1. **Any experiences with recording/documentation of use of HIVST, particularly those distributed/sales from pharmacies?**

   There are a number of experiences from different countries especially as we continue to support expansion of HIVST to amplify HTS approaches. We won't be presenting on this particular topic during today's presentation but welcome any folks from the field to share their experiences.

2. **How can we explain the situation tests conducted less than the number of positives identified?**

   In this trend analysis of testing and treatment outcomes from (Jan-Mar 2016) through (April-June 2021), the number of HIV tests conducted, positive test results, and HIV-positive individuals newly initiated on ART from 41 PEPFAR-support countries are presented. The right-hand primary axis presents POS and TX_NEW (orange and gray lines, respectively) while the left-hand secondary axis displays the number tested (blue line). By referencing the corresponding axes for each line, you can see that the number of positives does not surpass the number tested. More information on this analysis can be found here:

   https://www.croiconference.org/abstract/trends-in-hiv-testing-and-linkage-to-hiv-treatment-in-41-countries-2016-2021/

3. **The leaflet in the Asante test kit package says that it detects recency up to 6 months from infection. I have never appreciated how this was subsequently annualized to 12 months at the individual client level.**

   The mean duration of recent infection may differ by manufacturers and is about 6 months for the Sedia Asante RTRI assay and 4 months for the Maxim Swift RTRI assay; however, there is a distribution around the mean, which can vary from approximately 3 months to more than9 months across individuals due to variation in immune response. Therefore, at the individual level, it is appropriate to interpret recent HIV infection as having been acquired approximately within the past 12 months.

4. **Why RTRI is not recommended for age below 15 years?**

   TRIs should be offered to adults, generally >=15 years and although there is no age specification for persons <15 years of age are most likely to have been perinatally infected with HIV and previously diagnosed and on ART.

5. **How is recency testing being used as a tool for tracking missing men and AGYW?**

   Question was answered live.

6. **Can you talk to some of the main reasons people who are positive and on ARVs are retesting?**

   Several reasons have been identified, including persons testing to see if they have been "cured" (misunderstandings), site requirements to re-engage into care or transfer locations due to geographic change or to find more client friendly services. With multi-month dispensing of ARVs a client may have ARVs remaining while not being able (or interested) in continuing at their previous providers.

7. **Are any countries using recency testing to do epi investigations to determine outbreak clusters?**
   Recency assays (e.g lab-based LAg-Avidity EIA) have been used for outbreak investigations in Cambodia, Pakistan and in the U.S. (Indiana outbreak). It is also important to remember the caveat that recency will help us place infections in the same time frame but it doesn't necessarily imply connection between the infections (for example, non-overlapping sub populations or risk groups). Recency is being used to triangulate with other data sources to guide prevention efforts. There is also the need to respect autonomy and priority of needs for newly diagnosed persons and be judicious about investigations that involve subsequent interviews.

8. **Can you comment on insights from monitoring DREAMS through recency testing? Is there a recommended # of AGYW who need to be included to have enough precision about the estimated HIV incidence from RTRI testing to make conclusions about trends and needed targeting?**
   The percent of recently infected would be higher among AGYW, as expected. If using for incidence estimates, we would recommend lab-based LAg-Avidity EIA that has better precision compared to the RTRI assay. Sample size would depend on the expected number of RITA recent but may require statistical consultation. Additionally, representativeness of the population being tested should be assessed and if necessary, adjusted for to reduce potential bias of incidence estimates.

9. **What are the benefits of recent infection surveillance for key population programs and how this may contribute to strengthening programs in concentrated epidemics also?**
   Question was answered live.

10. **How are missing men identified if those men are not getting diagnosed to begin with? Can you speak to the importance of only interpreting results within the groups that are being tested?**
    Question was answered live.

11. **In Uganda where we have both D and A viral sub types circulating - validation of the Asante (Sedia) assay revealed a low specificity of under 50%. We nevertheless went ahead with it since it was not misclassifying long terms as recent. But the low specificity is quite disturbing. Any consideration of perhaps an algorithm that might include for instance POC VL testing?**
    Use of POC VL would certainly help with reclassification. The reason for high reclassification is because of high % of repeat testers/those on ART.

12. **Can you share examples of how recency surveillance has informed programming and targeting?**
    There are many examples, to name a few. Countries have used recency data to identify geographic areas with a high number of recent infections (hotspots) in time and space. This prompted investigation and response that lead to targeted scale up and program improvement for index testing and PrEP implementation targeting these locations. Further, community hotspots prompted examination of accessibility of suitable services and a multi-sector response to address service gaps.

13. **Why are long term infections positive on recency testing?**

    Both recent and LT infections are HIV-positive to start with. The recency test only helps identify those who may have been infected within the past 12 months from others infected more than 12 months ago.

14. **I understand PEPFAR is planning to introduce recency testing in some settings without VL testing. Given high retesting on ART in your data, how will it affect classification? Can you also speak to how conducting recency testing at testing sites and returning results has impacted patient flow or resource needs?**

    PEPFAR strongly recommends viral load testing among those who test RTRI-recent, as part of a RITA, to improve the classification of recency status. Further, it does not recommend the return of the recency result to individuals in any setting, but countries should defer to the ethical guidelines or processes established by local MOH or IRBs to inform such a decision. There are different models being implemented and a closer look at each of these models to identify potential efficiencies is something we plan to look into further.

15. **From the presentation, I noticed that the range of % reclassification is about 30-50%, is this same with False Recent Rate? I see FRR in many studies are less than 5%.**

    Depends on who are being tested with RTRI. If only newly diagnosed persons are tested, FRR would be much smaller.

16. **When is the expected time for the recency test kit to be WHO-prequalified? It hasn't been included in the WHO PQ list yet, as far as I know. Countries principally funded by Global Fund needs WHO-PQ for implementation.**

    WHO-PQ does not have a pathway for recency tests or other tests that are used for surveillance. We are in discussions with WHO/FDA to facilitate this but no timeline on the horizon. We are also working with Global Fund to see if recency tests, that are used for surveillance only, can be procured without WHO-PQ.

17. **Doesn't Eswatini have very high knowledge of status? How does that reconcile with most new diagnoses being long term infections?**

    Question was answered live.

18. **The validation of the Sedia Asante kit used sero-conversion panel. The sensitivity & specificity of the LT line on Asante is below 90%, its implication on the result and any update to improve.**

    The LT line is not meant for diagnosis of recency of HIV infection. The presence of a LT line indicates if HIV-1 positive diagnosis is long-term infection helping to distinguish recent and LT infections for the purpose of surveillance where accuracy of 90% is quite good.

19. **Whilst we note OPD has predominately being testing high proportion, I was wondering what the disaggregation by sex on these figures was. With men being known for reluctance on health seeking behavior, what was the proportions for their testing?**

    Question was answered live.

20. **In one of the slides shown earlier it was mentioned that 'Country A' had a unique distribution of recent cases across age groups--i.e., higher recency among older age groups. Any guesses why that might be? Are there differences in the HTS strategy in that country?**

    Question was answered live.

21. **Could you comment on how to go about the challenge posed by retesters in surveillance of recent infections and ensure they are enrolled into HIV care and/or treatment? What could be the key factors behind for retesters seeking HTS or recency testing from the studies you presented?**

    HIV testing programs may use screening procedures, patient histories, or case surveillance systems to recognize and reduce re-testing among already diagnosed HIV-positive persons, and if necessarily, assist with ART initiation, transfer-in, or re-engagement. In addition, VL testing remains strongly recommended at a part of a RITA to recognize and reclassify those PLHIV who are already diagnosed and on ART and have VL<1000 copies/ml.

    In the analysis presented today that looked to better understand correlates of retesters on ART in Eswatini, PLHIV tested after "COVID-19 stay-at-home" guidance, at community settings, and in older age-groups had higher probability of being repeat testers. Reasons for repeat testing may be many, from seeking simple routes to transfer care between health centers to poor health literacy. Further inquiry is needed to better understand motivations among repeat testers and allow programs to improve efficiency of testing strategies. More information on this analysis can be found here:

    ICASA 2021 Programme Book.indb (saafrica.org)

    Steiner C. et al. Have we met before? Understanding predictors of repeat HIV testing in Eswatini using HIV-1 recent infection surveillance data.

22. **Can you please elaborate a little bit more on how Recent infection in PHIA are different from recency (TRACE) testing?**

    The PHIA are national population-level surveys for estimation of national HIV incidence. Recency (TRACE) testing happens as an extension of routine HIV testing in HTS where people come for testing for a variety of reasons. This can help identify hotspots of transmission but should not be used for population incidence estimation.

23. **In the era of Test and Treat, do we expect some adjustments on the RITA algorithm especially in the classification of Recent cases?**

    Yes, testing and clinical history of a client can help improve accuracy of recency classification and should be used when available.

24. **Given that WHO guidelines recommend not performing basal VL, how will this impact recency surveillance and completion of the RITA?**

    VL testing among those who test RTRI-recent is being done as part of a RITA to improve accuracy of recency classification. The WHO strongly recommends inclusion of VL testing for this purpose.