

THE REPUBLIC OF THE GAMBIA



Ministry of Health & Social Welfare

Policy Guidelines for the Prevention of mother-to-Child HIV Transmission in the Gambia

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Foreword

Since the identification of the first case of HIV/AIDS in 1986 there has been a steady rise in the prevalence of the HIV virus, especially the more virulent HIV-1. Activities to stem the epidemic have focussed mainly on prevention and control activities. There has been limited emphasis on what we now know to be a major aspect of the epidemic: the countless number of children who are infected with the virus. Indeed, the transmission of HIV from mother to child is the main mode of spread of the infection to children.

In The Gambia studies have demonstrated that the chances of transmission are higher in women infected with HIV-1 (25%) compared to those infected with HIV-2 (4%). Since HIV-1 is now the predominant virus driving the epidemic in The Gambia there is now an urgent need to include the prevention of Mother-to-Child Transmission (PMTCT) into the overall national effort to control the further spread of HIV in The Gambia.

The long-term survival of the children born to HIV positive women is not only dependant on preventing the child from becoming infected but also ensuring that the mother survives. Therefore the PMTCT programme will not only focus on the child but also increase the access of the HIV positive mother to receive care, support and effective treatment.

The Ministry of Health & Social Welfare will support all efforts to encourage HIV Counselling and Testing (HCT) to encourage all parents now and in the future to have the right to know their status and protect their unborn child. HIV Counselling and Testing (HCT) will be offered in an integrated service delivery package, together with screening and management of Sexually Transmitted Infections (STIs), TB- screening for positive mothers and Family Planning (FP) services. All HIV positive women will be offered a full care package during pregnancy, labour and after birth. Of particular importance will be counselling and support on infant feeding issues for infants born to HIV positive mothers.

The capacity of communities will be built through sensitisation and mobilisation, to address key issues related to raising awareness on the prevention of Mother-to-Child Transmission of HIV infection, stigma and the involvement of men. The programme will enhance the full involvement of People Living with HIV at all stages of its implementation.

Mobilisation of resources will be required for the successful implementation of the programme to ensure its future sustainability and the successful reduction in the transmission of the virus from mother to child.

Finally, I would like to urge all health workers and our partners in the fight against HIV infection to make every effort to implement this important and comprehensive programme.

Signed

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Minster of Health and Social welfare

EXECUTIVE SUMMARY

The first case of HIV/AIDS was diagnosed in The Gambia in 1986. Since then there has been a steady rise in the prevalence of HIV. The 2000/01 sentinel surveillance amongst antenatal mothers indicated a further sharp rise in the prevalence of HIV-1 to 1.2% whereas HIV-2 was relatively stable at 0.9%. In 2007 the prevalence surveillance revealed that HIV-1 is still the predominant virus driving the epidemic.

The transmission of HIV from mother to child is the main mode of spread of the infection to children. 15% of new HIV infections each year are caused by MTCT. In view of this, measures to accelerate and improve programmes of prevention of Mother-to-Child Transmission (PMTCT) should be adopted into the overall effort to control the further spread of HIV in The Gambia. The prevalence of HIV infection in recent times has been erratic. Between 2004 and 2007 the rate decreased from 2.1% to 1.1% in 2005, then sharply increased to 2.8% in 2006 and yet another sharp decrease to 1.4% in 2007. This makes previous extrapolation rate of infected infants invalid. However, if current prevalence rates stay stable, the number of infected infants likely to be born to HIV positive pregnant mothers by 2014 is estimated to be 292.

In a study published in 2000 by Shaw et al in which HIV positive mothers and their children were followed up it was clearly demonstrated that the long-term survival of the children is dependent on whether or not the mother survives. Therefore programmes to prevent the transmission of the virus from mother to child will need to focus not only on the child but also increase the access of the mother to receive effective treatment care and support. In the light of recent scientific evidence a combination therapy is adopted. This will not only provide protection for the child, but also increase access to treatment for the mother and in addition prevent future resistance to antiretroviral drugs.

HIV counselling and testing (HCT) using provider initiated (PICT) and client initiated counselling and testing (CICT) methods increase availability and improve access to care. The individual including partner and family can readily find out their HIV status through this initiative. This would be offered in an integrated service delivery package where there will be screening of and management of Sexually Transmitted Infections (STIs) as well as Family Planning services.

Attention will be given to attendant problems faced by HIV positive mothers such as Vitamin A and nutritional deficiencies, Anaemia and Tuberculosis (TB). A full care package will be used to address the antenatal and post natal care of HIV positive women. Of particular importance will be the counselling and support provided for the feeding of infants born to HIV positive mothers.

The capacity of communities will be built through sensitisation and mobilisation to address key issues related to raising awareness on the prevention of Mother-to-Child Transmission of HIV, stigma and the involvement of men. The involvement of People Living with HIV will be important in all aspects of the programme.

The mobilisation of resources required for the implementation of interventions to reduce Mother-to-Child Transmission of HIV infection is important to ensure future sustainability of programmes and thereby the effective reduction in the transmission of the virus from mother to child.

ACRONYMS

AFASS	Acceptability Feasibility Affordability Sustainability Safety
AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti Retro Viral Drugs
ART	Anti Retro Viral Therapy
AZT	Zidovudine
BCC	Behavioral change communication
CHN	Community health Nurses
CHN/M	Community health Nurse/Midwife
CICT	Client initiated counseling and testing
EFV	Efavirenz
HCT	HIV Counseling and Testing
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IPT	Intermittent Preventative Treatment (for the prevention of malaria)
MDFT	Multi-Disciplinary Facilitating Team
MRC	Medical Research Council (of the Gambia)
MTCT	Mother-To-Child-Transmission of HIV
NGO	Non Governmental Organization
NAS	National Aids Secretariats
OVC	Orphans and vulnerable children
PCR	Polymerase chain reaction
PICT	Provider initiated counseling and testing
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-To-Child Transmission of HIV
RCOG	Royal College of Obstetricians Gynecologists
SdNVP	Single dose Nevirapine
STI	Sexually Transmitted Infections
TBA	(Trained) Traditional Birth Attendant
3TC	Lamivudine
UNICEF	United Nations Children Fund
VHW	Village Health Worker
WHO	World Health Organization

1.0 INTRODUCTION

1.1 HIV IN THE GAMBIA

In The Gambia the first case of Human Immuno-deficiency Virus (HIV) was diagnosed in May 1986. Since then there has been on-going efforts to combat the spread of HIV infection. One major milestone was the establishment of the National AIDS Control Programme (NACP) at the Ministry of Health. Like with most countries, the response gradually shifted from a health sector response to a multi-sectoral response culminating to the establishment of the National AIDS Council (NAC) served by the National AIDS Secretariat (NAS) as the coordinating body of the national response in 2001. In November 2001 high political support was demonstrated when the President publicly stated that HIV posed a major threat to development in The Gambia and also no single person will be dismissed from employment because of his/her HIV status.

The HIV prevalence rates in The Gambia are based on national sentinel surveillance (NSS) of pregnant women. The first sentinel surveillance among antenatal attendees was conducted in 2000-01 and the prevalence of HIV-1 was 1.2% and for HIV-2, 0.9% [2]. The steady increase in the prevalence rates of HIV1 continued to about 2.1% in 2004. The same period saw a decrease of HIV prevalence for HIV2 to 0.8% in 2004, this declining trend continued. The period 2004 to 2007, has been characterized by erratic changes in HIV prevalence rates. While between 2004 and 2005 prevalence rates decreased from 2.1% to 1.1%, the rates sharply increased from 1.1% in 2005 to 2.8% in 2006 and yet a sharp decrease from 2.8% in 2006 to 1.4% in 2007 [3]. Recent data from health facilities providing HIV services is showing a rise in the prevalence of dual infection (HIV 1&2).

The presence of Sexually Transmitted Infections (STI) increases the risk of contracting HIV infection notably in the presence of inflammatory genital infections (*Chlamydia trachomatis* and *Neisseria gonorrhoea*) or ulceration [4]. Young people are also at risk as indicated by a study conducted in 2000 in one of the regions of The Gambia. Nearly a quarter of those tested below the age of 25 years had evidence of a STI [5]. The high prevalence of STIs particularly amongst young people along with other potentiating cultural and economic factors can provide a fertile breeding ground for the acceleration of the HIV epidemic unless rigorous and sustained action is taken to provide a multi faceted response to the epidemic.

It is also noted that the major route of HIV transmission in The Gambia is through heterosexual contact. The transmission of HIV from mother to child is the main mode of spread of the infection to children. In view of this, it is therefore, essential to regularly review and update

strategies and programmes of prevention of Mother-to-Child Transmission (PMTCT) with the aim of improving our overall effort towards reduction of further spread of HIV in The Gambia.

A new national strategic framework 2009 – 2014 to guide the HIV/AIDS response in the country has been developed. The overall approach and strategic direction of the new framework is to establish PMTCT services in all public, private and NGO health facilities conducting RCH clinics and to extend such services at the outreach clinics. The involvement of males and communities will be a new thrust to the programme intervention.

The Primary Objectives of these guidelines include the following;

-To reduce mother to child transmission of HIV from 9.4% in 2006 to 4% by 2014.

-Similarly, the uptake of PMTCT counselling and testing is expected to increase following the strategic plan.

-The facilities based PMTCT uptake is above 80% however, the nation wide statistics reveal that access and coverage was 36% in 2007.

-The set target in these guidelines is to achieve 70%, nation wide coverage and access of PMTCT.

-However, the facility based uptake of PMTCT is expected to remain above 80% by 2014.

The Gambia has successfully implemented the Round 3 of the Global Fund grant and approval has been secured to commence Round 8 of the Global Fund grant October 2009 in order to accelerate prevention, treatment, care and support services in the country.

2.0 VERTICAL TRANSMISSION OF HIV IN THE GAMBIA

The HIV infection can be transmitted from mother to child before delivery, during childbirth and after delivery by breastfeeding. The risk of transmission from mother to child varies. During pregnancy the risk has been estimated between 5-10% and 15-20% during labour. For a child who is breastfeeding the risk is about 15-25%. In mothers who have a high viral load such as those who acquired new infection late in pregnancy and soon after delivery this can increase up to 40% depending on the length of breastfeeding and whether there is any mixed feeding [6]. This finding is similar in recent evidence, which estimated about 20-45% transmission rate where breastfeeding is allowed without prior intervention [7]. The prevention of transmission from mother to child is therefore a critical element in the implementation of strategies to address the HIV epidemic.

Between 1993 and 1995 The Gambian Government with the Medical Research Council initiated a five-year study of antenatal mothers [8]. The Significant factors that increased the likelihood of the mother becoming infected with HIV-1 included having more than one sexual partner; receiving gifts or money for sex; having a positive test for syphilis; the death of the previous baby and previous history of the husband travelling abroad. Those women with HIV-2 infection reported having had more than one sexual partner and had a positive test for syphilis.

Another important observation was that the higher the viral load seen when the disease progresses the more likely it was for a mother to transmit the virus to her unborn infant. This indicates the need to diagnose mothers before the disease has progressed far. Although it is recognised that the viral load, is also very high for a short period in the very early stage (sero-conversion) and this is associated with a high risk of transmission of infection. Subsequently, it was shown that as a result of breastfeeding one in five (20%) infants who were negative at birth became positive through breastfeeding [8]. The same study showed that infants born to mothers who were HIV 1 positive and who had a high viral load died more frequently than those whose mothers were HIV-2 positive.

Follow up of the mothers and children in The Gambian Government/MRC study found that 34% of all HIV infected antenatal mothers identified between 1993 and 1995 had subsequently died as did 69% of HIV-1 infected children and 66% of all orphan children irrespective of their HIV status [8]. This study also showed that for the long-term survival of the children it is vital that the mother survives. Therefore not only the infant but also the mother needs to receive effective treatment. This will ensure that care for the child can continue and the number of orphans may be controlled.

From this study, the rates of mother to child transmission of HIV-1 and HIV-2 were estimated at 25% and 4% respectively [8].

The most recent evidence which assessed the impact of our intervention programmes revealed a Mother-To-Child Transmission rate of 7.3% HIV 1; 2.1 % HIV 1 & 2 and 0.0% HIV 2. The total HIV positive cumulated to 9.4% overall, despite the variance in individual years (2004, 2005, 2006) [9].

This Gambia study is consistent with findings in other parts of the world whereby it is well established that advanced maternal HIV disease, low antenatal CD4 T-lymphocyte counts and high maternal plasma viral loads are associated with an increased risk of mother-to-child transmission [10]. The latter is now recognized as being the strongest predictor of transmission. Two large studies demonstrated that perinatal transmission was significantly associated with maternal plasma viral load [11, 12].

3.0 ANTENATAL CARE

3.1. PMTCT HIV COUNSELING AND TESTING

In the context of MTCT prevention, counselling and testing is a flexible intervention that is integrated into several settings where pregnant women and women of child bearing age receive services; antenatal, labour and delivery, postnatal, family planning, and others. Increasingly these programs are providing pre-test information and post-test counselling.

Provider Initiated HIV counselling and testing (PICT), is offered as a routine part of a standard package of care. The woman is given the opportunity to decline the test at any point of HCT should she choose to do so. This opt-out approach emphasises that HIV testing is an expected part of ANC. Provider Initiated HIV counselling and testing (PICT) in PMTCT, implies that HIV testing should be offered in all services delivery points for women (pregnancy and lactation) with ANC, labour/deliveries, FP etc; either on outreach or static points; same day results to the women and as much as possible pre test counselling included in health talk and minimize the waiting time of women during the individual pre test counselling.

However, clients may decline test. The provider through ongoing counselling may identify the problem and possibly resolve issues that are preventing a woman from accepting testing. This is one of the fundamental prerequisite of PICT and it has been found to increase uptake of HIV counselling and testing (HCT) in line with universal access to care.

When PMTCT is accessible to pregnant women and their partners appropriate services can be implemented for those identified as seropositive.

An essential element of effective HCT is privacy and confidentiality. However many factors hinder the likelihood of ensuring such privacy for the delivery of HCT services such as inadequate space, large numbers of women attending antenatal clinics and dwindling numbers of staff, particularly midwives in the public sector. However, the recommendation is that the counsellor should ensure at all times that the key elements of counselling are maintained [13].

Shared confidentiality should be privileged, so that other health workers would be aware and ready to provide treatment and care services to women at any given time as well as other family members or friends.

Counselling and Testing for HIV among pregnant women and their partners must be readily available, preferably at all facilities where antenatal care is offered. This necessitates training and re-orientation of counsellors and health workers on the issues related to PMTCT and the provision of adequate space and privacy for HCT. Spot tests will be used for both initial testing and confirmation and post-test counselling will be offered the same day.

3.1.1. POST TEST COUNSELLING

The recommendation is that, post test counselling is offered the same day in the same health facility. The counsellor should ensure that appropriate labelling was done; the test results obtained were performed according to stipulated guidelines; [13], and the client is willing and ready to receive results.

3.1.2. NEGATIVE RESULT

An explanation of test results including information about the window period for the appearance of the HIV anti-bodies and a recommendation to repeat testing three months later should be emphasized whether or not she will deliver before then. A pilot longitudinal observational study, which was undertaken in preparation of these guidelines, revealed that clients don't come for repeat testing and counselors do not emphasize it.

The recommendation is that a concerted effort should be made to emphasize repeat testing as evidence have shown that high viral load in early stage of infection is associated with high perinatal transmission rate.

In addition, it is important to ensure that women identified as HIV negative receive necessary, immediate support to prevent becoming infected during the course of pregnancy and the breast-feeding period. This will include basic information on methods to prevent HIV transmission, the provision of male and female condoms and guidance on their use.

In HIV negative mothers, HCT has an important role to play in enabling maintenance of their status through safer sex options that are advocated during the counselling undertaken both before and after testing.

As much as possible partners should be invited for HCT in order to ensure full couple support and effective STI prevention services for the family.

3.1.3 POSITIVE RESULT

The result is positive when 2 rapid spot tests showed positive on two samples taken from the same person at different times [13]. The result should be communicated clearly and simply following the guidelines [13].

There are several potential benefits for HIV positive mothers. These include: improved health status through good nutritional advice; increased awareness of safer options for reproductive health; wider access of pregnant women and their families to HIV preventive measures; wider access to support services (medical, psychological, social and community based support); increased opportunity to advocate for contact tracing or to reach partners of infected women; the opportunity for health personnel to better understand the psycho-social problems of HIV infected persons; earlier and wider access to care; ARVs and treatment for HIV related illnesses. These should be emphasized during this counselling.

3.2. ANTI-RETROVIRAL THERAPY/PROPHYLAXIS

The risk of MTCT can be reduced to under 2% by interventions that include antiretroviral (ARV) prophylaxis given to women during pregnancy and labour and first week in the postpartum and to the infant in the first weeks of life, obstetrical interventions including elective caesarean delivery (prior to the onset of labour and rupture of membranes), and complete avoidance of breastfeeding. With these interventions, new HIV infections in children are becoming increasingly rare in many parts of the world, particularly in high-income countries.

In our setting, elective caesarean delivery is seldom feasible [14] and it is often neither acceptable nor safe for mothers to refrain from breastfeeding.

Recently, to increase the effectiveness of PMTCT programmes, available evidence have shown that adopting more effective ARV regimens, beginning in the second trimester of pregnancy, can reduce the risk of transmission during pregnancy and childbirth to less than 5% [15, 16]. Even when these regimens are used, however, infants remain at substantial risk of acquiring infection during breastfeeding in particular when mixed feeding. Evidence is overwhelming regarding new approaches to preventing HIV transmission during breastfeeding [17, 18, 19, 20]. These evidences have been validated by the WHO and guidelines have been issued.

In this policy we recommend a comprehensive approach to care. A woman's clinical stage and her CD4 cell count should be assessed routinely in order to determine her eligibility for ART. Immunological assessment (CD4 count) is imperative as clinical stage does not always correlate with CD4 count (even viral load) and many HIV-infected persons appear clinically asymptomatic despite advanced/severe immune-suppression (i.e. CD4 count \leq 350). Thus if CD4 count is not

measured one may miss potentially eligible women. Therefore in this regard, access to CD4 measurement must be scaled-up and pregnant women should have at least one CD4 count done during pregnancy. The absolute CD4 count of 350 is the reference point. If it is 350 or below, ART should be initiated as soon as possible and when above 350 ARV prophylaxis should be commenced as recommended in these guidelines.

For a pregnant woman with indications for ART, such treatment reduces maternal mortality and morbidity, is the most effective method of preventing MTCT of HIV and, by securing the health of the woman, improves the chances of survival of her child.

For these reasons every effort should be made to ensure that all women who require ART (triple ARVs) have access to it. The criteria for eligibility for ART should be according to National guidelines.

For pregnant women who do not yet require ART (triple combination) should be given efficacious ARV regimen for prevention of MTCT. This consists of:

HIV-1 INFECTED WOMEN

Women living with HIV-1 who required ART in pregnancy should start ART irrespective of the gestational age. The first line regimen of (AZT/3TC/NVP) is recommended in pregnancy. The ARV prophylaxis for the baby is daily Nevirapine (NVP) immediately after birth until 6 weeks of age (if breastfeeding). Or receive daily AZT or NVP from birth until 6 weeks of age (if not breastfeeding).

Women who do not require ART for their own health;

Should start triple ARV from 14 weeks of pregnancy (or as soon as possible thereafter) until one week after all exposure to breast milk has ended.

- AZT+3TC+ABC **[21] (fixed dose combination to improve compliance)**
- For breastfeeding infant; daily NVP from birth until 6 weeks of age
- For non-breastfeeding infant; daily AZT or NVP from birth until 6 weeks of age

HIV-2 INFECTED WOMEN

Women living with HIV-2 who required ART in pregnancy the first line regimen of (AZT/3TC/LPV/r) are recommended in pregnancy as neither NVP nor EFV are sensitive to HIV type 2. The risk of MTCT of HIV-2 is relatively low; the benefits of giving ARVs may be outweighed by the risk of drug toxicities. However, for those who require ART in pregnancy, triple regimen (AZT/3TC/ LPV/r) are recommended and PIs (e.g. LPV/r) should still be used for patients who required 2nd line treatment **[21]**.

Women who do not require ART for their own health;

Should start triple ARV from 14 weeks of pregnancy (or as soon as possible thereafter) until one week after all exposure to breast milk has ended.

- AZT+3TC+ABC [21] (**fixed dose combination to improve compliance**)
- For breastfeeding infant; daily AZT from birth until 6 weeks of age
- For non-breastfeeding infant; daily AZT from birth until 6 weeks of age.

Type 2 infected Women who are on treatment with AZT/3TC/LVP/r for their health before pregnancy should continue on this regimen.

DUAL INFECTION (HIV-1 AND 2)

Women living with HIV-1 and 2 who required ART in pregnancy should start ART irrespective of the gestational age. The first line regimen of (AZT/3TC/ LPV/r) is recommended in pregnancy as neither NVP nor EFV are sensitive to HIV type 2. The ARV prophylaxis for the baby is daily NVP immediately after birth until 6 weeks of age (if breastfeeding). Or receive daily AZT or NVP from birth until 6 weeks of age (if not breastfeeding).

Protease inhibitors (e.g. LPV/r) should still be used for 2nd line treatment [21].

Women who do not require ART for their own health;

The risk of MTCT of HIV-1 is much higher than for HIV-2. [21]

Women living with both HIV-2 and HIV-1 should receive appropriate ARV prophylaxis as per the guidelines for prevention of **HIV-1 infection.**

The infant ARV prophylaxis remains as stated above.

Women who are dually infected (type 1&2) and on treatment with AZT/3TC/LVP/r for their health before pregnancy should continue on this regimen

Widespread implementation of this regimen will dramatically reduce the number of new HIV infections in infants and young children and result in low levels of HIV viral resistance.

3.3 SCREENING FOR GENITAL INFECTIONS AND EFFECTIVE STI MANAGEMENT

All pregnant women who are HIV positive should be screened for genital infections during pregnancy. This should be done as early as possible in pregnancy and repeated in the 3rd trimester (28 weeks and above). It is advocated that this should be integrated into RCH services.

Genital infection, especially genital ulcer disease, has been strongly associated with increased risk of HIV transmission. There is clear evidence that the presence of other STIs in association with HIV infection in pregnancy and during breastfeeding increase the risk of MTCT. Similarly, cervicitis in pregnancy or cervicovaginal secretions has been shown to correlate with Mother-to-Child HIV transmission [22]. It potentiates the transmission rate as the viral load in these secretions are significantly high.

In view of this, effective genital screening of STIs and other vulvo-vaginal conditions such as candidiasis, bacterial vaginosis, and early diagnosis, management and treatment should be enhanced to reduce MTCT. Syphilis screening is already included in standard antenatal care. Syndromic management of STIs should be adopted and implemented to facilitate active treatment of STIs as quickly and conveniently as possible. Integration into antenatal, postnatal and family planning services should involve active screening of women for STIs.

An HIV positive pregnant woman should be screened for hepatitis B and C as they are also sexually transmitted infections. When screened positive for hepatitis B or C the choice of ARV may be influenced.

The standardized management of STIs that is based on the syndromic approach should be instituted in all health facilities. Barrier methods of contraception, such as condoms are recommended during pregnancy and lactation for HIV positive mothers. Partner involvement and management is essential in the care and further control of STIs especially HIV infections. IEC, BCC and other advocacy initiatives shall be implemented to improve STI partner management.

3.4 TB- SCREENING

All HIV positive women should be screened for TB and vice versa.

Clinical screening should be performed at every antenatal visit. These include history of cough for more than two weeks, weight loss, night sweats, fever and hemoptysis.

All HIV positive women with cough that has lasted for more than 2-3 weeks should be screened for active TB. Both laboratory and radiological investigations can be performed in pregnancy.

These include Mantoux test, Rapid serum and sputum Acid Fast Bacilli (AFBx3) test and X-Ray with abdominal shielding.

When screened positive appropriate referral to TB treatment unit is recommended. For positive mothers who are already on NVP-based ART this should be changed to EFV-based regimen if the pregnancy is in the second or last trimester. If EFV is continued in the postpartum effective contraception should be ensured. If TB occurs in the first trimester EFV should be avoided and triple NRTIs (AZT/3TC/ABC) are recommended. The use of PIs is not recommended [23] See SOPs (ART-Manual update).

In pregnant women living with HIV and active TB, the first priority is to treat the TB. With careful clinical management, however, a woman with TB can receive ART and treatment for TB simultaneously.

3.5 THE USE OF CO-TRIMOXAZOLE (SEPTRIN)

The use of co-trimoxazole (Septrin) prophylaxis in pregnancy among HIV positive client is well established (24). Co- trimoxazole is among the most cost-effective interventions available for people with HIV and should be a top priority among efforts to reduce the risk of opportunistic infections in people with HIV.

The introduction of routine co-trimoxazole prophylaxis for women living with HIV who had CD4 cell counts <200 cells per mm³ have been shown to have significant improvements in birth outcomes, with reductions in chorioamnionitis, prematurity and neonatal mortality. 24].

In view of this evidence all pregnant HIV client on ART should be given co-trimoxazole (folate antagonists) regardless of the stage of pregnancy as the benefits outweighs the risk.

For those who are not on ART but required co-trimoxazole prophylaxis because CD4 is low (less than 500), the same recommendation as stated above should be applied.

For pregnant women with HIV who are receiving co-trimoxazole prophylaxis, additional sulfadoxine/pyrimethamine-based intermittent preventive therapy (IPT) for malaria is not recommended. [24]. However, those who are not on co-trimoxazole prophylaxis, IPT guidelines should be followed.

At 6 weeks post partum, baby should be on co-trimoxazole prophylaxis irrespective of infant HIV status as long as mother would like to breastfeed. For non-breastfeeding mothers, if the baby test negative at 6 weeks or thereafter co-trimoxazole prophylaxis is not recommended.

3.6 INFANT FEEDING COUNSELLING

Counselling on infant feeding issues (such as breastfeeding, complementary feeding and formula feeding) is fundamental in PMTCT programmes.

Guidelines on counselling for infant feeding for health workers should include:

- ◆ The choice of feeding for a baby whose mother is HIV positive should be that of the parent.
- ◆ Well-trained counsellors should provide mothers/partners with all the information available to enable them make an informed choice. The information should include all the advantages of breast milk and breastfeeding and also the risk associated with HIV transmission through breastfeeding. It should also include the reduced risk with exclusive breastfeeding as compared to mixed feeding.
- ◆ That the options available are exclusive breast feeding for the first months and formula feeding, IF the AFASS criteria is fulfilled, i.e. acceptability, feasibility, affordability, sustainability and safety.
- ◆ Considering that mixed feeding may result in a higher risk of HIV transmission, after counselling, if the mother chooses to breastfeed her child she should be encouraged to exclusively breastfeed (breast milk alone, no food or water with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines) for six months with on-going counselling. However, breastfeeding can continue for 12 months provided the ARV prophylaxis recommended in these guidelines is observed. **FOR 12MONTHS PROVIDED BOTH MOTHER AND CHILD ARE ON ARVS.**

The counsellor should expound that;

-Complimentary feeding is any food, whether manufactured or locally prepared, used as a complement to breast milk or to a breast-milk substitute. The child receives both breast milk or a breast-milk substitute and solid (or semi-solid) food. It is recommended that complimentary feeding from 6 months would be more appropriate as mixed feeding will occur if not properly guided.

-Mothers known to be HIV- infected (and whose infants are HIV-uninfected or of unknown HIV status) **should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complimentary foods thereafter, and continue breastfeeding for the first 12 months of life-** Breastfeeding should then only be stopped once a nutritionally adequate and safe diet without breast milk can be provided.

-Mothers known to be HIV infected who decide to stop breastfeeding at any time should stop gradually within one month. **Mothers** or infants who have been receiving ARV

prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.

-When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development.

-If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding up to the age 2 years and beyond.

3.6.1. EXCLUSIVE BREAST FEEDING

All health workers should continue to protect, promote and support breastfeeding. Despite the risk that babies become infected with HIV through breastfeeding, about six Out of ten babies born to HIV positive mother may not get the infection even if they are breastfed. However, children who are not breastfed are fourteen times more likely to die compared with children who are breastfed. Meta-analysis has shown that lack of breastfeeding compared with any breastfeeding exposes children to increased risk of malnutrition, diarrhea and pneumonia, especially in the first year of life [25].

The Code for Marketing Breast Milk Substitutes and the UNICEF/WHO ten steps to successful breastfeeding which has been adapted and adopted by The Gambian Government as their breastfeeding policies should be adhered to. The policy of promoting exclusive breastfeeding for six months for all mothers and the gains so far achieved in adhering to this policy should be promoted.

Mothers who are willing to stop breastfeeding will need nutritional support for infant feeding at that time.

Breastfeeding support should be provided both for HIV negative and those HIV positive mothers who choose to breastfeed to minimise breastfeeding problems and maximise exclusive breastfeeding.

3.6.2. FORMULA FEEDING

If the mother chooses not to breastfeed, all the risks associated with alternative or replacement feeding should be explained to the mother. The information provided should include a guide on the appropriate use of the feeds, environmental sanitation and the availability of follow-up support.

The assessment conducted by the counsellors to enable them to guide the mother, should include issues of acceptability, feasibility, affordability, sustainability and safety of alternative feeding (AFASS).

Mothers who choose not to breastfeed should be given full support in provision and management of alternative feeds.

3.7 NUTRITIONAL SUPPORT AND SUPPLEMENTATION

3.7.1. VITAMIN A SUPPLEMENTS

Vitamin A has a well-recognized role in maintaining epithelial cell integrity and hence may modify and enhance prevention of HIV transmission. HIV infected mothers with Vitamin A deficiency have a higher risk of MTCT. However, high dose vitamin A supplementation is not recommended during pregnancy and the use of multivitamin preparations would be preferred. The recommended vitamin A composition is the *B*-carotene and the dose should be less than 700 IU per day.

The national policy currently recommends routine Vitamin A supplementation for women six to eight weeks after delivery and for children 6-59 months following the national recommendation. It is recommended that this policy be continued and that multivitamins should be routinely administered during pregnancy.

3.7.2 ANAEMIA: PROPHYLAXIS AND TREATMENT

Anaemia is a common problem in pregnant women with HIV. HIV positive mothers should be given routine iron and folate supplementation during pregnancy and until six weeks after birth. If blood transfusion is necessary to correct anaemia, national blood transfusion guidelines should be followed. Special attention needs to be given to mothers receiving ART to ensure that anaemia is corrected early.

3.7.3 MALARIA PREVENTION

Intermittent Preventive Treatment (IPT) and insecticide treated bed-nets for the prevention of malaria is essential in order to prevent anaemia for all mothers particularly those living with HIV. In addition effective management and Intermittent Preventive Treatment (IPT) for malaria with sulfadoxine-pyrimethamine during pregnancy is essential as preterm delivery and small for date babies and attendant risk of increased MTCT will be minimised.

3.7.4 NUTRITIONAL SUPPLEMENTS

Beside micro-nutrients, mothers living with HIV have a need for high protein and energy foods. Necessary efforts will be undertaken to ensure that protein rich nutritional supports are provided for mothers during pregnancy and lactation. However this is to supplement family support on provision of balanced diet which should be emphasised during counselling.

3.7.5 FOCUSED AND INTEGRATED ANTENATAL CARE

For those mothers who are HIV positive routine antenatal care is a necessity, together with ongoing counselling, care and support specific to people living with HIV.

Additional staff time will be required to offer quality services.

The care package for women living with HIV should include:

- The diagnosis and assessment of clinical and immunological status
- Treatment and prevention of opportunistic infection
- STI management
- Counselling on infant feeding options
- Vitamin supplements and nutritional support
- Effective management and Intermittent Preventive Treatment (IPT) for malaria with sulfadoxine-pyrimethamine during pregnancy are essential. Also Provide ITN.
- Co-trimoxazole prophylaxis for pregnant mothers will be provided if they are severely immuno-compromised (CD4 count <500).
- PCR should be used to determine all exposed infant serostatus at 6 weeks. For women who prefer to breastfeed for up to 12 months or more, a confirmatory serology test may be done at 18 months.
- Psychological support should be offered at all stages of the care package.
- ARV prophylaxis or therapy

Facilities offering PMTCT services should link up and net work with ART clinical sites for work up for enrolment into ART and other benefits. All facilities providing routine antenatal care services will provide full PMTCT services including HCT and a care package for mothers and children. Human resources need to be trained, motivated and retained to provide effective services. Innovative models need to be developed and partnerships promoted in order to deliver high quality services.

4.0 INTRAPARTUM CARE

The presence of the virus in the body fluids such as blood and mucus in the birth canal poses a potential risk to the baby during labour and birth.

4.1. MODE OF DELIVERY

A meta-analysis of 15 prospective cohort studies which included 8533 mother –child pairs, reported a 50% reduction in the transmission rate in women who underwent an elective caesarean section before the onset of labour or rupture of the membranes [26].

However, some studies have suggested that postoperative complications, particularly sepsis, are increased in women who are HIV-infected compared with those who are uninfected with complication rates related to the level of maternal immuno compromise [27].

In view of the available evidence, elective caesarean section to all HIV positive pregnant women will not be recommended. However caesarean section for obstetric reasons should be undertaken. If, caesarean section is required necessary precaution should be observed in order to prevent sepsis postoperatively.

4.2. OBSTETRIC RISK FACTORS

Prolonged rupture of the membranes has been shown to increase the risk of transmission. Therefore, avoidance of artificial rupture of membrane (ARM) and maintenance of an intact membrane for as long as possible should be encouraged.

Invasive obstetrics procedures, including episiotomy, may increase the risk of transmission by increasing the level of infant exposure to maternal blood and genital secretions. These procedures should be minimised to reduce the risk of HIV transmission to infants.

Others include iatrogenic or inadvertent trauma to the baby should be avoided; instrumental delivery; prolonged rupture of membrane for more than 4 hours should be avoided. Labour management should be active and effective use of partogram ensured. The use of oxytocic agents is not contraindicated and should be judiciously used when indicated to expedite labour.

It is important to provide assistance and support during labour to reduce the length of time to which the baby is exposed to maternal blood and vaginal secretions.

The cord should be clamped as early as possible after delivery and milking should be avoided. The baby should be bathed immediately after birth.

4.3 INTRAPARTUM ANTIRETROVIRAL THERAPY (ART)

The midwife should ensure that ARVs are utilised as recommended in these guidelines. They should ensure that the daily regimen continued.

The primary objective is to maintain significant reduction of viral load at the time of delivery thereby optimising our effort towards successful reduction of MTCT.

4.4 UNIVERSAL PRECAUTION

Attending midwives should ensure that the universal precaution is practiced. Strict adherence to universal precautions is necessary whatever the environment, in order to prevent infection of others, including health workers. Also stigma and discrimination may be avoided on the labour ward if universal precaution is practiced for all patients. The place of vulva-vaginal antiseptic cleansing in labour (e.g.chlorhexadine) is as yet inclusive but the trend is towards reduction of MTCT.

5.0 POST PARTUM CARE

Postpartum care should include maternal and infant ARV prophylaxis; infant-feeding support and follow-up of mother and child.

5.1. POSTPARTUM ARV PROPHYLAXIS

5.1.1 MATERNAL ARV PROPHYLAXIS

Maternal triple ARV prophylaxis should continue until one week after all exposure to breast milk has ended.

- AZT+3TC+ABC (**fixed dose combination to improve compliance**)

5.1.2 NEONATAL ARV PROPHYLAXIS

- All infants born to women who are HIV positive should be given ARV prophylaxis. The recommended regimen;
- For breastfeeding infant; daily NVP from birth until 6 weeks of age
- For non-breastfeeding infant; daily AZT or NVP from birth until 6 weeks of age.

5.2 COUNSELLING AND SUPPORT ON INFANT FEEDING

Screening for AFASS of supplementary feeding options and understanding of her local context are important for counseling her regarding the appropriate feeding choice. After a choice is made, nurses and midwives must support this choice and assist a mother to exclusive and safe practice of that choice. The pilot observational study in the preparation of these guidelines revealed that most of the clients opted for exclusive breastfeeding. However, weaning at 6 months was difficult.

Babies who are breastfed remain at risk of infection for as long as breastfeeding continues. This risk increases with the duration of breastfeeding. Thus women should be encouraged to stop breastfeeding as soon as possible not just stop exclusive breastfeeding but avoiding mixed feeding completely. The success of this aspect of care package depends on how effective our counselling skills are. However, changes may occur as new evidence comes out.

The infant and mother must be monitored regularly for signs of infection and appropriate referral is required when indicated. It is recommended that monthly review in first year of life and start of complementary feeding at 6 months would be appropriate. This would reduce the number of lost to follow ups and facilitate early diagnosis at 6 weeks with polymerase chain reaction (PCR). At the monthly visit the child's growth curve should be monitored and infant feeding counselling reinforced. Malaria prevention strategies following the national protocol is recommended.

Typically, PCR tests are carried out at birth, then at three weeks, six weeks and six months. For non –breastfed babies, over 99% of those testing HIV- negative by PCR at six months will be uninfected [29].

For cost effectiveness, this policy recommends determination of all exposed infant serostatus at 6 weeks of age with PCR. If the infant is breastfed serology test at 18 months is also recommended.

6.0 PRE-PREGNANCY CARE

6.1. FAMILY PLANNING SERVICES

Family planning services play an essential role in promoting and protecting the right of all women and men to their sexual and reproductive health. Thus there is need to update and re-train family planning counsellors on STI screening and PMTCT. The integration of HCT into family planning services will be enhanced.

People living with HIV need to be counselled on the need for dual protection for both pregnancy and STI/HIV infection using hormonal contraception and condoms.

6.2. DISCORDANT COUPLES

For couples discordant for HIV infection who wish to conceive, appropriate advice should be given to optimise the chance of conception while minimizing the risk of sexual transmission.

6.2.1. POSITIVE MALE PARTNER

When the male partner is HIV positive, sperm washing where by spermatozoa are separated from surrounding HIV- infected seminal plasma by a sperm swim- up technique is recommended. This facility can be procured and effectively utilized for this purpose [30]. To date there have been no seroconversions in women inseminated with washed sperm [31].

However this is not currently available in the Gambia. Another alternative, which is not reassuring as the above technique, is limiting sexual intercourse around the time of ovulation. The estimated risk of transmission of HIV to a woman of HIV- positive partner is 1:500 to 1:1000 (0.02% to 0.1%) per sexual act [32]. However couples wishing to practice this technique must be counselled on the risk of transmission to the female partner.

6.2.2. POSITIVE FEMALE PARTNER

When the female partner is positive artificial insemination at the time of ovulation should be advised. However, this is not routinely available in the Gambia but may be procured for this purpose.

7.0 COUNSELLING, CARE AND SUPPORT

Currently there is considerable stigmatisation attached to HIV infection. Therefore, HIV positive women need social support. Counselling is necessary in order to cope with issues of pregnancy; their HIV status; taking antiretroviral drugs aimed at protecting not only the baby but also the mother; dealing with infant feeding issues and choosing a method of family planning and looking at HIV prevention.

Thus holistic care for the family, and not merely for protection of the infant, is essential. This will also include care and support for the spouse/partner.

Social services, peer education of people living with HIV and support groups plays an important role in ensuring a continuum of care from the home to the hospital level.

8.0 CAPACITY BUILDING OF HEALTH WORKERS

Health workers dealing with pregnant women and counsellors will be trained in the prevention of Mother -To-Child-Transmission. The training programme will include all health care providers. In addition community based health workers (TBA, MDFTs, VHW and volunteers) will also be included in a basic training on PMTCT. Each facility that will provide PMTCT services will have a team of trained service providers that will ensure quality service delivery.

Policy makers, health planners, administrators and health services managers will also be sensitised on the needs and nature of the programme. Provision of essential supplies for effective and quality implementation of services should be ensured.

9. COMMUNITY MOBILISATION FOR PMTCT

Community mobilisation will be an integral part of the PMTCT programme. The Ministry of Health and Social welfare will establish partnerships with existing community structures to ensure the successful implementation of the programme. Such community structures include community baby friendly initiatives and Mother to mother support groups. These initiatives would be prompted and established to ensure effective mobilisation for PMTCT.

Community mobilisation needs to address the issue of male involvement in the programme. It advocates for a more active role for men in the prenatal, intra partum and postpartum care of women.

Community mobilisation programmes will also address acceptability of HCT at community level for both partners and involve community leaders and gatekeepers at all levels. Gender issues and the creating of a supportive environment for PLHIV in collaboration with OVC is another essential component of the IEC/BCC programme.

All parts of civic society need to be involved in the process of strengthening the Sectoral links. Government's multi sectoral approach to combat HIV should be re-affirmed.

10. INVOLVEMENT OF PLHIV

People living with HIV play a key role in all aspects of programme development, implementation and monitoring. In addition PLHIV are involved in advocacy and also counselling and support. Support groups of PLHIV will provide socio-economic support and care to women, families and orphans within the programme. They should be made part of the care team in both ART and PMTCT sites.

11. MONITORING AND EVALUATION OF PMTCT INTERVENTIONS

The PMTCT interventions in The Gambia will require a well thought out monitoring and evaluation system. The national reproductive and child's health programme (RCH) will be responsible for Monitoring and Evaluation of the PMTCT programme in collaboration with the National AIDS Secretariat.

The Ministry of Health and Social Welfare will monitor implementation of activities and disseminate all findings to relevant stakeholders. All facilities providing PMTCT services; private, NGO and public will be required to submit and provide PMTCT data. In addition attention will be given to the following:

- ◆ Standard monitoring and evaluation of tools and procedures will be put in place.
- ◆ Outcome and impact indicators will be selected based on WHO guidelines.

12. RESOURCES AND SUSTAINABILITY

Given the socio-economic and health impact of HIV, the Ministry of Health and Social Welfare and the National AIDS Secretariat will seek to mobilise resources from as many sources as possible. This will include international and local collaborating partners. Resources will be used to scale up the programme and make services available countrywide. In addition this will strengthen the institutional capacity and human resource base in the country to ensure the delivery of high quality services.

13. PROGRAMME MANAGEMENT

The first priority in the implementation strategy of these guidelines is the assessment of capacity and appropriate consideration of readiness. Capacity building is pivotal in the introduction of any guideline. Evidence has shown that introduction of combination antiretroviral drugs in prevention of mother to child transmission of HIV required capacity development which may include human resources, infrastructure and procurement of necessary equipments.

Consideration of readiness to provide the service should include identification of the site and naming of a care team coordinator. The coordinator will have a defined role and should be part of the care team. Care team must be properly trained using the training and structured operational manuals.

The provision of PMTCT services in the government and non-government institutions should be at no cost. This should be emphasised during counselling. **Client should not pay for the services.**

Efficient information management systems should be designed. The monitoring and evaluation team should work out modality on the realization of efficient data management. The chain of communication between appropriate units should be seamless.

There should be a patient/treatment tracking system in place. This should be established from the booking date. Part of the patient/treatment tracking system is efficient linkages. As client events unfolds (e.g. low CD4 count, anaemia ect) proper referral system with feedback mechanism should be ensured (see SOPs). Efficient linkages between other health centres and PMTCT sites and in turn PMTCT sites and ART centres should be established. This communication should be seamless.

For effective programming and implementation of these guidelines it is imperative to incorporate maximum utilization of the community-based service providers such as VHW, MDFTS, Mother to Mother support group, Breast feeding club, VSGs TBAs, CHN and CHN/M in our effort towards reduction of MTCT. These organizations should be promoted where available. Their role in facilitating efficient client treatment/tracking can not be overemphasised. Therefore it is pertinent to strengthen these organizations

GLOSSERIES

CARE TEAM: This consists of people who work in the health facility providing care for the client. The team should have representatives from different cadre of professional status as well as in different departments such as maternity, pharmacy, laboratory, social work, nurse counsellors and lay counsellors e.g. PLHIV.

CARE TEAM COORDINATOR: This is the leader of the care team. He should have leadership role and be part of the team. He should be a health worker that belongs to any one of the above departments. His roles should be properly defined.

COMPLEMENTARY FEEDING: This is any food, whether manufactured or locally prepared, used as a complement to breast milk or to a breast-milk substitute. The child receives both breast milk or a breast-milk substitute and solid (or semi-solid) food. This is recommended from 6 months to avoid mixed feeding.

DISCORDANT COUPLES: This is where one partner is HIV positive and the other is negative.

PMTCT ACCESS: This is the ability to procure the services without hitches.

PMTCT COVERAGE: This is the same as scaling up strategy. Whereby the PMTCT services is made available in all communities at any given opportunity such as through out-reach and satellite clinics.

PMTCT UPTAKE: The antenatal mothers who accepted the services after counselling.

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EXCLUSIVE BREASTFEEDING

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