With grateful thanks to all the people who have contributed to this manual.

Constructive suggestions for improving and updating this manual will always be gratefully received.

This manual was designed and produced at the Department of Family & Community Health, Directorate General of Health Affairs Ministry of Health.
ABBREVIATIONS AND ACRONYMS

AIDS  Acquired human immunodeficiency syndrome
AN   Antenatal
ANC  Antenatal care
ARV  Antiretroviral
ART  Antiretroviral therapy
CD4  Cluster designation 4 positive lymphocytes
CMV  Cytomegalovirus
CPHL Central Public Health laboratory
EDTA Ethylene diamine tetra acetic acid
ELISA Enzyme linked immunosobent assay
EMRO East Mediterranean regional office
EMR  East Mediterranean region
EPI  Expanded Programme on Immunization
HIV  Human immunodeficiency virus
HAART Highly effective Antiretroviral therapy
IDU  Intra-venous drug users
ICSI  Intra Cytoplasmic Sperm Injection
IEC  Information, Education and Communication
IVF  In Vitro Fertilization
IPV  Injectable Poliomyellitis Vaccine
LSCS Lower Segment Caesarean Section
MCH  Maternal and child health
MOH  Ministry of health of Oman
MTCT Mother to child transmission of HIV
MARP5 Most at risk populations
- ve  Negative
OPV  Oral Poliomyellitis Vaccine
PAP  Papanicolaou
PCR  Polymerase chain reaction
PCP  pneumocystic carinii pneumonia
PMTCT Prevention of mother-to-child transmission of HIV
PNC  Post natal care
+ ve  Positive
RNA  Ribonucleic acid
RPHL  Regional Public Health laboratory
RT-PCR Real time polymerase chain reaction
SOP  Standard operating procedure
STIs  Sexually transmitted infections
TB   Tuberculosis
WB   Western Blot Test
ZDV  Zidovudine
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Measures adopted to prevent mother-to-child transmission of HIV are one of the most rewarding public health interventions. Failure to diagnose or manage the HIV infection in pregnancy may result in transmission of infection to offspring leading to severe morbidity while s/he is alive and ending in pre-mature death.

Hence, Department of Family and Community Health, through the Central MCH committee decided to initiate testing for HIV in pregnancy for all Omani women nationwide. This is another step forward to improve the health of women children and family in the country. Antenatal coverage of more than 99%, around 98% of deliveries attended by the health personnel and early visit to hospital by the home deliveries to avail child vaccination at birth, gives great opportunity to implement the HIV testing and timely management of woman and her infant.

This standard operative procedure manual on ‘HIV testing in Pregnancy’ provides information on the MOH policies and service provision: when, where, what, how and by whom, specifying the functions, roles and responsibilities as per the level of health care and category of health care provider. Hence, guidelines have been developed to help the health care providers of service providing facilities to organise the health care systems and maintain service standard and monitor the service delivery.

While developing these guidelines some parts have been adapted from the WHO, Generic Training Package Pocket Book on ‘Prevention of Mother to Child Transmission’ 2004. In addition, references have been taken from other literature to make it evidence-based.

This SOP manual has been developed as a complimentary document to the Guidelines for the management of HIV infection and AIDS developed by the National HIV/AIDS/STIs Control and Preventive section, MOH of Oman, hence, has to be used in conjunction with the same.

Educating and counselling women living with HIV, their family members, their contacts will be an important component of service delivery within the health care system. Efforts will also be done to educate the community on the mode of transmission, prevention of infection and benefits of screening.

We would like to thank all those who have supported us by reviewing this document and given their valuable inputs during its development. Our especial thanks to WHO mission in Oman for getting the first SOP draft reviewed.

We hope that service providers of all level will make the best use of thesees guidelines and by doing so help us in achieving goal of promoting the health of women, children and families.

Dr Yasmin Ahmed Jaffer
Head of women Health program
Director
Dept. Family & Community Health
POLICY HIGH LIGHTS

HIV Testing in pregnancy will be an integral part of the ANC services that will be provided in all regions of the Sultanate. The Ministry of Health through its ANC area of all health centres, extended health centres, and hospitals, sister government and private health institutions, will provide the following services:

- **Information, Education and Communication (I, E & C) at all health care levels**
- **Counselling services at all health care levels**
- **Therapeutic management for pregnant women HIV positive**
- **Contact tracing & Follow-up of husband & children under 15 years.**
- **Information, Education & Counselling through outreach teams.**

The anticipated recipients of these services will be all women booked at ANC clinics, and un-booked mothers who deliver in health institutions or attend after home delivery for post-natal services.

Antenatal HIV testing and counselling on HIV by MCH counsellors will be provided at all Primary Health Centre outlets. Therapeutic management (antiretroviral treatment for woman and prophylaxis for PMTCT) will be provided at the secondary and tertiary Health care level.

Contact tracing & follow-up care or outreach activities will be the responsibility of HIV focal points and HIV counsellors, identified by HIV control Section, for each region or willayate in the Sultanate.

Only trained service providers will provide counselling.

- **Organized information and education sessions on STIs/HIV/AIDS will be part of all PHC services.**
- **Trained counsellors should be assigned to conduct one-to-one counselling during Antenatal period and immediate post-partum period in hospitals.**
- **A trained Arabic speaking health staff will provide pre-testing information at the booking visit to the antenatal women before taking blood samples for routine and HIV tests. Verbal communication by the antenatal women will be considered enough for the purpose of obtaining informed consent.**
POLICY GUIDELINES

Each pregnant woman, following registration and having been issued a Maternal Health Record at the parent institution ANC clinic, will be given pre-testing information by a trained staff, regarding a short list of routine investigations being performed for ANC including STIs (syphilis) and HIV.

Verbal consent will be taken before collecting the blood sample, which will be following provision of pre-testing information to the woman.

PHC facilities with or without laboratory will collect blood for HIV and other tests for routine ANC. Blood for HIV tests will be sent to the Regional Public Hospital Laboratory (RPHL) where as, for other tests as per the feasibility will either be processed locally at the PHC laboratory, or sent to near by health care facility with laboratory, or sent directly to RPHL.

Confirmatroy tests for ELISA postitve cases will be performed at central public health laboratory (CPHL)

The HIV Positive pregnant woman being at high risk will be assessed for the maternal and foetal needs and managed accordingly at the secondary/tertiary health level.

CD4 testing, at secondary/tertiary health level, will be done for each HIV positive woman to guide decision making on whether to initiate antiretroviral therapy for the woman or antiretroviral prophylaxis for PMTCT.

Baseline laboratory tests such as viral load, haematology and biochemistry will be carried out to enable clinicians in making decisions on management and monitoring woman’s response to ARV drugs.

Family and contact screening (husband and children < 15 years age) and follow up will be done by the HIV focal points and HIV counsellors identified by HIV/AIDS/STIs control section for each region, as per the HIV/AIDS/STI SOP Manual.

Disclosure on the positive HIV status of woman to husband or other members of the family will only be done after taking the permission of the woman.
Women living with HIV are at risk of transmitting HIV to their infants during pregnancy, childbirth or breastfeeding. Well over 90% of new infections among infants and young children occur through Mother to Child transmission (MTCT). Without any intervention, between 20% to 45% of infants may become infected with HIV. The estimated risk of acquiring HIV being 5-10% during pregnancy, 10-15% during labour and delivery, and 5-20% through breastfeeding. This risk can be reduced to less than 2% by package of evidence-based timely interventions. (1)

GLOBAL REVIEW

At the end of year 2007, 33.2 million people were estimated to be living with HIV, 2.5 million people became newly infected and 2.1 million people died of AIDS, (2). see figure 1.

Figure 1

WHO Global estimates of adults and children, 2007

WHO, UNAIDS data, 2007
SITUATION IN EASTERN MEDITERRANEAN REGION

As of the end of year 2006; an estimated total of 75,000 people living with HIV/AIDS were living in EMR. An estimated 47,000 adults and children died as a result of HIV infection. 55.6% of reported AIDS cases in the region to date were adults aged between 25 and 39 years; 8.1% were youth aged between 15-24 years and 1.8% were children below 5 years of age. 30% of the cumulative total reported AIDS cases were female, (3). see Figure 2.

Figure 2

WHO EMR estimates of adults and children 2006

WHO, UNAIDS data, 2006

In the year 2007, in EMR countries, the estimated number of pregnant women living with HIV needing antiretroviral (ARV) treatment for preventing mother to child transmission of HIV was 24,000 {17,000 – 33,000}. (4)

The over all HIV prevalence in pregnant women in EMR is <1% (most countries in the region report low level of prevalence of HIV epidemic i.e. <1% HIV prevalence in general population and <5% in MARPs).


SITUATION IN OMAN

Amongst the total, 123 female HIV/AIDS cases registered in MOH health care facilities between the years 2001 to 2007, around 80% (98 cases) were in the age group of 15-49 years and around 8.1% (10 Cases) were below the age of 14 years. Although for the same period total male cases registered were 501, (5). See table 1.

A slight increase in total number of cases reported for HIV/AIDS has been seen from 2006 to 2007 year, 86 and 101, respectively.

Table 1

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Numbers (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14</td>
<td>10 (8.1)</td>
</tr>
<tr>
<td>15-24</td>
<td>18 (14.63)</td>
</tr>
<tr>
<td>25-49</td>
<td>80 (65.4)</td>
</tr>
<tr>
<td>50+</td>
<td>15 (12.2)</td>
</tr>
<tr>
<td>Total</td>
<td>123 (100)</td>
</tr>
</tbody>
</table>

A survey of ANC register for the year 2005 showed that a total of 51920 women were registered for ANC, in MOH care facilities from 1st Jan.-31 Dec. 2005, of which 32 had confirmed syphilis and, 7 were found to be HIV + ve. (6)
MOH data from October 2000-2007 (unpublished) showed that there were total 26 cases of HIV below the age of 15 years of which 23 (88%) were due to vertical transmission. 6 cases reported in less than 10 years age during 2006-2007 were infected from their mothers. (7)

<table>
<thead>
<tr>
<th>Mode of Transmission</th>
<th>HIV infection</th>
<th>AIDS Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion</td>
<td>49</td>
<td>111</td>
</tr>
<tr>
<td>Hetrosexual</td>
<td>292</td>
<td>293</td>
</tr>
<tr>
<td>Homo/Bisexual</td>
<td>118</td>
<td>90</td>
</tr>
<tr>
<td>IDU</td>
<td>59</td>
<td>20</td>
</tr>
<tr>
<td>Mother to Child</td>
<td>41</td>
<td>35</td>
</tr>
<tr>
<td>Multiple</td>
<td>41</td>
<td>12</td>
</tr>
<tr>
<td>Unknown</td>
<td>176</td>
<td>168</td>
</tr>
</tbody>
</table>

Since 1994 no case of HIV/AIDs due to Blood Transfusion has been reported.

In Oman the attendance of ANC services is estimated to be more than 99%. Annually 50,000 to 60,000 women attend the ANC clinics, thus providing an opportunity of early detection and intervention to prevent mother to child transmission (PMTCT) of HIV.

Hence, in view of positive impact of early management during antenatal, intrapartum and postpartum period, Department of Family and Community Health has planned to initiate HIV testing of all antenatal women in the year 2009.

HIV Testing and management will be carried out for all women registered for ANC in the govt. MOH. Sister Govt. health institutions and private health institutions in the country will also be encouraged to initiate the same.
GOALS AND OBJECTIVES

MATERNAL AND CHILD HEALTH SERVICES IN OMAN:

GOALS
To improve the health of mothers and children by:
• Reducing maternal and infant morbidity and mortality contributed by HIV infection

OBJECTIVES OF HIV TESTING SERVICES

- Prevention of HIV transmission from women living with HIV to their infants.
- Early detection, provision of optimal care and support to women living with HIV, their children and families.

INDICATORS

At Primary Health Care:
- Number and Percentage of women tested for HIV during pregnancy (including those confirmed perviously to be living with HIV)
- Number and percentage of women tested positive for HIV virus

At Higher care level
- Number of woman started on ARV for treatment
- Number of woman started on ARV for prophylaxis (PMTCT)
- Number and percentage of infants born for HIV positive mothers receive co-trimoxazole prophylaxis
- Number and percentage of Infants (who were born for HIV + mothers) tested for HIV at 18 months
**MOH POLICY:**

- All registered women in ANC clinics of MOH in Sultanate of Oman will be subjected to testing for HIV.

- Un-booked women coming for delivery or un-booked home deliveries coming in postnatal period will also be tested for HIV.

- Pre-testing information will be given to all women before collecting blood, which will cover, reason for testing, health benefits of testing for the woman herself, and her baby in utero by preventing mother to child transmission.

- All counsellors will be trained in reproductive health counselling and counselling specific for HIV/AIDS.

- Results of all tests performed whether routine or for HIV tests, irrespective of it being positive or negative will be explained to the women. Post test information/counselling will be done for both HIV negative and positive.

- All women with confirmed positive HIV would be counselled in greater details on the health implications of HIV on them and their infants and treated with antiretroviral (ARV) drugs for themselves and prophylaxis to prevent MTCT, and ARV prophylaxis given to newborns of HIV positive women in post-partum period. All women will be delivered by caesarean section. Other management and supportive care will be given to the women from pregnancies to post-partum including their newborns after birth.

- Each PHC facility will earmark a focal doctor who will be responsible for organisational set up in facility, receiving the HIV test reports, breaking the news and counselling HIV positive women, organising referrals to the treating HIV focal physician and maintaining records confidentially.

- Where feasible, confidential hotline communication should be established to facilitate early referral and exchange of, to and fro information on the management and follow up of the HIV positive cases.

- Case evaluation and provision of anti-retroviral therapy/prophylaxis or any other indicated management as per the guidelines will be free of cost for the Omani nationals and expatriates working in the Govt. sector.
**MOH POLICY:**

- A focal doctor will be earmarked at the secondary/tertiary level to receive the referrals of HIV positive women who will be responsible for organising the case management and maintaining the records confidentially.

- At regional level HIV expert focal physician, obstetricians, neonatologist, will team up to manage women and their babies with HIV/AIDS.

- It is also important that health care providers who will handle the HIV +ve case know the details of women and their children to provide optimal care. Only the providers involved in the management of the HIV +ve women will know the HIV status of women and they, at no point will disclose the information to other health care providers or even to women’s care takers without their consents.

- The identity of the detected cases and contacts, their record and management carried out, will always be kept confidential.

- All HIV +ve women will be assured of the confidentiality so as to encourage drug compliance, follow up and seek support of the providers as and when they require, without any hesitation.

- Woman’s husband, children below the age of 15 years and other contacts will be traced and tested for HIV. HIV Positive cases will be managed as per their individualized needs at facility with specialist (HIV focal doctor).

- At antenatal booking, Primary Health Care doctors/nursing staff/midwives, will give pre-testing information and obtain verbal consent from every pregnant woman, prior to collecting blood sample for HIV tests along with other routine blood tests and send the sample to the regional Public Health laboratory (RPHL).

- Samples positive for HIV at RPHL will be sent to Central Public Health Laboratory (CPHL) at Darseit and retested with ELISA and Western Blot tests. For the case identification of HIV positive samples, re-confirmation will be done by performing tests on the re-bleed sample at CPHL.

- No discrimination will be done while handling HIV positive cases or their contacts with respect to evaluation or management.
**MOH POLICY:**

- Sister government and private health institutions will be encouraged to adopt MOH policies. Those, without the facility to do tests in their health institutions can avail the services of central public health laboratory by paying the charges for the initial tests performed for all pregnant women. Where as, confirmatory tests performed on the detected positive cases or testing done for the contacts will be free of charge (refer to ministerial decree No. 55/2009 dated 27 April 2009 on the price list on medical services).

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**Pre-testing information and Verbal consent**

As part of Verbal consent at the time of blood collection,, every pregnant woman will be explained as follows

"Few routine blood tests are being done for you to check your health status. Some of these tests are related to nutrition, infections... etc which may indicate the need for an early and appropriate management"

---

**Confidentiality**

Only health care providers handling the HIV +ve woman will know her clinical details to optimise the care and support given to her. At no point of time woman’s HIV + status will be disclosed even to her close relatives, without her consent.
**MOH STRATEGY:**

**MINISTRY OF HEALTH'S STRATEGIES FOR TESTING HIV IN PREGNANCY:**

- To establish a universal system of HIV testing for women during pregnancy and during delivery or post-natally that have missed testing (unbooked antenatal women), at all level of health care institutions of Ministry of Health and, encourage other govt. sister and private institutions to do so.

- To institutionalise the training capabilities of all health regions and to make sure that trained MCH counsellors are available at all PHC level.

- To ensure that all health institutions organise client flow that is smooth user friendly and respects full privacy and confidentiality of woman and her family while conducting reproductive health counselling or doing clinical management.

- To make IEC an important component of health care delivery within and outside health care system so that community is aware about the various modes of transmission, how HIV transmission can be prevented, impacts of high risk behaviours on the health of individuals and family, and on the available services for HIV testing and management in the MOH.

- To use all contact opportunities in ANC, PNC clinics and home visits to counsel women living with HIV, support and refer each case for management according to their individualised needs.

- Ensure that curative, preventive and promotional health needs of each woman and, her new born, other children and family member’s needs are met.

- Monitor health care delivery and continue efforts to ensure that the best possible care and support is given to each HIV positive woman and her baby and her family, at all levels of health care systems.

- Ensure that all HIV positive women in their post-natal period are explained on the health risk of pregnancy to them and possibility of mother to child transmission of HIV, and advice on the suitable birth spacing method is given to them.
MOH STRATEGY:

- Continue confidence building efforts at all contact opportunities with woman and her family and community to encourage opting for HIV testing.

- Maintain database at central level on the HIV positive cases and share them with other stakeholders to strengthen preventive and promotional activities to reduce HIV/AIDS in pregnant and child population.
CLIENT FLOW

CIRCULATION OF CLIENTS AT THE ANC SITES:

- In health facilities, there should be enough private space provided for educational sessions on HIV and HIV in pregnancy.
- The flow of clients should be smooth from one room to another.
- Counselling session should take place in privacy.
- Clinical assessment and management should be done in room or a cubicle with full privacy.
- All necessary laboratory tests for ANC pregnant woman must be collected at booking. If by chance the tests are missed on the booking visit it should be ensured that they are collected on the subsequent visit.
- Request for re-bleed sample from CPHL will be sent to RPHL who in turn will ask for it from PHC facility laboratory/antenatal staff.
- Returning client for re-bleed or for post-test counselling, should be served first, and not to be subjected to go through same process again.
- Confirmed HIV +ve woman will be directed to the MCH counsellor for counselling and with the support of focal HIV doctor at PHC, referral will be organised to the secondary health care confidentially.
- Male counsellors should be trained and arrangements made for counselling the male partners.
MANAGEMENT INFORMATION SYSTEM

Information on HIV testing:

- Will be marked on maternal Health record and register as ‘done or not done’ only, in-order to maintain the client’s confidentiality.

- Regional Public health laboratories and Central Public Health Laboratories will keep case identification information on all blood/serum samples received and results of the tests performed.

- Record on the HIV positive cases new (detected for the first time) and old (known case embarking on pregnancy) will be maintained by the in-charge antenatal staff on separate notebook.

- MCH counsellor will keep records on a simple notebook of all HIV +ve women, their name, address, telephone numbers and parity whom they will counsel and other action taken.

- DFCH will obtain data on the Number of HIV +ve cases detected on request whenever required or annually from MCH counsellor.

- HIV notification PR 83 form will be filled by the HIV focal point/counsellor as usual and dispatched to HIV/AIDS Section.

In-order to maintain the confidentiality, results of negative as well as positive HIV tests will not be entered in the computer.
SERVICE PROVISION: COMPONENTS

COMPONENTS OF SERVICE PROVISION:

- Information and Education on HIV
- Pre-test information & counselling for HIV positive
- Testing for HIV
- Referral
- Clinical Management
- Follow up of women with HIV in Antenatal, postnatal period and babies post-natally

RECEIVERS OF SERVICES

- All women attending ANC clinics
- Un-booked women admitted in the labour room for deliveries
- Women delivering at home and attending health institution for themselves and their babies
- Children born to HIV positive mothers
- Contacts of HIV positive women (Husbands & children <15 years).
SERVICE PROVISION : HEALTH CARE LEVEL

AT PRIMARY HEALTH CARE ANTENATAL CLINIC:

- Receive pregnant woman & Register her for ANC.
- Do usual procedure of taking history and doing physical examinations.
- Inform antenatal woman about routine blood test including HIV test by using the pre-testing leaflet.
- For all antenatal (AN) women collect blood for regular routine test in 3 tubes (violet, red and green) for CBC, RBS, Blood group and VDRL.
- Collect 5 ml blood in SST (red top tube with gel) for HIV test in pre-labelled tubes with AN woman’s name and computer number and put it in separate plastic bag. PHC that has facility to centrifuge the sample, should separate the serum and transfer it to plain tube and dispatch it to RPHL preferably on the same day.
- If no facility to centrifuge the blood, dispatch the whole blood sample to RPHL, while maintaining the temperature between 4-8°C during transfer.
- Where it is not possible to dispatch the blood/serum on the same day, sample should be stored at temperature 4-8°C in the refrigerator and then transferred appropriately (maintaining the temperature during transportation).
- If HIV test for AN pregnant woman was not performed at the booking visit for any reason, it should be done on the next subsequent visit.
- Do routine follow up of the cases as per their health needs.
- Collect re-bleed sample as and when requested by CPHL for re-confirmation of the HIV positive samples.

Note: if blood is requested from CPHL for RT-PCR test, collect 5 ml of blood in EDTA tube and dispatch on the same day, while maintaining the temperature (PHC facility with laboratory should separate the plasma, transfer it to plain tube and send to CPHL).
Algorithm 1
HIV testing in pregnancy

WOMAN at ANC clinic

AT ANC CLINIC
- Verbal consent
- Collect 5 cc of blood in Serum Separating Tube (SST Tube Red cap with gel)
- If PHC facility has laboratory, centrifuge the blood and separate the serum put in the plain tube before dispatching
- PHC facility with no laboratory send the whole blood
- Send the blood/serum to the Regional Public Health Laboratory (RPHL)
- Samples +ve for HIV will be sent for retesting at the CPH lab

AT REGIONAL PUBLIC HEALTH LABORATORY (RPHL)
ELISA test

If ELISA test - negative, no further test is required Report to PHC facility

Inconclusive Result

Positive ELISA test

REFER TO CENTRAL PUBLIC HEALTH LABORATORY (CPHL) AT DARSEIT

In case samples can’t be dispatched on the same day, keep it in the refrigerator at temp. 4-8°C. transfer the sample within 24 hours. While transporting to RPHL ensure that appropriate temperature is maintained (4 - 8°C).
SERVICE PROVISION : HEALTH CARE LEVEL

REGIONAL PUBLIC HEALTH LABORATORY (RPHL)

- Perform ELISA Test on the serum on the blood/serum sample received from PHC
- Dispatch report of the HIV negative results to PHC
- Refer HIV +ve sample to CPHL at Darseit for confirmation with repeat ELISA & Western Blot Tests.
- Organise for re-bleed sample from PHC facility and send it to CPHL as and when requested (for confirmation of identity and for performing RT-PCR test as and when indicated, see algorithm 2)
- Keep database on the outcome of all tests performed for each woman.

CENTRAL PUBLIC HEALTH LABORATORY (CPHL)

- Perform ELISA and Western blot (WB) test on same serum sample received from RPHL & confirm.
- If both ELISA and WB test are positive, ask for re-bleed sample to reconfirm the identity.
- Indeterminant or negative ELISA/Western blot (WB) test, inform RPHL-HC and ask for re-bleed sample after 3 months for confirmation.
- For indeterminate samples i.e. ELISA +ve but inconclusive/-ve WB, perform RT-PCR test on re-bleed sample (collected in EDTA tube)
- Negative results are to be reported directly to their respective PHC facility and RPHL.
- All HIV positive confirmed (re-bleed sample) cases are to be reported as per the algorithm 2.
- Keep data base on the outcome of all tests performed for each woman.

AT DFCH

- Maintain data base on of all reported HIV +ve cases
- Track the action taken by the MCH counsellor on the HIV +ve women
- Compile reports and share with all stakeholders annually.
Algorithm 2

HIV testing in pregnancy

CENTRAL PUBLIC HEALTH LABORATORY

Repeat test on the same sample sent from RPHL

Negative ELISA test.
Report on Negative Result

Inconclusive Result
Re-bleed after 3 months

Positive ELISA test

Positive Western Blot (WB) Test
Confirm HIV infection
Urgently Request for re-bleed sample to confirm patient’s identity

If ELISA test & WB still inconclusive
RT-PCR

Report to DFCH and HIV/AIDS Control Section & PHC facility
Algorithm 3
HIV testing in pregnancy

HIV/AIDS CONTROL SECTION
Inform HIV focal physician

HIV/AIDS CONTROL SECTION
- Data entry on the reported HIV +ve cases
- Compile and prepare the final report
- Follow up and monitoring of cases through MCH counsellor

HIV COUNSELLORS (HIV/AIDS) FOR CONTACTS
- Trace & counsel the contacts (husband and children < 15 years) and arrange for their testing.
- Liaise with MCH counsellors

HIV FOCAL PHYSICIAN
- Fill the (PR 83) notification form
- Follow up with HIV counsellor
- Team up with Obstetrician to manage the index case
- Inform HIV counsellor
- Screen contacts and manage as per the need.

AT PHC MCH COUNSELLORS
- Counsel the HIV positive women
- Keep the record on the women and action taken; send to DFCH as and when requested
- Do follow up of the case
- Liaise with HIV counsellors (HIV/AIDS) for case follow up

HIV FOCAL DOCTOR
- Break the news, counsel
- Arrange Referral to HIV focal physician at Secondary health care level

Reporting on results of HIV positive case by CPHL
- Send report to DFCH and HIV/AIDS Control Section and PHC facility
SERVICE PROVISION : PROVIDER’S TASK

TASKS OF RESPECTIVE HEALTH CARE PROVIDERS

AT PHC - MCH COUNSELLORS

- While maintaining utmost confidentiality trace the antenatal woman.
- Counsel antenatal woman over her visits made to health care facility using the counselling Q-Card for HIV testing in pregnancy.
- Emphasize on the following during the counselling sessions: importance and need of tracing contacts (husband and children <15 years); taking anti-retroviral drugs for HIV regularly; regular follow up during pregnancy; and need for caesarean section.
- Educate & counsel HIV +ve woman and support her all along during pregnancy and post partum and any time, should she return.
- Arrange for referral to HIV focal person at the secondary care level in coordination with health centre MOIC, as when needed.
- Maintain record on HIV positive cases and send compiled report to DFCH when requested or otherwise, Annually.
- Liaise with HIV Counsellors as and when required.

AT REGIONAL HOSPITAL

HIV FOCAL PERSON (physician)

- Trace the HIV +ve woman on whom the information is received from HIV/AIDS section through MCH counsellors/or HIV counsellor.
- Fill in HIV ‘Notification Form (PR-83); send it by Fax to HIV/AIDS Control Section and original by post, while retaining yellow copy.
- Team up with obstetrician to plan the therapeutic management of the case (ART) and prophylaxis for PMTCT and for baby with paediatrician post-natally.
- Seek support of HIV counsellor to trace the husband and children less than 15 years of age, arrange for testing them and manage as per the need.
SERVICE PROVISION: PROVIDERS TASK

HIV COUNSELLORS
- Trace Husband and children less than 15 years and bring them to HIV focal physician for testing, counselling and clinical managing as per the need.
- Do follow up of index case and contacts all along.

OBSTETRICIAN

ANTENATAL CARE
- Team up with the HIV focal physician for the case management
- Continue follow-up of the case, ensure compliance with anti-retroviral drugs and other routine and specialised management.
- Assess woman's delivery needs and arrange delivery in facility that matches with it, i.e. secondary/tertiary health care level.
- Emphasise to the woman on the reasons for C/S and plan for it.
- Counsel the woman regarding avoidance of breast-feeding.
- Vaccinate the mother as per the EPI and HIV/AIDS SOP manual.

DELIVERY AND POSTNATAL CARE
- Prepare for the special needs of mother and baby during delivery and deliver woman by caesarean section.
- Continue follow up during PNC for the baby and mother as per their needs and keep woman informed on self-care and when to report.
- Vaccinate - baby as per HIV/AIDS and EPI SOP manuals.
- HIV testing should be done during labour for women who have not been subjected to testing during the antenatal period (un-booked) and those who deliver at home and report to health care facility.

PAEDIATRICIAN:
- Follow-up of baby from delivery until 18 month for HIV testing and management as per the protocol and longer as per the child’s need.
- Follow up of all children born to women living with HIV until 15 years age for HIV testing and management.
SERVICE PROVISION: HIV TESTING

PROVISION OF HIV TESTING:

Facilities with Lab services:
• All tests apart from tests for HIV (ELISA test) should be done at PHC facility laboratory.
• Blood tests for HIV (ELISA test) should be sent to the regional public health laboratory (RPHL).

Facilities with no Laboratory Services:
• Send all test done at ANC booking to the nearest laboratory for processing except tests for HIV (ELISA test)
• Send blood tests for HIV (ELISA test) to the RPHL.
• Send re-bleed samples to CPHL to perform confirmatory tests for HIV (ELISA, WB) and where indicated for RT-PCR test as and when requested.

EDUCATION:

• Raise awareness on HIV/AIDS/STIs:
  • At all health institutions
  • At all health clinics and wards like Antenatal, Postnatal, Gynecological and Child Health
  • During Home visits
  • At Community level

COUNSELING:

• Counselling will be one of the vital services. It will be offered at different points of contact by the trained health care provider, preferably Arabic speaking.
• Standard counselling materials designed specially for counselling purpose will be used for counselling.
WHO WILL PROVIDE COUNSELLING AND ON WHAT ASPECTS?

- **PHC ANC staff nurse/doctor in Antenatal clinics**: will provide pre-test information before collecting the blood sample for routine and HIV tests from pregnant woman attending ANC clinic or un-booked home deliveries attending for postnatal services.

- **Midwife or doctor in the labour room**: pre-test information to mother before collecting the blood sample for routine and HIV tests who were not tested during ANC period (un-booked women coming for delivery or home deliveries admitted to labour room)

- **HIV focal doctor at PHC Centre**: break the news of the HIV test result, counsel, arrange referral to the secondary/tertiary health care level and maintain the records.

- **MCH counsellors**: are health professionals involved in ANC services and are trained on counselling (Doctors, nurses, & midwives). They will be in-charge for counselling pregnant women with +ve HIV test.

- **HIV counsellors**: trained doctors and/or a Nurse by HIV control section, who will be in-charge of tracing & counselling all contacts.

- **HIV focal physician**: will counsel the woman on need for testing contact for HIV, her therapeutic management, drug compliance and follow up. Counsel the contacts on mode of transmission, safe sex and on therapeutic management, as per the individual needs.

- **Obstetrician**: will counsel woman therapeutic management, drug compliance and follow up from pregnancy to post partum, need for caesarean section and formula feed.

- **Paediatrician**: will counsel mother on the management and compliance and follow up of her newborn/s, formula feed, care at home and management and compliance of other children that are HIV positive.
SERVICE PROVISION : COUNSELLING

SCOPE OF COUNSELLING

- Pre-test information to all targeted women
- Post test information for all woman that are HIV negative
- Post test Counselling for HIV positive women
- Counselling women on infant feeding
  - Counselling on infant feeding to HIV negative women
  - Counselling on infant feeding to HIV positive women
  - Women opting to choose replacement feeding

Pre-test information :

- Tell all pregnant women attending ANC clinic, delivering in health institution or have delivered at home and are attending post-natal services that amongst all routine health screening blood tests, STI’s and HIV testing is also being done. Performing these tests is important as it will allow them to:
  - Receive appropriate timely intervention that can improve their health and their pregnancy outcome and baby’s health.

All women should be assured of trust and confidentiality of the providers. Women that refuse HIV testing should be encouraged to do so on subsequent visit but without any coercion.
SERVICE PROVISION : COUNSELLING

Post test information for Women that are HIV negative

• understand the importance of knowing the HIV status in pregnancy
• Inform her on the association of high risk behaviours with STI’s and HIV infection and the importance of practising safe sex

Post test Counselling for HIV +ve women (ELISA twice +ve & +ve WB test):

• Ensure that result belongs to the woman whom the test result is being disclosed
• Help woman to understand the meaning of positive HIV test
• Try to be straight forward in manner; be non-judgmental, supportive and confident while disclosing the result
• Encourage woman to ask questions and express feelings, and address her concerns. Tell her that you will be available to answer her questions when ever she had urge to ask them, any time

Explain to women on the :

• Need for referral to the HIV physician and obstetrician for specialised management and continuing and follow up at secondary/tertiary care hospital.
• Importance of taking antiretroviral treatment to prevent mother to child transmission of HIV during pregnancy, delivery.
• Importance of compliance with drugs during pregnancy and post-natally as advised by the physician.
• Need for caesarean section.
• Importance good nutritional and hygiene.
• Need for delivery at secondary/tertiary care hospital as per the assessed need by the treating team (physician and obstetrician).
SERVICE PROVISION: COUNSELLING

- Making informed decision on formula versus breast feeding
- Probability of giving HIV prophylaxis for the baby
- Guidance on safe sex practices as chances of transmitting infection to the baby are higher if her exposure to HIV infection continued
- Availability of MCH counsellor at PHC and seeking her help for any query that she has any time.

Counselling women with HIV + will always be done by trained providers only

Disclosure of HIV status

- **Do not disclose the results without woman’s consent**
- Tell woman on the importance of disclosing results to her husband and his supportive role
- Need for testing husband, children and other contacts of woman
- Make sure the understanding of the husband on the meaning of HIV positive result
- Discuss the plan with husband on HIV testing of the children
- Discuss possibility of need for treatment for family members that are HIV positive on testing
- If on disclosure, unexpected negative reactions come from the husband and family members, help her to cope up with it.
- Counsel husband and other family members to be supportive and non-discriminatory towards woman.
- As when disclosed the HIV status of woman, allay the fear of family members that HIV does not get transmitted with casual contacts with HIV infected person
- If desired by woman disclosure can be made to the person whom woman trusts and can seek support.
Counselling women on infant feeding

Infant feeding recommendation for HIV negative women

Tell woman to:
- breast feed exclusively for 6 months and continue up to 2 year
- introduce complimentary feeding when the infant is of 6 months age
- use birth spacing method to space pregnancies

Counseling on infant feeding to HIV positive women

Tell woman that:
- breast feeding is one of the proven mode of HIV transmission to the infant
- chances of transmitting infection are higher if:
  - Infection acquired recently, or if she continues to be further exposed to infection
  - Duration of breast feeding higher
  - Woman has Breast infection/abscess or cracked nipples
  - Infant Oral disease (thrush, mouth sores)
- avoiding breast feeding is the safest option to prevent transmission of HIV infection to the baby, provided replacement feeding is acceptable, feasible, affordable and sustainable
**SERVICE PROVISION : COUNSELLING**

**HIV positive woman that make informed decision on breast feeding**

- Can express the breast milk, boil it and cool it before use
- Teach how to maintain hygiene similar to what is required for the formula feed preparation

**Woman accepting replacement feeding**

**Teach mother how to prepare the feeds safely, such as:**

- Personal hygiene before preparing the feed and while feeding the baby
- Cleaning of teats, bottles and utensils
- Preparing fresh feeds each time and not to use left over prepared feeds
- Shift to cup feeding as early as possible as cleaning utensils is easier
- Explain to mother on the frequency of feeds and quantity of each feed as per the baby’s requirement
- Proper posture to feed the baby

Providers should not promote any commercial milk formula in favour of some personal advantage or hang any poster of any brand or keep the milk formula visible to other delivered women, as this may influence other women to use it, for whom breast-feeding is the best option.

**Counseling HIV +ve women on contraception**

Ensure that in the last month of pregnancy in the ANC clinic and in the postnatal wards before discharge every woman with HIV is explained on safe contraception.

Tell woman that :

- She needs to use condom all times to prevent further exposure to HIV or to other STIs.

- In addition to condom she needs to use another safe reliable method of contraception as unintended pregnancy with condoms are known to be higher.
SERVICE PROVISION: COUNSELLING

• Choice of reversible Contraceptive for HIV +ve is Injectables (depot medroxy progesterone acetate -150 mg/ml/1 ml vial) which needs to be taken every 3 months and can be continued as long as she wishes, with annual check with the gynaecologist.

Emergency contraception:
• Emergency contraception may be advised to women within 5 days of an unprotected sex to prevent unintended pregnancies.

Dose:
Advice women to take 4 COC tablets (Microgynon, containing Levonorgestrol 0.15 mg and Ethinylestradiol 0.03 mg) as soon as possible followed by 4 tablets of COC after 12 hours. Refer to Annex III for other possible pill formulations and dosing.

PRECONCEPTION COUNSELING
For couples wishing to conceive where one or both partners are HIV positive, the treating HIV physician should undertake pre-pregnancy counseling as follows:

• Allow couples to make informed decision about pregnancy by providing them with clear information on:
  – Chances of HIV transmission to infant and untoward impact of pregnancy on their health
  – Strategies to reduce risk of transmission to infant
  – Attainable of a stable, maximally suppressed maternal viral load prior to conception
  – Modification of antiretroviral therapy regimen to avoid teratogenicity on the fetus.

• For couples discordant for HIV infection, appropriate advice on Intra Cytoplasmic Sperm Injection (ICSI) and In Vitro Fertilization (IVF) should be given.

• For HIV discordant couple where the woman is HIV positive, the couple should be advised on how to perform artificial insemination at the time of ovulation.

• For the couple where woman is HIV negative and the husband is HIV positive, advice on limiting unprotected sexual intercourse to around the time of ovulation should be given.
**RISK FACTORS FOR MOTHER-CHILD TRANSMISSION**

**Risk factors for maternal to child transmission of HIV during pregnancy (1):**

- High maternal viral load (advanced HIV infection or AIDS).
- Other opportunistic viral, bacterial and parasitic placental infection (especially malaria).
- Sexually transmitted infections.
- Maternal malnutrition.

**Risk factors for HIV transmission to child during labour and delivery (1):**

- High maternal viral load (advanced HIV infection or AIDS).
- Rupture of membranes for more than 4 hours before the labour begins.
- Invasive delivery procedure.
- First infant in multiple births.
- Chorio-amnionitis (inflammation of the membrane covering foetus).

**INTERVENTIONS TO REDUCE THE RISK OF HIV TRANSMISSION (8):**

- Provide Anti-retroviral (ARV) therapy ante-natally and intra-partum to the woman and ARV prophylaxis to the neonate for the first 6 weeks of life.
- Delivery by elective caesarean section.
- Avoidance of breast-feeding.

Note: The implementation of these three interventions combined, is associated with a vertical transmission of less than 2%.
CLINICAL MANAGEMENT-ANC

Health care providers considering the use of antiretroviral agent, for HIV infected women during pregnancy must take into account two separate but related issues:
1- antiretroviral treatment of maternal HIV infection
2- Antiretroviral chemo-prophylaxis to reduce the risk for perinatal transmission

MANAGEMENT DURING ANTENATAL PERIOD:

• Refer the ANC pregnant woman to the HIV focal point/physician as soon as she is diagnosed to be positive for HIV/AIDS, for the following:
  – Assessment of the immunological status (CD4 T-cell count).
  – Assessment of the infectious status (viral load).

  Note: Persistence of HIV viral load of > 1000 copies/mL is considered as therapy failure/resistance. (9)
  – Decision on the ARV treatment/prophylaxis (see annex 1).

  Note: Antiretroviral therapy should be initiated when a CD4 T-cell count is < 350 cells/mm³. (9)
  – Decision on the prophylaxis of pneumocystic carinii pneumonia (PCP).

  Note: PCP prophylaxis is usually administered when the CD4 T-lymphocyte count is below 200 and the first line treatment is Cotrimoxazole. (8)

Dose: one double-strength tablet or two single-strength tablets once daily: the total daily dose is 960 mg (800 mg sulfamethoxazole + 160 mg trimethoprim). (10)

• At every visit look and manage for:
  – Lymphadenopathy and HIV related infections (TB, STI's, oral or vaginal thrush). (1,8)
  – HIV related opportunistic infections and for any other inter-current infections, such as urinary or respiratory infection. (1)

• Look for signs or symptoms of pre-eclampsia, cholestasis or other signs of liver dysfunction as they may indicate drug toxicity and an early liaison with HIV physicians should be sought. (8)
**CLINICAL MANAGEMENT-ANC**

- Provide health education on: safe sex practices, safe motherhood and infant feeding. (1,8)

- Emphasize on the importance of the following during the course of ANC visit:
  - Caesarean section in reducing the risk of MTCT.
  - Delivering in facility that matches the mother's & baby’s needs (secondary/tertiary).
  - Avoidance of breast-feeding.
CLINICAL MANAGEMENT-LABOUR

MANAGEMENT DURING LABOUR: (1,8,11)

Scheduled caesarean delivery after 38 weeks gestation is recommended for all women diagnosed to be HIV positive during pregnancy

OF THE MOTHER:
- Minimize cervical examination.
- Avoid:
  - Prolonged labour.
  - Routine rupture of membranes.
  - Unnecessary trauma/episiotomies and fetal scalp monitoring.
- If an assisted delivery is required, forceps may be preferable to vacuum extraction.
- Prophylactic antibiotics should be given for both elective and emergency caesarean section.
- Minimize potential risk of post-partum haemorrhage.
- Maternal sample for plasma viral load should be taken at delivery.

HIV- infected women who have an elected scheduled caesarean section but present in early labour or shortly after rupture of membranes:
- If labour is progressive rapidly, the woman may deliver vaginally.
- If cervical dilatation is minimal and a long period of labour is anticipated, some clinicians may choose to administer the loading dose of intravenous ZDV and proceed with caesarean section to minimize the duration of membranes rupture and avoid vaginal delivery. Others might consider augmentation to enhance contractions and potentially expedite delivery. (12)

OF THE NEWBORN:
- Maintain universal precautions.
- Clamp cord immediately after birth and avoid milking the cord; cover the cord with gloved hand and with gauze before cutting.
- Wipe infant's mouth and nostrils with gauze after the head delivery.
**CLINICAL MANAGEMENT-LABOUR**

- Avoid suctioning unless meconium stained liquor, use mechanical suction at less than 100 mm Hg pressure. Do not use mouth operated suction.
- Wipe the infant dry with towel.

**Note:**
- There is no contra-indication to the use of short-term steroids to promote fetal lung maturation in preterm labour.
CLINICAL MANAGEMENT -POSTPARTUM

MANAGEMENT DURING POSTPARTUM PERIOD: (1,8)
OF THE MOTHER:

- Provide all the usual postpartum care.
- Monitor, treat and refer to expert if:
  - Opportunistic infections.
  - Signs & symptoms of postnatal infections, such as: fever, dysuria, foul smelling lochia, cough or shortness of breath, lower abdominal pain or tenderness, infections of the wounds/LSCS site.
- Explain to the mother about the early symptoms and signs of infection at the time of hospital discharge. Instructions on perineal care and safe handling of lochia and blood stained sanitary pads should be given to all mothers.
- Guide mother how to prepare formula feeds hygienically, explain the advantages and disadvantages of formula milk.
- If woman insists on breast-feeding, explain the risk, advantages and disadvantages (see section on counselling, page 31).
- Perform PAP smear at 6-8 weeks PNC check up.
- Counsel and provide birth spacing methods.
- Refer back to the physician for the continuation of ARV therapy.

HIV infected mothers should be explained very strongly to avoid breastfeeding and use artificial feeding.

OF THE NEWBORN: (1,8,13)

- The infant should be bathed immediately after birth.
- Instil silver nitrate or other recommended eye drops in both eyes.
- Administer vitamin K.
- Perform complete blood count and differential as a base line evaluation before administration of ARV.
- Provide anti retroviral (ARV) prophylaxis (Annex 1).
Algorithm 4

HIV testing for infants and children less than 18 months age born to HIV positive mothers

HIV

Infant born to HIV positive mother

Perform RT-PCR within 48 hrs of birth

RT-PCR Positive

HIV infected

RT-PCR negative

Repeat RT-PCR At 3-6 weeks

RT-PCR negative

Repeat at 3 months

RT-PCR positive

Repeat RT-PCR immediately

HIV infected

RT-PCR positive

HIV infected

RT-PCR negative

Perform ELISA test at 18 months

Positive

HIV infected

Negative

HIV uninfected

Collecting Blood for RT-PCR test: 5 cc of blood has to be collected in pre-labelled EDTA tube, if feasible centrifuge the sample and transfer the plasma in the pre-labelled plain tube. Send it immediately to the RPHL/CPHL at Darseit directly, while ensuring proper temperature control during transfer.
CLINICAL MANAGEMENT-NEONATE

- HIV exposed infants will be treated as HIV +ve for the vaccination purpose, till HIV status is confirmed. (refer to EPI & HIV/AIDS SOP manual)

- Live attenuated vaccines are contra-indicated in HIV exposed children. Hence BCG should not be given, and replace OPV by IPV.

- Provide remaining immunization as per protocol (Refer to EPI SOP manual).

- Perform HIV testing as per protocol (algorithm 4).

AVR requirement for infants should be available in advance at the planned place of delivery
CLINICAL MANAGEMENT – INFANT

CO-TRIMOXAZOLE PROPHYLAXIS (10):

All HIV-exposed infants born to mothers living with HIV must receive co-trimoxazole prophylaxis, commencing at 6 weeks of age (after completion of the ZDV prophylaxis regimen) and continued until HIV infection can be excluded.

CONTRAINDICATIONS:
- Allergy to sulfa drugs.
- G6PD deficiency.

Alternative: Dapsone 2 mg/kg once daily can be used

Co-trimoxazole formulations and dosage for infants and children living with HIV or exposed to HIV, see table 4.

<table>
<thead>
<tr>
<th>Recommended daily dosage</th>
<th>Suspension (5 ml of syrup 200 mg/40 mg)</th>
<th>Child tablet (100 mg/20 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6 months 100 mg sulfamethoxazole/20 mg trimethoprim</td>
<td>2.5 ml</td>
<td>One tablet</td>
</tr>
<tr>
<td>6 months–5 years 200 mg sulfamethoxazole/40 mg trimethoprim</td>
<td>5 ml</td>
<td>Two tablets</td>
</tr>
</tbody>
</table>

Co-trimoxazole prophylaxis can be discontinued when HIV infection has been definitely excluded by a confirmed negative HIV virological test (PCR) six weeks after complete cessation of breastfeeding in an infant <18 months of age or a confirmed negative HIV antibody test in a child >18 months of age and six weeks after complete cessation of breastfeeding.
Counselling is a two ways process of communication by which one person helps another to identify her/his health needs and to make the most appropriate informed decision/s.

OBJECTIVES

- Provide I E & C to clients regarding advantage of testing for HIV in pregnancy and its impact on reducing chances of vertical transmission to the baby.
- Provide psychological support to those that are positive for HIV to overcome the shock and be able to take right decisions regarding their lives and their families too.

FACTORS INFLUENCING COUNSELLING

- Age
- Culture and social influences
- Who controls decision making
- Age of marriage
- Level of educational attainment
- Emotional status
- Readiness for behavioral changes

ENVIRONMENT

- Where ever counselling takes place it must be held privately.
- Room arrangement should facilitate communication between client and availability and use of visual aids to facilitate discussions.


COUNSELLING

COUNSELLOR’S APPROACH AND ATTITUDE

Who should do counselling?

- Every trained health worker in health institutions of all levels should be able to give accurate information.
- A trained Doctor or Nurse/ Midwife will provide Counselling.

BREAKING THE NEWS SHOULD PREFERABLY BE GIVEN BY A TRAINED DOCTOR

A good Counselor should have:

- Understanding and respect for client’s rights
- Sensitivity that earns the trust of clients
- Understanding of cultural and psychological factors that affect a woman’s /couple’s decision
- A non judgmental approach and treating the client with respect
- Ability to present information in a non-technical unbiased and client sensitive manner
- A way to encourage clients to ask questions
- Ability to recognize when referral is needed
- Appreciation of non-verbal communication (body language).

COUNSELLING PROCESS

Counselling is a function that should be integrated in all phases of the interaction between the client and the clinic staff.

Information should be given to aid client’s choice, not to persuade, press or induce a person to take a particular decision, but in situations when client is planning to pursue a risky path, we will have to step forward to convince her/him.
COUNSELLING

“GATHER“ APPROACH:

• Greet each client warmly
• Tell the client about ANC including HIV testing services
• Help the client to understand that testing for infections including HIV infection is best for her and her baby
• Explain how HIV infection is going to affect her and her baby’s health
• Tell her that you will call her when tests results are received.

TYPES OF COUNSELLING

There are 2 Phases for Counselling before and after HIV testing:

1. PRE-TESTING INFORMATION (by trained Nurses, Midwives)

• Simple leaflet has been designed to be used at this stage which may prove useful in remembering the relevant points & discussion

2. POST TEST INFORMATION FOR HIV NEGATIVE WOMEN (by trained Nurses, Midwives)

3. POST-TEST COUNSELLING FOR HIV +VE WOMEN (HIV focal doctor at PHC)

• Breaking the news
• Follow up counselling on the management
ANNEX I

Drug Management of women living with HIV during pregnancy

Clinical Scenario Summary Recommendations for Antiretroviral Drug Use by Pregnant HIV-Infected Women and Prevention of Perinatal HIV-1 Transmission

- ARV prophylaxis: short term use of antiretroviral drugs to reduce HIV transmission from mother to infant. It is indicated when CD4 count is $\geq 350$ cells/mm$^3$.
- ARV treatment: long term use of antiretroviral drugs to treat the mother's HIV/AIDS and prevent PMTCT. It is indicated when CD4 count is $< 350$ cells/mm$^3$. 
### Woman:

- **HIV-infected pregnant woman who never received antiretroviral drugs and does not require treatment for her own health.** (ARV Prophylaxis)

  **Woman:**
  - HAART is recommended for **prophylaxis** of perinatal transmission in women who do not require treatment for their own health.
    - Consider delaying HAART initiation until after first trimester is completed.
    - Avoid use of EFV or other potentially teratogenic drugs in the first trimester and drugs with known adverse potential for mother (combination d4T/ddI).
    - Use of ZDV as a component of the antiretroviral regimen is recommended.
  - NVP should only be used as a component of therapy in women with CD4 counts >250 cells/mm³ if the benefit clearly outweighs the risk due to an increased risk of severe hepatic toxicity.
  - Use of ZDV prophylaxis alone is controversial but may be considered for those women with plasma HIV RNA levels <1,000 copies/mL on no therapy.
  - Continue HAART regimen during intrapartum period (ZDV given as continuous infusion during labor while other antiretroviral agents are continued orally).
  - Evaluate need for continued therapy postpartum; discontinue HAART unless has indications for continued therapy. If regimen includes drug with long half-life like NNRTI, consider stopping NRTIs 7 days after stopping NNRTI.
  - Scheduled cesarean delivery after 38 weeks.

### Infant:

- **ZDV for 6 weeks started within 6 to 12 hours after birth.**

---

1. Continuous infusion
2. Usually 6.5 - 7.5 mg/kg per day.
II. HIV-infected pregnant woman who never received antiretroviral drugs and has indications for antiretroviral therapy. (ARV treatment)

**Woman:**
- Initiate HAART regimen.
  - Avoid use of EFV or other potentially teratogenic drugs in the first trimester and drugs with known adverse potential for mother (combination d4T/ddI).
  - Use of ZDV as a component of the antiretroviral regimen is recommended when feasible.
  - NVP can be used as a component of HAART for women with CD4 count $\leq 250$ cells/mm$^3$, but should only be used as a component of therapy in women with CD4 counts $>250$ cells/mm$^3$ if the benefit clearly outweighs the risk due to an increased risk of severe hepatic toxicity.
- Initiation of HAART should be deferred until after the first trimester.
- Continue HAART regimen during intrapartum period (ZDV given as continuous infusion during labor while other antiretroviral agents are continued orally) and postpartum.
- Scheduled cesarean delivery after 38 weeks gestation.

**Infant:**
  - ZDV for 6 weeks started within 6 to 12 hours after birth.\(^2\)
### III. A known HIV-infected woman who is receiving HAART and becomes pregnant

**Woman:**
- Continue current HAART regimen if successfully suppressing viremia, except avoid use of EFV or other potentially teratogenic drugs in the first trimester and drugs with known adverse potential for mother (combination d4T/ddI).
- HIV antiretroviral drug resistance testing is recommended if the woman has detectable viremia on therapy.
- In general, if woman requires treatment, antiretroviral drugs should not be stopped during the 1st trimester.
- Continue HAART regimen during intra-partum period (ZDV given as continuous infusion\(^1\) during labor while other antiretroviral agents are continued orally) and postpartum.
- Scheduled cesarean delivery after 38 weeks gestation.

**Infant:**
- ZDV for 6 weeks started within 6 to 12 hours after birth\(^2\).
IV. HIV-infected pregnant woman who is antiretroviral experienced but not currently receiving antiretroviral drugs

**Woman:**
- Obtain full antiretroviral treatment history and evaluate need for antiretroviral treatment for own health.

- Initiate HAART, with regimen chosen based on prior therapy history.
  - Avoid use of EFV or other potentially teratogenic drugs in the first trimester and drugs with known adverse potential for mother (combination d4T/ddI).
  - Use of ZDV as a component of the ARV regimen is recommended when feasible.
  - NVP should only be used as a component of therapy in women with CD4 counts >250 cells/mm3 if the benefit clearly outweighs the risk due to an increased risk of severe hepatic toxicity.

- Continue HAART regimen during intrapartum period (ZDV given as continuous infusion\(^1\) during labor while other antiretroviral agents are continued orally).

- Evaluate need for continued therapy postpartum; discontinue HAART unless has indications for continued therapy. If regimen includes drug with long half-life like NNRTI, consider stopping NRTIs 7 days after stopping NNRTI. (Limited data exist on this.)

- Scheduled cesarean delivery after 38 weeks gestation.

**Infant:**
- ZDV for 6 weeks started within 6 to 12 hours after birth.\(^2\)
V. HIV-infected woman who has received no antiretroviral therapy prior to labor

- **ZDV**

**Woman**: ZDV given as continuous infusion\(^1\) during labor.

**Infant**: ZDV for 6 weeks started within 6 to 12 hours after birth.\(^2\)

**OR**

**Combination ZDV + Single-Dose NVP**:  

**Woman**: ZDV given as continuous infusion\(^1\) during labor, plus single-dose NVP\(^3\) at onset of labor. Consideration should be given to adding 3TC during labor and maternal ZDV/3TC for 7 days postpartum, which may reduce development of NVP resistance.

**Infant**: Single-dose NVP\(^3\) plus ZDV for 6 weeks.

**OR**

**Woman**: ZDV given as continuous infusion\(^1\) during labor.

**Infant**: Some clinicians may choose to use ZDV in combination with additional drugs in the infant, but appropriate dosing for neonates is incompletely defined and the additional efficacy of this approach in reducing transmission is not known. Consultation with a pediatric HIV specialist is recommended.

Evaluate need for initiation of maternal therapy postpartum.
**VI. Infant born to HIV-infected woman who has received no antiretroviral therapy prior to or during labor**

- ZDV given for 6 weeks to the infant, started as soon as possible after birth.

**OR**

- Some clinicians may choose to use ZDV in combination with additional drugs, but appropriate dosing for neonates is incompletely defined and the additional efficacy of this approach in reducing transmission is not known. Consultation with a pediatric HIV specialist is recommended.

- Evaluate need for initiation of maternal therapy postpartum.

**VII. HIV-infected woman of childbearing potential but not pregnant and who has indications for initiating antiretroviral therapy**

- Initiate HAART as per adult treatment guidelines.

- Avoid drugs with teratogenic potential (e.g., EFV) in women of childbearing age unless adequate contraception ensured. Exclude pregnancy before starting treatment with EFV.
HAART: highly active antiretroviral therapy, a minimum of three antiretroviral agents.

1 ZDV continuous infusion: 2 mg/kg ZDV intravenously over 1 hour, followed by continuous infusion of 1 mg/kg/hour until delivery.

2 ZDV dosing for infants:
<35 weeks gestation at birth is 1.5 mg/kg/dose intravenously, or 2.0 mg/kg/dose orally, every 12 hours, advancing to every 8 hours at 2 weeks of age;
If >30 weeks gestation at birth or at 4 weeks of age;
If <30 weeks gestation at birth.

3 Single-dose NVP:

Mother: 200 mg given once orally at onset of labour;

Infant: 2 mg/kg body weight given once orally at 2–3 days of age if mother received intrapartum single-dose NVP, or given at birth if mother did not receive intrapartum single-dose NVP.
Perform HIV antiretroviral drug resistance testing prior to initiating repeat antiretroviral prophylaxis or therapy and if sub optimal viral suppression after initiation of HAART.
# Intrapartum Maternal and Neonatal Zidovudine Dosing for Prevention of Mother-to-Child HIV Transmission

## Maternal Intra-partum

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZDV</td>
<td>2 mg per kg body weight intravenously over 1 hour, followed by continuous infusion of 1 mg per kg body weight per hour</td>
<td>Onset of labor until delivery of infant</td>
</tr>
</tbody>
</table>

## Neonatal

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZDV (term [&gt;35 weeks] infant)</td>
<td>2 mg per kg body weight per dose given orally (or 1.5 mg per kg body weight per dose given intravenously) started as close to birth as possible (by 6–12 hours of delivery), then every 6 hours*</td>
<td>Birth to 6 weeks</td>
</tr>
<tr>
<td>ZDV (&lt;35 weeks but &gt;30 weeks)</td>
<td>2 mg per kg body weight per dose given orally (or 1.5 mg per kg body weight per dose given intravenously) every 12 hours, advanced to every 8 hours at 2 weeks of age</td>
<td>Birth to 6 weeks</td>
</tr>
<tr>
<td>ZDV (&lt;30 weeks)</td>
<td>2 mg per kg body weight per dose given orally (or 1.5 mg/kg/dose given intravenously) every 12 hours, advanced to every 8 hours at 4 weeks of age</td>
<td>Birth to 6 weeks</td>
</tr>
</tbody>
</table>

ZDV = zidovudine

- ZDV dosing of 4 mg per kg body weight per dose given every 12 hours has been used for infant prophylaxis in some international perinatal studies. Although there are no definitive data to show equivalent pharmacokinetic parameters or efficacy in preventing transmission, a regimen of ZDV 4 mg per kg body weight per dose given orally twice daily instead of 2 mg per kg body weight per dose given orally four times daily may be considered when there are concerns about adherence to drug administration to the infant.

## References:


Note:
- Teratogenic potential of most of HIV drugs is not known.
- All treatment options require careful assessment by specialist.

<table>
<thead>
<tr>
<th>Antiretroviral drug</th>
<th>FDA Pregnancy category</th>
<th>Teratogenicity according to BNF 55</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleoside and nucleotide analogue reverse transcriptase inhibitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abacavir (ABC)</td>
<td>C</td>
<td>Manufacturer advises avoid (toxicity in animal studies)</td>
</tr>
<tr>
<td>Didanosine (ddl)</td>
<td>B</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>C</td>
<td>Manufacturer advises avoid during first trimester</td>
</tr>
<tr>
<td>Stavudine (d4T)</td>
<td>C</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
<tr>
<td>Tenofovir Disoproxil (TDF)</td>
<td>B</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
<tr>
<td>Zidovudine (ZDV)</td>
<td>C</td>
<td>Manufacturer advises use only if clearly indicated</td>
</tr>
<tr>
<td><strong>Non-nucleoside reverse transcriptase inhibitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efavirenz (EFV)</td>
<td>D</td>
<td>Manufacturer advises avoid unless no alternative available</td>
</tr>
<tr>
<td><strong>Protease inhibitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indinavir (IDV)</td>
<td>C</td>
<td>Manufacturer advises use only if potential benefit outweighs the risk, toxicity in animal studies, risk of renal stones in neonates if used at term</td>
</tr>
<tr>
<td>Lopinavir with Ritonavir (LPV/r)</td>
<td>C</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
<tr>
<td>Nelfinavir (NFV)</td>
<td>B</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
<tr>
<td>Nevirapine (NVP)</td>
<td>B</td>
<td>Manufacturer advises avoid, may be appropriate to use if clearly indicated</td>
</tr>
<tr>
<td>Ritonavir (r)</td>
<td>B</td>
<td>Manufacturer advises use only if potential benefit outweighs risk</td>
</tr>
</tbody>
</table>

The information above were supplied by the Department of Rational Drug use on request.
Risk of teratogenicity is mentioned in this table according to the FDA teratogenicity classification and the BNF (British National Formulary).

Food and Drug Administration Pregnancy Categories:

**A**: Adequate and well-controlled studies of pregnant women fail to demonstrate a risk to the fetus during the first trimester of pregnancy (and no evidence exists of risk during later trimesters).

**B**: Animal reproduction studies fail to demonstrate a risk to the fetus, and adequate but well-controlled studies of pregnant women have not been conducted.

**C**: Safety in human pregnancy has not been determined; animal studies are either positive for fetal risk or have not been conducted, and the drug should not be used unless the potential benefit outweighs the potential risk to the fetus.

**D**: Positive evidence of human fetal risk that is based on adverse reaction data from investigational or marketing experiences, but the potential benefits from the use of the drug among pregnant women might be acceptable despite its potential risks.

**X**: Studies among animals or reports of adverse reactions have indicated that the risk associated with the use of the drug for pregnant women clearly outweighs any possible benefit.

**Remember:**
- Low dose is required if either indinavir is used in pregnancy because adequate drug concentration is achieved only with ritonavir boosting.
- Avoid use of Efavirenz (EFV) or other potentially teratogenic drugs in the first trimester.
- Didanosine (ddl), stavudine (d4T) and tenofovir (TDF) should be used in pregnancy only when no alternatives are available.
- NVP should only be used as a component of therapy in women with CD4 counts >350 cells/mm$^3$ if the benefit clearly outweighs the risk due to an increased risk of severe hepatic toxicity.
- For women who are receiving a d4T-containing antepartum regimen, d4T should be discontinued during labor while intravenous ZDV is being administered.

**Note:** The above listed drugs approved by central drug committee and agreed upon by the HIV control section.
# ANNEX III

Pill Formulations and Dosing for Emergency Contraceptive

<table>
<thead>
<tr>
<th>Pill Type</th>
<th>Total dosage to provide</th>
</tr>
</thead>
</table>
| POP       | • Levonorgestrel pills: 1.5 mg in a single dose.  
• Noregestrel pills: 3 mg in a single dose. |
| COC       | • Estrogen and levonorgestrel pills: 0.1 mg ethinyl estradiol + 0.5 mg levonorgestrel. Repeat the same dose after 12 hours.  
• Estrogen and norgestrel pills: 0.1 mg ethinyl estradiol + 1 mg norgestrel. Repeat the same dose after 12 hours.  
• Estrogen and norethindrone pills: 0.1 mg ethinyl estradiol + 2 mg norethindrone. Repeat the same dose after 12 hours. |
References


2. Global estimates of adults and Children 2007, living with HIV, Newly infected with HIV and Deaths due to HIV.


Bibliography


(5) Guidelines No. 39, April 2004, Royal college of obstetricians and gynaecologists, setting standards to improve women’s health ‘Management of HIV in pregnancy’


(10) GUIDANCE ON GLOBAL SCALE-UP THE PREVENTION OF MOTHER TO CHILD TRANSMISSION: Towards universal access for the women, infants and young children and eliminating HIV and AIDS among children, WHO/UNICEF with the Interagency Task Team (IATT) on Prevention of HIV infection in Pregnant Women, Mothers and their Children, 2007
PROVIDER’S TASKS AT DIFFERENT LEVELS

**At Antenatal Clinic**
- Trained staff nurse & doctor
- Routine ANC care
- Pre-counsel before blood collection
- Do Health education
- Collect blood for routine & HIV test
- PHC with lab. Centrifuge blood sample for HIV send serum to RPHL (those without lab. send blood, directly)

**At RPHL**
- Perform ELISA test
- Send report of –ve results to PHC
- Send + ve blood sample to CPHL
- Send re-bleed sample for reconfirmation to CPHL (+ve ELISA & +ve WB Test), for case identity.

**At CPHL**
- Perform ELISA and WB test
- For + ve sample for HIV, perform ELISA & WB test for reconfirmation of identity on re-bleed sample
- Perform RT PCR for non-conclusive test
- Sent all reports of + ve HIV test of pregnant women to PHC, DFCH and AIDS control section
- Maintain record on identity and results

**HIV focal person/physician**
- Trace HIV +ve pregnant woman
- Fill & send HIV Notification Form (PR-83) to HIV/AIDS Control Section
- Call for HIV Counsellors, trace contacts, screen and manage as per the need
- Team up with Obstetrician to manage HIV +ve pregnant women

**Paediatrician**
- Follow-up of the baby born to women with HIV till 18 months and other children until 15 years age

**HIV Counsellors**
- Trace contacts & index case
- Arrange for screening & management as per needs by focal physician
- Educate index case, contact and community
- Follow up of index case and contact for compliance with management

**MCH counsellor**
- Counsel HIV +ve pregnant women
- Follow up of mother until post partum
- Maintain record on action taken
- Send compiled report to DFCH

**HIV focal doctor at (PHC Centre)**
- Break the news, counsel
- Arrange for referral to HIV focal point at secondary care level as and when needed
- Maintain records confidentially