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SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

PROCESS EVALUATION OF PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV PROGRAMME IN TAMALE TEACHING HOSPITAL

BY

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DECLARATION

I Mbabilla Christian hereby declare that this dissertation is the outcome of my own investigation under the supervision of Professor Moses Aikins towards the award of Master of Science Public Health Monitoring and Evaluation. Any other material information that was cited in the dissertation has been acknowledged and appropriately referenced.

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DEDICATION

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I dedicate this piece of work to the Almighty God, for his abundant grace and mercies throughout my life.

Also, to my late mother, Madam Rukayatu Ali and the family for the support throughout my academic journey.

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LIST OF ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency Syndrome
ADC	-	Aids Dementia Complex
ANC	-	Antenatal Care
ARVT	-	Antiretroviral Treatment
ART	-	Antiretroviral Therapy
AZT	-	Azidothymidine/ Zidovudine
ANOVA	-	Analysis of Variance
BCG	-	Bacillus Calmette-Guerin
COVID-19	-	Coronavirus Disease 19
CD4	-	Cluster of Differentiation 4
DNA-PCR	-	Deoxyribonucleic Acid-Polymerase Chain Reaction
EID	-	Early Infant Diagnosis
HIV	-	Human Immunodeficiency Virus
HTC	-	HIV Testing and Counselling
MTCT	-	Mother-To- Child Transmission
MSM	-	Men who have Sex with Men
NRTI	-	Nucleoside/tide Reverse Transcriptase Inhibitors
NNRTI	-	Non-Nucleoside Reverse Transcriptase Inhibitors
NACP	-	National Aids Control Programme
NVP	-	Nevirapine
OI	-	Opportunistic Infections
PMTCT	-	Prevention of Mother-To- Child Transmission
PEP	-	Post Exposure Prophylaxis
STDs	-	Sexually Transmitted Diseases
TDV	-	Tenofovir
UNICEF	-	United Nations International Children's Emergency Fund
UNFPA	-	United Nations Population Fund for Activities

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UNGASS	-	United Nations General Assembly Special Session UNAIDS
UNAIDS	-	United Nations Programme on HIV/AIDS
VCT	-	Voluntary Counselling and Testing
3TC	-	Lamivudine

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DEFINITION OF TERMS

Antiretroviral Therapy: These are combination of two or three HIV medicines to control HIV infection.

Adherence: Taking medication correctly as prescribed

Attrition: Individuals on antiretroviral treatment who are lost to follow-up or dead.

Discrimination: This is prejudicial treatment meted out to individuals with HIV infection.

DNA-PCR Test: An antibody test for infants exposed to HIV infection within 6 weeks after delivery.

Early Infant diagnosis: A DNA-PCR test to isolate viral nucleic acid in HIV-exposed infants

Loss to follow-up: When patients who were actively participating in treatment regimen drops out, a discontinuation of ART while still in the treatment.

Retention: The ability of individuals on ART to continue to receive treatment till the end of the period through to the follow-up period.

Stigma: This is a negative attitude and discrimination against a person with a particular disease

Vertical transmission: This is the transfer of HIV virus from HIV-infected mothers to their infants across the placenta during pregnancy, birth and after delivery during breast milk.

Prevention of Mother-to-Child Transmission: Series of health interventions aimed at reducing the risk of HIV transmission in women during their reproductive age and their children.

Zidovudine: Antiretroviral regimen to prevent Mother-to-Child transmission of HIV.

Nevirapine: Antiretroviral regimen to prevent Mother-to-Child transmission of HIV.

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ABSTRACT

Background: The prevalence of HIV epidemic across the globe is a major public health concern that affects the social and economic well-being of people. With almost 37 million people globally living with the pandemic, sub-Saharan Africa have witnessed the worst form of transmission of the epidemic and account for about 22 million people living with the disease, and a half million excess HIV–related deaths in the continent. This study assessed the implementation of the PMTCT Programme, and the challenges and barriers to the full implementation of the PMTCT Programme in Tamale Teaching Hospital.

Methods: The study was a cross-sectional descriptive study; that employed both quantitative and qualitative methods. A survey was conducted using a checklist with structured questions on PMTCT activities and implementation guidelines was administered to fifteen (n=15) PMTCT implementers. Analysis was conducted using Microsoft Excel 2016. An in-depth interview as guide was carried out on PMTCT implementers (n=10). The interviews were audio-taped and transcribed. Codes were created, the analysis was then written using themes and sub-themes.

Results: The study revealed a 97.4% of implemented activities for Prong one (1), 92% for Prong two (2), then 99% for Prong three (3) and 96% of PMTCT implemented activities for Prong four (4). PMTCT implementers in the facility also had some challenges serving as barriers to complete implementation. The barriers to implementation were explored in qualitative interviews. Stigma, socio-cultural factors, supply chain issues, delayed EID results and frequent breakdown of PCR machines were identified as major challenges to implementation.

Conclusions: The PMTCT Programme of activities for prong 1, 2 and 4 were, recorded 97.4%, 92% and 96% respectively, except Prong three (3) with 99% of PMTCT Programme activities were fully implemented. Stigma, socio-cultural factors, inadequate PCR machines, breakdown of

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PCR machines, delayed viral load and EID results were identified as challenges that affects delivery of PMTCT services in the Tamale Teaching Hospital.

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CHAPTER ONE

INTRODUCTION

1.1 Background

Human immunodeficiency virus (HIV) has become a human tragedy that has caused so much deleterious consequences to humanity. This and many other reasons influenced the need by the Sustainable Development Goals target of 3.3 to end the global impact of Acquired Immunodeficiency Syndrome (AIDS) by 2030 (Interagency Coalition on AIDS and Development, 2016). According to UNAIDS, (2021) about 37 million people worldwide are living with HIV, with an annual incidence of 2 million, and 680,000 mortalities from AIDS related illnesses. A study by Mofenson (2010) states that about 430,000 of children infected with HIV in 2008 were mainly through mother-to-child transmission during pregnancy and childbirth.

The mode of transmission and spread of HIV/AIDS is heterogeneous, with 95% of the global infections living in developing countries (Gayle & Hill, 2001). HIV/AIDS comes with a first wave of viral infection, followed by several months and years of opportunistic diseases, with a final wave of the AIDS illness and subsequently death. The impact of HIV/AIDS on global society and economies spans across various spheres of life. It is believed the effects and impacts of this epidemic could extend to the second half of the 21st century (UNAIDS, 2003). Global HIV epidemic among men who have sex with men (MSM) continues to increase in most countries including Africa. Epidemiological findings show the high probability of transmission per sexual act through anal intercourse, this confirms the disproportionate disease burden of HIV among men who have sex with men (Beyrer et al., 2012).

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The narrative of HIV in Africa has led to continual epidemiological and biomedical studies on the complexities of the epidemic in the continent over the past decades. That notwithstanding, Sub-Saharan Africa continues to be the center of HIV with rapid rise in infection rates, this accounts for 67 % (over 22.0 million) of all people living with HIV (Endris, 2008). The economic burden of HIV in Africa over the past decades has been enormous, causing the death of young adults between the ages of 15 to 49, in their productive years (Quinn, 1996). The effects of the epidemic in Africa is influenced by heterosexual transmission (David Gisselquist, 2003). The impact of HIV is gravely felt among young women of childbearing age who have an increased risk for acquiring the infection from their sexual partners. This explains the increased number of HIV transmissions among females compared to their male counterparts (Logan, 2014). Limited laboratory capacity, lack of medical supplies and frequent stock outs at the Health care facilities in Sub-Saharan Africa pose as operational challenges to the implementation of the PMTCT Programme (Aizire et al., 2013). The main challenges and barriers against testing for HIV status at the society level are stigma, discrimination, marginalization, and fear of rejection by society. Some and other testing experiences such as negative response to test request by health staff and breach of confidentiality especially testing more than one patient at a time and additional staff present (Meyerson et al., 2014). An analysis of the PMTCT national programme data in Ghana show that a third (33%) of HIV positive pregnant women in Volta and Northern regions did not receive ARVs by the end of 2013 (Dako-Gyeke et al.,2016). The non-availability of a PMTCT implementation research in the Tamale Teaching Hospital mimic research gap. Hence the adoption of a process evaluation of the PMTCT Programme, to identify operational challenges and determine the status of providing HIV treatment to pregnant women infected with HIV.

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According to the Conventions on the Elimination of All forms of Discrimination Against Women (1979) and the Convention on the Rights of the Child (1989), every woman has the right to have access to HIV testing and counselling, and to know their status while children have a right to survival, development and health status (UNICEF/UNAIDS/WHO/UNFPA, 2003).

Prevention of mother-to-child transmission (PMTCT) of HIV is an important programme aimed at eliminating the spread of the virus to children from conception to birth through the implementation of an effective antiretroviral prophylaxis regimen and modification of obstetric care aimed at minimizing infant exposure to infected blood transmission from mother (UNICEF et al., 2003).

The use and implementation of pre-exposure prophylaxis among HIV negative individuals is a new approach for suppressing, slowing and protecting against the spread of the virus. The adoption of the new approach has been slow in some countries but there has been promising results of providing high protection against HIV. Access and reaching the priority users has been one of the challenges especially at the provider and client levels (McMahon et al., 2014).

The PMTCT cascade is an essential service delivery tool comprising of steps and with integrated health interventions to improve on the health of women and to ensure the survival of infants from HIV. The PMTCT evolved as a tool to assist countries attain their national and global objectives and targets (Hamilton et al., 2017). To prevent the transmission of HIV from mother to baby, the World Health Organization (2007) promotes a comprehensive approach, which includes the following four components:

1. Primary prevention of HIV infection among women of childbearing age;
2. Preventing unintended pregnancies among women living with HIV;
3. Preventing HIV transmission from a woman living with HIV to her infant; and

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4. Providing appropriate treatment, care and support to mothers living with HIV and their children and families.

This PMTCT Strategic Vision 2010–2015 defines WHO's commitment to help countries achieve agreed international goals on PMTCT, increase access to quality PMTCT services and integrate these services with maternal, newborn and child health and sexual and reproductive health programme (WHO, 2010). Antiretroviral therapy has averted 2.5 million deaths in low- and middle-income countries globally. UNAIDS recently calculated that more than 350 000 children have avoided becoming newly infected with HIV since 1995 because of the antiretroviral prophylaxis provided to pregnant women living with HIV

1.2 Problem Statement

Global records show that adherence to ART under the PMTCT programme reduce pediatric HIV infections by 40% annually (Chi & Stringer). The adoption of PMTCT in Africa is meant to give a lifelong antiretroviral treatment (ART) for HIV- infected women with the aim to eliminate pediatric HIV/AIDS (Schouten et al., 2011). Ghana as a member of WHO nations adopted the use of prophylaxis regimens and PMTCT national scale-up plan from the period between 2011 and 2015. It is estimated that the prevalence of HIV infection among pregnant women in Ghana stands at 1.7%, and regional variations of HIV in the country show that Eastern region recorded the highest (4.2%) prevalence, followed by Ashanti region (3.9%). HIV testing for pregnant women has significantly increased from 4% in 2005 to 68 % in 2010 at the antenatal clinic (ANC) and about 75% of those infected has received antiretroviral treatment (ARVs) for PMTCT in 2011 (Situation et al., 2015). In Ghana, HIV prevalence among pregnant women attending antenatal care is 1.6 % (Laar et al., 2018).

Evidence of HIV transmission has been found in breast milk, this confirms that viral infection is

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found in breastfed infants of mothers who were negative during pregnancy and at delivery but later tested positive for HIV while breastfeeding. (UNICEF/UNAIDS/WHO/UNFPA, 2003). Identifying the early possible causes of MTCT is very critical since risk reduction during breastfeeding has not been much of a success (Health, 1999).

HIV/AIDS lowers the immunity of pregnant women, increasing risk of developing urinary tract infections. The virus causes maternal complications such as postpartum sepsis, premature rupture of membranes and preterm premature delivery of babies (Arab et al.). Women with HIV infection are 75% more likely to have spontaneous abortions, stillbirths, prematurity and neonatal death (Rollins et al., 2007)

About 66% of postpartum women who are kept on prolong antiretroviral therapy fail to retain their treatment after childbirth compared to 75% among pregnant women. They either miss out on their schedules or loses out to follow-up after childbirth (Sakyi et al., 2020). A study by Kerkerian et al. (2018) show that women infected with HIV were not likely to begin and adhere to their ART at each level of the PMTCT prongs. The attrition rate among women were very high compared to the male. Zhu et al., (2012) found that ART attrition can lead to premature morbidity, mortality and could affect HIV resistant drug variants.

PMTCT treatment services and ART to women and children have been very helpful in maintaining optimum CD4 counts among women and children (Gourlay et al., 2013). The PMTCT programme has increased access to antiretroviral drugs by pregnant mothers, this has led to significant reduction in MTCT of HIV (Resistance, 2017). Knowledge deficit of healthcare providers on PMTCT services, inadequate experienced HIV counsellors on PMTCT services and guidelines are major problems affecting the objectives of the WHO option B+ PMTCT guidelines. This study is a process evaluation of the PMTCT Programme which seeks to investigate and review the

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implementation process of the four pronged PMTCT Programme, to identify the implementation challenges and to give a feedback whether the programme was implemented as intended in the Tamale Teaching Hospital

1.3 Justification of the study

The study is a process evaluation that assesses how the PMTCT programme was implemented in Tamale Teaching Hospital. The PMTCT programme plays a pivotal role in health education on HIV/AIDS in Africa. An evaluation study by Rutenberg et al., (2003) show that the PMTCT programme offers more education and information to women on HIV testing, disclosing HIV status to their partners, families and prevention of HIV as part of PMTCT services. Effective implementation of the PMTCT programme will strengthen the public health advocacy towards elimination of MTCT in the Region and facility. This process evaluation study therefore assessed the status of the PMTCT programme, assess the barriers and challenges faced by the programme implementers in the Tamale Teaching Hospital. The study will not only track the progress of PMTCT implementation but will help influence decisions on healthcare delivery for women and children infected with HIV.

1.4 Research Questions

1) What is the status of primary prevention of HIV infection under the PMTCT in Tamale Teaching Hospital?

2) What is the status of prevention of unintended pregnancy among HIV- infected women in Tamale Teaching Hospital?

3) What is the status of prevention of HIV transmission from women infected with HIV to

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their infants in Tamale Teaching Hospital?

4) What is the status of providing treatment, care, and support given to women infected with HIV, their infants, and families in Tamale Teaching Hospital?

5) What are the barriers and challenges to the implementation of the PMTCT programme in the Tamale Teaching Hospital?

1.5 Study Objective

1.6 1.5.1 General Objective

The general objective is to assess the four prongs of the PMTCT implementation process in Tamale Teaching Hospital

1.5.2 Specific Objectives

The specific objectives of the study are:

1. To evaluate the primary prevention of HIV infection services offered to pregnant women in Tamale Teaching Hospital.
2. To evaluate the status of prevention of unintended pregnancy among HIV-infected women of HIV infection in the Tamale Teaching Hospital.
3. To assess the status of prevention of HIV transmission from women infected with HIV to their infants in the Tamale Teaching Hospital.
4. To evaluate the status of provision of treatment, care, and support to women infected with HIV, their infants, and their families.
5. To determine the barriers to the full implementation of the PMTCT in Tamale Teaching Hospital.

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CHAPTER TWO

LITERATURE REVIEW

2.0. Introduction

This section provides details of the review of relevant related literature from other scholarly works**.** This involved a review of knowledge from different sources entails series of sections that describe the structure of the HIV virus, epidemiology of HIV, brief description of HIV and AIDS in Ghana, the PMTCT Programme for women, an outline of the recommended ART for HIV, description of the PMTCT components, brief account of PMTCT in low and developing countries of Africa, and contribution of the PMTCT and its challenges. The conclusion part of this review gave an overview of the various scholarly works.

2.1 HIV

The human Immunodeficiency Virus is classified and grouped to the genus Lentivirus within the family of Retroviridae and a subfamily of Orthoretrovirinae. HIV is further grouped into the types HIV-1 and HIV-2. The genomic structure of HIV consists of two identical single-stranded RNA molecules that are enclosed with the core of the virus particle. HIV-1 and 2 can lead to AIDS if left untreated (Seitz, 2016). HIV-1 is the main agent of AIDS across the globe while HIV-2 is mainly in some parts of western and central Africa (Gigantesco & Giuliani, 2011). The existence and build-up of lifelong viral reservoir in the human brain and the symptoms of neurological dysfunction could exhibit AIDS dementia complex (ADC) clinical appearance, these are caused by the entry of the human immunodeficiency virus into the central nervous system (Aquaro et al., 2005). Advanced clinical stage of HIV leads to AIDS thereby causing the depletion of CD4+ T lymphocytes. The attack on cell-mediated immune system is associated with HIV-

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Induced immunosuppression causing Kaposi sarcoma, non-Hodgkin lymphoma and other opportunistic diseases because of the reduction in CD4+ counts (Engels & Goedert, 2005).

2.2 Epidemiology of HIV infection

A study by Gayle, (2000) indicates that over 95% of the global HIV/AIDS cases are in the developing world, with 10% from Africa, less than 1% in India and Europe and about 18.8 million people have died so far. More than 47 million adults and children have been infected with HIV since the beginning of the epidemic. HIV/AIDS epidemic is a global human tragedy affecting people especially in Sub-Saharan Africa and at-risk populations of the world.

Heterosexual sex (mainly a result of sexual attraction between male and female) has been identified as one of the main cause of HIV/AIDS (Arora et al., 2012). This contributes about three quarters of new HIV infections among heterosexuals (De Cock et al., 2012). The immediate source of MTCT of HIV is mostly through vertical transmission, in the uterus, through the birth canal at delivery and breastfeeding (UNICEF et al., 2003).

The rate of HIV infection also becomes high when the partner has sexually transmitted disease (STDs) (Pilcher et al., 2004). The large number of new HIV infections has been men who have sex with men. A study of 4295 HIV-negative men enrolled in the US shows that, men who has sex with men were at high risk of HIV infection, with greater risk associated with receptive intercourse (Koblin et al., 2006). A study by Beyrer et al., (2012) show a disproportionate HIV burden among men who have sex with men compared to heterosexual transmissions. The risk of intrapartum transmission during pregnancy is high for HIV-infected mothers who have not received antenatal antiretroviral therapy due to high viral load (Magder et al., 2005). The rate of postpartum transmission is increasing while antepartum and intrapartum is decreasing due to the availability of antiretroviral therapy. A study conducted in South Africa confirms that

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postpartum infections showed significant and substantial association with the risk of vertical transmission of HIV (Hoenigl et al., 2019).

2.3 HIV and AIDS Situation in Ghana

Ghana recorded its first HIV case in 1986, this was confirmed at the Noguchi Memorial Institute for Medical Research. This led to the creation of National AIDS/STI control programme (NACP) formerly the National Technical Committee on AIDS. The NACP plays a lead role as an agency working in tandem with other stakeholders to combat the HIV epidemic. Though the country has achieved significant progress in the fight against the epidemic, there has been challenges such as low ART coverage and high lost to follow-up for treatment (Addo et al., 2014).

HIV prevalence in Ghana is 1.6%, classified as low-level epidemic and disproportionally high among female sex workers and men who have sex with men (Ali et al., 2019). A 2019 HIV sentinel site report showed that HIV prevalence in ANC clients for 2019 was 2.0%, with 9 out of 16 regions recording a prevalence above the national median prevalence of 2.0% with Bono region recording the highest prevalence of HIV cases in Ghana for the year 2019 **(**HIV Sentinel Survey Report**,** 2019**)**. The annual report on National AIDS/STI Control Program, (2020) revealed that in 2018, an estimated that 334,713 were the number of people living with HIV/AIDS in the country, with 65% of females and 35% males .However, the newly infected persons were estimated to be 19,931 and with AIDS-related death recorded as 14,181.Statistics also shows that in 2018, 300,00 children aged between 10 to 14 years got infected with HIV, about 230,000 children became orphans because their parents through HIV/AIDS (Owusu, 2020)

Counselling, testing and knowledge of HIV remains the key interventions in the prevention

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and control of HIV/AIDS in Ghana though the level of HIV testing is still very low. A study conducted among undergraduate students in a public university showed that knowledge of HIV was very good but with very low HIV testing levels (Asante, 2013). People living with HIV in Ghana are often faced with stigma and discrimination. They face exclusion, abuse, and denial of care (Charles, 2015).

Testing for CD4+ count remains a very crucial component of detecting and treating HIV infection. Testing and reaching out for the transgender men and women has been very challenging because of behavioral risk factors such as stigma and other unique barriers. Transgender men and women are sometimes not sufficiently reached by current HIV testing measures due to transphobia and violence (WHO/UNDP, 2015). Increasing the number or proportion of HIV testing among populations such as the transgender help reduces stigma and other barriers to HIV testing and treatment (Pitasi et al., 2014). Creating a database of up for HIV testing and counselling remains the best approach to the fight against HIV (WHO Europe, 2010)

The inequities and inaccessibility to free testing, condoms and lubricants, and other basic prevention strategies for men who have sex with men remains a big challenge to detecting and treating HIV (Scheim et al., 2016). HIV testing remains a very crucial indicator in the steps towards the PMTCT. Studies done by Kieffer et al., (2011) indicates that pregnant women are more vulnerable to HIV infection. The risk of acquiring HIV is very high during pregnancy than in the postpartum period due to some hormonal changes that affects the immune system (Gray et al., 2005). According to Merson and colleagues, behavioral change interventions in high risk populations are very crucial and effective strategies in the prevention of HIV transmission in low and middle-income countries especially among female sex workers and their clients (Merson et al., 2000). HIV impacts on the reproductive health of women by causing lower fertility mainly as result of the virus, existence of opportunistic infection and

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other sexual transmitted infections especially when the use of contraceptives is very low (Fabiani et al.,).

2.4 Prevention of Mother-to-child Transmission of HIV

The PMTCT cascade involves series of steps used to increase the health of pregnant women and their infants. These steps are classified into four components pronged tool for evidence-based decision in the implementation of the PMTCT plans. These four prongs include; primary prevention of HIV, prevention of unintended pregnancy among HIV-infected women, prevention of HIV transmission, provision of treatment, care, and support to women, and their families (Hamilton et al., 2017). Prevention of mother-to-child transmission of HIV consist of four components with a package of health interventions which involves voluntary counselling and testing for pregnant women, ARV prophylaxis for pregnant women and children, infant feeding, and postnatal visits. The PMTCT programme is currently ongoing and implemented throughout Africa (Msellati, 2009). Difficulties in translating the PMTCT guidelines into useful messages and information for clients, deeply rooted socio-cultural practices and attitudes of counsellors are some challenges of the PMTCT programme in Ghana (Laar et al., 2014). Low HIV testing among pregnant women, negative perceptions, stigma impedes successful use of PMTCT services in most resource constraints countries such as Ghana (Dako-Gyeke et al., 2016).

The UN Four-pronged strategy for PMTCT addresses a broad range of HIV-related prevention interventions. These include, 1) Primary prevention of HIV infection, 2) Prevention of unintended pregnancy among HIV-infected women, 3) Prevention of HIV transmission from womeninfected with HIV to their infants, 4) Provision of treatment, care, and support to women infected with HIV, their infants, and their families (WHO,2007).

Children get infected with HIV through vertical transmission of the virus during delivery or

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breastfeeding. Globally, there has been a reduction of about 47% new HIV infections since 2010, and about 2 million infections prevented from 2000 to 2017 (Points, 2015). There are several interventions towards eliminating HIV among children but uninfected infants are increasing becoming exposed to HIV infection through their infected mothers, this has caused morbidity and impaired growth of infants (Christine et al, 2016).

2.5 Recommended antiretroviral Therapy for HIV

This consist a combination of three or more antiretroviral medicines that are used to enhance viral suppression among people infected with HIV. The ART is a lifelong treatment prescribed for people living with HIV (WHO, 2013). These recommended choice of ART are health intervention services that provides co-trimoxazole prophylaxis, reduces CD4 cell counts, achieving viral suppressing, nutritional support and boost the immune system against opportunistic diseases among people living with HIV (Dybul et al., 2002).

2.6 PMTCT Interventions

These consist of full package of integrated health interventions which is delivered for women in their reproductive age. The PMTCT Programme consist of four prong intervention strategy or components with the main aim to ensure primary prevention of HIV transmission among women in their reproductive age, prevent unintended pregnancy among HIV infected women, prevention of HIV transmission from women infected with HIV to their infants, and provision of treatment, care, and support to women infected with HIV, their infants, and their families. Notwithstanding the significant strides and progress made in reducing HIV transmissions and reuptake of antiretroviral treatments, evaluation of the PMTCT Programme interventions in Africa has identified certain inadequacies and deficits in areas such as ARV prophylaxis uptake, HIV testing, delays in receipt of HIV test results (Doherty et al., 2009).

2.7 Components/Prongs of the PMTCT Programme

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The PMTCT Programme was a strategic vision and commitment by WHO at the United Nations General Assembly Special Session (UNGASS) held in 2010 within the context of the MDGs as part of the measures towards elimination of MTCT of HIV (PMTCT UNGASS, 2010). The PMTCT Programme is a cascade that contains a full package of health interventions for women in their reproductive age towards the elimination of HIV infections among women and children.

The four components of the PMTCT Programme are discussed in the text below;

2.7.1 Component 1: Primary prevention of HIV infection

Primary prevention of HIV infection involves various methods at reducing the incidence and prevalence of HIV transmission to women before, during pregnancy and after delivery.

Preventing the transmission of HIV to women means that these women cannot vertically transmit the HIV infection to their infants. Providing access to PMTCT services delivery through voluntary counselling and testing services and educating women on HIV at the ANC is very critical in reducing the risk of maternal transmission of HIV (Thorne & Newell, 2004)

2.7.2 Component 2: Prevention of unintended pregnancy among HIV-infected women

HIV infected Women need counselling and support when making their choice of contraceptives as part of meeting their unmet family needs. This reduces unplanned pregnancies for women. Most importantly, prevention of unintended pregnancy especially among HIV-infected women in their reproductive period minimizes the risk of transmitting the HIV infection to their children (Plan, 2011).

2.7.3 Component 3: Prevention of HIV transmission from women infected with HIV to their infants

Prevention of MTC transmission of HIV involves services rendered to HIV infected women

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before pregnancy, during pregnancy and postpartum period. These are interventions offered to women infected with HIV in their reproductive period. The package of services includes; antiretroviral drugs for HIV-infected mothers to maintain some optimum level of health, viral suppression and prevent transmission of HIV to infants. PMTCT services aimed at preventing MTC transmission are; infant feeding, counselling and support services, safe delivery practices, testing for HIV antibodies immediately after birth, and initiation of ART initiation immediately after birth. Infants

are also tested at age 18 months and after breastfeeding (WHO, 2002). An evaluation study on

factors associated with vertical HIV-1 transmission by Da Rosa et al., (2015) and

Grinsztejn et al., (2018) shows that complete adherence to the antiretroviral during

pregnancy and after delivery significantly reduces maternal transmission of HIV.

2.7.4 Component 4: Provision of treatment, care, and support to women infected with HIV, their infants, and their families.

This involves a combination of health intervention and support services that are delivered and tailored to the needs of HIV-infected women, their infants and family to increase the health outcomes, improve the health status of mothers and children. These integrated health services consist of support for mothers during ART and breastfeeding. Other critical care and support services includes; prophylaxis for children born to HIV-infected mothers, efficient antenatal care, obstetric care, sexual and reproductive health care of HIV-infected women (WHO, 2007).

2.8 PMTCT in low developing countries and Africa

Low-and-middle income countries accounts for about 71% of global HIV infection (Kharsany & Karim, 2016). The burden of HIV adversely affects productivity and human resource development of these nations (Shao & Williamson, 2012). In sub-Saharan Africa, 60% of female live with HIV with 90% being children (UNAIDS, 2010). Vertical transmission, prolong membrane rupture and other invasive process are associated with mother-to-child

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transmission of HIV (Liu et al., 2017). The introduction of PMTCT services in sub-Saharan Africa has not only increased availability of health service delivery but increased access and utilization of ANC services, maternal and child health services thereby reducing mortality and morbidity (Mutabazi et al., 2017). However, sustaining these gains of the PMTCT Programme has been very difficult to maintain especially in facilities that lacks adequate medical supplies and capacity building on the requisite knowledge needed by the PMTCT implementers to deliver the full package of services under the PMTCT programme (Mutabazi et al., 2020). The implementation of PMTCT in Sub-Saharan Africa has led to significant reduction in the number of children living with HIV/AIDS. South African for instance, recorded a significant drop in pediatric HIV infections, reducing by 84% between 2009 and 2015 (Mnyani et al., 2020).

Despite the gender and socio-cultural dynamic issues that affects accessibility to PMTCT services in low-and-middle income countries, lack of proper data collection and reporting mechanisms makes it difficult to have a full picture of the HIV epidemic especially in Africa. Also, lack of sufficient investments in data collection and improving monitoring and evaluation issues causes under-reporting and under-representation of data on the PMTCT programme in Sub-Saharan Africa (Daku, 2013).

2.9 Challenges and Barriers Associated with PMTCT Services

HIV testing and counselling at the antenatal clinic remains very crucial to the prevention of MTCT of HIV. However, lack of awareness on the need for routine testing, inadequate health-care infrastructure and the lack of knowledge on the linkages between HIV and maternal and child health services affects PMTCT service coverage since many women living with HIV are not reached. The side-effects of ART could also lead to lack adherence to the treatment regimen since most women stop taking these drugs (USAID, 2016).

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The deplorable road network, poor transport system, lack of infrastructural health facilities and poor communication system adversely affects decision-making for PMTCT services (Skinner et al., 2005). A recent study by Samburu et al (2021) in Kenya reported that individual beliefs and attitudes, stigma, social issues and failure to disclose HIV status to health workers poses serious challenges on exclusive breastfeeding in the context of mother-to-child transmission of HIV. A study by Kimambo & Foundation, (2018) in Ethiopia identified the need for an improved privacy in counselling rooms, adequate HIV test kits, PMTCT guideline, drugs and medical supplies and refresher trainings for healthcare providers.

In Ghana, a study conducted among pregnant women aged 18 years and above who were attending ANC services at Bolgatanga Regional Hospital showed that inadequate supply of logistics and medicines, lack of male couple involvement, inadequate trained personnel and work overload were some of the barriers affecting smooth implementation of the PMTCT programme in the facility (Osei et al., 2016). Apart from fear of rejection by society, hatred, stigma and non-disclosure of HIV status, other problems affecting smooth implementation of the PMTCT programme, much has to do with the national policy guidelines of the PMTCT. Sometimes lack of commitment and coordination by leadership at the local, regional and national level affects the PMTCT programme (Balcha et al., 2011). Poor retention of ART treatment after delivery, under-utilization of PMTCT services and withdrawal of HIV treatments by pregnant women also affects the implementation process of the PMTCT programme (Etoori et al., 2018).

2.10 Contribution of PMTCT Programme

The PMTCT service to mothers and infants in preventing MTCT of has seen tremendous progress over the years. This has led to significant increase in the proportion of HIV-infected pregnant mothers receiving antiretroviral treatment for HIV. Despite the challenges, there has

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been an increase from 7% in 2004 11% in 2005. Also, the proportion of infants receiving antiretroviral treatment rose from 5% to 8% in 2004 and 2005 respectively (Luo et al., 2017).

One of the strategic vision of PMTCT programme was to help member countries attain the agreed PMTCT goals of increasing access to quality PMTCT services and to integrate these services with maternal, newborn, child health and sexual reproductive health (WHO, 2010). The PMTCT programme is a very complex and comprehensive package of services to pregnant mothers and their unborn children. As a result, poor skills, and lack of knowledge of some healthcare workers on the programme, affects the delivery of the full package of interventions for pregnant women and children (Aishat & Olubunmi, 2016).

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2.11 Conclusion

The literature for this study focused on areas of HIV infection such as; the epidemiology of HIV and its prevalence as a global epidemic, the situation of HIV and AIDS in Ghana, an overview of PMTCT and the four prongs, the existence of PMTCT in low developing countries and Africa. The literature also looked at the challenges associated with PMTCT as well as the contribution of the PMTCTC programme in low developing countries and Sub-Saharan Africa, with some elaboration on the success story of the PMTCT in Africa. Despite increasing accessibility and utilization of PMTCT services in Africa, lack of proper data collection systems, weak monitoring and evaluation of HIV programme have always led to improper reporting and tracking of progress made by the PMTCT programme.

The literature shows lack of awareness on the need for routine testing and lack of knowledge on the linkage between HIV and maternal and health services which affects utilization of the PMTCT services. A process evaluation of the four components of the PMTCT programme guidelines will determine how these barriers and knowledge gaps could affect the implementation process of the PMTCT program in Tamale Teaching Hospital.

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CHAPTER THREE

METHODS

3.1 Study design

This is a cross-sectional descriptive study, which used both quantitative and qualitative approaches. For quantitative method, a survey was conducted using a PMTCT Programme checklist containing structured questionnaires. These were administered to fifteen (15) PMTCT implementers and healthcare providers to assess the current implementation status of the PMTCT programme in Tamale Teaching Hospital. An in-depth interview was granted to ten (10) PMTCT implementers as guide to seek their views about the operational challenges and barriers to the implementation of the PMTCT national guidelines. The implementers were selected purposively; each implementer was granted a face-to-face interview to seek their views and narratives about the implementation and to support the quantitative data. Each of the PMTCT activities was reviewed and compared to current status of the PMTCT programme in the facility. Evidence The study was conducted in five units or clinical wards in Tamale Teaching Hospital.

3.2 Study location

Tamale Teaching Hospital is in Tamale, the capital city of Northern Region of Ghana. Tamale shares boundaries to the south with Yendi municipality, to the North with Savelugu municipal, to the East with Tolon municipal and to the west with Gushegu, Nanton and Karaga Districts. Tamale Teaching Hospital was established in 1974 under Act 525 of the Ghana Health Service Act of 1996 to provide various healthcare services in Northern and the upper regions. It has a total land area of 490,000 m². The portion that has been developed is 122,000 m². Formerly known as Tamale Regional Hospital, the hospital was upgraded to a

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teaching hospital in 2005 under ACT 525 of the Teaching Hospital Act of 1996 help train medical doctors from the University for Development Studies. The hospital delivers tertiary health services to Tamale and the entire five regions of the North. These tertiary services include prevention of Mother-to-Child transmission of HIV. The facility also adopted the initiative to assist the Ministry of Health in its quest to implement the WHO option B+ towards reducing mortalities associated with MTCT of HIV. It is therefore crucial to embark on a process evaluation study of the PMTCT Programme to understand the status of implementation. Hence the adoption of the Tamale Teaching Hospital as the study site.

3.3 Study population

The study was conducted within a population involving PMTCT implementers such as; HIV/STI resource persons, family planning resource persons, nurses, midwives, who were part of the implementation process from the antenatal clinic, HIV/STI unit, family planning units, maternity, and labor unit. The study focused on the implementers of the PMTCT Programme in the facility. This also sought to identify the status of implementation of the PMTCT and to seek the views of implementers on the operational challenges

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3.4 Inclusion Criteria

The study recruited participants working as HIV/STI service providers, nurses and midwives who delivers PMTCT services and work in the following units or department; 1) HIV/STI unit, 2) Family planning unit, 3) Antenatal clinic, 4) Maternity/Postnatal, 5) Labour unit. Healthcare workers who were part of the PMTCT implementation programme in the facility were included in the study. Also, PMTCT implementers who were present at work on the day of the interview were recruited. Implementers gave their consent before granting interview

3.5 Exclusion Criteria

Healthcare providers working in the selected units who were not part of the PMTCT implementers were excluded. PMTCT implementers who were absent on the day of the interview were excluded. Participants who were not part of the PMTCT implementation process were also excluded.

PMTCT implementers without legal consent and who could not provide their consent to partake in the investigation were exempted.

3.6 Description of study Variables

The PMTCT activities were classified as independent variables. The outcome variable was classified as the implementation status of the PMTCT programme. The main variables to be measured were the activities under each of the four-pronged components of the PMTCT programme. Table 1 show the description of the variables for the study

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Table 1: Study Variable

Variable	Classification	Scale of Measurement
Prevention of HIV infection	Independent (Categorical)	No….0 Yes……1
HIV testing and counselling	Independent (Categorical)	No….0 Yes……1
HIV transmission and prevention	Independent (Categorical)	No….0 Yes……1
Informed consent	Independent (Categorical)	No….0 Yes……1
Information on HIV and AIDS	Independent (Categorical)	No….0 Yes……1
Training of healthcare providers on PMTCT services	Independent (Categorical)	No….0 Yes……1
HIV testing processes	Independent (Categorical)	No….0 Yes……1
Discuss meaning of test results	Independent (Categorical)	No….0 Yes…….1
Maintaining Confidentiality	Independent (Categorical)	No….0 Yes……1
Supportive HIV services	Independent (Categorical)	No….0 Yes……1
MTCT and prevention services	Independent (Categorical)	No….0 Yes……1
STI education and screening	Independent (Categorical)	No….0 Yes……1
Explain the benefits of PMTCT services and HIV test results	Independent (Categorical)	No….0 Yes……1
Nurses and midwives monitor pregnant women with partograph	Independent (Categorical)	No….0 Yes……1
Availability of counselling services	Independent (Categorical)	No….0 Yes……1

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Disclosure and partner testing	Independent (Categorical)	No….0 Yes……1
Access to PMTCT services	Independent (Categorical)	No….0 Yes……1
Encouraging partners to test for HIV	Independent (Categorical)	No….0 Yes……1
Counselling on HIV Positive test results	Independent (Categorical)	No….0 Yes……1
Discussing and support for initiation of ARV for mothers and prophylaxis for infants	Independent (Categorical)	No….0 Yes……1
Prevention of unintended Pregnancies among HIV-infected women		
Family planning counselling	Independent (Categorical)	No….0 Yes……1
HIV testing and counselling	Independent (Categorical)	No….0 Yes……1
Family planning services	Independent (Categorical)	No….0 Yes……1
Family planning commodities	Independent (Categorical)	No….0 Yes……1
Safer sex practices	Independent (Categorical)	No….0 Yes……1
Prevention of HIV transmission from HIV-infected women to their infants		
Antenatal care and delivery	Independent (Categorical)	No….0 Yes……1
HIV retesting and counselling in late pregnancy	Independent (Categorical)	No….0 Yes……1
Giving ART to pregnant women	Independent (Categorical)	No….0 Yes……1
Exclusive breastfeeding	Independent (Categorical)	No….0 Yes……1

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Administering ART according the national guidelines	Independent (Categorical)	No….0 Yes……1
Treatment with ARVs initiated as soon as possible	Independent (Categorical)	No….0 Yes……1
Encourage pregnant women to visit ANC	Independent (Categorical)	
Elective caesarean section for pregnant women, when indicated and where safe and feasible	Independent (Categorical)	No….0 Yes……1
Observe Safer delivery practices	Independent (Categorical)	No….0 Yes……1
Use of partograph to monitor labor/delivery	Independent (Categorical)	No….0 Yes……1
Safe blood transfusion	Independent (Categorical)	No….0 Yes……1
Post Exposure prophylaxis	Independent (Categorical)	No….0 Yes……1
Infection prevention methods during labour and after delivery	Independent (Categorical)	No….0 Yes……1
Measures to avoid prolong labour	Independent (Categorical)	No….0 Yes……1
Provision of treatment, care, and support to women infected with HIV, their infants, and families		
ART for HIV-infected women	Independent (Categorical	No….0 Yes……1
ARV prophylaxis for HIV-exposed infants eg (Zidovudine, Nevirapine, Cotrimoxazole)	Independent (Categorical)	No….0 Yes……1
Infant-feeding counselling and support for safer feeding practice	Independent (Categorical)	No….0 Yes……1
Nutritional care and support	Independent (Categorical)	No….0 Yes……1
Routine Immunization	Independent (Categorical)	No….0 Yes……1

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Prophylaxis for opportunistic diseases	Independent (Categorical)	No….0 Yes……1
Infection prevention practices during labor	Independent (Categorical)	No….0 Yes……1
DNA-PCR test for HIV-exposed at infants 6 weeks after birth	Independent (Categorical)	No….0 Yes……1
Recording and reporting all PMTCT activities	Independent (Categorical)	No….0 Yes……1
Challenges with Programme Implementation	Independent (Categorical)	No….0 Yes……1
PMTCT Programme	Independent (Descriptive)	Subjective
Insufficient medicines and logistics	Independent (Categorical)	Subjective
Inadequate training of healthcare providers on PMTCT services	Independent (Categorical)	Subjective
Implementation process	Independent (Descriptive)	Subjective
PMTCT services delivery at Facility	Independent (Descriptive)	Subjective

3.7 Sample Size Determination

Purposive sampling method was employed to select three (3) HIV/STI resource personnel, three (3) PMTCT implementers or staff delivering PMTCT services from antenatal unit, three (3) midwives from Postnatal/maternity units, three (3) healthcare providers from HIV/STI, three (3) from labour ward, three (3) from the family planning unit. A total of 15 units was selected for the study in the facility

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3.8 Data Collection Techniques

Data collection involved a PMTCT checklist consisting the original PMTCT implementation processes were reviewed and compared with current status of the PMTCT programme at the facility. In-depth interviews were conducted among 15 PMTCT implementers. Face-to-face interviews was granted to PMTCT implementers in the facility. All relevant documents and guidelines to the PMTCT policy were collected and reviewed.

3.9 Quality Control/Assurance

To ensure a good research study, two research assistants were trained on data collection and how to administer questionnaires**.** principal investigator trained research assistants on data collection tools, how to handle data, data uniformity and accuracy. They were also trained how to seek the consent of participants, administer questionnaires, and protect human participants. The confidentiality of participant information was maintained.

3.9.1 Pre-testing of data collection tools/questionnaires

Data collection was pre-tested at Tamale West Hospital. Pre-test data was doubled entered Microsoft Excel for cleaning and analysis. Data collection tools were revised after testing for internal and external validity on the data collected. A face-to-face interview with implementers using a checklist containing questions on various activities under the PMTCT programme were pre-tested at a PMTCT site different from the study facility; the findings from the pre-test was used to refine data collection tools.

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3.9.2 Revision of data collection tools

Data collection tools were revised and refined using the pre-tested results and analysis. The pre-test was done to ensure that data collection tools were able to elicit responses that could answer the objectives of the investigation.

3.9.3 Supervision of fieldwork

The two research assistants worked with the principal investigator. They were supervised to ensure that good quality data were collected. This was made possible through good communications between field assistants and the investigator. Every data was scrutinized to ensure that all issues are solved before, during and after the investigation.

3.10 Data processing

The data collected was thoroughly cross-checked to ensure accuracy as well as maintain consistency. Microsoft Excel Version 2016 was used to clean the data. Data from codes and questionnaires were entered into Microsoft Excel Version 2016 for cleaning to eliminate errors that occur during coding and other biases that could arise during data collection. Demographic and other characteristic was presented as variables that exhibited (e.g., age, sex, marital status, education, and rank) and all categorical variables were presented as frequencies (percent frequency). Tables and graphs were used to present results of the analysis.

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3.11 Data Entry

Numbers were assigned to the survey for each participant or respondents. Assigning numbers to each participant survey made the data entering easy. The data was entered into Microsoft Excel Version 2016 for cleaning, checked for consistency and accuracy. Microsoft Excel Version 2016 was used for the analysis and to produce graphical visualization of the data collected.

3.12.1 Data Analysis (Quantitative)

3.12.1 Determination the status of the PMTCT implementation process

The PMTCT Programme is a package of integrated health intervention activities, offered to mothers, aimed at preventing the transmission of HIV from women to their children, early HIV detection and during birth, providing treatment, ensure adherence to antiretroviral treatment and protect people who record negative for HIV from getting infected (GHS, 2014). These health intervention activities are categorized into four prongs or components. Using tertile statistics, the status of the PMTCT programme implementation was determined. This was determined using three percentile range score for each PMTCT prong into three groups namely; poor, partial and full implementation. A percentile score of 33.3% was classified as poorly implemented prong activities, a score between 33 – 67% as partially implemented while a score of 67 – 100% was classified as full implementation. The total scores of implemented activities for each prong was divided by the overall total score of implemented activities for each prong and further multiplied by 100 to arrive at the percentage. This was determined using three percentile range score for each PMTCT prong and categorized into three groups namely; poor, partial and full implementation. The implementation status for each PMTCT Prong was done using Microsoft Excel Version 2016. Using the PMTCT checklist of activities, a structured questionnaire on the PMTCT activities was granted to respondents and other healthcare providers to elicit responses on the challenges and

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barriers.

3.12.2 Prong 1. Primary prevention of HIV infection

Prong one (1) of the PMTCT programme consist of Primary prevention of HIV infection. A PMTCT programme checklist was used to illicit responses from the implementers. This was evaluated using evidence of Implementing the eighteen (18) pronged activities outlined in the PMTCT national guidelines (GHS, 2014). The Total implemented responses from fifteen (15) implementers summed up to two hundred and seventy (270) implemented activities.

The status of prong one implementation was determined using tertile statistics to divide the total score of implemented responses for prong one (1) into three parts. The implementation status of Prong one (1) PMTCT implemented activities was determined by classifying the total score of three percentile parts namely; score between < 33,3% was classified as poorly implemented prong activities, a score between 33% - 67% was classified as partially implemented, whereas a score range between 67% - 100% was classified as full implementation of activities. Determining the implementation status was done using Microsoft Excel Version 2016 to divide the total scores of implemented Prong activities by the overall total number of primary prevention of HIV infection activities in the PMTCT national programme guidelines, this was further multiplied by 100 to obtain the final percentage score.

3.12.3 Prong 2. Prevention of unintended pregnancy among HIV-infected women

Prong two (2) was also determined using evidence from implemented PMTCT activities from implementers. This prong contains eleven (11) PMTCT programme activities. Using a sample size of fifteen (15) respondents, the total score of the PMTCT implemented activities for prong two (2) was one hundred and sixty-five (165). Using tertile statistics, the implementation status was determined by dividing the total implemented score of activities of prong two (2) activities by the

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overall total score (165) of Prong 2 activities and multiplied by 100 to obtain the percentage. Tertile statistics was used to classify the implementation status into three parts namely; poor, partial and full implementation. This consists of three percentile point score ranges, the first tertile score of < 33% was classified as poor, a second tertile score range of 33% - 67% was classified as partial and a third tertile range between 67% - 100% indicated full implementation.

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3.12.4 Prong 3. Prevention of HIV transmission from women infected with HIV to their infants.

The third prong consists of seven-teen (17) PMTCT programme activities. The number of respondents for the study were fifteen (15). The total number of expected PMTCT programme activities by the 15 respondents will give a total implemented score of two hundred and fifty-five (255). The total implemented score was divided into three parts namely; poor, partial and full implementation. Tertile statistics was used to divide the total score of implemented activities into three tertile score range. A first tertile score range between < 33% was classified as poor, a second tertile range between 33% - 67% was classified as partial whereas a third tertile range between 67% - 100% was classified as fully implemented PMTCT activities.

3.12.5 Prong 4. Provision of treatment, care, and support to women infected with HIV, their infants, and their families.

The fourth and final prong contains nine (9) PMTCT programme activities. Total number of PMTCT activities in prong four (4) from the fifteen (15) respondents sum up to one hundred and thirty-five (135) programme activities. Using tertile statistics, the tertile score was determined by dividing the total implemented scores into three parts namely; poor, partial and full implementation. A first tertile score of < 33% was classified as poor, a second score of 33% - 67% was classified as partial whereas a third tertile score range between 67% - 100% was classified as full implementation of the PMTCT prong activities

3.13 Barriers to PMTCT Programme implementation

The barriers to implementation of the entire PMTCT was determined by respondents during an interview. The barriers and challenges were narrated and discussed using themes and sub-themes. The programme barriers and challenges were analyzed by compiling and categorizing the

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challenges enumerated by PMTCT implementers according their responses from each of the four Prongs. A proportion of the barriers and challenges mentioned was done,

3.14 Implementation status of the PMTCT Programme

This was determined using tertile statistics to evaluate the entire PMTCT Programme implemented activities in three parts. The implementation status of the PMTCT national programme was classified as poor, partial and or full implementation. A score range of < 33% was classified as poorly implemented, a score range between 33% - 67% was classified as partially implemented whereas a score range of 67% - 100% was also classified as fully implemented PMTCT Programme.

3.15 Data Analysis (Qualitative)

In-depth interview guide was granted to implementers. This served as a guide to PMTCT implementers and to explore their views and perspectives about the operational challenges of the program. Hence, data on the challenges of the PMTCT Programme were collected from implementers through face-to-face interviews. Saturation point was recorded on the 10th implementer, this was when implementers began to give similar responses during the interview.

This data was then audio recorded, then transcribing the audio data was done, proofreading of the transcription and narration was done to ensure accuracy of content. The data was then separated from the quantitative data. Sections of the transcribed data was highlighted to create codes. Themes were then created from the codes using the challenges enumerated by the implementers in the facility. The themes were then reviewed to give a true representation of the PMTCT Programme challenges. Themes were then renamed to reflect the meaning of the data into sub-themes. The qualitative data analysis was done before writing the interviews using the themes and sub-themes

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3.16 Ethical consideration

The Principal investigator met the criteria for ethical clearance and approval before commencing investigation. Ethical approval was sought from Ghana Health Service Ethics Review Committee, Accra.

3.16.1 Consent process:

The purpose of the study was explained to the participants to gain an insight about the need for embarking on a process evaluation of the PMTCT programme. Participants was informed about the amount to be spend in the interview and the procedures involved in the study.

Participants was allowed to voluntarily give their permission and consent for the study without being coerced

3.16.2 Privacy and confidentiality:

To ensure confidentiality, the identity of study participants was kept anonymous. Data collected from participants was safely guarded with strict confidentiality. The anonymity of participants was maintained to ensure that no one is able to identify their personal information from the data collected from the study. Interviews for the study was granted in serene and quiet environment to ensure privacy. All information about the study was strictly confidential and not shared with anyone

3.16.3 Potential risk/benefits:

The study is of minimal risk to the participants. Measures was put in place to protect research participants and to minimize any harm or risk. The results of the study were used to improve the health of women.

3.16.4 Voluntary withdrawal:

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Participants for the study had the right to refuse to be in the study. The study participants were given the right to withdraw from the investigation whenever they wish to withdraw.

3.16.5 Compensation:

Respondents recruited for the study did not receive any form of compensation.

3.16.6 Data storage, security, and usage:

Data and records from participants was secured and protected using password. The data from this study was not shared with anyone but was only used for academic work.

3.16.7 Declaration of conflict of interest:

The Principal Investigator had no conflict of interest whatsoever in the investigation. There was no conflict of interest before, during and after the study.

3.16.8 COVID-19 Issues:

COVID-19 protocols were adhered to, in order to protect study participants against the COVID-19 pandemic. COVID-19 protocols were observed, social distancing and the use of face masks during interviews was also strictly adhered. Proper handwashing techniques with soap under running water was strictly observed before and after the interview. Hand sanitizers were provided to participants for use as disinfectants (for external use only).

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CHAPTER FOUR

MONITORING AND EVALUATION ISSUES OF THE STUDY

4.1 Description of the PMTCT programme

The United Nations General Secretary in a quest to end inequalities and HIV infections in infants and young children set a target for 80% of pregnant women and their children to have access to essential prevention, treatment, and care by 2010 in order to reduce the rates and proportion of HIV infections in children. The aim was to expand testing and counseling services during antenatal visits, delivery, and postpartum services. This was possible because HIV was the leading cause of maternal morbidity and mortality (WHO, 2010).

4.2 PMTCT Concept in Ghana

The PMTCT programme is a full package consisting of four-pronged components, it consists of a package of health service intervention, which are integrated and offered to pregnant women and their children with the aim of reducing the risk of MTCT of HIV, provide protecting for infants from HIV, improve the life of people living with HIV, increase case detection, provide treatment for HIV-infected individuals and reduce the risk of infection to those not infected (negative) from getting infected (GHS, 2014). Ghana in its quest to reduce HIV infections has taken the initiative to implementing the WHO option B+ as part of the strategic plan towards reducing mortalities associated with the disease. Initiating ART treatment, accessibility to testing and counseling services at antenatal clinics is a very crucial component for the PMTCT programme.

4.3 HIV Testing and counseling services

Counseling is a personal conversation between a client and a healthcare provider or counselor to help the client endure the stress of personal decisions about HIV. Counselling psychologically

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prepares clients by explaining the meaning of test results prior to determining their serostatus and to make decisions on the outcome of HIV results (Subbiah, 2003). Pre-test counselling, informed consent, administering the HIV and post-test are vital components to the prevention of HIV (Technical Bulletin series, 2012)

HIV testing and counseling (HTC) are service intervention whereby individual, couple, or family receives HIV testing and counseling on HIV prevention, treatment, care, and support. Generally, HIV interventions consists of 5 core components: 1) Pre-test counseling, this outlines the testing process, 2) A risk-behavior assessment, 3) Informed consent of each participant, 4) Administration of the HIV test and Post-test counseling based on the test result(s). These HTC services serve as the baseline entry points to accessing HIV treatment, support and care. As a result, healthcare providers should maintain confidentiality, explain the significance and benefits of testing to clients seeking these services (GHS, 2014). Ghana has over the years recorded high testing and counseling services. This is due to increase in antenatal care attendance, there has been an increase to about 90% antenatal clinic attendance by pregnant women. An evaluation of the National Strategic Plan 2011 -2015 on HIV in Ghana, showed that about 70% of all pregnant women were tested and counseled for HIV and received their results. HIV-positive pregnant women who received their ARV prophylaxis to prevent the spread of HIV were 46% (Ghana AIDS Commission).

4.4 Antiretroviral treatment and prophylaxis

People living with HIV should be prepared before they are put on ARTs. The preparation begins with discussions to assess their readiness and willingness to initiate the ART for HIV. The dosage of ART is calculated and administered to these people after confirming their serostatus and for possible monitoring of adverse effects of antiretroviral therapy. When initiation of ART, the nutritional status, comorbidities, and other prescriptions should be considered in order to

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interactions, this could also help in adjusting doses These are medicines or drugs that are initiated immediately to suppress viral load, to reduce the risk of HIV, and for infants who are exposed to HIV infection through birth or breast milk (WHO, 2016).

The coverage of ART for the prevention of MTCT varies among nations. Global coverage of ARTs stands at 85%, Ghana currently records an antiretroviral coverage of 75% as at 2019 (World Bank Data, 2019). Antiretroviral treatments are meant to reduce CD4 cell count, they also improve quality of life, increases life expectancy and health of women and children. Antiretroviral treatments also reduce maternal mortality and morbidity. They are effective treatment interventions for preventing MTCT of HIV. The recommended regimen for preventing MTCT as requested programme managers consist; antepartum – azidothymidine (AZT) from 28 weeks of pregnancy (or as soon as possible after serology test confirms); intrapartum – AZT and lamivudine (3TC) plus a single dose of nevirapine (Single dose -NVP), and postpartum – AZT and 3TC for seven days for women and Single dose-NVP and AZT for one week for infants (WHO, 2006). Table 4 shows the recommended ART and dosage for the PMTCT Programme in Ghana.

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Table 2. Recommended Dosage of Antiretroviral Regimens for PMTCT

Regimen for Mother	Dosage	Regimen for Baby	Dosage
Preferred Regimen		**Preferred Regimen**	
TDF +3TC (or FTC) +EFV (300mg +300mg(or 200mg)+600m)]	One tablet daily	AZT (ZD)	4mg/kg body weight 12 hourly for 6 weeks
Alternate Regimen		**Alternate Regimen**	
TDF +3TC (or FTC) Fixed dose combinations) PLUS NVP (200mg)	One tablet daily One tablet 12 hourly	NVP (Use when AZT is contraindicated (Example anemia and bleeding)	200mg/m^2/ dose daily for 6 weeks (Use appropriate dosing chart)
AZT+3TC (300mg/150mg) PLUS NVP (200mg)	One tablet 12 hourly		

ART Guidelines from PMTCT Handbook for Healthcare providers in Ghana (GHS, 2014)

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4.5 Safer infant-feeding practices

Safe Feeding practices that reduce the risk of HIV transmission to infants during breastfeeding. Exclusive breastfeeding as a safe feeding practice reduces the risk of HIV transmission to infants (Otieno-Nyunya etal, 2008). To ensure safer infant-feeding practices, HIV-infected mothers are provided with antiretroviral therapy while breastfeeding or to the infant/child during the period of breastfeeding in order to reduce postnatal transmission. Using exclusive replacement feeds and complete avoidance of breastfeeding also reduces postnatal transmission (Rollins et al., 2004). Lack of support and involvement of male partners in PMTCT services affects safe infant feeding practices. Socio-cultural factors and low male partner involvement reduces the chances of HIV-infected women adopting safer breastfeeding practices, this undermines the efforts of the PMTCT implementation process and guidelines (Takah et al., 2018).

4.6 Safer delivery practices

Routine standard obstetric precautions are key pivotal interventions to clients during labor. Observing precaution during delivery and labor reduces the possibility of occupational transmission of HIV, and the risk of MTCT of HIV. These PMTCT service delivery programmes helps to reduce mother-to-child transmission of HIV during labor and delivery, they include; using good infection prevention methods, the use of a partograph to monitor labor during vaginal delivery, observing safe transfusion practices, avoiding prolong labor, minimizing the risk of postpartum hemorrhage and taking prompt decision for emergency caesarean section (GHS, 2014).

4.7 Type of Evaluation

The type of evaluation for the study was process evaluation. This involved an evaluation of the PMTCT programme, to assess the components and implementation plan in order to explain the interventions and activities that are delivered at the facility. A process evaluation of the

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components will give a clear picture and understanding between specific components and their outcomes (Saunders et al.,). Process evaluation also offers more information on programme implementation plan and ensures that interpreting programme outcomes become very easy (Dehar et al., 1993).

The investigation sought to conduct an evaluation of the following PMTCT programme components: 1) Primary prevention of HIV infection, 2) Prevention of unintended pregnancy among HIV-infected women, 3) Prevention of HIV transmission from women infected with HIV to their infants, 4) Provision of treatment, care, and support to women infected with HIV, their infants and families.

4.8 Implementation of PMTCT at the Teaching Hospital Tamale

These package of services to clients focuses on essential conditions such as anemia, malaria, personal hygiene and HIV.

4.8.1 Primary prevention of HIV infection among women and children

At the pre- test counseling section basic facts about HIV is given. These include;

1. Health information and education
2. HIV Testing and Counselling
3. Couple counselling and partner testing
4. Safer sex practices
5. Mode of transmission and prevention
6. Encouraging women to visit ANC for essential PMTCT services
7. Information on Mother-to-child transmission
8. HIV testing processes

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9. Benefits of testing and counselling services for couples
10. Maintaining Confidentiality
11. Informed consent refusal
12. Supportive HIV services
13. Information on Mother-to-child transmission
14. Discussing meaning of HIV test results
15. How the fetus in utero is infected
16. How the baby can be infected during delivery and breast feeding
17. Education on Sexually transmitted infections and HIV
18. Explaining negative and positive results

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4.8.2 Prevention of unintended pregnancy among HIV-infected women

19. Family Planning services
20. HIV testing services
21. Family planning counselling and services for decision-making
22. HIV testing and counselling in reproductive health
23. Safer sex practices
24. Family planning commodities
25. Exclusive breastfeeding
26. Reproductive healthcare services and education

4.8.3 Prevention of HIV transmission from women infected with HIV to their infants

27. Provide information about how to prevent future HIV infection
28. Informing clients about the risk of transmitting HIV to the infant duringpregnancy or breastfeeding.
29. ART treatment for pregnant women testing Positive for HIV
30. Discussing support for infant-feeding decisions

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31. Measure to avoid prolong labour
32. Quality antenatal and safe delivery practices
33. Safe transfusion practices during delivery
34. Infection prevention during labour and after delivery
35. Post-Exposure prophylaxis
36. Use of partograph to monitor labour/delivery
37. Caesarean section for pregnant women with complications, indicated when safe.

4.8.4 Provision of treatment, care, and support to women infected with HIV, their infants, and families.

38. Antiretroviral treatment for HIV-infected women
39. Infant feeding and support for safe feeding practices.
40. Giving prophylactic treatment for children exposed to HIV.
41. Nutritional counselling
42. Psychological support for HIV-infected women
43. Routine immunization
44. Prophylaxis for opportunistic diseases

A facility-based process evaluation of the PMTCT programme in Tamale Teaching Hospital gave a clear understanding whether the programme was partially or fully implemented.

4.9 Conceptual Framework for the PMTCT implementation Process

Figure 1 is an adapted conceptual framework depicting the relationship between components of the PMTCT programme and the outcome of its implementation. The PMTCT concept consist of four pronged approach such as; (1) Primary prevention of HIV infection, (2) Prevention of unintended pregnancy among HIV-infected women, (3) Prevention of HIV transmission from

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women infected with HIV to their infants, (4) Provision of treatment, care, and support to women infected with HIV, their infants, and their families. It is premised and conceptualized to show that successful implementation and utilization of the PMTCT programme at the facility level could be affected by lack of drugs, medical supplies, and other challenges, serving as independent mediating variables to the success and proper implementation of the PMTCT programme, leading to partial or poor implementation. Likewise, the PMTCT programme will be successfully and fully implemented at the facility when there are no impending barriers and challenges. This will lead to a full implementation the PMTCT programme. The framework also shows the four pronged programme of activities, whereby efficient process implementation of these health intervention activities without challenges such as deep rooted socio-cultural issues, stigma and inadequate trained healthcare and PMTCT implementers will ensure a successful implementation and delivery of the full package of PMTCT intervention services to reduce MTCT of HIV among pregnant women and children.

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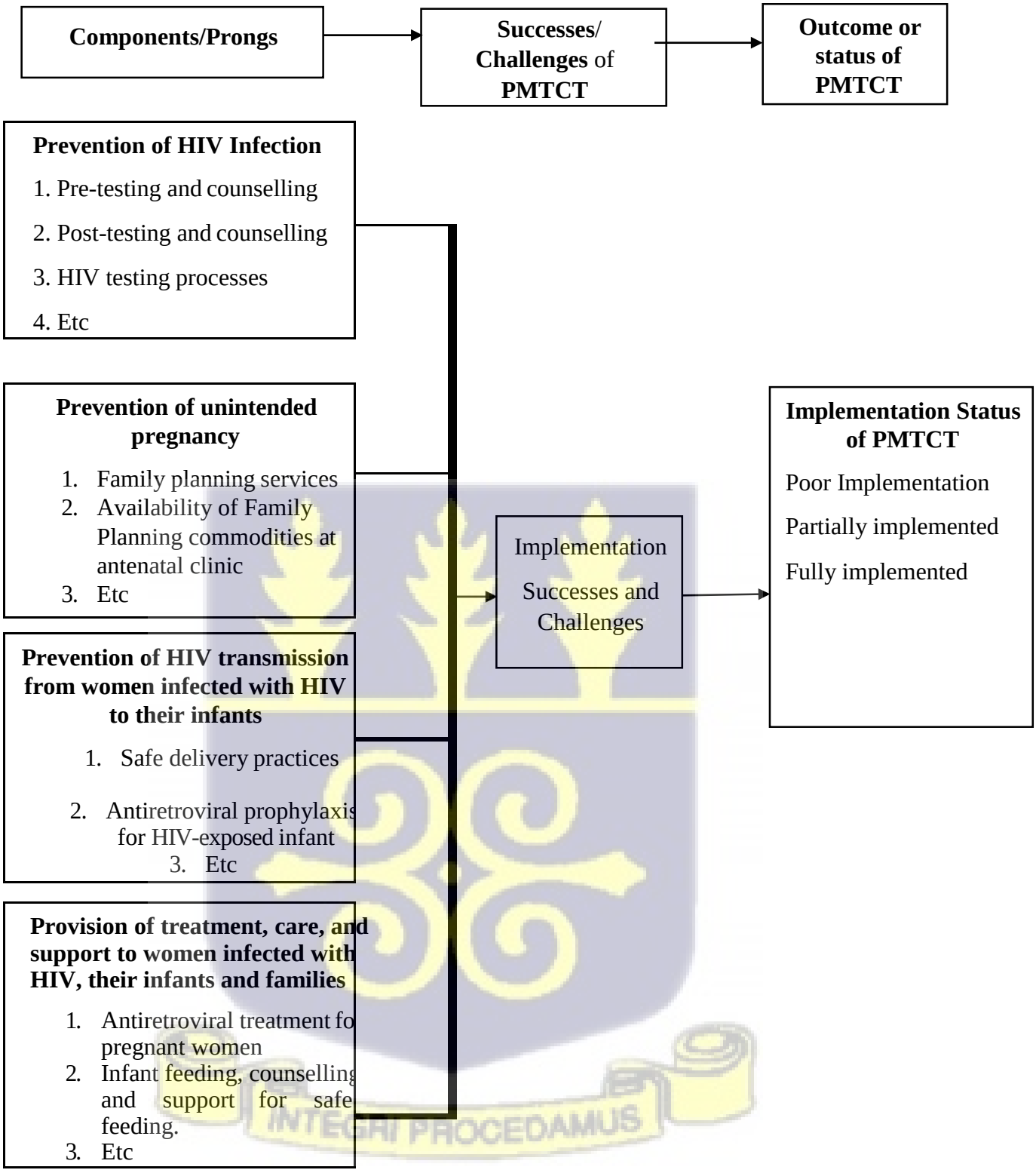


Figure 1: Conceptual Framework for the PMTCT Implementation process

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4.10 Logic model of PMTCT implementation process.

The PMTCT logic model is a description focused on four-pronged components and guidelines on mother-to-child transmission of HIV by the Ghana Health Service. The logic model will measure how the PMTCT national guidelines processes and concept are being adhered by healthcare providers delivering services in the prevention mother-to-child transmission of HIV at Tamale Teaching Hospital**. Tables 3, 4, 5 and 6** shows the logic model with four components from which specific activities are drawn. These activities will interact with appropriate four-pronged components to ensure that the risk for mother-to-child transmission of HIV is reduced drastically during pregnancy, labor, delivery, and breast feeding. PMTCT programme indicators measurements will be used to give evidence whether activities have been carried out.

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Table 3: Logic Model for the PMTCT Programme on primary prevention of HIV infection

Programme/components	Inputs	Activities	Outputs	Indicators
Primary prevention of HIV infection	Nurses and Midwives	Giving HIV and AIDS information to pregnant women at ANC	Pregnant women informed and educated on HIV/AIDS	Number of pregnant women educated on HIV/AIDS
	PMTCT manuals and in-service training	Healthcare providers educate couples using PMTCT manuals	Couples educated on HIV transmission and prevention estimated	Number of couples educated on HIV transmission and prevention.
	HIV testing kits and counselling services at ANC	Programme implementers Conducts HIV counselling and testing on pregnant women	Pregnant women at ANC identified and given counselling testing services	Number of pregnant women who are given HIV counselling and testing services
	Registers and record books	Record pregnant women registered for HIV testing and counselling services at ANC	HIV test and counselling services documented and recorded on register	Number of pregnant women registered for HIV testing and counselling

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	PMTCT training materials	Improve Knowledge of health staff on HIV testing processes	Training of healthcare providers on HIV testing processes	Number of training seminars on HIV testing processes
	Monitor and supervise HIV testing services HIV resource and healthcare providers	PMTCT implementers monitors and supervise testing services	HIV testing services monitored and supervised by PMTCT implementers	Monitoring and supervisory activities for HIV testing services
	HIV test kits	Assess HIV test kits in stock	HIV testing kits were available and in stock at stores	Number of HIV testing kits for pregnant women
	Training on PMTCT services	Train healthcare providers on the provision of PMTCT services	Nurses and midwives were trained on PMTCT services	Number of PMCTC related training for healthcare providers
	Consent forms for pregnant women before HIV	Seek consent before testing and maintain confidentiality during HIV testing	Pregnant women consent was sought	Number of consent forms received from pregnant women before testing for HIV. Number of pregnant women who consented before taking HIV testing

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				results
	Test for CD4 cell count	Record and document CD4 cell count test	ANC clients register shows records of CD4 cell count test results	Number of women testing for CD4 cell count
	Nurses, midwives, and HIV resource personnel	Explain HIV Testing Processes	HIV testing processes explained	Number of HIV testing processes
	ANC records book	List ANC clients in the PMTCT register	ANC client's records listed in PMTCT register	Number of ANC clients listed in the PMTCT register
	Monthly Report book	Document monthly report on PMTCT	Monthly report on PMTCT book documented	Number of monthly reports recorded on PMTCT book

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Table 4: Logic Model for the PMTCT Programme on prevention of unintended pregnancies among HIV-infected women

Programme /Components	**Inputs**	**Activities**	**Outputs**	**Indicators**
Prevention of unintended pregnancy among HIV- infected women	Identify family planning services	Document Family planning services available	Family planning services identified	Number of family planning services available
	Identify adolescents for counselling on family planning activities	Counsel adolescents on Family planning activities	Adolescents identified for counselling on family planning	Number of adolescents counselled on family planning activities
	Contraceptives and other commodities	Check family planning commodities	Contraceptives for family planning available	Number of family planning commodities
	PMTCT and family planning services	Inform pregnant women about essential PMTCT services available	Pregnant women informed about PMTCT services available	Number of PMTCT services available
	Contraceptive methods and choices	Support women and mother to make choices on contraceptive methods	Mothers given support on making contraceptive choice	Number of women given support on choice of contraceptive methods

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	HIV/STI resource personnel	Provide education regarding early STI treatment	Education on STIs given	Number of women educated on STIs treatment
	Manuals on exclusive breastfeeding	Encourage exclusive breastfeeding	HIV infected women encouraged to exclusively breastfeed	Number of HIV infected women on exclusive breastfeeding
	Safer sex practices	Educate women on safer sex practices	PMTCT implementers educates adolescents and women safe sex practices	Number of women educated on safer sex practices

Table 5: Logic Model for the PMTCT Programme on prevention of HIV transmission from women infected with HIV to infants, and their families.

Prongs/ components	Inputs	Activities	Outputs	Indicators
Prevention of HIV transmission from women infected with HIV to infants	HIV test kits for re-testing at 34 weeks(Third trimester)	Provide HIV tests kits for re-testing at 34 weeks (Third trimester)	Pregnant women re-tested for HIV at 34 weeks of gestation	Number of pregnant women re-tested at 34 weeks of gestation

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	HIV test kits to screen women for HIV	Early detection of HIV among pregnant women	Pregnant women screened for HIV	Number of pregnant women screened for HIV

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	Check CD4 and assess clinical signs of pregnant women	Availability of CD4 reagents and sample bottles for investigation of CD4 cell count.	DC4 reagents used to enumerate the absolute counts of CD4 T lymphocytes	Number of CD4 T lymphocytes cell counts results for HIV-infected pregnant women
	Do a DNA/PCR testing for EID at 6 weeks and after completion of breastfeeding	Resource personnel at HIV/STIs unit	Follow-up on DNA-PCR testing at 6 weeks after delivery and completion of breastfeeding	Number of DNA- PCR testing of infants at 6 weeks after delivery
	Early detection of HIV in infants	Case detection report forms	Daily and routine reporting of data on HIV infection in infants	Number of infants screened for HIV infection
	Breastfeed exclusively	Use Breastfeeding manuals for support on safe exclusive breastfeeding practices	Monthly reports of safe exclusive breastfeeding practices	Number of mothers supported on exclusive breastfeeding practices

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	Post-exposure prophylaxis	Give Healthcare providers Post-Exposure Prophylaxis within 1 – 2 hours and 72 hours	Routine Post Exposure prophylaxis effective within 1-2 hours and not more 72 hours	Number of healthcare providers who are given post-exposure prophylaxis

Table 6: Logic Model for the PMTCT Programme on provision of treatment, care, and support to women infected with HIV to their infants and their families.

Programme/Components	**Inputs**	**Activities**	**Outputs**	**Indicators**
Provision of treatment, care, and support to women infected with their infants, and their families	Antiretroviral drugs	Serve HIV-infected pregnant women with antiretroviral treatment	Antiretroviral drugs delivered to HIV infected pregnant women	Number of HIV-infected pregnant women served with antiretroviral treatments
	Prophylaxis	Giving prophylaxis to infants exposed to HIV immediately after delivery	Prophylaxis delivered to HIV-exposed infants immediately after delivery	Number of prophylaxis served to infants exposed to HIV during delivery

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	Prophylaxis for HIV Patients with opportunistic diseases.	Serve Prophylaxis for HIV patients with opportunistic diseases	Prophylaxis promptly served to HIV-infected women	Number of prophylaxis served HIV exposed women with opportunistic
	HIV treatment care sheet/ ART records book	Check antiretroviral treatment regimens for mother and baby	ART treatment regimen properly checked before serving	Number of ART regimen checked before serving to HIV mothers
	PMTCT national guidelines for ART	Serve ART according to PMTCT national guidelines	Served ART according to the PMTCT national guidelines	Number of ART drugs served according to ART national guidelines
	PCR and EID machines for antibodies	Estimate HIV antibody for ages between at 6 weeks and (18 months <5 years)	HIV antibodies estimated for ages between 6 weeks and (18 months and < 5 years	Number of HIV antibodies examined for infants between 18 months and less than 5 years
	Nurses and midwives adopts infection	Observe good infection prevention practice during delivery	Good Infection prevention practices	Number of women delivered with strict infection prevention

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	prevention methods		observed during labour	infection practices
	Partograph to monitor labour	Midwives/Nurses use partograph to monitor women in labour	Vaginal delivery was monitored using a partograph	Number of partographs used for monitoring vaginal delivery
	Safe transfusing practices during labour and delivery	Screen blood by grouping and cross-matching in the laboratory	Blood screened, grouping and cross-matching was done	Number of blood screened, grouped and cross-matched before transfusion
	Identify HIV-infected women and infants exposed for HIV.	Give infants feeding, counselling support to infants-exposed to HIV for safe breastfeeding practices.	HIV-infected women and their infants identified for breastfeeding counselling	Number of women and infants counselled for safe feeding practices

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	Vital signs records sheet	Monitor vital signs of HIV-infected mothers before, during and after delivery for complications	Vital signs monitored for HIV infected women before, during and after delivery	Number of women whose vital signs were monitored while in labour
	Nutritional care and support	Identify nutritionist to offer nutritional support and care	Infants and mothers were given nutritional care and support	Number of infants and women who had nutritional support and care
	Antiretroviral drugs	Start ARVs for HIV-infected mothers at labour ward	ART for HIV was administered to mothers in labour	Number of women receiving ART for HIV during labour
	PMTCT resource personnel	Check HIV-infected mothers on adherence of ART interactions and side effects at labour room	HIV-infected mothers monitored for adherence and side effects	Number of infected mothers monitored for adherence and side effects

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	Equipment for physical examination	Embark on Physical examination of HIV exposed infants	Physical examination of infants done to exclude abnormalities	Number of physical examinations on infants
	Newborn, delivery records book	Record newborn weight, length and head circumference in Child record Booklets	Newborn weight, length and head circumference documented in Child Record Booklet	Number of completed records of newborn in Child Records Booklet
	Postpartum visit schedules at clinic	Schedule postpartum visits and follow-up after delivery	Postpartum women were scheduled for postnatal Clinic visits	Number of scheduled postpartum visits at Postnatal Clinic after delivery
	PMTCT activities	Record all PMTCT activities	All PMTCT activities recorded and reported	Number of PMTCT activities recorded and reported

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4.11 Definition of Indicators

Indicators are quantitative or qualitative variables that give information about progress and measures achievements associated to a program or intervention. Quantitative indicators are reported as numbers in the form of rates, proportions and units whereas qualitative indicators are reported as words and statements (Nigel Simister, 2015). These variables are used to measure program activities (FAO, 2016). Table 5 show the measurements of the various for the study.

Table 7: Measurement of Indicators

Components/ Prongs	**Indicator**	**Measurement**	**Evidence**
Primary prevention of HIV infection	**Implementation process**	**Available/ Not available**	**Evidence/Where to find indicator**
	Pregnant women given HIV counselling and testing services	Available	HIV testing and counselling register
	Routine immunizations	Available	Expanded immunization records book
	Couples educated on HIV transmission and prevention	Available	HIV transmission and prevention education schedule records
	Number of training seminars on HIV testing services	Not available	Records of HIV training seminars
	Pregnant women registered for HIV testing and counselling	Information not given by implementers	HIV testing services records book

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	Monitoring and supervisory activities for HIV testing services	Available	HIV monitoring and supervision records book
	HIV testing kits for pregnant women	Available	Records of HIV testing kits
	PMTCT training seminars for healthcare providers	Not every PMTCT implementer has the manual. No regular PMTCT training seminars	Training materials on PMTCT service delivery
	Pregnant women consented before taking HIV testing results	Available	HIV informed consent records book
	ANC clients listed in the PMTCT register	Available	ANC clients register
	Monthly reports recorded on PMTCT book	Available	PMTCT monthly reports book
Prevention of unintended pregnancy among HIV-infected women	Family planning services	Available	Family planning services records book
	Adolescents counselled on family planning services	Available	Family planning counselling register
	Family	Available	Family planning logistics records book

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	planning commodities		
	Availability of PMTCT services services available	Available	Evidence of PMTCT services on ANC records book
	Pregnant and non-pregnant women screened and treated for STIs	Available	STI screening register
	Giving support for women making choices on contraceptive methods	Available	Family planning records book
	Educating women on STIs	Available	STI training records
	Records of HIV infected women on exclusive breastfeeding	Women	Exclusive breastfeeding records book
Prevention of HIV transmission from HIV-infected women to their infants	Pregnant women re-tested at 34 weeks of gestation	Available	HIV testing records book
	Hours allocated for training and supervision of postpartum women on exclusive breastfeeding	Two hours per every visit. 30 minutes supervision	Postpartum visits records book

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	DNA-PCR testing of infants at 6 weeks after delivery	Available	At least one DNA-PCR testing results for infants at 6 weeks after delivery
	Pregnant women screened for HIV infection	Available	HIV screening records book
	Infants screened for HIV infection	Available	HIV screening records book
Provision of Treatment, care, and support to women infected with HIV, their infants and families	HIV-infected pregnant women served with ARVs	ARV administered to HIV-infected pregnant women	ARVs therapy records book
	Prophylaxis served to infants exposed to HIV during delivery	Available	Prophylaxis records book
	ART regimen checked before serving to HIV mothers to prevent reactions with other treatments	ART regimens cross-checked with other prescriptions	ART treatment sheets
	Healthcare providers given post-exposure prophylaxis after exposure	Available	Post-exposure prophylaxis records book
	ART drugs served according to	Available	PMTCT treatment manual

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	national guidelines		
	HIV antibodies examined for infants between 18 months and less than 5 years	Available	HIV antibody records book
	Women delivered with strict infection prevention practices	Available	Delivery records sheets
	Monitoring women on vaginal delivery with partograph	Available	Records of partograph on delivery records sheets
	Screen and cross-matching blood before transfusion	Available	Blood transfusion record sheet
	Monitor women vital signs during labour	Available	Vital signs records sheets
	Women and infants counselled for safe feeding practices	Available	Counselling records book
	Give HIV-infected women ART for during labour	Available	ART treatment sheet
	HIV-infected mothers monitored for ART adherence and side effects	Regularly monitored	ART records book or ART incidence book

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	Physical examinations for HIV exposed infants	Available	Physical assessment records book
	Evidence of records of newborns in Child Records Booklet	Available	Newborn delivery records book
	Schedule postpartum visits to Postnatal Clinic after delivery	Available	Postnatal clinic register

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CHAPTER FIVE

RESULTS

5.1 Introduction

This chapter contains written outcomes from the analysis of the investigation. The findings and results were presented to give a clear and more vivid understanding about the background characteristics of the study participants. This gives an in-depth information about data presented.

5.2 Background Characteristics of the PMTCT implementers

A total of fifteen (15) PMTCT Programme implementers were evaluated to understand the implementation status of the PMTCT programme guidelines. Nine (9) participants (60%) were within the age range of < 29, four (4) of the participants (26.6%) were aged between 30 and 34 whereas two (2) of the participants (13%) were within 35 and 50+. Regarding sex, 2 were male (13%) whereas 87% were female. About 11 of the implementers (73%) were married, 3 other participants were still single with one (10 divorce. All the implementers or participants (100%) had their education to the tertiary level. In addition, 20% of the implementers were midwifery officers, 13% were senior staff midwife, 33% had their rank as nursing officers. The remaining implementers were; senior midwifery officer (7%), senior staff nurse (7%), staff nurse (7%), deputy C.M.O (7%) senior community health nurse (7%) respectively. This is illustrated in table 8.

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Table 8: Background Characteristics of the PMTCT implementers

Variable	Number	Percentage (%)
Age (years):		
< 29	9	60
30 – 34	4	27
35 - 50+	2	13
Sex:		
Male	2	13
Female	13	87
Marital Status:		
Married	11	73
Single	3	20
Divorced	1	7
Education:		
Tertiary	15	100
Rank:		
Sen. Midwifery Officer	1	7
Midwifery Officer	3	20
Sen. Staff Midwife	2	13
Nursing Officer	5	33
Senior Staff Nurse	1	7
Staff Nurse	1	7
Deputy C.M.O	1	7
Sen. Comm. Health Nurse	1	7
Total	**15**	**100%**

C.M.O = Community Midwifery Officer

5.3 Status of PMTCT Programme Prongs

5.3.1 Prong 1. Primary prevention of HIV infection

Regarding the implementation of primary prevention of HIV infection, 263 responses from the implementers indicated that 97.4% of the activities were implemented as shown in table 9. Thus Prong 1 activities were fully implemented (Table 9).

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Table 9. Prong 1 Implementation status

No.	Prong One	Prong 1 Responses		
	Primary Prevention of HIV infection	**Implemented**	**unimplemented**	**Total Responses**
1	Encourage couple testing	15	0	15
2	HIV/AIDS information to patient	15	0	15
3	HIV testing services	15	0	15
4	Education on HIV transmission and prevention	15	0	15
5	Informed consent for HIV patients	15	0	15
6	MTCT counselling and prevention methods	15	0	15
7	Post-test counselling	15	0	15
8	HIV testing processes	15	0	15
9	Explain PMTCT services and HIV test to clients	14	1	15
10	Take client history	15	0	15
11	Maintain confidentiality	15	0	15
12	Opportunity for informed consent refusal	15	0	15
13	Discuss meaning of test results	15	0	15
14	Discuss post-testing in separate place	13	2	15
15	Couple or partner testing	13	2	15
16	Screen and treat STIs	15	0	15

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17	Give prophylaxis to healthcare providers exposed to HIV-infected patients	14	1	15
18	Give Post-Exposure Prophylaxis within 1- 2 hours and not more than 72 hours after exposure	14	1	15
Total		**263**	**7**	270

5.3.2 Prong 2. Prevention of unintended pregnancy among HIV-infected women

On the prevention of unintended pregnancy among HIV-infected women, 151 responses indicated that 92% of the activities were implemented as shown in Table 10 shows. Thus Prong 2 activities was also classified as full implementation.

Table 10. Prong 2 Implementation Responses

No.	Prong two (2) activities	Prong two (2) Responses		
		Implemented	**Unimplemented**	**Total**
1	Family planning services in facility	15	0	15
2	Family planning counselling	15	0	15
3	Reproductive health counsel for HIV-infected women	15	0	15
4	HIV testing and counselling in reproductive health	15	0	15
5	Family planning or contraceptives methods available	15	0	15
6	Use PMTCT training manuals for reference and care of infants	5	10	15
7	Initiate breastfeeding within 30 minutes to one hour after delivery	14	1	15

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8	Educate HIV-infected women on safer obstetric practices	15	0	15
9	Family planning methods for HIV-infected women	15	0	15
10	Support HIV-infected mothers to breastfeed safely	12	3	15
11	Educate HIV-infected women on safe sex practices	15	0	15
	Total	**151**	**14**	**165**

5.3.3 Prong 3. Prevention of HIV transmission from women infected with HIV to their infants

The data show that 254 responses from the implementers indicate that 99% of Prong 3 activities were implemented, this was classified as full implementation (Table 11)

Table 11. PMTCT Prong 3 implementation responses

	PMTCT Prong 3 activities	**Prong three (3) Responses**		
No.		**Implemented**	**Unimplemented**	**Total**
1	Educating pregnant women about high risk of transmitting HIV to infants	15	0	15
2	Pregnant women have access to PMTCT services and interventions	15	0	15
3	Pregnant women visit ANC regularly	15	0	15
4	Pregnant women have access to PMTCT services during delivery	15	0	15
5	Give ART to infants according to national treatment guidelines	15	0	15

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6	Give ART to pregnant women newly diagnosed with HIV	15	0	15
7	Administer prophylaxis/ART immediately/48hrs after delivery	15	0	15
8	Serve/administer recommended prophylaxis for HIV-exposed infants (eg Zidovudine)	14	1	15
9	Render HIV testing and counselling services to pregnant women	15	0	15
10	Facility have ART prophylaxis for MTCT prevention for pregnant women exposed to HIV	15	0	15
11	Nurses and midwives monitor pregnant women in labour with partograph	15	0	15
12	Give ART for pregnant women eligible for treatment	15	0	15
13	Observe good infection and prevention methods when caring for HIV-infected women	15	0	15
14	Observe safe delivery practices for pregnant women in labour	15	0	15
15	Cross-match and screen blood to ensure safe blood transfusion	15	0	15
16	Take prompt decisions on Caesarean Section for complicated obstetric emergencies	15	0	15
17	Discuss and give support for initiation of ART for infants	15	0	15
	Total	**254**	**1**	**255**

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5.3.4 Prong 4. Provision of treatment, care, and support to women infected with HIV, their infants and their families

Table 12 shows 129 responses from the implementers which indicates that 96% of Prong 4 activities were implemented, this was classified as full implementation.

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Table 12. Prong 4. Prevision of treatment, care, and support to women infected with HIV, their infants, and their families.

No.	PMTCT Prong 4 activities. Activities	Prong four (4) Responses		
		Implemented	**Unimplemented**	**Total**
1	Routine immunization services are available	15	0	15
2	Give ART to HIV-infected women	15	0	15
3	Provide nutritional services to HIV-infected women and children.	9	6	15
4	Reproductive health services for HIV-infected women after delivery	15	0	15
5	Give antiretroviral treatment as soon as possible for newly diagnosed HIV-infected women	15	0	15
6	Starting infant prophylaxis immediately after delivery (within 48 hours)	15	0	15
7	Stock prophylaxis for infants exposed to HIV from their mothers	15	0	15
8	Antibody testing done for infants after delivery	15	0	15
9	Testing for antibodies using the DNA-PCR test for all infants exposed at 6 weeks, and repeated 6 weeks and after breastfeeding	15	0	15
	Total	**129**	**6**	**135**

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Figure 2: shows the summary of the percentage distribution of Prong implementation status of the PMTCT Programme.

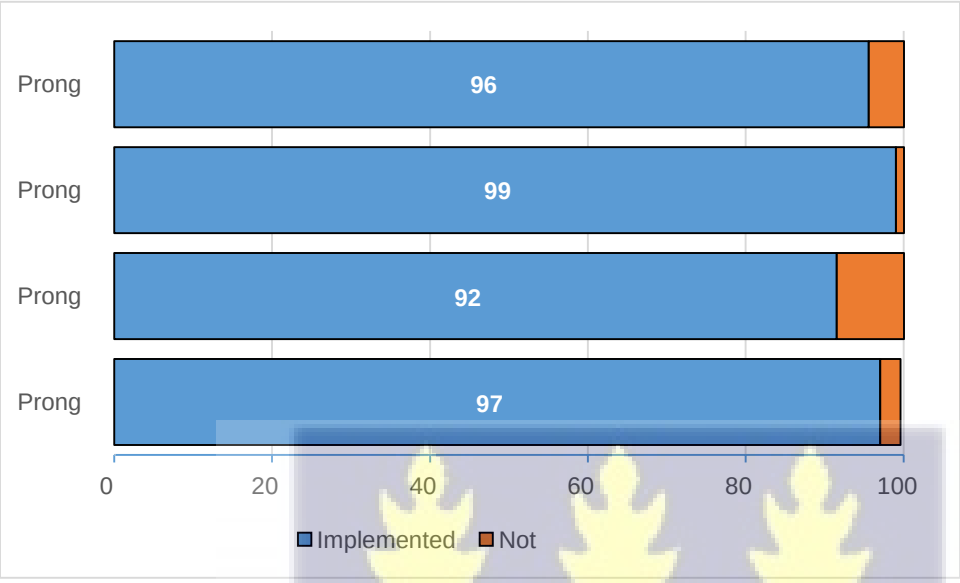


Figure 2: Implementation status of the PMTCT Programme Prongs

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5.3.5 Unimplemented activities by PMTCT Prongs

Table 13. Show the distribution of unimplemented activities by Prongs.

Prongs	Unimplemented activities
Prong 1	• Explaining PMTCT and HIV testing services to clients • Discussing post-testing in a separate place • Discuss disclosure and partner testing • Giving prophylaxis to healthcare providers exposed to body fluids of HIV patients • Giving Post-Exposure prophylaxis within 72 hours
Prong 2	• Use PMTCT manuals for reference, regular in-service training and details on treatment and infant feeding • Supporting HIV-infected mothers to breastfeed safely
Prong 3	• Administering recommended prophylaxis for HIV-exposed infant within the stipulated time
Prong 4	• Providing nutritional care and support •

Figure 3 show the proportion of unimplemented PMTCT prong activities. Prong 1 recorded the highest proportion (56%) of activities, Prong 2 recorded 22% whilst Prongs 3 and 4 recorded the least score (11%) of the unimplemented activities.

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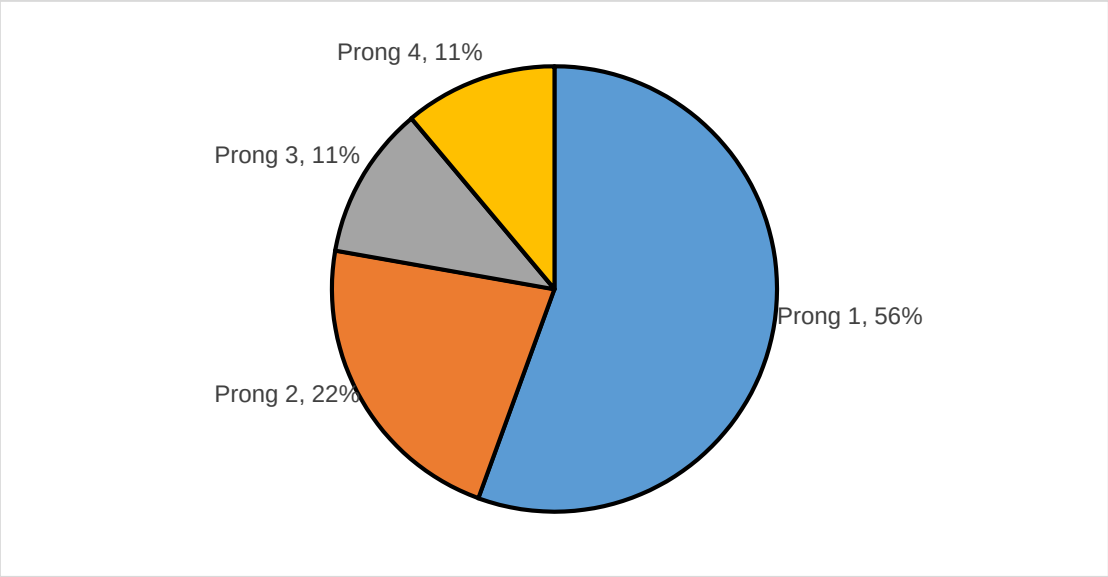


Figure 3: Unimplemented prong activities of PMTCT Programme guidelines

5.3.6 PMTCT Prong barriers and challenges

Table 14 shows the challenges and barriers to PMTCT Prong implementation. One of the main challenges reported by all participants was stigma (100%). Other challenges affecting the smooth implementation of the programme was Inadequate EID machines, delayed EID and viral load results, these were reported by the implementers in prong three prongs (prong 1, 3 and 4). The PMTCT implementers reported about 34%, 16%, 26% and 24% of challenges in prong 1, prong 2, prong 3 and prong 3 respectively.

Qualitative data was collected from participants or PMTCT implementers working in the facility. This data was collected by conducting an in-depth interview for ten (10) consented or recruited health care workers comprising of Midwives and nurses.

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Table 14 Themes on the PMTCT Challenges and barriers

PMTCT Prongs	Main Themes	Sub Themes
Prong 1,2, 3 and 4	• Stigma	• Effects of stigma on PMTCT services • Clients changing facility for treatment
Prong 1,	• Husbands refuse couple testing	• Mistrust and unstable relationships • Fear of HIV and stereotype
Prong 1	• Altering HIV test results	• Clients understands meaning of HIV test results value of 279 (+ve) and test value of 280 (-ve) • Changing of HIV positive value of 279 to a negative value of 280 on ANC cards
Prong 1, 3 and 4	• Delayed viral load and EID results	• Causes of viral and EID results delays • Impact of delays on care
Prong 1, 3 and 4	• Breakdown of PCR machines	• Frequent breakdown of PCR machines • EID results takes longtime at the public health lab
Prong 1,3, and 4	• Inadequate number of PCR machines	• Frequent breakdown of PCR machines • Lack of PCR machines causes delays of EID result • Implementers adopt presumptive treatments on infants exposed to HIV

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Prong 1	• Refusal to go for ARTs	• Defaults on HIV treatments
Prong 1, 2 and 4	• No PMTCT implementation manual and in-service training	• Availability of PMTCT manual and in-service training. • Reference point for service delivery
Prong 2	• Myths and misconceptions	• Religious believes • Perceptions about contraceptives
Prong 1, 2 and 3	• Illiteracy	• Non-compliance to treatments routines and medical advise

All the PMTCT implementers who were recruited for this study had different views about the work and the challenges facing the prevention of mother-to-child transmission. The PMTCT national guidelines is a series of health intervention activities that seeks to prevent and provide treatment for pregnant women infected with HIV.

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Stigma

All the participant complained that stigma continuous to be a major problem affecting clients who test positive. PMTCT implementers and healthcare providers rendering services for HIV-infected women are often challenged with issues related to stigma.

> *"Stigma is still a problem and challenge for us here. When these women test positive, you counsel them, we go with them to the STI clinic for the drugs, after taking the drugs they don't go back to the clinic for the subsequent doses of ARTs, that one is a very big challenge. Sometimes after knowing their status here, because they know some of the people here, they tend to change the clinic for their drugs, because of stigma, they don't come again. Ahaa .and at times too, others will beg you not to indicate their status in their ANC book, they will go to the extent of kneeling down sometimes with tears running down their eyes, begging you not indicate their status in the ANC book*
>
> *When you question them they will tell you that if the spouse knows about it, their husbands will divorce them. And also some of the pregnant women able to convince their husbands to come for testing" (Implementer 2)*

Husbands refuse couple testing

Participants who were part of the PMTCT implementers expressed their professional views on HIV testing and counselling as key component of the PMTCT Programme. According the implementers, unstable marital relationships, stigma and fear of rejection from society have always influenced most married men and husband's refusal to go with the wife to the facility for counselling and testing services.

> *"we are still behind when it comes to couple testing, as for the women, they come for testing especially during ANC visits. We have tried educating the women on the*

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importance of convincing their husbands to come for counselling and testing. The perception of people about HIV as a deadly disease and with no treatment leads to discrimination and stigma, as a result they refuse to come. Some husbands are doing well, they come with their wives for counselling and testing, those who test positive are kept on treatment. That notwithstanding, this is a big problem. Again, in this part of the country, especially in the north, husbands do not accompany their wives to the hospital, not even when they are going for ANC visits. So you see, it's a serious challenge here" (Implementer 1)

Altering HIV test results

A midwife at postnatal clinic shares her view on the challenges that affects service delivery to pregnant women on the PMTCT Programme. Most times, pregnant women because of the stress of disclosing their HIV status to their partners for fear of rejection.

"…our biggest challenge is, erhm, now we don't know how they got understand some of the terms we use here, we don't know what's happening in the system, clients have gotten to know the meaning of the HIV test value of 279 (positive) and 280 (negative), so when they attend antenatal clinic and they test positive, we normally write values like 279 as positive test result, they go home and change it to 280 which means negative, when they come and we do the re-testing that's when we realize that they are already tested positive and are on drugs, they know their status. But they passed through the delivery process and other things. All those clients involved were not aware of how the results are written. So we don't know how clients have gotten to know the results and how it's written and how they can also change it to suit themselves, that is our challenge here" (Implementer 7)

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Delayed viral load and EID results

The investigation identified delayed HIV test results as barriers to the PMTCT implementers or healthcare personnel delivering PMTCT services. Prompt arrival of EID and viral load results are crucial to case detection and treatment of HIV. Some other participants expressed concerns about the delays in receiving viral results from the public Health Laboratory.

> *"…the challenge is that, we don't get the results early whenever we send sample to the public health lab, the EID and viral results delays at the lab. Our major problem is the delay of viral load and EID results. The results take long time to come. There are few times we had to send the sample to private labs. So because of that we are forced to do presumptive treatment for the infants exposed to HIV, when we see the baby is having some signs and symptoms of HIV, we start with treatment, when the EID results come and its negative, we stop the treatment but when it is positive we continue with the treatment"(Implementer 3)*

Breakdown of PCR machines

About 80% of the PMTCT implementers made mention of the frequent breakdown of the PCR machines. According the healthcare professionals recruited for the study, the frequent breakdown of the machines causes delays in viral load and Early infant diagnosis (EID) results.

> *"When it comes to logistics, we don't have a problem. But it's just at the reference public health laboratory where most times our PCR machines are not working, they easily break down. Sometimes the early infant diagnosis (EID) samples takes more than three weeks, sometimes more than a month before the results are ready for collection. This sometimes leads to verbal attacks by clients because of long waiting time for results" (Implementer 4)*

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Inadequate PCR machines

There were challenges regarding the use of Early Infant Diagnosis machines. Some PMTCT implementers said that they need new PCR machines, this is because the one currently available easily breaks down, and when they break own, the results takes a long time at the public health laboratory.

> *"We need the PCR machines to be fixed, the hospital should consider buying new PCR machines. Again, the machines used for HIV viral load should also be looked at, because that is what we are using to assess the progress of the client's conditions, I mean the viral load results and EID results. When we don't have viral load and EID results, we cannot determine what is wrong with the patient, physically we are seeing the clients, we want to know what's going-on within the client, we want to know whether the virus is going down or high, and whether the drugs are working well or not. We would be glad if hospital management can look at the problems of delayed viral load results and the frequent breakdown of the EID machine, this is really affecting our work" (Implementer 6)*

Refusal to go for ARTs

The data also show that women infected with HIV refused to come back to the facility for their supply of their ARTs because of stigma and fear of being rejected in society. This sometimes leads to retention. Confidentiality of patient health and their HIV status is very crucial to improving the HIV counselling, testing and treatment. Another PMTCT implementer has this to say;

> *"One of the biggest challenge we face has to do with some pregnant women refusing to come back for the doses of the ARTs. This is especially so when at the time of checking*

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their HIV status, they see someone they know here, they go home and will not come back for subsequent doses of the drugs. And when that happens, they will try to hide their status from their husband" (Implementer 8

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Lack of PMTCT Programme guideline manual for implementers

Some of PMTCT implementers working in certain units did not have access to copies of the PMTCT manual for reference during service delivery. According to implementers, this was a challenge since they had no reference manual as a guide when delivering the PMTCT services. Another PMTCT implementer said;

> *"I don't have a copy of the PMTCT Programme manual, some of my colleagues in other units may have copies, but I haven't seen one in this unit. I have seen one before, if I remember well, I saw a copy of the manual at the HIV/STI unit, that was last year. As for my unit, we don't have any copy of the PMTCT manual. Since HIV among pregnant women is a critical to the preventing of MTCT, it's important we are all provided with copies of the manual, maybe the unit in-charges should make request on behalf their wards. The manual will serve as reference point for us, especially those of us delivering PMTCT services" (Implementer 9)*

Myths and Misconceptions

From the data, another participant reported that myths and misconceptions were also the social factors that posed barriers and challenges to the healthcare provider delivering PMTCT services.

> *"…another issue that makes the work challenging in this unit are myths and misconceptions. Religion is very important here, especially the perceptions of most women about contraceptives. people adore their religious believes more than anything. Sometimes women in their reproductive age who test positive for HIV don't understand why they should adopt a contraceptive method or family planning when she can give birth. You talk to the woman and the family, if she is married, you have to involve the husband. This becomes very challenging especially when their religion does not accept contraceptive methods. But there are times the woman and husband agree to adopt a contraceptive method" (Implementer 10)*

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Some other PMTCT implementers reported illiteracy as a barrier that affects the delivery of PMTCT services to clients.

> *"Again, illiteracy is another issue we are faced here, some women accessing PMTCT services find it difficult to follow the treatment guidelines and instructions. Sometimes those on antiretroviral default during the course of the treatment. We are doing our best, we have intensified education, we believe educating them on the need for HIV testing, counselling and treatment will help change the situation" (Implementer 5).*

5.4 Summary of findings

In this study, ten out of fifteen healthcare professionals delivering PMTCT services were recruited for an in- depth interview. The ages of the implementers recruited for the study were between the ages ranges of < 29 and age 50+ years. Responses from the healthcare providers or implementers show that the status of PMTCT Prong activities as evaluated in the five units of the facility was not fully implemented. The overall analysis of the study from the PMTCT implementers show that stigma, delayed PCR and viral load results, frequent breakdown of PCR machines, inadequate PCR machines, altering of HIV test values on cards, refusal to go for ARTs, lack of in-service training on PMTCT, husband's refusal to go for counselling and testing services, illiteracy, myths and misconceptions about family planning methods and lack of PMTCT implementation manual were the main barriers and challenges affecting the implementation of the PMTCT programme.

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CHAPTER SIX

DISCUSSION

6.1 Introduction

This was an evaluation study on the four PMTCT pronged activities, to evaluate and determine the status of PMTCT Programme implementation at the Tamale Teaching Hospital. Study results and findings were discussed in relation to other studies. Generally, none of the PMTCT Prong activities that was evaluated recorded 100% implementation. That notwithstanding, prong three (3) activities recorded 99%, hence was classified as fully implemented. The evidence of the programme implementation was discussed according the PMTCT Programme national guidelines and prongs and with reference to the previous existing literature of the study.

6.2 PMTCT Programme guidelines

The findings of the study show that 97% activities targeted at primary prevention of HIV infection were implemented. The findings of the study demonstrate that HIV testing and counselling activities has increased in the facility over the years thereby reducing the level of undiagnosed HIV cases within the community. This associates with the study by Ayisi Addo et al., (2018) which indicate that HIV testing, counselling and ART services are available in most facilities in Ghana. This has led to increased case detection and access to HIV treatment for pregnant women. This also confirms and associates with a systematic review on impact of HIV testing and counselling as community-based approach on women and their husbands (Sulat et al., 2018). The finding implies that clients now have access to information and HIV services which reduces the risk of acquiring HIV. The study findings also correlates with the study by F. Baiden et al., (2005) which show that Ghana vision for HIV control is achievable through the integration of voluntary counselling

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and HIV testing for couples and pregnant women. This is because, HIV testing and voluntary counselling has the potential to propel Ghana achieve the 90-90-90 HIV agenda. That notwithstanding, the perceived lack of confidentiality from health care staff, people preference for traditional healers and fear of HIV testing due to stigma remain a major challenge to voluntary testing and counselling for HIV in most parts of northern region (Leblanc & Andes, 2015). HTC is the best strategy to reach out to everyone within the community. Most HIV infected women do not want be seen at the facility seeking PMTCT services (Dirisu et al., 2020). Even-though, not all the activities targeted at primary prevention of HIV infection was achieved but a percentage score of 97% was classified as full implementation at the facility. Good quality information on HIV education, decision-making and prioritizing women at risk HIV are very crucial to the PMTCT programme. Women diagnosed with HIV needs the best information in other to manage their health status. This is not only crucial but a key prerequisite of primary prevention of HIV infection in the facility. This illustrates and associates with Stonbraker et al., (2019) on the priority topics needed for health education to support people living with HIV. It is therefore necessary to educate women on HIV and PMTCT intervention services since education will give a clear understanding of HIV transmission and treatment. A focused group interview for HIV positive Post-natal women in Tshwane, South African confirmed that knowledge on PMTCT intervention services helps prevent HIV transmission to their babies (Madiba & Letsoalo, 2013). HIV education, testing and support services are offered to the women from first time of visit at the ANC till delivery since that is their right (UNICEF/UNAIDS/WHO/UNFPA, 2003). This could likely reduce HIV transmission rates, thus from infected pregnant women to their infants and adherence to treatment. The PMTCT implementers kept HIV testing records in their registers and adhered to standard operating procedures on HIV testing, counselling, and treatment. However, social problems which are influenced by poverty, discrimination and stigma impacted negatively on partner testing on the

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primary prevention of HIV infection. This associates with Steps et al., (2017) which suggest that the concept of HIV should be reconsidered and transformed into modernized primary prevention of HIV towards a community-led approach to address social factors such as discrimination and stigma. That is a basis for future studies on the feasibility of the primary prevention of HIV on a community led approach. This can increase access to PMTCT services, promote the uptake of HIV testing and counselling. A review of PMTCT national guidelines showed that about 67% (10) of the implementers did not have copies of the PMTCT manual for reference during service delivery. Some allude that they have not been given regular in-service training. The PMTCT training manuals contains health intervention activities, precautions ,information, and provide health care workers with skills necessary to deliver PMTCT services (Read, 2006). The PMTCT manual assess the quality of PMTCT services rendered to clients. The implementers said their units have not been provided with copies of the PMTCT training manual. This meant that the implementers could not make references to the PMTCT national guidelines and activities for details on HIV treatments and care. World Health Organization, (2004) recommends the use of PMTCT Programme training manual, an evidenced- based checklist that offers scientific treatment of HIV and prevention of MTCT of HIV.

The findings of the results in prong 2 illustrates that 92% of the activities targeted at prevention of unintended pregnancy among HIV-infected women were fully implemented. The study found that socio-cultural factors such as myths and misconceptions adversely affect contraceptive use among women with HIV infection. This confirms and associates with Eliason et al., (2014) on factors that determine the use of family planning. Socio-cultural factors were cited as the major barriers militating against the use of modern contraceptives among women. Cultural beliefs and other socio-economic factors also account for the reasons why male partners in Africa do not get

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involved in the PMTCT Programme (Byamugisha et al., 2010). PMTCT implementers should intensify couple counselling services, integrate contraceptive education with social communication among women infected with HIV in order to change the myths and misconception that affects the utilization of contraceptives. This findings agree with a study by Kankponang Laar et al.,(2014) identified inadequate in-service training and deep rooted socio-cultural factors affects the delivery of PMTCT services in Ghana. Meanwhile, prevention of unintended pregnancies among HIV infected women reduces the risk of morbidity, mortality and prevents the transmission of HIV to infants/babies. This finding further confirms the study by Gelagay et al., (2018) in northwest Ethiopia, which revealed that the utilization of contraceptives and other family planning methods are affected by myths, misconceptions and the unbridled intentions of most women to deliver. As part of the PMTCT programme, the implementers also give reproductive health information to non-pregnant HIV women. The findings reveal that implementers provide family planning services by integrating PMTCT Prong activities with contraceptive use, hence making the services accessible and acceptable. The findings show that Prong 2 activities (8%) were not properly implemented as required by the programme due to stigma, institutional inefficiency and regular training on the programme, however access to PMTCT services and family planning services has reduced the number of infants exposed to HIV during birth and improved the living conditions of women with HIV. Non-disclosure of HIV status by couples testing positive for HIV at the ANC and lack of male partners getting involved in PMTCT Programme adversely affects couple choice for a family planning method. The non-disclosure of their status is because of the fear of abandonment and divorce by their husbands. Hence, most HIV infected women have difficulties making a choice for contraceptives as they end up giving birth to infants exposed to HIV.

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The findings in prong three (3) of the PMTCT programme show that 99% of activities that are rendered towards the prevention of HIV transmission from women infected with HIV to their infants were implemented. The implementers confirmed that there was increased ART adherence level among pregnant women. This indicate that HIV infected women will have reduced viral load and low risk of drug-resistant HIV. This support the study conducted by Grinsztejn et al., (2018) that ART and strict adherence to antiretroviral treatment during pregnancy is critical in reducing maternal transmission of HIV. The implementers had in stock adequate supply of antiretroviral drugs and other logistics for providing PMTCT services. Review of records at the facility show that pregnant women infected with HIV receives the triple combination antiretroviral regimen. This will help reduce CD4 counts and suppress viral loads among pregnant women and children to optimal levels. This implies that scaling up HIV treatment in the facility will help achieve the UNAIDS target of 90-90-90 by 2030.This also confirms a systematic overview study by Bartlett et al., (2006) on the triple combination ART among HIV-infected adults. The increased ART coverage has helped improve the quality of life of women. The study finding is in tandem with a recent report that Ghana has maintained an antiretroviral coverage of 75% in 2019 (World Bank, 2019). However, delays in processing viral load and EID results identified as a major problem affecting early treatment of HIV-exposed infants in the facility, late arrival of EID results meant that infants exposed to HIV could not receive their recommended prophylaxis very early, implementers resorted to presumptive treatment for all HIV-exposed infants while waiting for the EID results. This phenomenon also led to late initiation of ART for infants. According to Ferrand (2017), this could lead to infant mortality since infants whose EID results were received within one month had low risk of death from the virus compared to infants whose EID results arrived late. This is because PCR and EID results have an impact on HIV related infant mortalities. The breakdown of PCR machine at the public health laboratory of the hospital also caused delays in

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processing the EID samples. This confirms the findings by Ankrah et al., (2021) on the factors influencing the uptake of early infant diagnosis.

The study also revealed that, most of the implementers rendering PMTCT services to the women were below age 29 years, some with less than four (4) years working experience. The survival of the PMTCT Programme in the hospital depends on good quality skills and competent team with the requisite experience to manage emergencies. This could have negative consequences on professional competencies and experience on PMTCT Programme service delivery, thereby affecting the full implementation process. This necessitate the need for regular in-service training on the programme. A study by Nguyen et al., (2009) confirms that lack of knowledge on HIV testing, counselling and treatment services affects the competencies of healthcare professionals working on the PMTCT Programme.

Findings of the study on the status of Prong four (4) activities of the PMTCT programme revealed that 96% of the activities were implemented whereas 4% were not properly implemented. The study show evidence that activities targeted at preventing HIV transmission from women infected with HIV to their infants were not fully implemented. HIV-exposed infants at 6 weeks and more were taken through the PCR and antibody test. This illustrates and confirms a study conducted by WHO, (2002) on the relevance of testing infants for PCR at 6 weeks and 9 months, and at 18 months for the antibodies as part of the PMTCT Programme. However, about 4% of the prong activities were not properly implemented. Notwithstanding the increased uptake of antiretroviral drugs, myths, misconceptions, poor knowledge on HIV treatment and ARVs from HIV infected women reduces retention to HIV treatment and ARVs. A study by Gourlay et al., (2013) acknowledges that beliefs, lack of knowledge on HIV transmission and antiretroviral drugs reduces retention on the PMTCT programme. Most women infected with HIV fail to take their ARVs, they

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hesitate and harbor some doubt about PMTCT Programme for HIV.

The PMTCT Programme services is very vital to the prevention of HIV among pregnant women and their children. More efforts should be made to involve male partners in the PMTCT service delivery. PMTCT service providers should be empowered through capacity building in the form of in-service training on the programme and adequate provision of logistics to ensure efficiency and quality provision of PMTCT services. The findings of study demonstrate that the implementation of the PMTCT Programme activities were still not fully implemented according national guidelines possibly due to the challenges that were mentioned by the PMTCT implementers at the facility.

6.3 Barriers and challenges to the full implementation of the PMTCT Programme.

A review with the checklist containing the programme guideline show that the implementers complied with the PMTCT Programme implementation guideline however they were faced with some challenges The challenges as reported included: stigma as socio-cultural factor, inadequate PCR machines, delayed EID and viral load results, alteration of HIV test results, illiteracy, husbands refusing to go for couple testing. The study by Kebede et al., (2014) confirms that the challenges to full implementation of the PMTCT Programme are logistical, delayed infant early diagnosis and testing as well as initiation of HIV treatment for infants born to HIV- infected mothers. These increases infants the risk for HIV transmission, late initiation of antiretroviral treatment and death.

The PMTCT implementers identified stigma as a major social problem militating against the successful implementation of the programme. Stigma had social and psychological impact on pregnant women with HIV especially when they come to the antenatal clinic for counselling and

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treatment. Stigma was a major barrier to the utilization of PMTCT intervention services in the hospital. Prudden et al., (2017) concludes that whereas the impact of stigma on maternal retention could be very minimal, reducing transmission of HIV among women and infants was adversely affected by stigma, this suggest that reducing stigma was very crucial towards the prevention of mother-to-child transmission of HIV. Most times, pregnant women diagnosed with HIV at the facility changed their subsequent clinical appointments to different facilities for their antiretroviral treatments because they feel implementers, other health staff and prospective clients who see them at the ANC or HIV/STI unit will disclose their identities to their husbands and family members. This causes social rejection or stigma among HIV infected women in their communities. The findings also add to a growing body of literature which indicates that people living with HIV in the country are faced with stigma, abuse, exclusion and discrimination (Charles, 2015). Review of existing PMTCT programme activities revealed that about 86.6% of the implementers did not have copies of the PMTCT programme guideline manual during service delivery. This could indicate that some PMTCT implementers do not use the PMTCT Programme manual as their reference document during service delivery.

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All healthcare professionals delivering PMTCT services in the facility had tertiary education, they had some level of skills on PMTCT services, however, some of the implementers reported the lack of regular in-service training for staff on PMTCT services in recent times. Healthcare providers delivering PMTCT health services require regular training, education and resources to offer quality health care for clients. This is because regular training on PMTCT services is key to the programme implementation (Ntsime et al., 2022). This could have an impact on how the PMTCT programme guidelines are currently implemented in the facility. A study by Ramoshaba & Sithole, (2017) suggest that healthcare providers delivering PMTCT services should be given continuous training and awareness creation on the PMTCT programme.

Findings from the study in the facility also reveal that, some pregnant women diagnosed with HIV alter their HIV test results. For instance, a positive HIV test value of 279 is changed to negative HIV test value of 280 in their ANC cards. These pregnant women who test positive for HIV hide their status from their husbands, they have so much stress disclosing their HIV status to their husbands because of the fear of getting divorced or rejection. This finding correlates with the study by Siegel et al., (2005) which revealed that pregnant women diagnosed with HIV have difficulty disclosing their serostatus to their sexual partners due to rejection and stigma. There also the fears of possible breach of client confidentiality by the implementers and other health staff, as they overtly and covertly breach confidentiality about their clients' health status. A study by Dapaah & Senah, (2016) indicates that women with HIV protect their identity in their quest seek treatment and services for HIV. This has the tendency to cause non-adherence to antiretroviral therapy thereby leading to drug resistance and HIV treatment failure.

Furthermore, inadequate PCR machines and frequent breakdown causes delay in processing EID results, making infant diagnosis very challenging. They have also reported delays in the arrival of viral load results from the laboratory due to faulty machines. This has not only led to

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long waiting time for receipt of their HIV test results but verbal attacks on the implementers due to delays of viral load results. The results indicates that the late arrival of EID results increases risk of infants death and late initiation of antiretroviral treatment, hence poses a challenge to the Option B+ PMTCT Programme guidelines In addition, husband's refusal to report to the clinic with their pregnant wives for couple HIV testing was another challenge affecting the implementation of the PMTCT programme. All attempts to encourage male partners to go for couple testing have proven futile. Also, the lack of trust by some male partners about their wives and the social stereotype of HIV makes couple testing very challenging. This confirms the study conducted by Larsson et al., (2010) on the views of men and experiences on couple testing at the ANC. The implementers also cited myths and misconceptions of HIV-infected women about contraceptives. This could be a potential research area for HIV-infected women at the community level. This agrees with a study by Abdulai et al., (2020) that demographic and socio-cultural factors among women in their reproductive age affects the women in their choice of contraceptive methods. Whereas some HIV-infected women agreed to choose a family planning method some of the women declined to choose a contraceptive method because of their cultural and religious beliefs, these has led to very low adoption of permanent contraceptives by women within Sub-Saharan Africa. This confirms and associates with a study by Olakunde et al., (2019) which identified myths and misconceptions as the barriers to the uptake of permanent contraceptives. This further indicate that the PMTCT Programme will achieve the desired results of ensuring effective HIV intervention and HIV-free generation when stakeholders adopt a community-led and controlled approach. A systematic review of 58 studies within Sub-Saharan Africa by Blackstone et al., (2017) revealed that misconception and disapproval from male partners reduces the utilization of contraceptive methods. The rest of the challenges were distance to facility for antenatal and PMTCT services and illiteracy rate of HIV-infected women.

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The findings of the study met not only the objectives but answered the questions posed in the study. The results of the study provided an insight into the relationship between the implementation status and the challenges or barriers affecting the PMTCT Programme in the facility.

6.4 Strengths of the Study

The study employed structured questionnaire to identify the implementation status of the PMTCT Programme and the operational barriers and challenges to the programme. The results of the study therefore identified the implementation status of the PMTCT Programme activities at the facility. The study results also indicate the need for in-service training on PMTCT services other supply chain challenges with HIV/AIDS commodities in the Tamale Teaching hospital.

6.5 Limitations of the study

The sample of fifteen (15) PMTCT implementers recruited for the study cannot be generalized. Most of the healthcare personnel with a decade experience on PMTCT services were reported to have gone on compulsory retirement whereas some of the healthcare professionals delivering PMTCT services left for other units. The study focused on only the PMTCT implementers and does not include the beneficiaries. Some of the implementers declined the request to participate in the study, this could have led to insufficient information about the PMTCT Programme in the facility.

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CHAPTER SEVEN

CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusion

The evidence of the investigation showed that the PMTCT Programme guidelines were not fully implemented at the facility. The study findings again show that only Prong 3 activities were almost fully (99%) implemented. Based on the findings, stigma, socio-cultural factors, lack of in-service training, inadequate PCR machines for processing EID samples, frequent breakdown of the PCR machines which leads to delayed viral load and EID results have always adversely affected and posed serious challenges and barriers to healthcare professionals delivering PMTCT services. These could have been part of the reasons associated with the inability of healthcare professionals to fully implement the PMTCT national guidelines at the facility.

7.2 Recommendations

From the evidence deduced on the conclusion of this study, the investigator recommends that;

1. PMTCT implementers should improve strategies aimed at increasing couple testing and discuss post-test results with infected and non-infected women in quiet and separate place.
2. Provision of well-functioning PCR machines to the main public health laboratory of the hospital. All faulty PCR machines should be regularly checked and repaired. This will prevent the delays in releasing EID results.
3. Community sensitization on stigmatizing against pregnant women infect with HIV/AIDS
4. Educating HIV infected pregnant women on the relevance of adhering to the recommended dosage of antiretroviral regimens for PMTCT
5. The PMTCT national guidelines for implementation should be adhered and followed to provide adequate nutritional care and support services to HIV-infected women to complete

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implementation at the facility.

6. Healthcare providers delivering PMTCT services should support HIV-infected mothers to breastfeed and initiate breastfeeding within 30 minutes to 1 hour after delivery.
7. Healthcare professionals delivering PMTCT services should employ mechanisms aimed at reducing stigma and stress associated with disclosing serostatus.
8. PMTCT implementers should be provided with PMTCT national guideline manuals as reference checklist during service delivery and regular in-service training. The PMTCT national guidelines for implementation should be adhered and followed to ensure complete implementation at the Tamale Teaching Hospital.

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APPENDICES

APPENDIX A: QUESTIONNAIRE

DATA COLLECTION TOOL

My name's Christian Mbabilla, a student from the school of public health, University of Ghana and the principal investigator for a study to conduct a process evaluation on the Prevention of Mother-to-Child Transmission of HIV in five units of the Tamale Teaching Hospital. This is not a test, there are no right or wrong answers. I intend to ask you series of questions on PMTCT national programme, the challenges and barriers facing healthcare providers in their line work at Tamale Teaching Hospital. These questions will be focused on the national PMTCT intervention activities contained in the national PMTCT guideline implementation process on the risk of MTCT of HIV in this facility.

Section A: To be administered to PMTCT implementers and other healthcare providers in selected five units (HIV/STI unit, ANC, Family planning, Maternity/Postnatal, Labour

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Section A. Questionnaire for PMTCT implementer/ healthcare providers Implementers

Characteristics ID…….

No	Question and Filters	Answers	Codes	
1	Date of interview			
2	Age of implementer or healthcare provider	< 29 30 - 34 35 - 39 40 - 44 45 - 49 50 +	[1] [2] [3] [4] [5] [6]	
3	Gender	Male Female	[1] [2]	

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4	What is your marital status	Married Single Divorced Widowed	[1] [2] [3] [4]	
5	What is your level of education	Tertiary Secondary Primary No education	[1] [2] [3] [4]	
6	What is your occupation	Nursing Medicine Midwifery	[1] [2] [3]	
7	What is your Rank	……		

Section B: This is to be administered to PMTCT implementers in the hospital and healthcare providers CHECKLIST FOR PMTCT IMPLEMENTATION GUIDELINES

Que No.	**Questions from prong one (1)** **Primary prevention of HIV infection**	**Answers for Prong one (1)**	**Codes**	**Skip**
8	Do you encourage couple testing at ANC?	Yes…….1 No……..2	[1] [2]	
9	Do you give HIV and AIDS information to pregnant women at ANC	Yes No	[1] [2]	

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10	Are there HIV testing Services in the unit?	Yes No	[1] [2]	
11	Do you give education on HIV transmission and prevention	Yes No	[1] [2]	
12	Confidentiality and Informed consent	Yes… .....1 No…..... 2	[1] [2]	
13	Counselling on MTCT and prevention methods	Yes……1 No…..... 2	[1] [2]	
14	Post-test counselling at the ANC	Yes… .....1 No…..... 2	[1] [2]	
15	Do you have HIV testing processes	Yes… .....1 No…..... 2	[1]	
16	Do you explain benefits of PMTCT services and HIV testing	Yes… .....1 No…..... 2	[1] [2]	
17	Client history at ANC. Do you take client history at ANC?	Yes… .....1 No…..... 2	[1] [2]	
18	Do you Maintain Confidentiality of Patients	Yes… .....1 No…..... 2	[1] [2]	

19	Gives opportunity for Informed consent refusal by patients	Yes No	[1] [2]	
20	Discussing the meaning of test results	Yes… .....1 No…..... 2	[1] [2]	
21	Discussing post-testing in a separate place	Yes… 1	[1]	

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		No…..... 2	[2]	
22	Discussing disclosure and partner testing	Yes… .....1 No…..... 2	[1] [2]	
23	Screening and treatment of STIs	Yes… .....1 No…..... 2	[1] [2]	
24	Do you give prophylaxis to healthcare providers exposed to blood fluids from HIV infected patients	Yes… .....1 No…..... 2	[1] [2]	
25	How many hours do you give PEP after exposure	Within 1- 2 hours and not more than 72 hours Within 2 hours and not more than 4 days	[1] [2]	
26	What are the challenges faced at the facility when providing	Subjective		
	services to prevent HIV infection among women and children ?			

Question Number	**Questions from prong two (2) Prevention of unintended pregnancy among HIV-infected women**	**Answers for Prong two (2)**	**Codes**	**Skip**
27	Are there Family Planning services in the facility?	Yes…..... 1 No… 2	[1] [2]	

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28	Family planning counselling and services for decision-making	Yes…..... 1 No… 2	[1] [2]	
29	Do you Counsel HIV-infected women in reproductive health	Yes…..... 1 No… 2	[1] [2]	
30	Do you educate HIV-infected on safer sex practices	Yes…..... 1 No… 2	[1] [2]	
31	Does your facility offer HIV testing and counselling in reproductive health	Yes…..... 1 No… 2	[1] [2]	
32	Are there Family Planning or contraceptive methods in the unit?	Available… .....1 Not available…..2	[1] [2]	
33	Use PMTCT training manuals for details on infant feeding	Yes…..... 1 No… 2	[1] [2]	
34	Do you initiate breastfeeding within 30mn to one hour after delivery	Yes…..... 1 No… 2	[1] [2]	
35	Do you educate HIV-infected women on safer obstetric practices	Yes…..... 1 No… 2	[1] [2]	
36	Are there Family planning methods for HIV infected women	Yes…..... 1 No… 2	[1] [2]	
37	Do you Support HIV-infected mothers to breastfeed safely	Yes…..... 1 No… 2	[1] [2]	
38	What are the challenges faced at the facility when providing services to prevent unintended pregnancies among HIV-infected women?	Subjective		

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Question Number	Questions from prong 3. Prevention of HIV transmission from women infected with HIV to their infants	Answers for Prong 3	Codes	Skip
39	Do educate pregnant women about the high risk of transmitting HIV to the infant if she is newly diagnosed during pregnancy or breastfeeding?	Yes…..... 1 No…..... 2	[1] [2]	
40	Does pregnant women have access to PMTCT services and interventions?	Yes…..... 1 No…..... 2	[1] [2]	
41	Does pregnant women visit ANC regularly?	Yes…..... 1 No…..... 2	[1] [2]	
42	Does pregnant women have access to PMTCT services during delivery?	Yes… .....1 No…..... 2	[1] [2]	
43	Do you give ART to infants according to national treatment guidelines?	Yes… .....1 No…..... 2	[1] [2]	
44	Do you give ART to pregnant women newly diagnosed with HIV?	Yes… .....1 No…..... 2	[1] [2]	
45	Do you administer prophylaxis/ ART to immediately after delivery (within 48 hours)	Yes… .....1 No…..... 2	[1] [2]	

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46	Do you administer/ serve the recommended prophylaxis for HIV-exposed infants (Zidovudine, AZT) syrup 10mg/ml	Yes… .....1 No….....2	[1] [2]	
47	Do you render services like HIV testing and Counselling to pregnant at ANC?	Yes… .....1 No….....2	[1] [2]	
48	Does your facility have ART prophylaxis for MTCT prevention for not receiving ART and for exposed infants?	Yes… .....1 No….....2	[1] [2]	
49	Do nurses and midwives monitor pregnant women in labour using the partograph?	Yes… .....1 No….....2	[1] [2]	
50	Do you give ART for pregnant women eligible for treatment?	Yes… .....1 No….....2	[1] [2]	
51	Do you observe good infection and prevention methods when caring for HIV-infected women?	Yes… .....1 No….....2	[1] [2]	
52	Do you observe safe delivery practices for pregnant women in labour?	Yes… .....1 No….....2	[1] [2]	
53	Do you cross-match and screen blood to ensure safe blood transfusion?	Yes… .....1 No….....2	[1] [2]	
54	Do you take prompt decisions on Caesarean Section for complicated obstetric emergencies?	Yes… .....1 No….....2	[1] [2]	

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55	Do you discuss and give support for initiation of ART for infants?	Yes… .....1 No….....2	[1] [2]	
56	What are the challenges faced at the facility when providing services to prevent HIV transmission from HIV-infected women to their infants?	Subjective		

Question Number	Questions from prong 4 Provision of treatment, care, and support to women infected with HIV, their infants and their families.	Answers for Prong 4	Codes	Skip
57	Are there routine Immunization services in the facility?	Yes……1 No…....2	[1] [2]	
58	Do you give ART to HIV-infected women	Yes……1 No…....2	[1] [2]	
59	Do you provide nutritional care and support services to HIV-infected women	Yes…….1 No…....2	[1] [2]	
	and children?			
60	Are there Sexual and reproductive health services for HIV-infected women after delivery?	Yes…….1 No…….2	[1] [2]	
61	Do you give Antiretroviral treatment as soon possible for newly diagnosed HIV-infected women	Yes… .....1 No….....2	[1] [2]	
62	Starting Infant prophylaxis immediately after delivery(within 48 hours)	Yes… .....1 No….....2	[1] [2]	

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63	Do you have in stock prophylaxis for infants exposed to HIV from their mothers?	Yes……1 No….....2	[1] [2]	
64	What antibody testing is done for infants after delivery?	Yes……1 No….....2	[1] [2]	
65	Do you test for antibodies using the DNA-PCR test for all infants exposed, at 6 weeks, and repeated 6 weeks and after completing breastfeeding?	Yes… .....1 No….....2	[1] [2]	
66	Which are the challenges faced at the facility when providing services to provide treatment, care, and support to women infected with HIV, their infants and families?	Subjective		

Barriers and Challenges of the PMTCT Programme national guidelines

Interview Guide for the PMTCT implementers

5.3.A.1 Which barriers and challenges does PMTCT implementers face when providing services to clients under the PMTCT Programme?

5.3.A.2 How does these challenges affect PMTCT Programme service delivery at the facility?

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APPENDIX B: CONSENT FORM

CONSENT FORM FOR HEALTHCARE PROVIDERS AND PMTCT IMPLEMENTERS AT THE TAMALE TEACHING HOSPITAL.

(Antenatal clinic ☐ Family Planning unit ☐ HIV/STI Unit ☐ Labour unit Postnatal Unit /Maternity ☐

Title of Study: PROCESS EVALUATION FOR PREVENTION OF MOTHER-TO- CHILD TRANSMISSION OF HIV IN TAMALE TEACHING HOSPITAL.

I ..... declare that, the purpose for this study and content in this document was explained to me in a language that I understand. I fully understand the contents and any potential implications as well as my right to change my mind (ie withdraw from the research) even after signing the form. I therefore give the permission to audio-record my short interview (15 minutes) with you. It is my

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right to refuse answering the questions or stop participating in the study at any point if I desire to do so.

I therefore agree to be part of this study and given the permission to audio- record the interview for transcription.

PMTCT implementer Signature ……..... ID ……

Date: …….

INVESTIGATOR STATEMENT AND SIGNATURE

I Mbabilla Christian certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher's name……. Signature …….

Date……

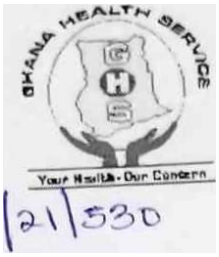


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GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

Research & Development Division

In case of reply
The number and date of this Letter should be quoted



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My Ref GHS/RDD/ERC/Admin/App
Your Ref No,

29th November, 2021

Christian Mbabilla
C/O University of Ghana
Department of Health Policy, Planning and Management
School of Public Health
P. O. Box LG 13 Legon, Accra, Ghana

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your study protocol.

GHS-ERC Number	GHS-ERC: 035/11/21
Study Title	Process Evaluation of Prevention of Mother-To-Child Transmission of HIV Programme in Tamale Teaching Hospital
Approval Date	29th November, 2021
Expiry Date	28th November, 2022
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

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You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....

Dr. James Akazili

(Head, Ethics & Research Management Department)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

1. der the PMTCT Programme.

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