### Table of Contents

**FOREWORD**

**Acronyms**

**Executive Summary**

1. HIV CONTROL IN UGANDA
2. JUSTIFICATION FOR ANTIRETROVIRAL THERAPY IN PREGNANCY
3. VERTICLE TRANSMISSION
4. ANTIRETROVIRAL THERAPY IN THE REDUCTION OF MTCT-GLOBAL
5. MOTHER TO CHILD TRANSMISSION OF HIV IN UGANDA
6. THE PMTCT INTERVENTION
7. MONITORING THE MTCT INTERVENTIONS
8. TRAINING
9. POICY ISSUES
   9.1 ANTI RETRO VIRAL THERAPY (ARV) IN REDUCTION OF MTCT IN UGANDA
9.2 VOLUNTARY COUNSELLING AND TESTING (VCT)

9.2.1 THE ROLE OF VCT

9.3 INFANT FEEDING ISSUES
   a) Major benefits to breast feeding
   b) Risk and inconveniences of breast feeding

9.4 ADDITIONAL INTERVENTIONS LIKELY TO REDUCE MTCT

9.4.1 VITAMIN A SUPPLEMENTS

9.4.2 ANAEMIA PROPHYLAXIS AND TREATMENT

9.4.3 STI DIAGNOSIS AND TREATMENT

9.4.4 MODIFICATION OF OBSTETRICAL CARE

9.4.5 FAMILY PLANNING SERVICES

9.5 SUPPORT FOR MOTHERS AND INFANTS

9.6 PUBLIC MESSAGES IN RELATION TO MTCT

9.7 RESOURCES AND SUSTAINABILITY

ANNEX 1

Cost per Regimen

REFERENCES

FOREWORD

The HIV/AIDS epidemic started in Uganda two decades ago. Since then, a lot of effort has been channeled towards addressing the prevention and control of its spread within the population. Over the past decade specifically, this effort has focused on prevention of sexual spread of the infection. As a result, some successes have been recorded. Recent surveillance reports from the STD/AIDS Control Programme indicate that the HIV prevalence is declining in some population groups in the country. However, the rates are still unacceptably high as in the urban centers between 10-12% of pregnant women attending the antenatal clinics are found to be HIV positive. This calls for continued efforts and diversification of the control strategies including Prevention of Mother to Child Transmission. It is important to address mother to child transmission of HIV since it is the second major mode of HIV transmission in Uganda as well as the main mode of spread of HIV infection to children.

Research conducted in USA, France and Thailand and more recently in South Africa, Tanzania and Uganda showed that administration of antiretroviral drugs during pregnancy, labour and post partum period can result in significant reduction of mother to child transmission of HIV. The success of the intervention also significantly depended upon its implementation within a context of a strong and comprehensive antenatal, labour and postnatal care services.

Given the above useful findings, there is need to translate the research findings into practical intervention activities that are integrated within the normal health care delivery system. This implies that a number of different stakeholders such as partners from government, Non-Governmental Organisation and the private
sector are to be involved this venture. For this to be done well, there is need for the development of a policy document that can guide the different actors, set the standards and ensure quality control of the implemented activities. Hence, the rationale of this document.

This policy document has been developed for use by planners and managers who are involved in implementation of activities for prevention of mother to child transmission of HIV (PMTCT) at both the national and district levels. It aims at streamlining and guiding the process of initiating and implementing PMTCT interventions in Uganda. Due to the importance of this policy document, I strongly appeal to all stakeholders to use it as reference point during implementation of the PMTCT interventions.

Hon. Dr. Beatrice Wabudeya
MINISTER OF STATE FOR HEALTH
PRIMARY HEALTH CARE

Acronyms

3TC Lamivudine
ACTG 076 AIDS Clinical Trials Group, Trial 076
AIC AIDS Information Centre
AIDS Acquired Immune Deficiency Syndrome
ANC Antenatal Clinic
ARV Anti Retro Viral Drugs
ART Anti Retro Viral Therapy
AZT Zidovudine
CBO Community Based Organisation
DAI HIV Aids Drug Access Initiative
ELISA Enzyme Linked Immuno Sorbent Assay
HIV Human Immunodeficiency Virus
IEC Information, Education and Communication
IGAs Income Generating Activities
MIS Management Information System
MTCT Mother to Child Transmission of HIV
NGO Non Governmental Organisation
NIH American National Institute of Health
NVP Nevirapine
OIs Opportunistic Infections
PCR Polymerase Chain Reaction
EXECUTIVE SUMMARY

Mother-to-Child HIV Transmission (MTCT), is the second major mode of spread of the virus in Uganda and is the main route by which children get infected. The relatively high prevalence of HIV among women of reproductive age in Uganda, coupled with a high fertility rate implies that without an intervention, the number of children who are likely to be infected with HIV is very high. Research studies have shown that provision of anti retroviral drugs to HIV infected pregnant mothers within a context of a comprehensive antenatal, intranatal and postnatal care services, can reduce the risk of MTCT by up to half. It is against this background that this policy for reduction of MTCT was developed to guide the intervention in this area.

This Policy document addresses the key issues related to prevention of mother to child transmission of HIV, which are as follows:

**Anti retroviral therapy in reduction of MTCT**

Women with HIV infection who are pregnant should be treated with either:

Nevirapine at the onset of labour and Nevirapine syrup to the baby within 72 hours of birth; Zidovudine from 36 weeks of gestation until one week after delivery and syrup to the baby for the first week after birth or Zidovudine and Lamivudine from 36 weeks of gestation until one week after delivery for the mother and to the baby for the first week after birth.

**Voluntary counselling and testing**

Voluntary Counselling and HIV Testing within the antenatal clinic is recommended for pregnant women, with at least two laboratory tests: one for screening and another for confirmation.

**Infant feeding**

A mother who is HIV positive should not breast feed but if she has to as a result of social or economic reasons, then exclusive breast-feeding for about three months is recommended.
Other interventions for reduction of MTCT

- Routine administration of multivitamins in pregnancy and vitamin A to post partum mothers and in children.
- Routine iron and folate supplementation as well as safe blood transfusion.
- Control and treatment of Sexually Transmitted Infections and the use of barrier methods such as condoms during pregnancy and lactation.
- Vaginal cleansing, delayed rupture of membranes in labour and limited use of episiotomy among pregnant women.

Support for mothers and infants

VCT for the spouse or partner should also be within the antenatal clinics or as conveniently as possible.

Public messages

The development of inter-sectoral links and re-affirmation of the Government's policy of multi-sectoral approach to combat HIV.

Resources and sustainability

Initially it is a pilot programme while the mode of financing it from the public and private resources is being explored but will with time, spread throughout the country.

1. HIV CONTROL IN UGANDA

Background

It is estimated that by the end of 2000, the cumulative number of Ugandans who have been infected with HIV was about 2.276 million. Approximately 1.438 million of these persons are living with HIV while the remaining 838,000 have died from the disease since 1982. Most of the infected people are within the reproductive age group of 15 - 49 years (only 143,000 are children below 11 years) and women form a significant proportion of this. The data from HIV sentinel surveillance in the country shows that in the early 90s, at some centres up to 30% of women attending antenatal clinics were HIV positive. Though there are indications that there is a declining trend of HIV infection in Uganda, the rates are still unacceptably high. In ANC within the urban centres, it is on average 8.7% but the rate of infection in rural settings is relatively lower."

The major routes of HIV transmission in Uganda are through heterosexual contact or mother to child transmission. Government has put in place an environment conducive for the interventions of HIV prevention and control. This has included the pillars of political commitment, openness about the disease, decentralisation and the multi-sectoral approach. Government has also implemented many activities to control the HIV pandemic and promoted positive living for people with HIV/AIDS. JEC campaigns have played a very big role in curbing the spread of HIV in the country. This policy has been consistently implemented since the recognition of the epidemic in the 1980s. Some of the interventions that have been put in place for the prevention and control of HIV have included:
• Political commitment with openness and public education
• Surveillance and syndromic treatment of other STIs
• Safe blood transfusions
• Promotion of care for symptomatic HIV/AIDS at public and private health facilities.
• Non-discrimination of people living with HIV/AIDS at public places as well as at the places of work
• Advocacy and promotion of safer sex practices at all times, faithfulness and abstinence
• Research
• Promotion of wider access to drugs for the treatment of opportunistic infections.

All these interventions have greatly contributed to the control and possible reduction of HIV in the country and have been emphasized all the time.

With the advent of major advances in anti-retroviral therapy and research on HIV vaccines still in infancy stage, Government cautiously initiated a pilot project to make available anti-retroviral drugs in the country in 1998. This initiative is spearheaded by UNAIDS in collaboration with other International Agencies and stakeholders. This document outlines policy guidelines for one such intervention, Reduction of Mother-to-Child-Transmission of HIV (MTCT).

2. JUSTIFICATION FOR ANTIRETROVIRAL THERAPY IN PREGNANCY

According to recent UNAIDS estimates, of the almost 1,600 new infections per day in children under the age of 15 in the world, vertical transmission accounts for the vast majority. It is virtually the only source of infection in young children below two years. In 2000, an estimated 600,000 children below the age of 15 years worldwide were infected with the virus, bringing the number of children living with HIV to 1.4 million at the end of 2000. Of these children infected with HIV since the beginning of the pandemic, about 80% have been born in Africa, owing to a combination of the high prevalence among pregnant women (women of reproductive age account for 80% of HIV/AIDS cases among women) and high fertility rates. By the year 2010, it is estimated that AIDS may have increased mortality of children under the age of 5 by more than 100% in regions most affected by the virus.

Human Immunodeficiency Virus infection in Uganda is predominantly HIV-1, mainly transmitted by heterosexual contact and vertical transmission from Mother to Child’s. Since the beginning of the epidemic in the 1980s, it is estimated that 10-12% of the Ugandan population have been infected with HIV. The age group most affected is the reproductive age group (15-49 years) and newborn children. Government has maintained a policy of monitoring HIV sero-prevalence and incidence through surveillance and special studies. Sero-prevalence surveillance has been carried out by anonymous testing of pregnant women in 20 sentinel sites throughout the country.

However, this cannot be generalized for the whole country because it overestimates sero-prevalence in the general population. HIV surveillance results show that HIV sero-positivity among pregnant women in Uganda has continued to decline from an average of 30% in 1992 to an average of 8.7% in some urban areas and 4.2% in rural areas in 2000. Sero-prevalence is also monitored through STD clinics. This has also shown a steady decline, for example at the Mulago STD clinic, it has declined from 44.2% in 1989 to 20.5% in 2000. HIV sero-prevalence among blood
donors has also shown steady decline.

At the end of 2000, a cumulative total of 58,165 AIDS cases had been reported to the STD/AIDS Control Programme in Uganda and 4,286 of these were children aged less than 12 years. The overall mean age for the paediatric cases is 2.12 years and for practical purposes more than 90% acquired the infection through MTCT. It is important to note however, that the mean age for reported paediatric cases in 2000 was 4.3 years. Studies in Mulago have shown that only one third of babies infected with HIV live to see their second birthday, although no similar mortality has been seen elsewhere”. Paediatric HIV/AIDS mortality may reverse the gains made in Uganda in relation to reduction of childhood mortality by immunizations and better nutrition. Reduction in MTCT would therefore go a long way in abolishing paediatric HIV/AIDS cases.

Although control measures such as IEC, management of STDs, use of barrier methods like condoms, safe blood transfusion and counselling are beginning to bear fruits in Uganda, it is apparent that MTCT and paediatric HIV/AIDS cases will continue to increase if no mitigating measures are taken. Many studies have shown that anti retroviral therapy in pregnancy is cost effective. It is against this background that Government feels justified to introduce ARVs to reduce MTCT of HIV and reduce paediatric HIV cases.

3. VERTICAL TRANSMISSION

Most studies suggest that without AZT the probability of a baby born to an HIV sero-positive mother acquiring the infection is 15-25% in the developed countries 3, 15.9.20 and 25-45% in developing countries. Some of the factors responsible for these differences are.

1. The frequency of breast feeding
2. Maternal characteristics such as poor Nutritional status
3. Exposure to infectious diseases
4. Factors surrounding the delivery
5. Re-infection in pregnancy and during breast feeding
6. The different study methodologies.

In Uganda studies in Mulago have shown a transmission rate of 27.5% in a cohort of 800 HIV positive and negative women who were breast-feeding. This level is similar to a rate of 25% seen in developed countries without breast-feeding and if AZT is not used.

In the recent years, advances have been made in understanding some of the important contributory factors to HIV vertical transmission. Although some of the interventions are still being studied, some have already been proven effective.

4. ANTIRETROVIRAL THERAPY IN REDUCTION OF MTCT - GLOBAL

Studies done in USA, France and Thailand; and more recently in South Africa, Tanzania and Uganda, showed that administration of anti retroviral drugs during pregnancy, labour and post partum period has been associated with tremendous reduction of mother to child transmission (MTCT) of HIV by up to 50%. There was a difference in reduction depending on whether the mothers enrolled in these studies breastfed their infants or not. The success of the intervention however, also strongly depended upon being implemented within a context of a strong and comprehensive ante natal, labour and post natal care services.
In 1994, a clinical trial demonstrated that a regimen of Zidovudine (ZDV, AZT) known as ACTG 076 regimen, administered to non-breast feeding HIV-positive pregnant women reduced the risk of HIV vertical transmission by almost 70% (from 25% without AZT to 8% with AZT). During the trial, AZT was administered orally to women five times a day starting at an average age of 26 weeks gestation (16-28 weeks) and continuing throughout pregnancy. It was then given intravenously during labour and thereafter twice a day for six weeks postpartum. The baby received Zidovudine in syrup form for six weeks after birth. This became the standard care in developed countries resulting in significant decline in prenatal HIV infection.

The cost of this anti-retroviral therapy (ART) alone was close to 1,000 US dollars. Since the children were not breast-fed, the cost of substitute formula feeds for one year was an additional 600-1,000 US dollars.

In spite of the well-known benefits of this regimen, it has not been implemented in the developing countries including Uganda for the following reasons:

- Costs of ARVs and substitute feeding are prohibitive;
- The majority of women in developing countries present late for the first prenatal visit especially in the rural areas; and
- Intravenous drug administration in labour is not easy to accomplish

Intensified research efforts to find alternative affordable therapeutic regimens for developing countries are ongoing. Preliminary findings from one such study in Thailand (June 1998) by Centers for Disease Control and Prevention, showed that a short course of AZT given to HIV positive women in the last four weeks of pregnancy and during delivery reduced the rate of HIV transmission to infants by half (from 18.6%-9.2%).

In 1997, UNAIDS initiated a multi-centre clinical trial in Kampala (Mulago and Nsambya), Dar-es-salaam in Tanzania, Durban and Johannesburg in South Africa. The aim was to see if the administration of AZT+3TC to pregnant women from the 36th week of pregnancy, in labour and 1st week of postpartum period and where the babies also received the drugs would reduce mother to child HIV transmission. The study also aimed at assessing the cost effectiveness of the intervention. The study had four arms, which are depicted in the box below.

1800 mothers were recruited and the last delivery was conducted at the beginning of June 1998. About 1/3 of the babies were followed for 18 months with PCR at 3 weeks, 6 weeks, 3 months and 6 months and ELISA at 15 and 18 months. Mothers were allowed to breastfeed in most centres with the exception of South Africa.

An analysis was done at the beginning of January 1999 and the results were announced on February 1, 1999 in Chicago (USA), which were very encouraging. They showed that the long arm of Petra (Petra A) was associated with a 50% reduction in the rate of HIV transmission while Petra B led to a 37% reduction in the rate of HIV transmission. The results further showed that Petra arms C and D had no effect on the rate of HIV transmission. In terms of the actual rate of transmission, the above results showed that Petra A and B were associated with HIV transmission rates of 8.6% and 10.9%, respectively. These results therefore indicate that giving AZT in combination with 3TC from the 36th week of pregnancy, at labour and up to one week postpartum is more superior to giving AZT alone. Furthermore, compared to the Thai’s study, the Petra study has revealed that giving AZT, in combination with 3TC in settings where HIV-positive women breast-fed was useful. However, follow up results revealed that this benefit was reduced when the breastfeeding period was prolonged.

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<th>Pregnancy</th>
<th>Labour</th>
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<tr>
<td>ARM A</td>
<td>1. AZT+3TC</td>
<td>AZT+3TC</td>
<td>AZT+3TC (mother + baby)</td>
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In November 1997, another study HIVNET 012 was started at Mulago Hospital in Uganda. The National Institute for Health (NIH), USA supported the study in collaboration with Johns Hopkins University and Makerere University. The study involved the administration of a single 200mg dose of Nevirapine (NVP) to the HIV infected mothers at the onset of labour. In addition, the baby received a single dose of NVP syrup (2 mg/kg) within 72 hours of delivery. This was compared with intra partum AZT 600mg loading dose, 300mg 3 hourly until delivery while the infant received 4mg/kg twice a day AZT syrup for 1 week. The mothers and infants were to be followed for 18 months.

An interim analysis on 618 mothers (308 AZT, 310 NVP) was done in June 1999. Both drugs appeared safe and well tolerated. At 14-16 weeks of age 13.6% of infants who received NVP were infected compared with 25.1% of those in the AZT group. Thus, short course NVP led to a 50% reduction in mother to child transmission of HIV compared to short course AZT. The short course regimen above at the time cost US $4 compared to $225 for the long arm AZT + 3TC regimen of the PETRA study and US$ 50 for the AZT alone.

5. MOTHER-TO-CHILD TRANSMISSION OF HIV UGANDA

The high HIV infection rate among women of reproductive age has serious implications on the mother to child transmission of HIV (MTCT). Taking the Ugandan birth rate of 52.2 per 1,000 population, about 5.2% of the Ugandan female population are expected to be pregnant annually. Given the 2000 population estimate for Uganda of 21 million, a total of 1,092,000 female Ugandans are expected to be pregnant in one year. With an average HIV sero-prevalence of 6.1% in the Antenatal clinics in Uganda, we expect to have about 67,000 HIV positive pregnant women each year.

A large epidemiological study at Mulago hospital from 1991-95 that looked at the consequences of HIV-1 in pregnancy, showed that the vertical transmission rate is about 27.5 percent, without any intervention. This means that about 20,000 of the 67,000 babies born to HIV infected mothers in a year are infected. It is also known that even with standard care, HIV-1 infection in children is fatal because anti retro viral therapy is not yet widely accessible. The majority of these infected children usually die by their second birthday. This therefore makes the prevention of vertical transmission of HIV extremely important, especially since it is the main route through which children get infected.

6. THE PMCTC INTERVENTION

Given the heavy burden likely to arise from the association between HIV/AIDS and pregnancies in the country, and after recognising the potential benefits of averting vertical transmission of HIV, a pilot programme for prevention of mother to child HIV transmission (PMTCT) in Uganda was initiated. This programme involves the provision of a comprehensive package of care including the administration of anti retroviral (ARV) drugs to pregnant mothers during pregnancy, labour and immediate post partum period.
The Government of Uganda in collaboration with UNAIDS, UNICEF and other partners, initiated a two year pilot programme to admin-ister AZT to 1,000 HIV positive pregnant moth­ers per site over the period. It is recommended that these mothers receive AZT from 36th week of pregnancy, during labour and for 1-week in the immediate postpartum period while the ba-bies receive AZT syrup for one week after birth. The HIV positive mothers are counselled and given all the necessary information on the risks of HIV transmission through breast milk and infant feeding alternatives so that they are able to make an informed choice regarding the in-fant feeding options. Given the good results observed with nevirapine, this has formed an alternative option where the mothers receive a single dose of the drug at onset of labour and the infant also gets a single dose of syrup within 72 hours of birth. This pilot programme has used the existing institutional framework for the HIV/AIDS Drug Access Initiative (DAI) in Uganda, which already had guidelines and a sub committee for MTCT in place.

It is worth noting that in all the above studies and initiatives, mothers are not considered dur­ing the short and long term postpartum period. If a baby is to grow up well, it needs a mother who is alive and active. It is a well-known fact that a strong association exists between failure to thrive and loss of babies. Therefore, it is extremely important that mothers be considered in future initiatives that aim at averting MTCT of HIV. One of the current challenges is that not all pregnant women attend ANC. While up to 90% of pregnant women make contact with a health care provider at least once during that pregnancy, only thirty eight percent (38%) de­liver in hospital. Despite these challenges, the potential benefits of the intervention are signifi-cant and consequently, Government has gone ahead to make a plan for scaling up the Programme to cover the entire country.

The policy on MTCT of HIV is in line with the National Health Policy. Prevention of MTCT of HIV features prominently under Reproduc-tive Health as well as the HIV prevention and control intervention areas. In addition, all are part of the components of the minimum national health care package as spelt out in the national health policy. Furthermore, MTCT policy and its implementation take into consideration the Sector Wide Approach to health care delivery (SWAP).

It is important that measures that will allow sustainability be put in place right from the con-ceptual period of the programme. Women em­powerment through Income Generating Activi­ties (IGAs) seems to be the most feasible strat­egy to achieve this. Therefore, funds should be made available to members so that they can be assisted to initiate IGAs. Activities that can help generate funds for HIV positive women will need to be implemented, in order to ensure a better success and sustainability. The selection of the IGAs will have to be done very carefully with the full participation and involvement of the beneficiaries. Money generated from the IGAs will be expected to go towards purchase of drugs and improvement of nutritional status of the women.

The implementation sites for PMTCT are in different stages of preparedness in terms of hu­man and structural resources. In order for some of the centres or hospitals to fully participate in the programme, there will be need to upgrade the facilities. In the scale up plan, particular attention will have to be paid on human resource and development of the infrastructure.

7. MONITORING THE MTCT INTERVENTIONS

Implementation of MTCT reduction interven­tion in Uganda needs well thought out moni­toring to enable proper evaluation. Ministry of Health recommends that the following should be developed and / or strengthened:

- Guidelines for minimum requirements at a health facility level for participation in anti retroviral therapy in pregnancy for reduc­tion of MTCT
• Health and social indicators for monitoring the intervention
• Surveillance, monitoring and evaluation tools
• Criteria for inclusion of women in the programme (such as: confirmed HIV positive status, HIV status accepted, intervention understood and consent given, no concurrent ARVs being used, the baby is alive and haemoglobin level >8.0g%)
• Advice on change of policy whenever necessary as new evidence comes to light
• Relevant messages about MTCT for advocacy and public education
• Research to understand the psychosocial impact of giving women therapy aimed at benefiting only babies in a fatal condition such as HIV.
• Operational research to find the impact of this intervention package on MCH/FP ser-vice in the country.

Additional staff time will be required to offer routine growth monitoring, nutrition counselling and support to the mothers during the antenatal period. After delivery, growth monitoring for the babies, counselling on nutrition, family planning and prevention of re-infection including ongoing support will put extra demand on the health workers’ time. Apart from the routine scheduled visits like for immunisation, there will be need for extra visits to monitor the mothers and their babies, as well as when the children or mothers are experiencing problems. The social services or support groups will have to come in at appropriate times and hence there will be need for a continuum of care network. Despite the fact that all the selected hospitals have community activities and social services, extra staff time will definitely be required.

8. TRAINING

Prior to implementation of anti retroviral therapy in pregnancy, training of health workers should cover the following areas: use of ARVs, VCT, infant feeding, other interventions that may modify MTCT and communication skills.

Health workers to be trained or sensitised include:

• Counsellors and Social Workers
• Doctors, Midwives and nurses in antenatal clinics, obstetric wards, labour wards, postnatal wards and postnatal and family planning clinics
• Laboratory workers and other auxiliary staff.
• Pharmacy and records staff.

Administrators and health services managers also need to be sensitised on the needs and nature of the programme.

9.0 POLICY ISSUES

9.1 ANTI RETRO VIRAL THERAPY (ARV) IN REDUCTION OF MTCT IN UGANDA

The therapeutic regimens described earlier have each been associated with reduction in the rate of HIV transmission from the mothers to infants of about 50%. The modified CDC Thailand short course AZT regimen (includes a one-week postpartum administration to both the mother and baby), currently costs about US $125. The PETRA long arm regimen (PETRA-A), costs about US
$90 for a mother-baby pair. The Nevirapine regimen currently costs about US $ 1 per mother-baby pair. If the costs are taken into consideration, then Nevirapine is cheaper and relatively more affordable than the other regimens. In addition, it is as effective as the other regimens yet administration is very simple. This factor is important in the monitoring of drug use and is likely to improve compliance by the mothers.

9.2 VOLUNTARY COUNSELLING AND TESTING (VCT)

In Uganda, only a fraction of HIV infected individuals are aware of their HIV status. Although HIV sero-prevalence is largely conducted among pregnant women, this is done anonymously and therefore the women remain ignorant of their status. VCT is not routinely available at antenatal clinics in the country. Health workers handling pregnant women and even counselors are still largely ignorant of the issues of HIV Mother to child transmission. Therefore an update and retraining of health workers and counselors is necessary.

Ministry of Health recommends that women with HIV infection who are pregnant should be treated with one of the following anti retro viral drug regimens:

1. Nevirapine tablet 200mg orally as single dose at the onset of labour
   And Nevirapine syrup 2mg/kg body weight single dose to the baby within 72 hours of birth.
2. Zidovudine (ZDJ’ AZT) tablets 300ntg orally twice a day front 36 weeks of gestation until onset of labour;
   Then 300mg orally, 3 hourly front onset of labour until delivery of the baby;
   Followed by 300ntg orally twice a day for one week after delivery.
   And Zidovudine syrup 4mg/kg body weight, twice a day to the baby for the first week after birth.

3. Zidovudine (ZDV, AZT) tablets 300ing and Lantivu( line (3TC) tablets 150mg orally twice a day from 36 weeks of gestation until onset of labour;
   Then 600mg-loading (lose of Zidovudine orally followed by 300mg 3 hourly, with 150mg of Lamivudine twice a day front onset of labour;
   And then 300ing Zidovudine with 150mg Lrunivudine twice a day for one week after delivery of the baby.
   And Zidovudine syrup 4mg/kg body weight with Lamivudine syrup 2mg/kg-body weight, twice a day to the baby for the first week after birth.

9.2.1 THE ROLE OF VCT

- VCT plays a key role in implementation of the Programme for reduction of MTCT since it helps to identify HIV infected women who should benefit from ARVs.
- The risks of pregnancy to an HIV infected woman are made known during the counselling.
- VCT by itself is an important strategy for HIV/AIDS prevention and care.
- Potential benefits to the individuals include improved health status through good nutritional advice, earlier and wider access to care and treatment for HIV related illnesses.
- Increased awareness of safer options for reproductive health
- Safer sex practices and correct option for infant feeding
- Wider access of pregnant women and their families to HIV preventive measures.
- Wider access to support services (medical, psychological, social and community based support).

It is in this regard that:

*The Ministry of Health recommends the concept and practice of Voluntary Counselling and Testing for HIV among pregnant women. This necessitates training and re-orientation of counselors and health workers on the issues related to MTCT. At least two laboratory tests are recommended: one screening test and one confirmatory test. It is recommended that VCT should be available at the same facility where antenatal care is offered.*

### 9.3 INFANT FEEDING ISSUES

In one review, it is estimated globally that 1,000 children become infected with HIV by vertical transmission per day and that 500 of these are associated with breast-feeding. Another important review of more than 40 studies by Ruth Nduati makes important conclusions about the limitations of the study models in this area. Several studies are ongoing in Uganda and other countries in Sub-Saharan Africa, which may provide more information regarding this problem.

The magnitude of the problem of HIV transmission through breast-feeding however, has not been adequately quantified and there are still some unresolved issues:

- Although the benefits of breast feeding are not in dispute, the data quantifying the risk of not breast feeding are inadequate;
- There are inadequate estimates of early breast - milk transmission
- The assumption that the risk of acquisition of HIV remains constant over time may be inaccurate as there are indications that infant vulnerability changes over time
- The potential role of cofounders such as vitamin A deficiency, and malnutrition has not been adequately explored.
- The risk of HIV transmission when different types of foods and drinks are mixed with breast feeding is not clearly understood

In the most recent multi-centre-pooled-analysis of late postnatal MTCT, an International working group on mother to child transmission, Leroy V et al, made the following findings:

- Less than 5% of the 2807 children in some studies in industrialized countries (USA, Switzerland and France) were breast-fed and no HIV-1 infection was diagnosed.
- By contrast, late postnatal transmission occurred in 49 (5%) of the 902 children in four cohorts from developing countries in which breast-feeding was the norm (Rwanda, Ivory Coast and Kenya).
- The estimated risk was 3.2 per 100 child years of breast feeding follow up (95% CI 3.1-3.8), and similar estimates were found in individual studies (p=0.10).
- Exact information on timing of infection and duration of breast-feeding was
available for 20 out of 49 children with late postnatal transmission.

- If breast-feeding had stopped at the age of four months, transmission would have occurred in none of the infants and in three if it had stopped at six months.

They concluded that the risk of late postnatal transmission is consistently shown to be substantial for breast-fed children born to HIV-1 positive mothers. However there were some methodological issues in this analysis casting doubts on the significance of the conclusions.

Whereas the MTCT before the implementation of ACTG 076 among non-breast feeding women in the developed countries was 25%, MTCT in a cohort of breast-feeding women in Mulago was only 27%. The rates are very close to each other and reaffirm the problem that the relationship between breast-feeding and HIV transmission is not as straightforward as it may appear.

a) **Major benefits of breast-feeding**
- Promotes Mother - Child bonding.
- Maternal-infant antibody and vitamin transfer
- Protection against diarrhoea) diseases, acute respiratory infections and otitis media
- Reduces the risk of septicaemia and necrotising enterocolitis in new-born infants
- Breast milk contains enough water even in very hot areas
- Convenient, safe and affordable
- Breast milk is easily digested and its composition changes to meet the development needs of the growing infant

b) **Risk and inconveniences of breast feeding**
- Transmission of HIV
- Only the mother can safely feed the baby

c) **Benefits of artificial feeding (exclusive Replacement feeding)**
- Reduces the risk of HIV MTCT through breast feeding
- The baby can be fed by any other person while the mother is away

d) **Risk of artificial feeding**
- Increased risks of bacterial GIT, upper respiratory tract and ENT infections
- No transfer of maternal-child protective antibodies and vitamins
- Risk of gastro-enteritis if no safe water for feed preparation or if attendant has poor hygiene
- Expensive, requires fuel for boiling water etc.
- Poorly constituted milk may lead to malnutrition
Mixed feeding has a higher risk of HIV vertical transmission than exclusive replacement feeding. However, a recent study from South Africa revealed that the rate of transmission among babies who were exclusively breastfed for three months was comparable to the rate among babies who were purely on replacement feeding. The rate among these groups was lower than among the group who was given mixed feeding. Follow up data revealed that this difference was consistent and still significant at six months of age. However, in Uganda there is inadequate information on the practice and strict adherence to exclusive breast feeding since observations seem to indicate that under normal circumstances, a good proportion of mothers actually carry out mixed feeding.

Lastly, it is important to point out that women who choose not to breast feed will not benefit from lactational amenorrhoea associated with breast feeding; which is also an important method of avoiding a pregnancy especially in the first six months of exclusive breast feeding.

- Ministry of Health recommends that every HIV seropositive mother should be informed of the benefits and risks of breast-feeding and alternative feeds. As much information as possible should be given to the woman and her partner so as to be able to make an informed choice on infant feeding.
- All women should be supported in a non-judgmental manner irrespective of their choices on infant feeding. HIV-positive women who choose not to breast feed their infants need the information and support to carry out replacement feeding as safely as possible, as recommended by UNAIDS policy on HIV and infant feeding (some of the possible local substitutes of breast milk are cows milk and formula feeds).

In helping women and their partners to make informed choices, the needs of the individual woman and assessment of her living conditions should be paramount. The risks of HIV transmission through breast milk should be balanced against:

- The effects of early weaning on infant mortality and morbidity
- HIV prevention measures taken by the woman in the postpartum period
- Possible stigmatisation and social isolation of the woman if she does not breast feed

Against this background, the Ministry of Health states that:

> Ideally, a mother who is HIV positive should not breast feed. However, if the woman must breastfeed because of social or economic reasons, then exclusive breast feeding for about three months is recommended. Emphasis will be put on locally available products for replacement feeding and the mothers will be trained on their proper preparation and use.

### 9.4 ADDITIONAL INTERVENTIONS LIKELY TO REDUCE MTCT

#### 9.4.1 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. Vitamin A deficiency in HIV-infected mothers has been shown in cross-sectional studies to be associated with a higher risk of HIV MTCT. There are presently experimental trials in Malawi, South Africa and Zimbabwe on vitamin A Supplement going on.

Some of the preliminary results are inconclusive. Vitamin A supplementation is low cost, does not require prior HIV testing and has other health benefits. However, it is important to note that high
dose vitamin A supplementation is not recommended during pregnancy and in this situ-ation, the use of multivitamin preparations would be preferred.

Ministry of Health recommends routine admin-istration of multivitamins in pregnancy, and vitamin A in post partuin mothers and in chil-dren.

9.4.2 ANAEMIA PROPHYLAXIS AND TREATMENT
Anaemia is a common problem in Uganda especially among pregnant women. Anaemia in an HIV-infected woman will lead to lower tol­erance of anti retroviral drugs and should be corrected. Iron and folate supplements may be useful throughout pregnancy and are encour-aged in the postpartum period. However some of the anaemia in HIV infection is due to bone marrow depression rather than iron and folate deficiency. If blood transfusion is necessary to correct anaemia, national blood transfusion guidelines should be followed. The mothers on the drug zidovudine should specifically be in-vestigated in order to ensure that they are not anaemic since this is one of the recognised side effects of the drug.

Ministry of Health re-affirms existing policies on routine iron and folate supplemen­tation and safe blood transfusion.

9.4.3 STI DIAGNOSIS AND TREATMENT
Genital infection, especially genital ulcer dis-ease has been strongly associated with increased risk of HIV transmission. Early diagnosis and treatment of STIs have numerous advantages for both the mother and the child, which may also lead to reduction of MTCT. Syphilis screening is already included in standard pre-natal care. Adoption and implementation of syndromic management of STIs is meant to fa-cilitate active treatment of STIs as quickly and conveniently as possible. Integration in ante-natal, postnatal and family planning services should involve active screening of women for STIs. There is clear evidence that STIs and HIV infection or re-infection in pregnancy and dur-ing breast-feeding increase the risk of MTCT.

The Ministry of Health therefore, re-affirms the STI control and treatment policies in an attempt to reduce MTCT of HIV and recom­mends the use of barrier methods such as condoms during pregnancy and lactation.

9.4.4 MODIFICATION OF OBSTETRICAL CARE
Invasive obstetrical procedures including epi-siotomy, (amniocentesis, and use of scalp elec-trodes) 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. Meta-analysis of large pooled studies in Europe and other studies showed that elective caesarean section reduces the risk of HIV MTCT.

However because of limited capacity and other implications of caesarean sections in our envi­ronment such as prolonged morbidity and likelihood of subsequent unsupervised delivery; this intervention is not recommended purely for pre-vention of MTCT. Caesarean sections can be performed in some cases in appropriate circum-stances.
The presence of the HIV in blood and mucus in the birth canal increases the relative risk of transmission of the virus to the baby during delivery. In a large trial performed in Malawi, lavage of the vagina using chlorhexidine showed no overall difference in rates of transmission. However, in cases where the membranes had been ruptured for more than 4 hours, there was significant reduction of transmission and also significant reduction of infant mortality and morbidity when lavage of the vagina with chlorhexidine was performed. Cleansing of the neonate may also help to reduce the risk of infant HIV infection.

Ministry recommends a policy of vaginal cleansing, delayed rupture of membranes in labour and limited use of episiotomy among pregnant women.

9.4.5 FAMILY PLANNING SERVICES

All women and men have a right to their sexual reproductive health. There is need to update and retrain family planning counsellors on STI screening and MTCT. Integration of VCT into family planning services is encouraged. Whereas some methods of family planning such as hormonal contraceptives and intra uterine device are very effective in preventing pregnancy, they do not provide any protection against HIV transmission.

Clients of family planning services should be screened for STIs and appropriately managed. The use of barrier methods such as condoms is recommended for prevention of HIV and other STIs.

This message needs to be emphasized in family planning counselling and the Ministry re-affirms this policy in prevention of MTCT.

9.5 SUPPORT FOR MOTHERS AND INFANTS

Considering the extent of the HIV pandemic in Uganda, there is hardly any family in the country that has not been affected by HIV infection. The level of awareness about HIV is very high even in the rural areas. However a large number of pregnant women believe they do not have HIV infection.

Introduction of VCT routinely in antenatal clinics therefore has wider social and psychological implications. Unlike voluntary testing at AIDS Information Centre (AIC) where clients seek HIV tests after careful thought, the woman's confidence is shattered when in the course of her prenatal visit she is found to be HIV positive.

She is faced by many issues at short notice, the most disturbing being to inform the husband or partner or other "important next of kin". This is further complicated by the fact that the woman may not be married and men do not accompany their wives to antenatal clinics.

Even if the men "changed overnight" and started accompanying their wives to antenatal clinics, there is inadequate space and privacy.

Breast-feeding is not only a medical issue but is seen as a social event in the family and community. There have been very intense campaigns by the ministry of health to promote breast-feeding but there is now evidence that a mother can transmit HIV to her baby through breast milk. Both partners should make the decision on infant feeding option if the mother is to get all the necessary economic and social support. The VCT gives an opportunity for the couple to
begin the process together.

*The Ministry recommends that in providing VCT in antenatal clinics provision should be made for the spouse or partner of the woman to get VCT at the same place or as conveniently as possible.*

### 9.6 PUBLIC MESSAGES IN RELATION TO MTCT

Current Government efforts to promote breast-feeding through the baby friendly initiative encourages all health workers in antenatal clinics, labour wards and post natal wards to promote breast-feeding. Subsequently, breast-feeding in the country is nearly 100% in early infancy. In this situation choosing not to breast-feed risks compromising the woman's confidentiality (of her HIV status) in the course of routine contacts with health workers in the clinics and wards. It could be a source of stigma for the woman.

The majority of women in this country do not have formal office jobs and failure to breast-feed can be more easily noticed in the family and the community. Choosing not to breast-feed after a month or two or infant mixed feeding is more acceptable for women in formal employment, which is usually in the urban areas.

It is widely accepted and recognised that against this background, the woman needs social support in order to cope with:

- The pregnancy
- Her HIV status
- Taking anti retroviral drugs aimed at protecting only the baby (and she has no possibility to continue with treatment).
- Choosing a method of infant feeding
- Choosing a method of family planning and HIV prevention.

The Ministry would like to promote holistic care of the women, and not merely for protection of the infant. It would be desirable for these women to access anti retroviral therapy, which would enhance their health and ensure quality survival of children. The Ministry therefore encourages any efforts in this direction. Care and support for the spouse/partners should be part of the comprehensive care available to the affected individuals.

Ministry of Health cannot provide for all these needs alone. The preoccupation of the Ministry is not only to provide anti retroviral drugs, but also to seek ways of working with the other stakeholders who normally support women and children. It also advocates for a more active role for men in prenatal, intra partum and post-partum care of women.

*In introducing new programmes such as re-duction of MTCT, Ministry of Health is aware of the need to develop inter-sectoral links and re-affirm Government's policy of multi-sectoral approach to combat HIV.*

### 9.7 RESOURCES AND SUSTAINABILITY

Ministry of Health shall seek to mobilise re-sources from existing MCH/FP services, STD/ACP and
other programmes as well as to identify which components of MTCT intervention can be financed. It is important to mobilise resources from as many sources as possible considering the health and social-economic impact of HIV. Ministry of health will also mobilize resources from international and local collaborating partners to meet funding gaps.

Projected anti-retroviral drug costs for MTCT in Uganda is shown in a table in annex I. Other costs such as for drugs for treatment of opportunistic infections, training of personnel, support services such as counseling plus that for upgrading of participating health units in the areas of laboratory facilities, data management, storage and patient care facilities will have to be developed.

In the initial phase, government will seek the assistance of other partners in implementing the programme in the pilot sites in the country. The actual cost of carrying out the intervention will become clear and the mode of financing this activity from the public and private resources is being explored and with time the programme is expected to spread throughout the country.

ANNEX I

Projected ARV Drug Costs for prevention of MTCT of HIV in Uganda

<table>
<thead>
<tr>
<th>Number of mother-baby pairs.</th>
<th>Cost per Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>One mother-baby pair</td>
<td>Modified Thai -</td>
</tr>
<tr>
<td></td>
<td>$125.0</td>
</tr>
<tr>
<td></td>
<td>Petra arm A</td>
</tr>
<tr>
<td></td>
<td>$90.0</td>
</tr>
<tr>
<td></td>
<td>Nevirapine</td>
</tr>
<tr>
<td></td>
<td>$1.0</td>
</tr>
<tr>
<td>67,000 mother-baby pairs.</td>
<td></td>
</tr>
<tr>
<td>$8,375,000</td>
<td>$6,030,000</td>
</tr>
<tr>
<td>$67,000</td>
<td></td>
</tr>
<tr>
<td>38,500 mother-baby pairs.</td>
<td></td>
</tr>
<tr>
<td>$4,187,000</td>
<td>$3,015,000</td>
</tr>
<tr>
<td>$38,500</td>
<td></td>
</tr>
</tbody>
</table>

Note: Costs are based on the current HIV/AIDS Drug Access Initiative (DAI) prices as of March 2001.

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