

# **Recommendations Regarding Provision of ART for all Persons Living with HIV (“Test and START”)**

## **PEPFAR Scientific Advisory Board (SAB)**

*Submitted by the Test and START Expert Working Group (EWG) to the SAB*

*Approved by the SAB on October 14, 2015*

### **Members of the Test and START EWG**

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### **General Recommendations:**

1. The EWG fully supports the concept of Test and START and endorses the plans to roll out this new initiative across sites where PEPFAR is providing support. The START study findings add much anticipated randomized trial data to end the debate about when to start ART and, together with data from other trials (TEMPRANO, HPTN 052/A5345, etc.), argue that the benefits of early ART clearly outweigh evidence of harm. Now, the focus needs to turn to how best to most efficiently and expeditiously implement these findings in the PEPFAR supported sites with a focus not only on scale-up but also in improving outcomes.
2. The EWG recommends the continued funding support by PEPFAR for implementation science projects to help define best practices. In addition, continued efforts to highlight the process for ensuring that new data from these efforts is translated into practices on the ground (e.g. lessons from SEARCH, PopART).
3. The EWG acknowledges that it is a priority to initially focus efforts on high burden sites which, in many countries, means a focus on urban areas. However, the group hopes that there will be an opportunity for novel ideas to efficiently expand activities to rural areas with lower prevalence and that Test and START will be considered as ultimately an approach that addresses both urban and rural epidemics.
4. The EWG recommends that while Test and START should be the guiding principle, there is an ethical imperative to ensure that systems are in place to prioritize the sickest people for treatment when Test and START is rolled out. Moreover, it is critical to maintain the

balance between new initiatives and investment in effective programming to improve access and retention for still under-treated and vulnerable populations such as children and adolescents with HIV/AIDS.

5. The EWG feels that it will be important to frame Test and START as a new paradigm, since we have moved from stopping DEATH and prolonging life to stopping AIDS, promoting well-being and restoring longevity. This new paradigm will require a new approach, with attention to the following issues:
  - a. In particularly high burden countries every effort should be made to use this opportunity to realize even greater efficiencies and more systematized approaches, otherwise the scale of the task will be overwhelming.
  - b. Health workers should have a clear understanding of the long term and continuing benefits (both in terms of public health and economic gains), since Test and START will inevitably increase the immediate individual workload.
  - c. A real effort should be made to communicate the START data in clear terms and ensure ongoing education and communication on the shifting emphasis of the ART program.
  - d. Since nurses and community care workers are the backbone of service delivery, they should receive clear, ongoing education in terms that they can relay to their patients.
  - e. To accomplish this paradigm shift, the resources required for staff education, and clear and consistent public messaging about the benefits of Test and START, must be understood by MOH and other key decision makers, who should support the rapid deployment of the necessary assets.
  
6. Viral load (VL) monitoring is critical for retention in care and long term efficacy, hence VL testing resources should be strengthened wherever Test and START rolls out, although the unavailability of VL testing should not be a barrier to ART.

### **Specific Considerations for Test and START Across the HIV Cascade**

#### **Testing and linkage:**

- Prior to initiating the activities, PEPFAR should ensure that National AIDS Programs fully supports the Test and START strategy, and incorporates it in the national guidelines.
- The education of counselors and all members (e.g. peer educators, community health workers, etc.) of the team involved in testing and offering treatment (including orientation to the benefits of treatment and removing barriers to starting treatment) will require ongoing resources for training. Inclusion of counseling for mental health issues is also important in these settings.
- Provider-initiated counseling and testing should be reinforced to increase access to HIV services.
- Health providers should promote couples counseling and testing to identify HIV discordant couples. Where possible, providers should offer partner or family testing as a

standard practice rather than an exception.

- There should be a review of counseling messages, and an offer of risk reduction counseling and clear instructions on why, where and how to access ART.
- The lessons learned from ongoing studies of mobile and community-based testing campaigns about the value of mass health screenings should be shared, as should innovations on effective linkages from community based testing (including homes) to treatment centers.
- Health services should remove any barriers to making treatment available in the same settings where people are tested, including exploring community based initiation of care especially for the asymptomatic patient, which may be especially important for reaching young men. The identification of novel venues and settings for providing treatment needs to be explored; this may require countries to review pharmacy policies and laws.
- ART Programs should expand the use of community based resources for linkage, such as navigators and peers.

### **Starting ART:**

- Encourage ongoing efforts to safely task shift and task share.
- Ensure the availability of improved, low side effect, first-line ART that is also compatible with hormonal implants and other long acting reversible contraceptives (e.g. IUDs and rings).
- Ensure the availability of improved, best option, low side effect, second line ART.
- Redefine and emphasize comprehensive HIV care. For example, contraception, vaccine status, TB screening, and INH for latent TB should be included in all care programs.
- Enhance awareness of potential NCDs (non-communicable diseases) and integration of care for chronic NCDs.
- There should be coordination with programs currently offering B+ to expand treatment to partners at these same sites and insuring all children of women enrolled in B+ are HIV-tested.
- Remove CD4 testing as a barrier for starting ART. CD4 should still be available and will certainly have value for clinical management but the availability of CD4 testing should not be a barrier or incur delays to starting ART.
- The capacity for VL testing should be expanded. While not required to start ART, VL will have critical value in managing ART, and in enhancing adherence. All members of the health team (nurses, counselors) as well as peer educators should take part in education programs on VL interpretation and required subsequent clinical interventions.
- The timing of ART start should reflect evidence-based guidelines that include rapid start for persons with OIs, pregnancy, or TB. For asymptomatic persons, consideration of early/same day ART start awaiting evidence-based studies conducted in programmatic settings. Patient buy-in and understanding are valued and counseling should reflect this without requiring compulsory systematized “literacy training”.

### **Retention on Treatment:**

- Identify the best mechanisms for differentiated care in highest burden settings, consider and share the lessons learned from Community Adherence Clubs, home ART delivery and other community-based models. There is a need for more work to define the optimum timing for the transition to community-based care in the various settings (e.g.

from ANC or facility-based ART initiation).

- Review alternate delivery locations (e.g. adherence clubs/models, motorbike deliveries for ART and/or ART dispensing integrated with testing/referral sites).
- VL monitoring is critical for retention in care and long term efficacy and the role of point of care (POC) VL testing in settings off-site from referral sites should be expanded/investigated.
- Expand the role of POC diagnostics at mobile or “out of health facility” settings for ART delivery and care (e.g. pregnancy, VL, STI and TB screening).
- Monitor the need for increased adherence support and motivators for adherence in asymptomatic populations at risk for treatment fatigue.

### **Managing Co-Morbidities and Second Line ART**

- Recognizing comorbidities in “out of facility, step down sites” and ensure safe up-referral.
- Recognizing regimen failure timeously-, which might not be possible without 6 monthly VL (perhaps moving to annual VL for people with long-term stable suppression).
- Develop easy algorithms for transition to second line therapies without needing up-referral.
- Foster awareness of and develop a clear approach to chronic Non Communicable Diseases.
- Ensure the education of community support teams to adjust to shift from AIDS-related morbidity to aging-related morbidities.