REGIONAL WORKSHOP ON PREVENTION OF HIV MOTHER-TO-CHILD TRANSMISSION (PMTCT OPTION B+): THE PATH TO TREATMENT FOR ALL Gathering Knowledge and Best Practices

Victoria Falls, Zimbabwe, 23-26 August 2016

# **REPORT**

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3TC	Lamivudine
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
AZT	Azidothymidine (also known as zidovudine)
EID	Early Infant Diagnosis
EMTCT	Elimination of mother-to-child transmission (of HIV)
FDC	Fixed-dose combination
FP	Family planning
GBV	Gender-based violence
HCW	Health-care worker
HEI	HIV-exposed infants
HF	Health facility
HIV	Human immunodeficiency virus
IPT	Isoniazid Preventive therapy
LTFU	Lost-to-follow-up
MCH	Maternal and child health
MNCH	Maternal, newborn and child health
MOH	Ministry of health
M&E	Monitoring and evaluation
NVP	Nevirapine



PBW	Pregnant breastfeeding women
PCR	Polymerase chain reaction
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission (of HIV)
PrEP	Pre-exposure prophylaxis
RDT	Rapid diagnostic test
RMNCAH	Reproductive maternal, new-born, child and adolescent health
SDG	Sustainable Development Goals
ТВ	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
VL	Viral load
YFS	Youth-friendly services
WLHIV	Women living with HIV



The 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection<sup>1</sup> recommended that all pregnant and breastfeeding women initiate triple antiretroviral therapy (ART), regardless of their clinical or immunological status. Since then, several high-burden countries have rolled out the implementation of lifelong ART for all pregnant and breastfeeding women (Option B+) on the path towards elimination of mother-to-child transmission of HIV (EMTCT). In addition to decreasing the risk of MTCT, benefits of the B+ approach include gains for the mother's health through early initiation of ART; prevention of horizontal transmission to sexual partners; decreased risk of drug resistance, after stopping and re-starting antiretroviral drugs (with repeated pregnancies and prophylaxis regimens with subsequent pregnancies); and further decrease in MTCT risk in future pregnancies (by being on ART at conception).

These recommendations represented a major paradigm shift, reflecting both the programmatic advantages of one simplified approach for all, as well as the focus on mothers' health, preventing vertical transmission and public health benefits.<sup>2</sup>

The B+ recommendation (or Treat All for Pregnant and Breastfeeding Women) was made largely based on operational and programmatic considerations<sup>1.</sup> With the successful rollout of 2013 guidelines in most countries, there has been an increase in the rate of ART initiation for HIV-infected pregnant women, which has brought about decreasing numbers of HIV-infected infants.<sup>3</sup> However, several challenges to successful delivery of services remain, from HIV testing through transition to long-term adult ART programmes. As programmes push to achieve elimination, emerging issues include, preventing MTCT in adolescents, and new thinking around the importance of viral load testing as part of prevention of mother-to-child transmission (PMTCT). In addition, there are several cross-cutting issues that merit discussion, including monitoring and evaluation (M&E) and supply chain logistics.



The revised 2015 Guidelines on "When to Start ART", have taken the next step to a "TREAT ALL" approach (offer of ART to all people living with HIV, irrespective of age, clinical and/or immunological status).<sup>4</sup> Lessons learnt from countries that were early adopters of B+ are useful for countries that have more nascent B+ programmes, particularly for better understanding of operational best practices along the continuum of care, from testing through treatment to transition. Furthermore, beyond the impact of improved PMTCT, B+ implementation experience is essential to inform roll-out of the new 2015 guidelines. As countries begin to consider adopting "Treatment for All", we can learn from PMTCT programmes that have years of experience implementing a "Treat All" approach for HIV-infected pregnant and breastfeeding women.

To this end, a four-day meeting was convened in Victoria Falls, Zimbabwe, by WHO and UNICEF in partnership with EMTCT IATT. Its purpose was for managers to learn from experts and each other on programmatic experience, lessons and future directions with B+ and was attended by 179 participants drawn from delegations of the 20 African countries with high burden of HIV and experience in implementing Option B+.

Each country delegation included a Ministry of Health (MoH) ART programme manager, PMTCT programme manager and Maternal and Child Health (MCH)/Family Planning (FP) programme manager, implementing partners selected by the MoH and UNICEF, and WHO country office focal point for PMTCT. Representatives of civil society and network of women living with HIV (WLHIV) and technical experts from CDC, USAID UNAIDS and UNICEF also participated as speakers and facilitators.

The list of participants is provided in Annex 2.



The specific objectives of the meeting were to:

- (a) promote dialogue and sharing of experiences south-south learning among ART/PMTCT/MCH programme managers on programmatic implications of Option B+/Treat All for pregnant and breastfeeding women (PBW) and their children/families;
- (b) assess and document key challenges and identify optimal operational approaches to address the five identified operational challenges along the continuum of care in the context of B+ and Treat All:
  - (i) High-quality HIV testing: retesting of negative PBW during pregnancy and breastfeeding; testing of family members of all PBW, in particular male partners; verification of results of those testing HIV positive prior to initiating treatment.
  - (iii) ART initiation: optimal process to start ART for PBW ensuring prompt initiation together with patients' readiness; promoting patient acceptance to start ART and follow-up of PBW that refuse ART initiation, and maintaining a public health approach; timeframe and process for initiation of patients on Treat All.
  - (iv) Retention in care: optimizing Antiretroviral (ARV) adherence and retention both ante- and postpartum and ensuring mother-infant pair follow-up, as well as effective transition of women to general ART services.
  - (v) Viral load and postnatal prophylaxis: algorithm to be used by countries to assess viral suppression among PBW and key points that such algorithm should address.
  - (vi) Treat all and Integrating Care in the MCH platform, including how to leverage B+ to deliver Treat All.



- (A) Raise awareness of key emerging issues including:
  - (i) prevention of HIV in HIV-negative women: PrEP and combination prevention;
  - (ii) new family planning technologies for women living with HIV;
  - (iii) PMTCT for Adolescents
  - (iv) elimination of MTCT of HIV & congenital syphilis: an opportunity to achieve EMTCT and strengthen reproductive, maternal, newborn, child and adolescent health (RMNCAH) systems.
- (B) Highlight the importance of addressing key cross-cutting elements in national programmes: supply chain, M&E, training for task shifting, and community engagement.
- (C) Enable national programmes to develop a list of targeted action items for urgent incorporation into national strategies and HIV service delivery rollout plans; to strengthen national-level decision-making and contribute to achievement of the Sustainable Development Goals (SDGs); the targets of the Global Strategy for Women's, Adolescents' and Children's Health; the '90:90:90' targets to End the AIDS Epidemic; and the dual elimination of MTCT of HIV and syphilis.



The meeting generated discussion and consensus around the optimal operational approaches to addressing the key operational challenges identified, and had outputs including:

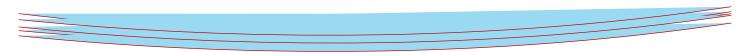
- (a) a meeting report detailing the proceedings of the meeting and its participants as well as the key consensus decisions;
- (b) a policy brief to highlight the key operational learning elements outlining the important barriers and solutions proposed;
- (c) individual sets of targeted country action items.



A survey on country policies, programme results and challenges faced in implementing Treat All for Pregnant and Breastfeeding Women was undertaken to gather information prior to the meeting. Country responses were compiled, analyzed and disseminated during the meeting to provide baseline information for debate on the best approaches.

The meeting was conducted with three different modalities: group work sessions, panels of country presentations and plenary sessions. Civil society representatives joined in each plenary and panel session to present community perspective. All sessions included a short background on the topic (see Agenda in Annex 1) and specific questions for the audience to address. Group work sessions were introduced by a country team that presented its own experience in the topic area, after which countries were grouped into clusters to discuss the key issue, and to reach a consensus on best operational approaches. In the panel sessions, the plenary was led by a subject expert, whose presentation was followed by experiences of three countries, which were then followed by discussions moderated by a facilitator. Emerging topics were presented at plenary sessions by experts, and were discussed in plenary.

At the end of the meeting, each country team developed a list of targeted action items for urgent incorporation into national strategies focused on optimizing PMTCT services as well as rolling out Treat All services.



# **1. TESTING**

### 1.1 Retesting of HIV-negative women during pregnancy and breastfeeding

In high-burden countries, the incident of HIV during pregnancy and breastfeeding is a source of ongoing transmission to babies. Eighteen out of 20 countries reported that retesting HIV-negative women during pregnancy and/or breastfeeding is already a policy. However, there is a large variation in timing and practice.

After discussions, the consensus was that:

- (a) country policy on retesting of PBW would need to be context-specific, taking into consideration HIV prevalence/incidence, data on seroconversion during pregnancy and BF, commodities, feasibility of testing (human resource constrains);
- (b) an enhanced testing policy might be considered for populations with higher risk for HIV infection, such as adolescents, women in discordant relationships/with HIV-positive partners, and female sex workers;
- (c) Timing of retesting of HIV-negative PBW:
  - (i) Retesting every 3 months would be ideal, but it is often neither feasible nor cost effective;
  - (ii) Critical time points for retesting are at/before delivery, since diagnosis at that time allows for interventions such as enhanced infant prophylaxis, and also during early postpartum, since it could be at higher risk for HIV acquisition and HIV transmission than later;

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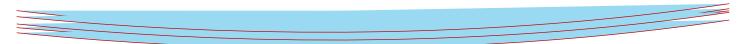
- (iii) Thus, the minimal standard for retesting during pregnancy could be considered as retesting during the third trimester and at delivery;
- (iv) For breastfeeding women, the schedule would depend on country contexts, but could make provision for two or three points during breastfeeding, based on child immunization schedule and/or family planning services, so as to limit burden on women and increase uptake.

### **1.2 Male partner testing**

Testing male partners within MNCH settings can have clear benefits, since it leads to identification of HIV-infected male partner of HIV-negative PBW, allowing intervention to prevent transmission and to protect both the mother and the baby. However, male partner testing is not always implemented and sometimes it is only implemented for male partners of HIV-positive women. Health facilities often lack the conditions to support male partner presence at antenatal clinics (ANC) and at delivery. In addition, the pressure on health-care workers (HCWs) to improve male testing could lead to increased waiting time for unaccompanied women. Nevertheless, increasing male testing during pregnancy should not be delayed any longer.

Common country discussion points were as follows:

- (a) more focus is required for scaling up testing to all male partners: partners of both HIV-positive and HIV-negative women, and all male sexual partners of each woman, not just the official "husband";
- (b) it may be worth offering HIV tests in different settings that are more conducive to men, such as at health facility, during non-clinic times, on Saturdays, at community, home visits;
- (c) reporting on male testing may be improved to inform decision-making;
- (d) a key point is to guarantee the safety of women and avoid coercion.



### **1.3 Verification of positive**

Misdiagnosis of HIV, due to field performance of rapid tests and health worker skills, is common. In the context of Treat All, with patients starting treatment without CD4 or clinical criteria, the implications of these errors are even more serious than before. Therefore, retesting all clients diagnosed HIV-positive, prior to initiation of ART for verification of their results, is imperative. Currently, only five countries have policies for the verification of HIV-positive status/results, although there are no available data on actual implementation even in these countries. The verification of results needs to be done with a new specimen, using the same testing algorithm, and preferably conducted by a different provider.

Country discussions were mostly on the feasibility of having the second health worker perform the test and on messages for the community, thus:

- (a) in settings where no other providers are available, it is suggested that verification testing be conducted by the same provider rather than not being done at all;
- (b) the verification of positive results should be clearly explained to the community before implementation of the strategy to avoid myths, disbeliefs, etc.;
- (c) clients need to be aware of the importance of verification, and the messages about it must be included in the pretest counselling.

## 2. ART INITIATION

With roll-out of B+ (as well with Treat All), barriers to quick initiation of ART were removed and many countries translated this into the paradigm of same-day initiation. However, there is a difficult balance between starting just after diagnosis to increase coverage, and waiting for women to be ready to start with the risk of continuous exposure of the foetus while waiting. Starting on the same day enabled more women to initiate ART, and early start potentially



increases the chances for women to reach virological suppression by the time of delivery. Waiting gives women the chance to process their diagnosis, to disclose to a partner and/or family, to bring a treatment buddy and allows heath workers more time to educate and counsel them. Evidence showed that with the implementation of B+, there has been higher uptake of ART among PBW, and also that B+ has been characterized by lower retention rates and greater early loss to follow-up, particularly in women who started on same day. Clearly, just because a woman leaves the health facility with ARV drugs does not mean she will take them.

ART is a life-changing decision, and the most consistent reason why women would refuse ART was because they were not ready. Still, there is a large proportion of women who felt they were ready and remained on treatment after initiating on same day of diagnosis.

Consensus that emerged from the discussions centred on the following:

- (a) focus should not be on "when" to start but more on "how to start"; how to prepare the client;
- (b) taking into consideration the urgency of starting ART during pregnancy and breastfeeding, and the evidence on low retention on B+, an approach that takes into account the possibility of either same-day starting or waiting, while strengthening counselling and depending on individual client needs, might be more effective;
- (c) countries proposed definition of a more structured preparation package that could include:
  - (i) readiness assessment tools that help health-care workers to identify women who need more time to be prepared prior to starting, and women that are ready to start just after diagnosis;
  - (ii) an enhanced counselling preparation package, including stronger peer and community support for women and strengthening HCWs skills on counselling.
- (d) treatment initiation should be considered a process and not a starting point; thus, continuous counselling and support could be highly beneficial during treatment;
- (e) furthermore, higher focus on community literacy might improve readiness of clients, even before they get tested.



# **3. RETENTION AND TRANSITION**

Loss to follow-up (LTFU) is a major issue, particularly among B+ clients. The most critical period for all clients is the first six months but many pregnant women never return after initiation, which could be considered 'non initiation' rather than a loss to follow-up.

It is important to recognize the difference between the monitoring and clinical definitions of LTFU, particularly for PBW. Programme monitoring definition of LTFU (60 or 90 days without picking up drugs), can be considered not strict enough for achieving the PMTCT goal of avoiding vertical transmission. For the success of PMTCT, it is necessary for a woman to visit every attendance day, without missing any ARV pick-up. Thus, programmes need to focus on clients who miss appointments, rather than on those said to be LTFU; and to avoid default, early identification of defaulters and their tracking is critical.

At the same time, women on B+ face high risk of loss during transition time points: delivery, from ANC to postnatal services, from MCH to ART clinic for general/chronic adult care. These transitions are weak points along the continuum of care and require facilitation and improvement. Strategies could include: escorting patients, counselling women early to prepare them for transition, using networks of people/women living with HIV to support transition.

Results from the discussion within workgroups can be categorized into five main areas:



# 3.1 Preventing early defaulters and lost-to-follow-up across the continuum of care for pregnant and breastfeeding women

Suggestions for possible effective strategies were grouped into 3 main categories:

### 3.1.1 Interventions to improve service delivery through

- (a) decentralization of ART services;
- (b) integration of more services into one service delivery point, limiting the waiting time for women;
- (c) use of less heavy registers to reduce provider workload and increase data completeness;
- (d) stigma reduction within health facilities (HCW attitude and infrastructure);
- (e) ensuring constant presence of commodities, including ARV drugs.

### 3.1.2 Package of care

- (a) improve clients' preparation prior to, and support during ART;
- (b) improve follow-up of PBW by pairing/connecting each woman to a peer counsellor that can perform home visits;
- (c) establish family support groups to enhance psychological support.

### 3.1.3 Community

- (a) enhance country investment in community interventions;
- (b) strengthen communication strategies: mass media involvement, massive communication campaigns, videos at health facility and in community ("mobile cinema in rural areas"), and social networks.



# 3.2 Preventing LTFU at the transition points for PBW (from ANC to postpartum care and to general ART clinic)

- (a) start the preparation for transition from the time of client's enrolment in care;
- (b) link the mother-baby pair for an integrated follow-up that could be merged with immunization schedule;
- (c) scale up ART services for all patients so as to offer services for the entire family at the same HF;
- (d) if feasible, consider maintaining the mother-baby pair within the MCH platform for an extended period, (example: end of breastfeeding, 2 years after delivery).
- (e) involve community workers and community stakeholders in linking and follow up of women after the delivery.

### 3.3 Detecting early defaulters among pregnant and breastfeeding women

- (a) improve awareness of HCWs and of the health system about retention and about early defaulters;
- (b) update the M&E system to link mothers and babies, and to allow early identification of defaulters, instead of waiting for them to become LTFU.

### 3.4 Tracking defaulters across the continuum

- (a) use SMS for reminders;
- (b) employ community health workers, peer educators or other cadre to conduct home visits and track defaulters;
- (c) integrate tracking of defaulters from HIV service with the tracking of defaulters from other services, such as TB care.



### 3.5 Using B+ experience for implementation of TREAT ALL: what we could do to prevent lost-to-follow-up

- (a) engage all possible stakeholders well before initiation of the roll-out;
- (b) deliver a consistent message to community using all possible means to increase community awareness, education and readiness;
- (c) develop clear SOP for operationalization of the Treat All policy within the health system.

# 4. TREAT ALL AND INTEGRATING CARE, IN THE MCH, INCLUDING HOW TO LEVERAGE B+ TO DELIVER TREAT ALL.

### Integration of TB and MCH

There is a high burden of TB among women of reproductive age. Maternal and Child Health (MCH) services could provide a platform to enhance access to TB services among adult women. However, this is seldom done due to lack of data on screening of People Living with HIV (PLHIV) for TB, and also on Isoniazid Preventive Therapy (IPT). Integration of TB and HIV services does exist in some settings, but it is poorly documented and the linkage is weak.

While integration between TB and MCH services is feasible, it requires advocacy and commitment from all stakeholders, with MCH providing a strong platform and access to a large population in reproductive and child health; therefore, the opportunity to integrate TB activities, such as screening and IPT, should not be missed. The form and degree of integration should be clear, well-assessed and discussed at country level. Scale-up of integrated TB/HIV services to all health facilities should also be considered jointly with strengthening integration between MCH and TB services.



### Use of MCH platform to reach men

In several countries, there are many more facilities providing MCH care than ART care. Facilities with MCH care provide lifelong ART for women but not for men, and so many countries are planning on implementing TREAT ALL and to enhance male access to ART, for which the MCH platform could be used.

The general messages from the discussion that followed panel presentation included the following:

- (a) There are some challenges associated with treating men within MCH platform, and so countries would probably need to consider that:
  - (i) MCH is a safe space for women; bringing men in could compromise services offered to women and women's accessibility;
  - (ii) MCH is seen as a "female" space, and so men could be unwilling to use the service due to social norms;
  - (iii) human resource working at MCH are already stretched to provide many health-care services, and adding more clients may be not feasible. Thus, it would be necessary to increase the investment in the MCH platform (human resource and infrastructure) before adding on more clients and/or programmes in some contexts.
- (b) There are also some benefits of treating men within MCH platform:
  - (i) in terms of equity, men currently have less access to care with poorer outcomes;
  - (ii) limiting treatment to women brings about high risk of pill sharing and gender-based violence (GBV) within couples;
  - (iii) some women implied that it would be easier for them to accept and access their own treatment, if their partner could also access treatment.
- (c) In settings where ART is not as accessible as MCH, integration could be discussed at country level, involving all stakeholders (health system, community, private sector) during the preparatory phase.
- (d) Higher level of integration could be achieved with higher investment in training for health providers, and also in logistics such as supply chains.



# **5. VIRAL LOAD IN PW AND POSTNATAL PROPHYLAXIS**

### **Viral load**

Only four of the 20 countries participating in the meeting had specific viral load (VL) schedules for PBW. Special focus for VL in this population (four countries) is justified by the benefit that monitoring HIV VL provides (improved maternal health, reduced sexual transmission, reduced vertical transmission, long-term health of children & families), and by the higher risk of transmission with non-suppression during pregnancy and breastfeeding. In a South African cohort of 620 women, who started on ART during pregnancy, 90% achieved suppression at delivery, but 30% had rebound during the postnatal period. Moreover, South African data suggested that among women already on ART upon arrival at ANC, about 25% are not virologically suppressed.

Therefore, special precautions should be taken when designing a VL algorithm for PBW:

- (a) Two different women population groups could be recognized within pregnant women on ART:
  - (i) those on ART prior to conception, and
  - (ii) those starting ART while pregnant.
- (b) Timing: Viral load assessment should be done as soon as the woman is expected to be virologically suppressed. This would mean that a first VL could be considered at 1st ANC for women in group (a) and after 3 months for women in group (b). Follow-up of VL timing would depend on results, but it could be suggested to continue monitoring at three-month intervals during breastfeeding, particularly for women that started ART during pregnancy.
- (c) Urgency: turnaround times for VLs are variable and long. During pregnancy and breastfeeding, there is a daily risk of transmission, therefore effort should be made to reduce turnaround times and ensure that results are available on time to act to protect the health of both mother and child.



(d) Action: countries should develop clear action plans for managing women with high VL, including definition of enhanced support and counselling, and of timing of re-assessment of VL long enough to allow suppression but short enough to allow benefit for mother and baby.

Countries face numerous logistic challenges; with VL programme implementation, however, it should be considered that VL measurements share the same platform as virological testing for early infant diagnosis (EID) for HIV-exposed infants, as specimens are collected the same way and are processed by the same laboratories and machine. In addition, the EID platform is already strongly embedded within MCH in many countries. Technologies like SMS are already used by several countries to return Polymerase Chain Reaction (PCR) results faster, and the same could be used for VL. In summary, the EID platform could be used to scale up VL for PBW, and also; this would simplify reaching the woman during the postnatal period, aligning mother and child visits and data analysis during the said period.

### **Postnatal prophylaxis**

New WHO recommendation for postnatal prophylaxis in HIV-exposed infants includes longer periods of prophylaxis with multiple dugs for infants at high risk of vertical transmission. High-risk infants are infants whose mothers received no ART during pregnancy, or those who received ART but for less than 4 weeks prior to delivery and without available VL, and, infants of mothers on ART and with VL >1,000 copies/ml at or 4 weeks before delivery.

Infants at low risk should continue as per previous recommendation, with 6 weeks of Nevirapine (NVP) syrup.

Infants at high risk could receive two modalities of high-risk prophylaxis, both for a 12-week duration:

- (a) Zidovudine (AZT) plus NVP for the first 6 weeks, plus NVP for 6 more weeks.
- (b) AZT plus NVP for the 12 weeks, with higher dosage during the second 6 weeks.



The choice between the two modalities is highly context-specific. Whatever the country choice would be, it is crucial to remember that the first action for infection prevention is to start and retain the mother on ART, and so countries should not focus on infant prophylaxis as first action for infant protection.

Operational elements discussed were:

- (a) complexity of dosage: syrup could be used for both modalities, implying supply and use of two different syrups. Another option could be using the AZT/3TC/NVP FDC tablet; this would be feasible for the first six weeks but would result in too high dose of NVP during the second period;
- (b) complexity of eligibility criteria: a proposal was to provide high-risk prophylaxis for all exposed infants. However, this choice would need to be balanced, considering benefit (easy approach) and harms (toxicity for all children) and, such choice would be highly context-specific ART uptake and median time of initiation among HIV-positive pregnant women, their retention during pregnancy, accessibility of VL, etc.

The general messages and consensus from the discussion, following presentation, included the following:

- (a) Countries agreed on the need for more focus on VL for PBW, and in some countries where the VL for this population is already prioritized, to reduce their turnaround time;
- (b) Considerations with regard to the algorithm for VL for PBW:
  - (i) frequency of VL during pregnancy would depend on the context, including frequency of ANC visits and result turnaround time;
  - (ii) first VL for PW could be considered to be done, as soon as it is expected the woman would be virologically suppressed, not less than one month, but not more than three months after starting ART. The contextspecific factors to be considered include the time of first visit of women at ANC (first, second or third trimester) and the turnaround time, since there should be enough time both for women to reach suppression, and for VL results to be received before delivery;



- (iii) harmonize VL collection for women on ART before pregnancy: coordinating the VL collection across services can be difficult, and it may be better to repeat a VL rather than miss opportunity to test patient while HCWs search for previous VL result. The preference would be to over-monitor rather than to miss opportunity or under-monitor).
- (a) Some countries raised concerns about the extended prophylaxis (12 weeks) versus the duration of breastfeeding (24 months). It was emphasized that the most effective way to protect the baby is by providing ART to the mother. High-risk infant prophylaxis is a bridging strategy to get mothers into antiretroviral treatment, and to get them virologically suppressed so infants can safely breastfeed without the need for them to be on prophylaxis;
- (b) Civil society felt that more effort was necessary to deliver clear and consistent messages to community, to increase demand creation for VL and to make HIV-infected PBW more aware of the implications of suppressed VL. An interesting campaign had been developed in Zambia to increase demand and community awareness (www.knowyourviralload.org). In addition, more should be done at country level to increase accessibility to VL.



### (a) Prevention of HIV in HIV-negative women: PrEP and combination prevention

The HIV epidemic is characterized by feminization as, since its beginning, more women than men have been infected. Epidemiologic data show that in the lasts two decades, the population of adolescents and youth (15-24 years) has increased considerably in Southern Africa, and is expected to continue increasing in the coming decades. This translates into more adolescents at risk of HIV infection.

Pregnancy and breastfeeding periods are high-risk phases for new infection, hence higher risk of vertical transmission, because of acute and unrecognized infection. At the same time, the antenatal care platform provides a key entry point for providing HIV-prevention interventions; these are:

- (i) identification of HIV-negative women and enhanced programme for prevention (including PrEP);
- (ii) male testing and male involvement in treatment and prevention programmes.

PrEP has been proved to be effective in reducing HIV acquisition and WHO recommends it for individuals at higher risk of infection. TDF-based PrEP regimens are considered safe for use during pregnancy, in terms of maternal, pregnancy, and infant outcomes. However, as PrEP in women of childbearing age is implemented, it would be important to continue surveillance of maternal, pregnancy and infant outcomes to confirm safety.

There is still need to remember that PrEP is not considered a lifelong prevention measure for HIVnegative women, and it should be offered as part of combination prevention options for people at substantial risk of HIV infection (i.e. HIV-negative partner of an HIV-positive person - till the latter is



started on ART and reaches virological suppression; youth with high-risk behaviour). Validation of scoring criteria could help to define which populations are at higher risk and so eligible for PrEP.

To maintain an HIV-negative status, combination of prevention options are required, including: partner testing, PrEP, male involvement, empowerment of young women and young girls, cash transfers, improved knowledge in HIV prevention, etc.

#### Key issues that emerged during discussions were:

- (a) young women between the ages of 15 and 24 constitute a particularly high-risk group; they are at high risk of infection but have a low level of risk perception; they could be faithful to one partner to reduce risk but their relationships are often of short duration, exposing them to a high number of partners; they are driven by emotions, peer pressure and status; in some cases decisions on their health are made by their families and not by themselves.
- (b) information on PrEP provided to people need to be strengthened to improve adherence, (including clarification that many side effects are reduced after the first weeks).
- (c) more and clearer messages on PrEP would probably be necessary to enhance community knowledge on it, and, also, to emphasize that PrEP:
  - (i) is an option among many options and should not replace structural interventions to prevent HIV;
  - (ii) is **not** a lifelong treatment;
  - (iii) should be considered to reduce the risk while the HIV-positive partner starts treatment (bridge intervention);
  - (iv) could also be considered in case of young girls when at high risk due to GBV and risk behaviours.



### (b) New family planning technologies for women living with HIV

Most women of reproductive age become aware of their HIV status during pregnancy. Women living with HIV (WLHIV) are eight times at higher risk of pregnancy-related deaths and adverse birth outcomes, and when seeking abortion, are at greater risk of complications and death. HIV prevention starts before ANC: more effort should be made in reaching women and their partners before they become infected, and if infected, before they become pregnant.

Access to sexual and reproductive health and family planning (FP) is a basic human right, but women need adequate information to exercise this right and make informed choices on preferred methods of contraception. The rate of unintended pregnancy among women is still high (51to 84% of pregnancies are not planned) and even higher rates among WLHIV. Moreover, the most common FP method promoted is the condom, while use of dual methods is very low.

Medical eligibility criteria for contraceptives

- (i) For women at high risk of HIV or living with HIV, WHO recommends no restrictions with regard to use of family planning methods. People should be informed about HIV preventative measures, including male and female condoms.
- (ii) For women taking ART, WHO recommends that they are generally eligible to use hormonal contraception. Special consideration for efavirenz and some protease inhibitors may be warranted.
- (iii) Initiation of IUD should be generally avoided in women in advanced/severe disease situations.

Integration of services (offer of family planning methods at ART clinic and at all MCH entry points) would increase access and could then improve uptake of FP methods. Focus is also needed on training of health providers to improve their knowledge on eligibility criteria of family planning methods for different clients and to reduce the stigmatizing practices by health-care providers.



### Key issues that emerged during discussions were:

- (i) HIV prevention starts before pregnancy; it involves developing a package to strengthen prevention among HIVnegative women seeking reproductive health services;
- (ii) countries pointed out the relevance of the cervical screening programme, which is often not given the needed attention, compared to other programmes. One of the main constraints is the absence of financing for this programme;
- (iii) however, supplies for cervical cancer screening for running the programme, once set up, are usually inexpensive and could be provided locally;
- (iv) the programme of cervical cancer screening could be strengthened through effective integration of all reproductive health and HIV programmes. Better integration could potentially increase access to screening for cervical cancer. Integration with HIV service may be particularly effective, since cervical cancer prevalence and mortality is higher among WLHIV; and once established its response to antiretroviral treatment is poor.
- (v) HPV vaccine is safe in adolescents living with HIV, thus prevention includes vaccination and screening.

### (c) PMTCT for Adolescents

Utilization of reproductive health and family planning services is lower among adolescents, resulting in lower uptake of family planning methods and higher rates of unintended pregnancy. Data from 19 Global Plan countries show that around 4% of all HIV+ pregnant women are adolescents. However, it should also be considered that data on adolescents are not easily available and more data are needed. Pregnant adolescents are also known to attend their first antenatal care visit later than the rest of pregnant women; they are more likely to receive HIV testing later (in the third trimester), have lower retention in PMTCT care and treatment, and, as a result, have higher MTCT rates.



### Key issues that emerged during discussions were:

- (i) adolescents sometimes do not use health services because they are "bullied out of care";
- (ii) youth-friendly services (YFS) could help to address the specific needs of adolescents and youth. Youth-friendly service does not imply the existence of different infrastructure for adolescents, which is often not feasible in many contexts. It implies the presence of youth-friendly service providers, with counsellors and HCWs trained on how to approach adolescents, while avoiding judgmental attitudes and treating them professionally;
- (iii) community involvement: adults in the community might be helpful to engage more adolescents, and key people (i.e. leaders, parents), would need to be sensitized with regard to adolescents and their needs;
- (iv) root causes of high prevalence of HIV, and of early pregnancy among adolescents should be assessed and addressed; the community could help in this and by reaching out to adolescents and educating them;
- (v) HIV-prevention activities, addressing GBV and child marriages could be highly efficacious if they targeted communities and schools, particularly young girls.

### (d) Elimination and pre-elimination

African countries have made considerable progress towards elimination of mother-to-child transmission of HIV (EMTCT,) but they are not close to elimination, neither are they ready for validation. For this reason, the process of pre -elimination has been developed to provide a method for recognizing progress. This process excludes the measurement of case rates from the criteria for validation.

Among the criteria considered for the validation process is Equity: human rights are still not upheld in several countries, while laws that criminalize vertical transmission are not acceptable. Informal coercion exists and gender violence is endemic in countries. Pre-elimination validation could, therefore, help countries to progress towards ensuring that human rights are observed, and to this end, a continuous engagement of all stakeholders would be needed.



**COUNTRY PLANS** 

Each country selected 3 key areas to be included/expanded in their already existing national plan. The table below summarizes the choices made by countries, disaggregated by key areas.



	Number of	Marks distribution (%)				Average	
Assessed areas	evaluations	Excellent=1	2	3	4	Poor= 5	value
Overall rate	112	46%	49%	4%	1%	0%	1.6
Overall workshop content	112	50%	44%	4%	2%	0%	1.6
Group methodology	113	40%	47%	11%	3%	0%	1.8
Group 1: Testing	108	37%	44%	18%	2%	0%	1.8
Group 2: Initiation	112	47%	39%	11%	3%	0%	1.7
Group 3: Retention	109	39%	48%	12%	2%	0%	1.8
PrEP presentation	108	22%	47%	24%	6%	1%	2.2
Adolescent presentation	112	29%	47%	21%	3%	0%	2.0
Family Planning presentation	111	60%	32%	5%	3%	0%	1.5
Pre-Elimination presentation	99	29%	54%	16%	1%	0%	1.9
Viral Load presentation	109	46%	43%	9%	2%	0%	1.7
Viral Load discussion	110	28%	59%	12%	1%	0%	1.9
Integration presentation	111	32%	44%	22%	2%	0%	1.9
Integration discussion	107	29%	57%	14%	0%	0%	1.9
Market place	109	32%	44%	21%	3%	0%	1.9
Consensus	111	32%	57%	9%	1%	1%	1.8



# ANNEX 1: AGENDA

DAY 1-Tuesday 23 August			
Fime Agenda Item	Presenter		
	Presenter		
08:00-08:30     Registration       08:30-09:00     Official opening and welcome remarks	MoH Zimbabwe (Angela Mushavi) WHO representative (David Okello) UNICEF representative (Sostena Romano)		
09:00–09:30 Introductions of Participants — country team nominates a lead who introduces each team members of the delegation	Day 1 CHAIRS Innocent Modisaotsile (UNFPA) Landry Tsague (UNICEF)		
Review of Meeting         • Intro to "secretariat" and roles         • Overview, objectives, agenda and structure of the meeting         • Admin, Logistics, Housekeeping         • What we hope to come away with	Shaffiq Essajee (WHO HQ) Morkor Newman (WHO IST)		
10:15–10:45 Coffee Break			
PLENARY 1: State of the Art           10:45-11:45         Viral Load testing in Pregnant and Breastfeeding women and rationale for Postnatal Prophylaxis.	Landon Myer (University of Cape Town, South Africa) Shaffiq Essajee (WHO)		
11:45–13:15 1st Panel Discussion VL implementation for PLW and Post-natal prophylaxis	Led by Landon Myer. Panel of civil society and countries (see below) presenting their perspectives and experi- ences on planning roll out of VL for PLW and issues with high risk infant prophylaxis All participants discuss and develop practical approaches for defining algorithm and ap- proach to high risk PNP		
13:15–14:15 Lunch			
14:15–14:45 GROUP WORK 1: Lead Discussant KENYA Testing quality and access	KENYA team and facilitators presents background, rationale, survey results and draft "key considerations" in plenary		
I4:45–16:30         GROUP WORK 1 Continued: Groups A to E           How can we ensure accurate results and better use of ANC settings to test all, and retest negative women	Each group has 4 facilitators, one to lead the discussion around the key considerations, and others to support and record the discussion		
I6:30–17:00         Tea Break           Group work facilitators meet to develop consensus across the group	oups		
<ul> <li>MARKET PLACE</li> <li>Training for Task shifting including IATT tools and resources MEC tools</li> <li>B+ M&amp;E framework, registers and tools</li> <li>Pharmaceutical commodity management for Treat All</li> <li>Community engagement</li> </ul>	TEAMS – each team "presents" twice during the session Vindi Singh & Nancy Kadula (WHO), Jessica Rodriguez (UNICEF) Fatima Tsouris (ICAP), Chika Hayashi (WHO) David Mabirizi & Kofi Nyame (MSH) Aditi Sharma (GNP), Florence Anam (ICW)		

DAY 2- Wednesda	DAY 2- Wednesday 24 August				
Time	Agenda	Presenter			
Day 2 CHAIRS: Morkor Newman (WHO), David Sullivan (USAID)					
08:30-09:00	Recap of the previous day group work consensus	FACILITATOR			
09:00-10:00	PLENARY 2: State of the Art PMTCT for Adolescents: A systematic review and an approach to implementation	Surbhi Modi (CDC) Sostena Romano (UNICEF) Community Commentary Annah Sango			
10:00-10:30	GROUP WORK 2 : Lead Discussant Malawi When & How to start after diagnosis	MALAWI team and facilitators presents background, rationale, survey results and draft "key considerations" in plenary			
10:30-11:00	Coffee Break				
11:00–12:30	<ul> <li>Group WORK 2 continued: Groups A to E</li> <li>How can we avoid delays in initiation but ensure that women are ready and willing to start?</li> </ul>	Each group has 4 facilitators, one to lead the discussion around the key considerations, and others to support and record the discussion			
12:30-13:30	12:30–13:30 Lunch				
13:30-16:00	Down time! Relax, Nap, visit the Falls, go for a long walk, network etc.				
16:00–16:30	GROUP WORK 3 : Lead Discussant Rwanda Retention and Transition	RWANDA team and facilitators presents background, rationale, survey results and draft "key considerations" in plenary			
16:00-16:30	Tea Break				
16:30–18:30	<ul> <li>GROUP WORK 3 Continued: Groups A to E</li> <li>Optimizing pre and postpartum retention</li> <li>Defining the package of care (for groups with low and high risk of LTFU)</li> <li>When to transition women from PMTCT to ART</li> </ul>	Each group has 4 facilitators, one to lead the discussion around the key considerations, and others to support and record the discussion			
18:30-19:30	RECEPTION!				



DAY 3 - Thursday	DAY 3 - Thursday 25 August						
Time	Agenda	Presenter					
Day 3 CHAIRS: Ly	Day 3 CHAIRS: Lydia Mungherera (GCWA), David Mabirizi (MSH)						
08:30-09:00	Recap of the previous day inc group work consensus	FACILITATOR					
09:00—10:00	PLENARY 3: State of the Art New technologies for Family Planning: Recalling the forgotten prong	Nancy Kidula (WHO IST) Community Commentary: Martha Tholanah					
10:00-11:00	PLENARY 4: State of the Art Taking the MCH platform to a new level. Treatment for all in MCH including male partners and children and provision of comprehensive care in MCH showcasing TB care and treatment in for mothers and children	Morkor Newman (WHO); Wilfred Nkhoma (WHO)					
11:00-11:30	Coffee Break						
11:30—13:00	PANEL Discussion: Treat All and Integration. Using MCH as a platform for Treat All and integrating care for PW into	Led by Morkor Newman Owiredu & Wilfred Nkhoma. Panel of civil society and countries (see below) presenting their perspectives and experiences on integration of services for HIV positive women and their families, and possible barriers to integration. All participants discuss and develop practical approaches for integration and Treat All in MCH					
13:00-14:00 LUNCH							
14:00-15:30	PLENARY 5: State of the Art Preventing new infections in young women: Combination prevention/PrEP	Heather Watts (PEPFAR) Community Commentary Florence Anam					
15.30-16:00	Tea Break						
16:00-18:00	MARKET PLACE <ul> <li>Training for Task shifting including IATT tools and resources MEC tools</li> <li>B+ M&amp;E framework, clinic registers and tools</li> <li>Pharmaceutical commodity management</li> <li>Community engagement</li> </ul>	<ul> <li>TEAMS – each team "presents" twice during the session</li> <li>Vindi Singh &amp; Nancy Kadula (WHO), Jessica Rodriguez (UNICEF)</li> <li>Fatima Tsouris (ICAP), Chika Hayashi (WHO)</li> <li>David Mabirizi &amp; Kofi Nyame (MSH)</li> <li>Aditi Sharma (GNP), Florence Anam (ICW)</li> </ul>					



DAY 4 — Friday 26 August						
Time	Agenda	Presenter				
Day 4 CHAIRS: Surbhi Modi (CDC), Bia	Day 4 CHAIRS: Surbhi Modi (CDC), Biziwick Mwale (UNAIDS)					
08:30-09:00	Recap of the previous day inc work group work consensus	FACILITATOR				
09:00-10:00	PLENARY 6: State of the ArtInnocent Nuwagira (WHO)Pre-elimination of MTCT of HIV: an opportunity to achieve EMTCT and strengthen MCH systems. Understanding the tools, the processes and the role of the Regional Validation SecretariatInnocent Nuwagira (WHO)					
10:00-10:30	Coffee Bro	eak				
10:30-13:00	Country work and country "Plan of Action" using provided templates if needed					
13:00-14:00	Lunch					
14:00-15:00	Country work and country "Plan of Action" continued					
15:00-16:00	All countries present their "Plan of Action" in 5 minutes					
16:00–16:30	Tea Brea	ak				
16:30–17:30	Meeting Summary & Close	Morkor Newman Sostena Romano				



## **ANNEX 2: LIST OF PARTICIPANTS**

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<sup>1.</sup> 2013 Consol ARV Guidelines

<sup>2.</sup> 2012 WHO PMTCT Programmatic Update

<sup>3.</sup> GARPR 2015

<sup>4.</sup> 2015 When to Start Guidelines

