THE REPUBLIC  OF THE GAMBIA

STANDARD OPERATING PROCEDURES (SOPs) FOR PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) – EARLY INFANT DIAGNOSIS (EID)

NATIONAL AIDS CONTROL PROGRAM (NACP)
MINISTRY OF HEALTH AND SOCIAL WELFARE

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RATIONALE/BACKGROUND

Infants and young children have an exceptionally high risk of poor outcomes from HIV infection. Up to 52% of children die before the age of two years in the absence of any intervention.

Because of this high risk of death before the age of 2 years among HIV-infected infants, and given the increasing availability of paediatric antiretroviral treatment in many resource-limited settings; WHO recommends that national programmes should establish the capacity to provide early virological testing of infants for HIV.

Serological assays suitable for HIV antibody detection in adults cannot be reliably used for confirmatory diagnosis of HIV in infants as the interpretation of positive HIV antibody testing is complicated by the fact that maternal HIV antibody can persist for 18 months (although it usually clears by 9−12 months).

Antibody-negative results suggest that infants are unexposed and or uninfected, however, if the infant is breastfeeding the risk of acquiring HIV continues throughout the entire breastfeeding period.
Therefore Early virological diagnosis of HIV infection in infants and children:

- Enables the early identification of who have HIV-infection, as a first step in securing their treatment and care;
- Enables the identification of those who are HIV-exposed but uninfected, facilitating follow-up care and prevention measures that will help to ensure that they remain uninfected;
- Assists in the effective use of essential resourcesby targeting ART on children who need treatment;
- Improves the psychosocial well-being of families and children, reducing potential stigma, discrimination and psychological distress;
- Facilitates life-planning for parents and/or children who have HIV;
- Assists in decision-making on breastfeeding;[3]
- An HIV-positive mother with an HIV-uninfected baby can be counselled and supported to stopbreastfeeding if replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS).If the baby is HIV-infected the mother can be counselled and supported to continue breastfeeding;[3]

INTEGRATION OF PMTCT SERVICES INTO RCH

Mother-to-child transmission of HIV accounts for the vast majority (>90%) of children under the age of 15 years who are estimated to be living with HIV and almost 90% of them in sub-Saharan Africa. In2011 the Gambia reportedthat 44.4% of ANC facilities provided PMTCT services;52% of pregnant women were counseled and tested for HIV;56% of pregnant women delivered at health facilities and 1400 children living with HIV. This may be gross under estimation as many would have died before the age of 2 years undiagnosed because EID was not offered and many pregnant mothers did not access PMTCT services. Therefore given the considerable burden of HIV in pregnancy in the country, the full integration of PMTCT will maximize and strengthen the RCH platform and accelerate HIV prevention efforts.

ANTENATAL CLINIC

All pregnant mothers should be informed of HIV Counseling and Testing (HCT) in PMTCT services and encouraged to access HIV test.

All HIV positive mothers should be on ARVs for their health and prevention of Mother-To-Child-Transmission of HIV

Blood should be taken for HB, CD4 count, Blood group, RPR (VDRL) and Urine for urinalysis.

Infant feeding and family planning counseling should be offered and discussion on Early Infant Diagnosis introduced.

Ensure iron and multivitamin supplements are given but vitamin A is not recommended in the antenatal period.

At 36 weeks, repeat HB test and collect blood for **V**iral **L**oad assessment.

All HIV negative mothers should receive counseling on safe sex practices and repeat HIV test at 36 weeks or at the maternity.

Those mothers who declined HIV testing should be reoffered counseling at 36 weeks or at the maternity.

LABOUR AND DELIVERY

This is the most critical stage in the process of MTCT (15-20%) of HIV that is mostly byhandled by care providers.

The ARV drugs should continue as usual; **N**o **A**lteration

The midwife and the team should ensure universal precaution and safe obstetrics practices are applied.

Safe **O**bstetrics **P**ractices includes;

- Avoid Artificial Rupture of membranes (ARM), Routine Episiotomy, Scalp Trauma, Vacuum extractor, Forceps delivery and Fetal blood Sampling.
- Ensure early cord clamp and quick removal of baby from maternal body fluids (blood and liquor)
- Ensure immediate neonatal luke warm water bath,dry and keep the baby warm
- Ensure active management of 3rd stage of labour to reduce post partum haemorrhage.
- Collect blood for Viral Load assessment if not collected at 36 weeks
- Initiate Breastfeeding within one hour post delivery (confirm with NaNA) if breastfeeding is the infant feeding choice
- AFASS (Acceptable, Feasible, Affordable, Sustainable and Safe) should be reviewed if Formula Feed is the feeding choice
- Offer counseling on contraception options for PLHIVs.

- Ensure Follow up appointment is discussed and documented. Early infant diagnosis should be emphasized.
- Infant ARV prophylaxis should commence within 72 Hours post delivery
- If the infant was delivered at home or other health center the same treatment as stated above should be offered.
- Offer HIV repeat test for Negative mothers and those who declined test in the antenatal period should be reoffered counseling.
- The labour ward staff should be well informed and appropriate communication between members of the team is essential.

POST NATAL CARE AND FOLLOW UP

Continuation of Care: Maternal and Infant ARVsshould continue as in the policy guidelines.

- Infant feeding choice should be supported and maintained
- First post natal care should be done immediately after birth
- First follow up appointment should occur within 1-2 weeks post delivery
- If she did not come effort should be made by the care providers (PMTCT focal person or social worker) to call or do home visit.
- Second follow up appointment should occur within 4-6 weeks post delivery
- If she did not come effort should be made by the care providers (PMTCT focal person or social worker) to call or do home visit.
- Early Infant Diagnosis (EID) should be offered at 6-8 weeks post delivery.
- Commence infant Cotrimoxazole prophylaxis at 6-8 weeks post delivery.
- Linkage of various units in the facility should be promoted using standard coding system. This would facilitate easy identification of Maternal- Infant couple and increase access to Early Infant Diagnosis (EID).
- The Infant welfare clinic and involvement of public health officers is essential to reduce lost to follow up and improve uptake of EID.

DRIED BLOOD SPOT (DBS) SAMPLE COLLECTION

Materials and supplies

- Powder-free gloves
- Alcohol pad
- Filter paper – Whatman (formerly Schleicher &Schuell) 903™ card or equivalent
- Lancet
- Cotton or tissue (Kimwipe or equivalent)
- Ziplock plastic bag
- Silica desiccant
- Bandage

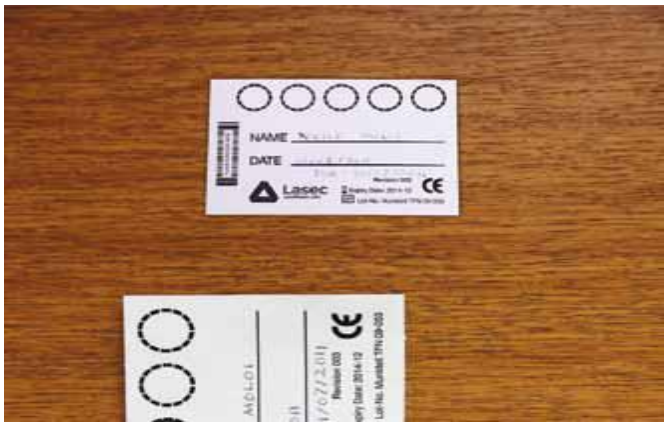
Sample collection procedure

1. Check the expiry date of the DBS card prior to use (**do not use if expired**).

2. Wash your hands with soap and running tap water.

3. Wear gloves prior to sample collection.

4. Label card with patient ID (PMTCT Number) as in request form using a ballpoint pen or permanent marker. In case of twin delivery identify the PMTCT with a,b, c etc



5. Select puncture area based on the age/weight of infant
   - **6-8 weeks/less than 6 kg - Heel**

6. Wipe the puncture area with alcohol swab and allow alcohol to dry up for 30 seconds.
   - **do not blow on the heel or finger to dry the alcohol**
   - **do not wipe off the alcohol**
   - **do not perform the finger, toe or heel prick until alcohol is completely dry.**

7. Make a puncture on the disinfected puncture site.

8. Position the foot or hand with the puncture site downwards.

9. Apply and release pressure to allow for the formation of a drop of blood. (avoid excessive squeezing of the heel this may lead to greater hemolysis and more pain)
10. Wipe away the first drop of blood with a dry cotton wool.
11. Place a drop of blood on each spot on the DBS card (3 - 5 spots) and make sure that the spot is completely filled with the blood.

12. If blood stops flowing, wipe away any clot that may have formed at the incision site with alcohol swap. Release pressure to allow capillary refill, then reapply pressure to allow blood drop to form again.

13. When collection is complete, apply pressure to the puncture site using gauze or cotton wool until bleeding stops. Apply bandage.

14.Discard the blood lancet used in a sharp container.

<u>Note:</u> Do not touch the pre-printed areas on the DBS card prior to and after blood sample collection.

Complications of Procedure

Complications of heel stick include the following:

- Pain
- Infection
- Scarring
- Inaccurate results (e.g. hemolysis causing hyperkalemia, air bubbles causing erroneous blood gas results, platelet clumping)
- A too-deep incision (potentially making contact with calcaneus)
- **NOTE: Please inform the mother to report to the facility if the infant shows any of the above complications.**

Method for drying sample on DBS

1. Place one DBS card into each slot of the drying rack or a flat surface withoutallowing the cards to touch each other.

2. Dry for at least three hours at room temperature. Do not **dry artificially with heat or expose to direct sunlight**.

3. Dry completely before packing. Properly dried blood spots are **dark red or brown**in colour.

DBS sample packaging

1. Each properly dried DBS card should be packed into the zip-lock plastic bag provided in the DBS collection kit, with atleastone desiccant sachet. **Do not pack if samples are not completely dry.**

2. Place these cards in a larger zip-lock biohazard bag with the accompanying request forms.

3. Place the larger zip-lock biohazard bag with the packed samples into the sample transportation container for transportation.

Specimen storage

Store all DBS specimens at 2-8°C or room temperature (20-25°C) with each card sealed in a zip-lock plastic bag with a desiccant.

DOCUMENTATION

For each visit, indicate the following;

- Date of visit
- Infant feeding mode at the time of visit
- Infant weight in Kg
- Immunisation status
- The amount of Cotrimoxazole supplied
- Type of HIV test done and the results if applicable
- Mother's family planning method

CATCH UP TESTING

In view of extended pilot sites and roll in programme of early infant diagnosis of HIV using PCR in all regions of the country, it is prudent to consider maternal-infant couple who are below 12 months for testing. This will give information as to effectiveness of the programme and assessing the ability of the pilot sites in the area of patient tracking and potential reduction of loss to follow up and defaulters.

Catch up testing will enable relative early identification of HIV positive infants who would benefit from early intervention in treatment, support and care with overall improved survival advantage. It is an extended programme to ensure wider coverage.

Therefore, all PMTCT sites should be encouraged to track those babies and consider a date for DBS collection.

Communication between the facility, RHT and the National Health Laboratory Services should be well established to ensure appropriate samples collection and transportation.

Targeted Turn-around time (interval between sample collection and notification of result) should be between 14 and 21 days.

REFERENCES

1.Eliminating new HIV infection amongst children, 2012. UNAIDS.Website http://www.unaids.org/en/targetsandcommitments/eliminatingnewhivinfectionamongchildren/. Accessed April23, 2014.

2. Early detection of HIV infection in infants and children; Guidance note on the selection of technology for the early diagnosis of HIV in infants and children2007. World Health Organization Web sitehttp://www.who.int/diagnostics_laboratory/procurement/viral_load/en/index.html. Accessed October 30, 2014.

3. HIV and infant feeding: Framework for priority action 2006. WHO/UNICEF Web site http://www.who.int/childadolescenthealth/New_Publications/NUTRITION/HIV_IF_Framework_pp.pdf. Accessed October 30, 2014.

4.The Republic of Gambia. National Policy and Guidelines for prevention of Mother to Child Transmission of HIV (PMTCT). Banjul: Ministry of Health and Social Welfare; 2010.

5. Williams PJ, Hull HF. Status of Measles in The Gambia, 1981. Rev Infect Dis 1983;5:391-4

6. National Health Laboratory Services, South Africa, 2011. "*Taking blood from infants for HIV PCR test – Standard Operating Procedure"*; 9th edition.

Further information

The WHO Diagnostics and Laboratory Technology web site (http://www.who.int/diagnostics_laboratory/en/) is a useful resource, providing information on evaluated assays, bulk procurement, quality assurance, and guidance and training.

The WHO Department of HIV/AIDS web site includes a page on paediatric HIV infection(http://www.who.int/hiv/paediatric/en/index.html)