Monitoring Strategies for HIV Drug Resistance in PrEP Rollout Settings

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Background

- HIV drug resistance (HIVDR) among pre-exposure prophylaxis (PrEP) seroconverters is a concern as some antiretrovirals (ART) are used for both HIV prevention and treatment.
- Breakthrough infection and subsequent selection of resistance with continued use of PrEP during acute infection could compromise the effectiveness of first-line ART.
- Efficacy of PrEP could be reduced if the transmitted variant is from a partner failing an ART regimen with virus that is cross-resistant to PrEP.
- Evidence on HIVDR in PrEP seroconverters is limited and comes from PrEP efficacy studies with different HIV testing intervals and adherence support strategies compared to PrEP rollout.

Potential Outcomes of PrEP Programs

- Low PrEP retention could result in initial exposure to PrEP drug, if a person then seroconverts with inadequate drug levels in their system they could develop HIVDR.
- Limited funding for PrEP in some programs could result in drug stock outs and clients going on/off PrEP during times of HIV risk.

Why monitor for HIVDR with PrEP?

- More data are needed to understand the risk of HIVDR in real-world implementation.

GEMS HIVDR Monitoring Toolkit

- OEGS Collection Job Aid and training video
- OEGS preparation SOP
- Acute seroconversion assessment
- HIVDR counseling messages
- SOP for Receiving ODS Sample Cards
- HIVDR Testing Factsheet
- SOP for high-throughput Next Generation Sequencing HIVDR Assays
- PrEP and HIVDR Fact sheet
- SMM Plan for monitoring HIVDR with PrEP
- Activity Planner for establishing an HIVDR Monitoring Program
- General HIV Drug Resistance Monitoring Protocol
- HIVDR Testing Factsheet
- Training modules on HIVDR (key concepts)

Lessons Learned

- HIVDR monitoring for PrEP seroconverters is feasible with a one-time dried blood spot specimen collection at seroconversion.
- Countries have varying degrees of resources and stakeholder engagement for integrating DRT for PrEP delivery, impacting monitoring strategy. Approaches to monitoring will vary and may evolve as new data are analyzed.
- Advantages and limitation of monitoring strategies should be weighed in context of ART testing capacity, program cost, PrEP rollout stage, and levels of pre-treatment HIV drug resistance.
- Currently, countries are supportive of conducting a time-limited evaluation of drug resistance in the absence of clear data and during early stages of PrEP rollout.
- As DRM laboratory testing technology evolves, more efficient and effective options could impact monitoring.
- These proposed methods and GEMS implementation support materials will assist countries in developing policies that best fit their PrEP program needs and resources.
- Information learned from DRM monitoring protocols and demonstration projects are anticipated in 2020. These data will inform efforts by MOHs to maximize preventive impact of PrEP while maintaining effectiveness of ART.

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