PEPFAR SAB Recency Testing Expert Working Group: Recommendations on Communicating Individual Results from Recency Testing

Quarraisha Abdool Karim* on behalf of the PEPFAR SAB Recency Testing Expert Working Group
Members of the Recency Testing EWG

- Quarraisha Abdool Karim, Ph.D. (Chair)
- Sofia Gruskin, J.D., M.I.A.
- Lejeune Lockett, DM, MSPH
- Ruth Macklin, Ph.D.
- Celia Maxwell, M.D.
- Kenneth Mayer, M.D.
- Rev. Edwin C. Sanders, II
- Fredrick Sawe, MBChB, MMED

Secretariat Support: Sara Klucking
Objectives

- Establish a task force from the Scientific Advisory Board consisting of 5 to 6 members. Include Nominations for non-SAB members.
  - Ensure cross-discipline representation that includes, at a minimum, scientists, ethicists, and patient advocates.
  - Define and communicate the roles of all participating entities, including chair/co-chair(s).
  - Establish a work plan and timeline for achieving milestones.

- Participate in a one- or two-day consultation on recency testing with Ministries of Health (MoH), implementing agencies, and community stakeholders from operating units (OUs) that have piloted recency testing.

- Glean insights on the operationalization of recency testing and the risks/benefits of returning test results to individuals.

- Develop and document recommendations and key considerations on the return of recency test results.

- Deliver documents and recommendations to SGAC by February 15, 2019

- Deliverables: Document(s) to inform Ministries of Health and PEPFAR stakeholders considering the return of recency test results to patients.
Process

• Telephonic Consultation with a broad stakeholder group supplemented with several EWG teleconferences and emails
  • Ministries of Health, Implementing Agencies, Bilateral Partners, and Community Stakeholders from Operating Units (OUs) that have piloted recency testing in order
  • Provide recommendations and key considerations on the use of recency testing for routine, epidemiological monitoring and for improving patients’ clinical outcomes.

• Recommendations are based on available data from current generation recency tests validated to differentiate infections that have occurred within 12 months or >12 months

• Inclusive of recency testing at: Point of Care Provision; Laboratory Surveillance & Field Surveys

• Expert Inputs and Literature Review
Outcomes and Key Recommendations

• No blanket recommendation on return of results to individuals can be made:
  • diversity in epidemic typology, magnitude, populations at risk; preparedness of users and providers; human rights and ethical considerations

• Current recency assays could be an important adjunct to field and laboratory surveys to identify clusters of new infections spatially to target efforts that are more concerted.

• Recency information could be especially helpful in the context of achieving the first two 90s of the 90-90-90 strategy with respect to prioritization of HIV testing efforts and linkage to care activities.

• Important knowledge gaps remain on the risks and benefits of providing and individual with their recency test results. Disclosure of individual results should consider:
  • If benefits outweigh risks
  • Experiences and outcomes of community, affected populations, and key stakeholder consultations;
  • Country level legal, social and ethical considerations including criminalization of non-disclosure of HIV status or specific behaviors or sexual identities, gender-power disparities
Recommendations – Human Rights and Public Health Perspectives

• In the context of widely available access to HIV testing, care and prevention services
• Little perceived individual or public health benefits to individual knowledge of recency test results regardless of where and why testing is undertaken.
  • The risks may be less clear in specific locations or contexts, and with specific populations.
  • Countries in which suspected HIV transmission is a criminal offense;
  • Situations in which persons who come for testing bring one or more partners who do not know their HIV status, and within that group, a potential difference between risks to women and to men found to be recently infected.
  • Empirical evidence regarding these situations and other relevant data are needed to inform country level decisions on communication of recent infection results to the individual.
Recommendations – Point of Care Recency Testing - Considerations

• As part of point of care service provision: More effort and training is needed for providers before making it part of routine services.

• Current POC antibody tests are comparable to available recency tests and adequate for detection of those who are infected.

• Receiving positive results of recent HIV infection is usually an emotional experience and adequate support should be in place for the individual to cope with their status before having the added pressure to disclose to others including partner notification.

• Assistance with Active Case Finding/Provision of data for Partner Notification - Emphasis that this is Voluntary (to newly diagnosed HIV infected individual)
Recommendations: Voluntary Partner Notification – Social and Sexual networks

• Monitor experiences at an individual and community level
• Document social or legal harms being experienced and strategies being used to mitigate such harms.
• Empiric evidence of potential harms of results disclosure will expedite evidence-based decision making at an individual, public health and programmatic level.
Recommendations – Looking Ahead

• Given that the current generation of recency test assays are antibody based, individuals who are recently infected and not yet antibody positive are not identified

• No individual benefit of sharing a result with someone who may be infected and not know their status or someone with a high viral load as a result of acute infection unknowingly infecting others.

• As new generation assays are developed that enable detection of acute infection, the current EWG recommendation will need to be reviewed as these are likely to have substantial individual and public health implications.

• Together with other emerging empiric evidence, as long as the legal, ethical and social systems are supportive, there is likely to be substantial benefits to identifying individuals who are infected and unaware of their status or who will not test positive on available routine diagnostic tests.

• These individuals will need to have their recency test results confirmed to ensure/ facilitate linkage to care and other services.