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POLICY BRIEF

Introduction of Point-Of-Care (POC) virological testing for pregnant and breastfeeding women and Early Infant Diagnosis (EID) in Tanzania

Key messages

- As of 2019, the rate of mother to child transmission in Tanzania was 11%. This is substantially higher than the desired target of <0.5%.
- Despite the broad coverage and availability of sample referral systems to the central laboratories for maternal viral load and early infant diagnosis (EID), this cascade is still prone to long turn-around times, with delay in availability of results especially at primary health facilities.
- The identification of the level of risk for mother to child HIV transmission (MTCT) is what determines which prophylaxis is appropriate for an exposed infant.
- Introduction of maternal virological monitoring during pregnancy, at delivery and during breastfeeding by the use of Point Of Care (POC) tests will help in identifying the level of risk for MTCT
- POC and near point of care maternal viral load and EID testing will reduce the turnaround time for sample analysis making the results available for prompt clinical decisions.

Executive summary

Despite major improvements in reduction of MTCT, Tanzania is still among the countries with considerable high rates of vertical HIV transmission. Currently, mother-to-child transmission rates stand at 3.6 per cent when a baby is six weeks old, but can double by the end of breastfeeding without monitoring and treatment (UNICEF, no date b). Maternal viral load and duration on antiretroviral therapy (ART) are the most critical determinants of MTCT in utero, intrapartum and during breastfeeding. The WHO defines a high-risk infant as an infant whose mother was first identified as HIV-infected at delivery or in the postpartum with or without a negative HIV test prenatally, infected during pregnancy or breastfeeding, started ART late in pregnancy (less than 4 weeks) or did not achieve viral suppression (<1000 copies/ml) in the four weeks before delivery (WHO, 2016, 2021).

Tanzania unlike other countries in sub-Saharan Africa, has opted for categorization of infants according to the level of MTCT risk, which is a determinant for whether the infant will receive mono antiretroviral (ARV) prophylaxis or a dual (enhanced) ARV prophylaxis. However, the conventional cascade of centralized viral load testing is prone to long turn-around times delaying clinical PMTCT decisions. This results in inadequacy in classifying infants who are at low or high risk of MTCT, to advice the choice of appropriated ARV prophylaxis for their newborns and the decision to perform birth DNA-PCR testing to identify those already infected in-utero. Without a timely Early infant diagnosis (EID) and ART initiation, 10% to 15% of children infected during pregnancy are likely to die by the age of 6 weeks, 50% by age of 2 years and 80% by age of 5 years(Newell *et al.*, 2004). Currently, there is still a limited capacity to perform DNA-PCR for HIV testing in most health facilities thus, denying

accessibility for timely EID of HIV exposed infants (Sabi *et al.*, 2019; Boeke *et al.*, 2021). In addition, about a half of mother–infant pairs become lost to follow up in the EID cascade, thus unable to ascertain the HIV status of the infant and delay in initiation of ART (UNICEF, no date a; Chiduo *et al.*, 2013).

POC or near point of care maternal viral load testing and EID have shown to increase the proportion of mothers that receive viral load testing at around delivery, decrease the turn-around time for results and time for clinical action for those with unsuppressed viral load (Meggi *et al.*, 2018; Sabi *et al.*, 2019).

Problem statement

About 43% of HIV-exposed infants did not access EID services within 2 months of age in a study done in Tanzania (Bwana *et al.*, 2018). Despite the known fact that high maternal plasma viral load near delivery is a strong determinant of MTCT, the practice and skills to classify mothers with either high or low risk of MTCT is still unsatisfactory in most countries (Leroy *et al.*, 2002; Komtenza *et al.*, 2019). Measures that assist to classify high-risk mothers are highly needed, as these will in turn influence the choice for prophylaxis for newborns to prevent them from contracting HIV infection. The availability of centralized zonal and regional laboratories with the capacity to perform HIV testing for DNA PCR testing in Tanzania provides an opportunity for HIV-exposed infants to know their HIV status (MOH, 2019;Sabi *et al.*, 2019). However, the system is challenged by the long turnaround time of PCR test results from the central laboratory to health facilities, as most peripheral health facilities have limited capacity to conduct virological and EID testing (Chiduo *et al.*, 2013; Bwana *et al.*, 2018).

With prompt availability of POC results, mothers will be able to obtain EID results on the same day, with immediate treatment initiation for the infant and thus mitigate structural challenges that contribute to high rate of lost-to-follow-up and delays in treatment initiation.

Policy Options

1. Introduction of POC HIV testing so as to shorten the turnaround time for EID, and upscale EID services.
2. POC for EID and maternal viral load testing can be introduced to supplement the conventional centralized testing in those facilities with high burden of tests.

Implementation considerations

POC HIV testing machine are currently available for a wider use in TB diagnostic testing all over the country. A few facilities use these platforms for viral load (VL) testing, hence justifying the room for supporting these platforms and maximizing their use for VL. There is no need for advanced infrastructures and skills to operate and maintain the machine (Meggi *et al.*, 2018;Sabi *et al.*, 2019;Spooner *et al.*, 2019). The cost per successfully completed test using m-PIMA is about Tshs 110,000/= for m-PIMA with platform purchase and Tshs 70,000/= for m-PIMA reagent rental while that for GeneXpert IV with platform purchase is about Tshs 70,000/= under a scenario assuming no equipment costs (Mukherjee *et al.*, 2020; Elsbernd *et al.*, 2022). The machine has the capacity to perform both fresh blood sample (100microliter) and Dried Blood Spot (DBS) sample. Studies have shown good operationalization and acceptability of POC tests among primary health facility health care workers such as nurses (Meggi *et al.*, 2018; Sabi *et al.*, 2019; Mohamed *et al.*, 2020). This will allow for an opportunity for capacity building, task-shifting and optimal use of the current health care worker capacity (Simmonds *et al.*, 2020).

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Competing interests

The authors declare that they have no competing interests.

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