. Significant association found with worm infestation, lower serum ferritin, insanitary water-sanitation facility and extra salt use, indicating infection, infestation and iron deficiency as major cause of anaemia. Dietary diversification found effective.

CONCLUSIONS

High anaemia prevalence requires urgent attention. Implementation of different intervention in an integrated manner was found effective.

KEYWORDS

Dietary diversification, Anaemia, tea tribe, adolescent girls, Iron folic acid supplementation (IFA), Assam.

INTRODUCTION

Nutrition, an input and output of development, recognized internationally as, indicator of National development. [1] Malnutrition restrains growth and lowers resistance. [2] Anaemia, a “female disease” - red alert for Indian women affects productivity as evident that taller women in tea-estates as having greater arm circumference, plucks more green leaves earn higher wages with less absenteeism. [3, 4] Interventions on adolescent have intergenerational effect. [5, 6] Study revealed very high burden of communicable, non-communicable and nutritional disorders amongst tea-tribes. [7] AHS 2012-13, showed Assam is having highest MMR (301/ lakh live birth) of which upper Assam (401/ lakh live birth) constitute most. [8,9] This prompted us to assess effect of different interventions on anaemia.

MATERIALS AND METHODS

SETTING

Assam is the World’s largest tea growing region. More than 51% of India’s tea – accounting for 1/6th of global tea production – is grown in the tea estates, of the country’s north-eastern state of Assam. Most of the workers are descendants of tribal communities brought to Assam from neighbouring States by the British to work on the tea estates in early 20th century, who have retained their unique tribal socio-cultural identity. They live within the estates in designated settlements called ‘labour lines’. Tea community represents approximately 17% of Assam’s
population and 27% of Dibrugarh district. Dibrugarh District is selected as it has 159 registered tea estates contributing to 27% of Assam production.\[8\]

**ETHICAL STATEMENT**

The study protocol was approved by the Institutional Ethics Committee of Assam Medical College, and necessary permissions were obtained in addition from District Health Authority and Assam Branch of Indian Tea Association. After explaining study procedures, a written informed consent was sought from all eligible participants along with assent for inclusion of below 18 years participants, and those consenting were included in the study. In case a participants who could not read or write, verbal information was provided, and consent was recorded as a thumb impression in presence of two impartial witnesses. The surveys were preceded by meetings with community leaders to ensure community wide participation. All study participants found to be having morbidities were treated by Government supplied Medicine through sub centres situated in the tea estates.

**SAMPLE SIZE**

Considering 68% girls as anaemic, with 5% relative precision and 95% confidence interval the required minimum sample size is 723. Taking 10% non-response rate and rounding up the sample size becomes 800.\[9\]

**STUDY DESIGN**

It was a ‘community based before-after intervention study’. Multistage random sampling method was used for selection of study subjects. As the District has seven rural and one urban block having tea estates, therefore 16 tea estates were selected, two from each block using computerised random number. From each tea estates 50 adolescent’s girls aged between 10-19 years were selected using simple random sample from the list of adolescent girls maintained in each tea estates. Data collection was done by house to house survey. Demographic, socio economic, environmental history was taken along with clinical assessment. Reproductive tract infection was assessed by syndromic approach. Anaemia and related morbidities were assessed using predesigned, pretested schedule. Standard case definition for morbidity was used and a recall period of fifteen days was taken for morbidity assessment along with clinical examination.\[11\] Anthropometric measurements like weight and height measurements were converted into three standard indices i.e., height-for-age (stunting), body mass index BMI -for-age (thinness) and weight-for-age (underweight). Each of the three nutritional status indicators was expressed in standard deviation units (Z-scores) from the median of the reference population (The new WHO growth standard).\[12\]

Community based intervention was given by monthly nutritional health education program (NHED), quarterly healthy cooking demonstration to all selected girls and yearly cooking competition amongst different adolescents girls groups was done to encourage healthy cooking.
practices. The topics of NHED were decided based on baseline study and focus group discussion amongst adolescent girls. Non-compliant girls for WIFS were assessed by barrier analysis and common barriers identified were addressed. Creation of community owned kitchen garden and individual household kitchen garden was done with the help of tea garden management and local NGO and girls club to improve availability of different fruits and vegetables. Weekly iron folic acid supplementation (WIFS) as ongoing Government run program was continued, but given in a supervised way in the form of directly observed therapy, where a community volunteer from each tea estates were given the task with compliance monitoring. Dietary survey was done before and after two years of intervention by using food frequency questionnaire and 24 hour recall method.

Laboratory investigation - Haemoglobin estimation using cyan-meth-haemoglobin method for all consenting girls and serum ferritin using mini VIDUS enzymatic method and gel electrophoresis for haemoglobinopathy was conducted in a subgroup of population. Cross checking of 10% samples was done by ICMR laboratory for quality assurance.

All the equipment for measurements of height and weight were similar at all the centres for ensuring uniformity. Height was measured using stadiometer (accuracy 0.1cm) and weight using calibrated spring weighing machines (accuracy 0.1kg). Standard protocols were used to obtain these measurements. Body mass index [BMI] was calculated. Worm prevalence was assessed through stool examination in a subsample population (50%). Blood samples for Serum Ferritin was also done in 50%, first 50% of consecutive samples of those enrolled adolescent girls were examined for serum ferritin level. Haemoglobin cut off of less than 12 gm/dl was taken to label as anaemia. Total study period was from Sept 2011 to Dec 2013.

Statistical analysis was done using rates, ratios, proportion, chi-square test, Fisher Exact test, t-test and multiple regression using SPSS and EpiInfo software.

Study Design Showing Enrolment in Different Steps of Procedure
RESULTS

The mean age of the study participant was 14.8±2.3 years. Majority were Hindu (724, 90.3%) by religion. Literacy status among study participants was better (677, 84.4%) compared to their parents [father 442 (55.1%) and mother 170 (21.2)]. Some adolescent girls (140, 17.5%) were working in the tea estate as tea pluckers of which 132 (16.5%) were temporary workers, while 8 (1.0%) were permanent workers. Most of the parents of study population were permanent workers.

Baseline study

- Total Block 8 ➔ Total TEs 159 ➔ 2 TE per block (2x8= 16), Participant enrolled – 802
- Study variables – Socio demographic, stool examination, Hb typing, serum ferritin level.
- Methods – Quantitative – pretested format, qualitative – FGDs, IDIs.

Intervention study

- Monthly NHED,
- Quarterly cooking demonstration and
- Yearly cooking competition
- Kitchen garden promotion,
- Barrier analysis and intervention (n=130, 10% of non-compliant).
- Weekly iron folic Acid supplementation by directly observed treatment with compliance monitoring for all adolescent girls (n=7620)

End line study

- Total Block 8 ➔ Total TEs 159 ➔ 2 TE per block (2x8= 16), Participant enrolled – 802
- Study variables – Socio demographic, stool examination, sickling test, serum ferritin level.
- Methods – Quantitative – Pretested format.
of the tea estate with an average monthly income of Rs.2634. Average family size was six with a range of 2-18 people. (Table1)

Prevalence of anaemia was 96.3% (772/802) in baseline study. Pallor as physical examination finding was found in 61.3% (492/802). Lower ferritin level (< 20 mg/ml) was found in 39.2% (123/314) participants, while sickle cell anaemia was prevalent in 12% (38/316). Worm infestation by routine stool examination was found in 84.2% (314) participant. Regarding environmental health, only 205 (25.6%) adolescent girls were living in pucca house (solid and permanent structure), while 353(44%) were living in kutcha house (temporary houses) and 244(30.4%) living in kutcha-pucca house (combined variety) during baseline study. Access to own toilet was found in 648 (80.8%), while 9(1.1%) used public toilet and community / shared toilet use was 8(1.0%). Open air defecation was prevalent in 137(17.1%). The source of drinking water was shallow tube well 747(93.1%) in majority, followed by tap water 50(6.2%), kutcha well (temporary well with unsafe drinking water) 3(0.4%) and pucca well 2(0.2%). Boiling of water was done in 301(37.5%) and filtration in 32(4.0%). No purification of drinking water was done in 58.5% (469) before consumption. Kutcha latrine (temporary insanitary toilet) was situated within the cone of filtration in 319(39.80%) houses. Source of drinking water was accessible to domestic animal in 140 (17.50%) cases. Other contamination like dumping areas, stagnant waste water found in 454 (56.6%) houses. The waste water collection in the platform of water source was found in 649(82.2%). Drainage channel from water source was missing, damaged or blocked with debris in 652 (81.50%) houses. Regular bathing, washing of clothes and cooking utensils at the platform or near the water source was found in 755(94.30%) households. Overall mean haemoglobin level during baseline study was 9.71 ± 1.61 which was increased to 11.19 + 1.03 with a mean difference of 1.48 which was statistically significant (p=0.000). (Figure 1)

Symptoms related to anaemia and associated morbidities were present amongst 75.8% (608) adolescent girls and 59% (473) had past health related complaints. All signs and symptoms related to anaemia showed improvement after two years of different interventions (Figure 2).

Use of their own toilet facility, purification of water by boiling showed significant improvement in end line while compared with baseline study. Health complains like loss of appetite and weakness also showing improvement significantly. Present complain of any illness was also found significantly less during endline study. Prevalence of anaemia declined significantly with 13.5% reduction in endline compared to baseline study. Reproductive tract infection and worm infestation also showed significant improvement. Body mass index and height for age is also showing significant improvement. Serum ferritin level is also improving though the change is not statistically significant. The mean height and weight of the study participants was 146.2 ± 6.5 cm and 37.9± 6.5 kg BMI for age using Z score was normal i.e., between (-2SD) to (+ 2 SD) in 661 (82.4%), thinness below (-3 SD) was found in 30 (3.7%) participants, while 110 (13.7%) were between (-3SD) to -2SD). Only one girl (0.1%) was found overweight. According to height for age classification using Z – score; severe stunting was
documented amongst 243 (30.30%) and mild to moderate stunting was found in 157 (19.60%) participants. Only 50.1% (402) were having normal height for age. Comparison of baseline and end line assessment of body mass index and height for age showed improvement. There is significant improvement in water sanitation facilities in endline result compared to baseline study results. (Table 2)

Multiple logistic regression analysis using < 10gm / dl as cut off ( moderate and severe anaemia combined) showed significant association with worm infestation [ OR 3.2 (95% CI 1.8-5.71, p=0.000], lower serum ferritin [OR 2.02 (95% CI 13.72-53.24), p=0.000], insanitary water sanitation facility [OR 2.16 (95% CI 1.01- 4.6), p=0.046] and extra salt use [OR 1.85 (95% CI 1.38-2.46, p=0.000]. (Table 3).

Intervention in the form of nutrition health education program was designed based on findings of baseline study and focus group discussion. Key areas of concern emerged in baseline study was lack of knowledge regarding dietary requirement, healthy cooking practice, hand hygiene and menstrual hygiene, need for consuming safe water and basic sanitation, footwear while going to toilet and different food taboos like not taking any citrus and non-vegetarian food during menstruation, restriction of food during pregnancy and different illness, draining excess water while cooking rice- leading to loss of nutrient form rice, too much frying in open pan causing loss of iodine and other micronutrient and not taking fruits, vegetables, meat, fish, egg and milk due to lack of purchasing power. Low cost locally available nutritious diet was not perceived as good food. Based on these finding nutrition health education program was designed and conducted in each month including topics like hand washing demonstration, cooking demonstration, group discussion on infection prevention practices, training on dietary diversification, counseling on weekly iron folic acid consumption and compliance monitoring at a monthly interval, modular training on menstrual hygiene etc. Cooking competition was held to improve the healthy cooking practices amongst adolescent girls and the adolescent girls group in the form of adolescent club - created both community and individual kitchen garden for making vegetables and fruits available to the community. In- depth interview was done for barrier analysis amongst non –compliant adolescent girls. Ignorance about usefulness of iron folic acid tablet, fear of side effect, inconvenient time of IFA supply, distance of facility supplying IFA were found to be the common reasons for non-compliance. (Figure 3).

Following different interventions for dietary diversification like kitchen garden promotion, nutrition health education program, promotion of healthy cooking practices the consumption of fish, egg, all forms and different varieties of vegetable, soyabean and other lentil consumption showed significant improvement. Other healthy food consumption like fruits, dairy product also showed improvement though not significant. (Table 4).

Discussion: The response to this study was very good as all consented participated in the study. Prevalence of anaemia was almost universal (96.3% vs 82.8%) in baseline and end line study. According to National family health survey -3 reports, anaemia prevalence amongst adolescent
boys and girls aged 15 – 19 years is 30%. Compared to NFHS 3 report; our study finding reveals very high prevalence of anaemia which warrant urgent action to avoid preventable morbidities and mortalities. The District is having highest maternal mortality in Assam (430/lakh) and according to finding of maternal death review most of the death was occurring amongst tea garden population and anaemia and pregnancy induced hypertension was found as the leading cause of death amongst this group.[8] An earlier study has indicated that almost 96% of pregnant mothers and 100% of adolescent girls are anaemic (mild to severe); similarly 55% of mothers and 46% of girls are below BMI.[13] Dibrugarh, one of the 16 Districts surveyed by ICMR reports anaemia prevalence as 93.3% with 35.5% mildly anaemic, 49.9% moderately anaemic and 8.8% severely anaemic.[14] ICMR study reveals similar result with our study indicating that in Assam almost all adolescent girls are anaemic. Lower serum ferritin level indicates iron deficiency as the main cause of anaemia. Sickle cell anaemia is common amongst 12% of anaemic individuals. There is wide variation in expected range of values amongst normal female population varying from 9.3ng/ml to 159 ng/ml with a mean value 58 ng/ml. Mean value of serum ferritin in our study population was lower (27.9 vs 58 ng/ml) than the findings of reference population. A study done in urban slum also shows, family size, menstrual lost and bioavailable iron are influencing factor of low iron states.[15] Stool examination findings indicating high prevalence of soil transmitted helminthiasis (84.20%). Other studies; also shows high prevalence of helminthic infestations.[7,16,17] The association between poor housing, water supply and sanitation with occurrence of diarrhoea has already been documented.[18] The high prevalence of anaemia may be because of frequent occurrence of diarrhoea and high worm infestation related to poor housing condition and environmental sanitation. Another study done in adolescent girls living in slums of Ahmedabad shows significant association between fathers occupation, habit of tea consumption with food, habit of green leafy vegetable consumption and body mass index.[19] There is evidence of significant improvement in anaemia and associated factors like worm infestation, symptoms of reproductive tract infection, several symptoms of anaemia and other micronutrient malnutrition and environmental influencer following active intervention by giving nutrition health education program, different health promotional activities, kitchen garden promotion, cooking demonstration and holding of cooking competition amongst adolescent girls.

Mild to moderate stunting was prevalent in 19.3% and 30.6% (229) were having severe stunting. Higher prevalence of stunting amongst adolescent may be influenced by genetic as well as nutritional deficiencies indicating chronic malnutrition. District level household survey done in 2007-08 reported 20.8% girls getting married before 18 years of age.[19] Correction of nutrition during early years by 1000 days nutrition intervention and continuum of care may prove fruitful in such situation.[20]

Reproductive tract infection was found to be very common. White discharge, lower abdominal pain and ulcer were found as symptoms of RTI. Improvement of menstrual hygiene may reduce the prevalence of RTI. Higher prevalence of night blindness (5.7%) indicates the necessity of
screening of adolescent girls for vitamin A deficiency disorder and promotion of practice of dietary diversification. Goitre was found in 1.87% which indicates presence of iodine deficiency disorder and it was observed that some of them are still not using iodized salt and the salt preservation technique to prevent iodine evaporation was also found defective in few households.[21]

Nutritional anaemia is one of the major public health problems in India affecting almost 70% of children and 56% amongst ever married women.[22] There is convincing evidence that iron deficiency and anaemia causes impaired growth, developmental delay, decreased physical activity, behavioural abnormalities and impairs cognitive function (poorer attention span, memory, concentration and concept acquisition) leading to poor school performance.[23,24] Nutrition awareness and education are particularly giving importance for children and adolescents' to improve knowledge of anaemia, diet and health generally and of iron-rich foods specifically through different health and ICDS Schemes like celebration of village health and nutrition day, supplementary nutrition program i.e., supply of take home ration (THR) for adolescent girls and hot cooked food for children through Anganwadi centres and SABLA scheme for adolescent girls. Therefore, parents as well as children need to learn about nutrition in order to give appropriate information or advice to improve the diets of their children. The ICMR study also revealed high magnitude of under nutrition and infectious diseases among tea garden population of Assam. Their finding shows nutritional problems like underweight among children (59.9%), thinness among adults (69.8%) and micronutrient deficiency disorders like anaemia (72%) were widespread. Common infectious diseases were worm infestation (65.4%), respiratory problems (6.7%), diarrhoea (1.7%), skin infections, filariasis (0.6%) and pulmonary tuberculosis (11.7/000).[7] Poor nutrition among them also probably makes them vulnerable to infectious diseases and vice versa. Presence of household toilet was found to reduce orofecally-transmitted diseases, as also reported earlier.[25] However, high prevalence even among toilet holders may be because of contaminations of surroundings due to open field defecation by large numbers of other community members and poor maintenance of toilets facilities.

Multiple logistic regression analysis showed significant association of moderate and severe anaemia with worm infestation, lower serum ferritin, insanitary water-sanitation facility and extra salt use, indicating infection, infestation and iron deficiency as major cause of anaemia. Consumption of salty tea during work hours may be another cause of anaemia as tannic acid in tea is a known inhibitor of iron absorption. Anaemia is recognized to be public health problem and both nutritional (such as iron and other mineral and vitamin deficiencies) and non-nutritional (such as infection, infestation and haemoglobinopathies) factors contribute to the onset of anaemia and iron deficiencies.[26,27] Among variant haemoglobins, Haemoglobin E (Hb E) and sickle cell anaemia is widely prevalent in this part of the country. In South east Asia and the Indian Subcontinent, Hb E considered as common disorders of blood posing a major genetic and public health problem. [28,29] Haemoglobinopathy, particularly HbE and sickle cell haemoglobin (HbS) and thalassemia are considered to be the other contributing factor in occurrence of
anaemia in Assam and Hb S was reported to be mostly restricted to the tea garden community of Assam. The tribal population is vulnerable population, in terms of social development, isolating dwelling places in difficult terrain, rigid customs and beliefs, illiteracy and separation from non-tribal population exposes them to many health and social issues. In India, 8.19% population distributed in different states have tribal population.[30] Coverage target of key strategic Approach to Reproductive, Maternal, New-born, Child and Adolescent Health (RMNCH+A) in India needs to be holistically implemented where 6% decline in anaemia per year is proposed with weekly iron folic acid supplementation program (WIFS) and newer iron + initiatives so that from 53% (NFHS-3) to 30% prevalence could be achieved by 2017.[6] As prevalence amongst tea tribe adolescent girls was found higher than the national average more focus attention and better coverage is essential. Although evidence from robust randomized controlled trials is scarce, a range of interventions in the adolescent period affecting maternal, new-born, and child health and nutrition outcomes is available through different programs. Inequities in undernutrition also exist between the different demographic, socio-economic and geographic groups of India as evidenced from NFHS I, II & III data. More investment and better management of programs are needed to reduce malnutrition. Inadequate dietary intake and diseases are the most significant immediate causes of malnutrition which results from the unequal distribution of resources, food insecurity and inaccessibility of basic health services and healthy environment along with lack of nutritional knowledge.

Dietary diversification through different interventions like nutrition health education program, kitchen garden promotion to improve accessibility, cooking demonstration and competition to inculcate healthy cooking practices was found effective for the adolescent girls.

Applied and action research in the field of adolescent health is another area where lot remains to be done. Different intervention models, multi-sectoral and integrated approach with creation of good evidence base by proper documentation of successes have the potential to change the health and nutritional scenario of adolescent living in tea estates of Assam.

CONCLUSION

Dietary diversification in an integrated approach by community based intervention for prevention and correction of anaemia and related symptoms was found useful and operationally feasible. There is a need to sustain the effort by different means like community ownership which can be achieved by social and behaviour change communication and Government ownership by advocacy, for long term sustainability of the project.

REFERENCE


16. MOHFW; GOI; A Strategic Approach to Reproductive, Maternal, Newborn, Child and Adolescent Health(RMNCH+A) in India; January 2013; pg-12,


18. nrhmassam.info/DashBoard/md_index2.php; status of maternal death in Assam assessed in 17/09/13.


27. The Ministry of Tribal Affairs, Govt of India, Introduction; Scheduled Tribes; Statistics, Dec 2011; Registrar General of India. Percentage of scheduled caste and scheduled tribe population in district, villages and UAs/ Towns-India; Primary Census Abstract, Census of India.


Table 1: Socio-demographic information of the study participants

<table>
<thead>
<tr>
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<th>Number</th>
<th>Percentage</th>
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</tr>
<tr>
<td>10-12</td>
<td>149</td>
<td>18.6</td>
</tr>
<tr>
<td>13-15</td>
<td>343</td>
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<td>16-19</td>
<td>310</td>
<td>38.7</td>
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<td>Christian</td>
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<td>8.5</td>
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<td>Muslim</td>
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<td><strong>Caste</strong></td>
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<tr>
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<tr>
<td>High school</td>
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<tr>
<td>Above</td>
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<td><strong>Father education</strong></td>
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<tr>
<td>High school</td>
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<td>Above</td>
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Mother education

<table>
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<tr>
<th>Education Level</th>
<th>Count</th>
<th>Mean</th>
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<td>632</td>
<td>78.8</td>
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<tr>
<td>Primary school</td>
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<tr>
<td>Middle school</td>
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<td>5.4</td>
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<tr>
<td>High school</td>
<td>27</td>
<td>3.4</td>
</tr>
<tr>
<td>Above</td>
<td>4</td>
<td>0.5</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>1.6</td>
</tr>
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</table>

Figure 1: Comparison of mean haemoglobin level in studied tea estates before and after intervention
Figure 2: Before and after (baseline – end line) comparison of health complaints

Table 2: Comparison of different determinant of anaemia during baseline and endline study

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Endline</th>
<th>Change in % (Increase/Decreases)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toilet facility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Owned</td>
<td>80.8%</td>
<td>90.3%</td>
<td>9.5%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Open air defecation</td>
<td>17.1%</td>
<td>8.6%</td>
<td>-8.5%</td>
<td>0.1035</td>
</tr>
<tr>
<td>Public/community</td>
<td>2.1%</td>
<td>1.1%</td>
<td>-1.0%</td>
<td>0.860</td>
</tr>
<tr>
<td>Purified Water</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>None</td>
<td>58.5%</td>
<td>30.9%</td>
<td>-27.6%</td>
<td>&lt;0.0001</td>
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<td>Filtration</td>
<td>4.0%</td>
<td>8.6%</td>
<td>4.6%</td>
<td>0.4036</td>
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<td>Health complaints</td>
<td>Menstrual problem</td>
<td>23.0%</td>
<td>22.6%</td>
<td>-0.4%</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-------------------------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>Loss of weight</td>
<td></td>
<td>9.9%</td>
<td>8.6%</td>
<td>-1.3%</td>
</tr>
<tr>
<td>Loose motion</td>
<td></td>
<td>13.0%</td>
<td>5.9%</td>
<td>-7.1%</td>
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<tr>
<td>Gumbleeding</td>
<td></td>
<td>23.6%</td>
<td>20.6%</td>
<td>-3.0%</td>
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<tr>
<td>Loss of appetite</td>
<td></td>
<td>37.5%</td>
<td>15.3%</td>
<td>-22.2%</td>
</tr>
<tr>
<td>Weakness</td>
<td></td>
<td>62.1%</td>
<td>32.0%</td>
<td>-30.1%</td>
</tr>
<tr>
<td>Night blindness</td>
<td></td>
<td>5.6%</td>
<td>3.9%</td>
<td>-1.7%</td>
</tr>
<tr>
<td>Passage of worm in stool/mouth</td>
<td></td>
<td>9.1%</td>
<td>10.5%</td>
<td>1.4%</td>
</tr>
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<td>Present complaint at the time of visit</td>
<td>Yes</td>
<td>75.8%</td>
<td>59.9%</td>
<td>-15.9%</td>
</tr>
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<td>Anaemic prevalence</td>
<td>Normal</td>
<td>3.7%</td>
<td>17.2%</td>
<td>13.5%</td>
</tr>
<tr>
<td>Mild Anaemic</td>
<td></td>
<td>41.4%</td>
<td>74.4%</td>
<td>33.0%</td>
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<tr>
<td>Moderate Anaemic</td>
<td></td>
<td>49.4%</td>
<td>7.5%</td>
<td>-41.9%</td>
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<tr>
<td>Severe Anaemic</td>
<td></td>
<td>5.5%</td>
<td>0.9%</td>
<td>-4.6%</td>
</tr>
<tr>
<td>Prevalence of anaemia</td>
<td>Anaemic</td>
<td>96.3%</td>
<td>82.8%</td>
<td>-13.5%</td>
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<tr>
<td>RTI infection</td>
<td>Vaginal discharge</td>
<td>42.4%</td>
<td>14.6%</td>
<td>-27.8%</td>
</tr>
<tr>
<td>Lower abdominal pain</td>
<td></td>
<td>50.4%</td>
<td>29.0%</td>
<td>-21.4%</td>
</tr>
<tr>
<td>Any ulcer in perennial region</td>
<td></td>
<td>4.1%</td>
<td>1.7%</td>
<td>-2.4%</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>Serum ferritin level</td>
<td>BMI</td>
<td>Height for age</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------</td>
<td>----------------------</td>
<td>-----</td>
<td>---------------</td>
</tr>
<tr>
<td>Worms Infestation</td>
<td>84.2%</td>
<td>57.0%</td>
<td>-27.2%</td>
<td>&lt;0.000</td>
</tr>
<tr>
<td>Serum ferritin level &lt;30</td>
<td>59.2%</td>
<td>46.8%</td>
<td>-12.4%</td>
<td>0.0693</td>
</tr>
<tr>
<td>Serum ferritin level &gt;=30</td>
<td>40.8%</td>
<td>53.2%</td>
<td>12.4%</td>
<td>0.0763</td>
</tr>
<tr>
<td>BMI Normal</td>
<td>82.5%</td>
<td>88.4%</td>
<td>5.9%</td>
<td>0.0019</td>
</tr>
<tr>
<td>BMI Thin</td>
<td>13.7%</td>
<td>10.0%</td>
<td>-3.7%</td>
<td>0.4407</td>
</tr>
<tr>
<td>BMI Severe</td>
<td>3.7%</td>
<td>1.6%</td>
<td>-2.1%</td>
<td>0.7137</td>
</tr>
<tr>
<td>Height for age Normal</td>
<td>49.4%</td>
<td>57.7%</td>
<td>8.3%</td>
<td>0.015</td>
</tr>
<tr>
<td>Height for age Thin</td>
<td>19.7%</td>
<td>27.2%</td>
<td>7.5%</td>
<td>0.093</td>
</tr>
<tr>
<td>Height for age Severe</td>
<td>30.9%</td>
<td>15.1%</td>
<td>-15.8%</td>
<td>0.0011</td>
</tr>
<tr>
<td>Water sanitation facilities</td>
<td>latrine within 10 m of the water source</td>
<td>39.8%</td>
<td>38.9%</td>
<td>-0.9%</td>
</tr>
<tr>
<td>Water sanitation facilities</td>
<td>water is accessible to domestic animals</td>
<td>17.5%</td>
<td>32.6%</td>
<td>15.1%</td>
</tr>
<tr>
<td>Water sanitation facilities</td>
<td>Other contamination like dumping areas, drainage etc within 10 m radius</td>
<td>56.6%</td>
<td>31.2%</td>
<td>-25.4%</td>
</tr>
<tr>
<td>Waste water collection on the platform of water source.</td>
<td>82.2%</td>
<td>46.8%</td>
<td>-35.4%</td>
<td>0.0000</td>
</tr>
<tr>
<td>Drainage channel was missing, damaged or blocked with debris of households</td>
<td>81.5%</td>
<td>41.3%</td>
<td>-40.2%</td>
<td>0.0000</td>
</tr>
</tbody>
</table>
Regular bathing, washing of clothes and cooking utensils at the platform or near the water sources in of cases.

Table 3. Multiple logistic regression analysis of different determinants for moderate and severe anaemia

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
<th>PR (%)</th>
<th>OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Father Education Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High/above</td>
<td>147 (18.3)</td>
<td>73 (49.7)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>Middle</td>
<td>115 (14.3)</td>
<td>54 (47.0)</td>
<td>0.89 (0.55 - 1.46)</td>
<td>0.664</td>
</tr>
<tr>
<td>Primary</td>
<td>180 (22.4)</td>
<td>103 (57.2)</td>
<td>1.35 (0.87 - 2.10)</td>
<td>0.173</td>
</tr>
<tr>
<td>Illiterate</td>
<td>360 (44.9)</td>
<td>210 (58.3)</td>
<td>1.41 (0.96 - 2.08)</td>
<td>0.075</td>
</tr>
<tr>
<td>Mother Education Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High/above</td>
<td>44 (5.5)</td>
<td>19 (43.2)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>Middle</td>
<td>43 (5.4)</td>
<td>20 (46.5)</td>
<td>1.14 (0.49 - 2.66)</td>
<td>0.755</td>
</tr>
<tr>
<td>Primary</td>
<td>83 (10.3)</td>
<td>42 (50.6)</td>
<td>1.34 (0.64 - 2.81)</td>
<td>0.426</td>
</tr>
<tr>
<td>Illiterate</td>
<td>632 (78.8)</td>
<td>359 (56.8)</td>
<td>1.73 (0.93 - 3.20)</td>
<td>0.082</td>
</tr>
<tr>
<td>Toilet facility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Owned/community</td>
<td>665 (82.9)</td>
<td>372 (55.9)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>Open air defecation</td>
<td>137 (17.1)</td>
<td>68 (49.6)</td>
<td>0.77 (0.53 - 1.12)</td>
<td>0.178</td>
</tr>
<tr>
<td>Purified Water</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filtration/Boiling</td>
<td>333 (41.5)</td>
<td>172 (51.7)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>469 (58.5)</td>
<td>268 (57.1)</td>
<td>1.24 (0.94 - 1.65)</td>
<td>0.124</td>
</tr>
<tr>
<td>Present complaint at the time of visit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>194 (24.4)</td>
<td>115 (59.3)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>608 (75.8)</td>
<td>325 (53.5)</td>
<td>0.78 (0.56 - 1.09)</td>
<td>0.156</td>
</tr>
<tr>
<td>RTI infection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>368 (45.9)</td>
<td>203 (55.2)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Absent</td>
<td>Present</td>
<td>Odds Ratio (95% CI)</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------</td>
<td>-------------</td>
<td>-------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Worms Infestation (n=373)</td>
<td>Yes</td>
<td>434 (54.1)</td>
<td>237 (54.6)</td>
<td>0.97 (0.74 - 1.29)</td>
</tr>
<tr>
<td></td>
<td>Absent</td>
<td>59 (15.8)</td>
<td>22 (37.3)</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>314 (84.2)</td>
<td>206 (65.6)</td>
<td>3.20 (1.80 - 5.71)</td>
</tr>
<tr>
<td>Serum ferritin level (n=314)</td>
<td>&lt;30</td>
<td>186 (59.2)</td>
<td>137 (73.7)</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td>&gt;=30</td>
<td>128 (40.8)</td>
<td>12 (9.4)</td>
<td>2.02 (1.37 - 53.24)</td>
</tr>
<tr>
<td>BMI Normal</td>
<td>Yes</td>
<td>662 (82.5)</td>
<td>369 (55.7)</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td>Absent</td>
<td>110 (13.7)</td>
<td>52 (47.3)</td>
<td>1.37 (0.64 - 2.92)</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>30 (3.7)</td>
<td>19 (63.3)</td>
<td>0.71 (0.47 - 1.06)</td>
</tr>
<tr>
<td>Height for age Normal</td>
<td>Yes</td>
<td>396 (49.4)</td>
<td>228 (57.6)</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td>Absent</td>
<td>158 (19.7)</td>
<td>87 (55.1)</td>
<td>0.74 (0.54 - 1.03)</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>248 (30.9)</td>
<td>125 (50.4)</td>
<td>0.90 (0.62 - 1.30)</td>
</tr>
<tr>
<td>Water sanitation</td>
<td>Yes</td>
<td>30 (3.7)</td>
<td>11 (36.7)</td>
<td>Ref.</td>
</tr>
<tr>
<td>facilities</td>
<td>Absent</td>
<td>772 (96.3)</td>
<td>429 (55.6)</td>
<td>2.16 (1.01 - 4.60)</td>
</tr>
<tr>
<td>Extra Salt User No</td>
<td>Yes</td>
<td>469 (58.5)</td>
<td>228 (48.6)</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td>Absent</td>
<td>333 (41.5)</td>
<td>212 (63.7)</td>
<td>1.85 (1.38 - 2.46)</td>
</tr>
</tbody>
</table>

Figure 3: Barrier analysis- reasons for irregular intake of IFA supplementation
Table 4: Comparison of food consumption pattern during baseline and endline study.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Baseline (Average)</th>
<th>Endline (Average)</th>
<th>Mean difference (gm)</th>
<th>Std. Deviation</th>
<th>95% CI</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat (monthly in gm)</td>
<td>847.61</td>
<td>848.47</td>
<td>0.86</td>
<td>367.31</td>
<td>29.49 – 31.21</td>
<td>0.056</td>
<td>0.956</td>
</tr>
<tr>
<td>Fish (monthly in gm)</td>
<td>562.42</td>
<td>604.78</td>
<td>42.36</td>
<td>353.39</td>
<td>8.39 – 76.34</td>
<td>2.451</td>
<td>0.015</td>
</tr>
<tr>
<td>Egg (monthly in gm)</td>
<td>267.22</td>
<td>301.73</td>
<td>34.51</td>
<td>281.68</td>
<td>2.45 – 66.57</td>
<td>2.119</td>
<td>0.035</td>
</tr>
<tr>
<td>Rice (Daily in gm)</td>
<td>545.66</td>
<td>583.31</td>
<td>37.65</td>
<td>20.94</td>
<td>1.81 – 77.12</td>
<td>1.874</td>
<td>0.061</td>
</tr>
<tr>
<td>Refined milled grain (monthly in gm)</td>
<td>2483.81</td>
<td>2591.01</td>
<td>107.19</td>
<td>2134.68</td>
<td>152.49 – 366.88</td>
<td>0.813</td>
<td>0.417</td>
</tr>
<tr>
<td>Dairy product (monthly in gm)</td>
<td>423.33</td>
<td>454.21</td>
<td>30.88</td>
<td>715.86</td>
<td>109.72 – 171.49</td>
<td>0.0436</td>
<td>0.664</td>
</tr>
<tr>
<td>Deep fried food (monthly in gm)</td>
<td>471.93</td>
<td>504.77</td>
<td>32.83</td>
<td>363.65</td>
<td>30.51 – 96.19</td>
<td>1.026</td>
<td>0.307</td>
</tr>
<tr>
<td>Pickled veg. (monthly in gm)</td>
<td>118.86</td>
<td>178.38</td>
<td>59.51</td>
<td>317.46</td>
<td>23.19 – 95.82</td>
<td>3.225</td>
<td>0.001</td>
</tr>
<tr>
<td>Dessert/sweet (monthly in gm)</td>
<td>210.30</td>
<td>223.48</td>
<td>13.18</td>
<td>304.54</td>
<td>26.21 – 52.57</td>
<td>0.659</td>
<td>0.510</td>
</tr>
<tr>
<td>Category</td>
<td>Mean</td>
<td>Median</td>
<td>Mode</td>
<td>Minimum</td>
<td>Maximum</td>
<td>Standard Deviation</td>
<td>P-value</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>-------</td>
<td>-----------</td>
<td>-----------</td>
<td>--------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Soyabean (monthly in gm)</td>
<td>196.61</td>
<td>221.18</td>
<td>24.57</td>
<td>237.59</td>
<td>1.95 – 47.20</td>
<td>2.135</td>
<td>0.033</td>
</tr>
<tr>
<td>Legumes (monthly in gm)</td>
<td>415.63</td>
<td>503.18</td>
<td>87.54</td>
<td>409.95</td>
<td>46.83 – 128.25</td>
<td>4.228</td>
<td>0.000</td>
</tr>
<tr>
<td>Fruit (monthly in gm)</td>
<td>499.45</td>
<td>518.52</td>
<td>19.07</td>
<td>337.83</td>
<td>23.18 – 61.32</td>
<td>0.889</td>
<td>0.375</td>
</tr>
<tr>
<td>Leafy green vegetable (monthly in gm)</td>
<td>632.56</td>
<td>910.12</td>
<td>277.55</td>
<td>761.48</td>
<td>208.46 – 346.65</td>
<td>7.894</td>
<td>0.000</td>
</tr>
<tr>
<td>Other vegetable cooked (monthly in gm)</td>
<td>1324.92</td>
<td>2383.38</td>
<td>1058.45</td>
<td>2452.46</td>
<td>822.66 – 1294.2</td>
<td>8.824</td>
<td>0.000</td>
</tr>
</tbody>
</table>
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