
PrEP Learning Network Regional Workshop
SunBird Hotel Blantyre, Malawi
11th November 2019

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GEMS Program Manager - Kenya
Outline

1. Background on GEMS and resistance monitoring
2. Toolkit Materials for Resistance Monitoring
3. Experience with Resistance Monitoring in Kenya
4. Discussion of Successes and Challenges
What is GEMS?

The Global Evaluation of Microbicide Sensitivity (GEMS) is one of five microbicide projects funded by the U.S. Agency for International Development (USAID), in partnership with the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR).

Overall goal:
To provide a comprehensive assessment of HIV drug resistance risk with PrEP use
3 Ways that Drug Resistance Can Occur

1. HIV-Negative person becomes infected on PrEP
   - He/she keeps taking PrEP until he/she gets a positive rapid test result
   - HIV-1 becomes drug resistant

2. HIV-Positive person starts PrEP during acute infection
   - He/she keeps taking PrEP until he/she gets a positive rapid test result
   - HIV-1 becomes drug resistant

3. HIV-Negative person’s partner has a drug resistant virus
   - PrEP does not protect against the resistant virus
   - PrEP user becomes infected with drug resistant HIV-1
Monitoring for HIV Drug Resistance in PrEP Seroconverters is Important

- Guide individual treatment options
- Ensure effectiveness of National PrEP program & whether additional client support needed for PrEP adherence and/or routine HIV testing
- Assess whether the frequency of HIV testing is adequate to capture seroconversions as quickly as possible
GEMS Resistance Monitoring for PrEP

PrEP

HIV Seroconversion

Sample Collection

Testing

Results

Policy and Guidance
GEMS Toolkit and Training Materials

http://gems.pitt.edu/toolkit

- DBS Collection Job Aid and training video
- DBS preparation SOP
- Acute seroconversion assessment
- HIVDR counseling messages

- SOP for Receiving DBS Sample Cards
- HIVDR Testing Factsheet
- SOP for high-throughput Next Generation Sequencing HIVDR Assay

- PrEP and HIVDR Fact sheet
- M&E Plan for monitoring HIVDR with PrEP
- Activity Planner for establishing an HIVDR Monitoring Program

- Generic HIV Drug Resistance Monitoring Protocol
- HIV Testing Factsheet
- Training modules on HIVDR (key concepts)
Training Video on DBS Collection

https://youtu.be/Gy039s-WwKk

Module | Training Topic
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I | HIV and drug resistance
II | Risk of drug resistance and PrEP
III | Drug Resistance testing among PrEP seroconverters
IV | Dried blood spot collection steps: fingerprick
V | Dried blood spot collection steps: venipuncture
VI | Understanding resistance test results
VII | Counseling messages to PrEP clients
Each monitoring strategy involves different approaches with distinct timeline, budget and scope implications.
GEMS Approaches to Resistance Monitoring

**Standalone Study Protocol**
Implement research protocol to assess HIV drug resistance in PrEP seroconverters

- **SOUTH AFRICA**
- **KENYA**
- **ZIMBABWE**
- **ESWATINI**

Protocol to assess HIVDR among TG and FSW

**Demonstration Project**
Partner with existing PrEP Demonstration Projects to add DRM to their protocol or procedures

- **KENYA**
- **UGANDA**
- **SOUTH AFRICA**

DRT incorporated into existing demo projects for AGYW, MSM and serodiscordant couples

Protocols to assess HIVDR among a national sample of PrEP users
HIV Drug Resistance Monitoring in PrEP Rollout:

Experience from Kenya
Successes, Challenges and Lessons Learned

PI: Dr. Bhavna Chohan,
Kenya Medical Research Institution, Nairobi
PrEP Rollout and HIV Drug Resistance (DR) testing among PrEP seroconvertors in Kenya

- **PrEP launched in Kenya**
- **Oct 2017**: PrEP Seroconversion HIVDR Protocol developed
- **Jan 2018**: Protocol submitted for ethics approval
- **Mar 2018**: Protocol received ethics approval; start of HIVDR Monitoring with PrEP - ongoing
People living with HIV (2019) ≈ 1,500,000

New HIV Infections (2019) ≈ 52,800

Number currently on PrEP (July 2019) ≈ 29,530

Current # of PrEP sites ≈ 1,500

*Data from <prep.nascop.org>
PrEP Seroconverter HIV Drug Resistance Test Flowchart

**Flowchart for Seroconversion PrEP to HIV DR testing**

**Abbreviations:**
- ART - Antiretroviral Treatment;
- DBS - Dried Blood Spot;
- LRF - Lab requisition form;
- PrEP - Pre-exposure Prophylaxis

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**PrEP Seroconverter HIV Drug Resistance Test Flowchart**

- **HIV test performed on PrEP client**
  - **HIV-negative**
    - No further evaluation needed; continue PrEP as indicated
  - **HIV-positive**
    - Inform client about the survey
    - Fill in the clinical summary form and send to Uliza NASCOP
    - Consent for DBS collection
    - Link to ART

**Request for the Seroconversion kit from CASCO, collect sample per the package insert and job aid and follow the process outlined:**
- Complete Lab Requisition Form (LRF)
- Collect blood via venipuncture
- Prepare two DBS cards
- Package dried DBS cards
- Call GS to ship sample to Kisumu KEMRI lab (addressed envelope in the kit)
*Sample must be shipped within 3 days*

**Return of HIV Drug Resistance Test Results:**
- Results returned to KEMRI Lab to requesting PrEP sites
- Results sent to Uliza NASCOP (ulizanascope@gmail.com)

**NB:** PrEP sites are encouraged to seek guidance from their County HIV Clinical TWG/PrEP or Uliza NASCOP for management of PrEP seroconverter if mutations detected.
HIV test performed on PrEP client

HIV-negative

No further evaluation needed; continue PrEP as indicated

HIV-positive

• Inform client about the study
• Fill in the clinical summary form and send to Uliza NASCOP
• Consent for blood collection (consent form)
• Link to antiretroviral (ART) treatment (at CCC)

Consented

Yes

No

Thank client; refer to ART provider at CCC
DBS Collection Kit

- Flow-chart
- Job Aid/instructions
- Laboratory Requisition Form (LRF)
- Consent Forms
- Kit insert for DBS preparation
- Barcoded stickers (5)
- Gloves
- Alcohol wipe
- 2 DBS collection cards
- Ziploc bags
- Desiccants
- Sterile disposable plastic dropper
- 5mL EDTA tube
- Vacutainer holder and needle
- DBS Shipment addressed envelope
## Job Aid for DBS Collection (Kenya)

### Version 1.0 June 2018

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Upon confirmation of HIV infection with PrEP client, review procedures for DBS collection. If client agrees, continue.</td>
</tr>
<tr>
<td>2</td>
<td>Complete the lab requisition form to collect client demographic and adherence data.</td>
</tr>
<tr>
<td>3</td>
<td>Ensure there are 5 barcode stickers with identical numbers. Affix one barcode labeled sticker to each of the following items: 1. Two (2) DBS cards 2. Lab Requisition Form 3. Blood collection tube 4. Client’s medical file</td>
</tr>
<tr>
<td>4</td>
<td>Wash hands with soap and water; put on gloves once hands are dry.</td>
</tr>
<tr>
<td>5</td>
<td>Apply a tourniquet above the puncture site. Wipe the puncture site with the alcohol wipe; allow the site to air dry.</td>
</tr>
<tr>
<td>6</td>
<td>Guide the needle into the vein and fill the connected EDTA blood tube. Once done, release tourniquet, withdraw needle, and apply a gauze pad to site.</td>
</tr>
<tr>
<td>7</td>
<td>Gently invert the blood collection tube 2 to 4 times and then open the stopper carefully.</td>
</tr>
<tr>
<td>8</td>
<td>Aspirate whole venous blood to the line closest to the bulb on a transfer pipette, avoiding air bubbles (approximately 50 μl).</td>
</tr>
<tr>
<td>9</td>
<td>Transfer 1-2 drops of blood to the center of each of 5 circles (on each of the 2 cards) without touching the filter paper directly with the tip of the pipette. Try to fully saturate the circle.</td>
</tr>
<tr>
<td>10</td>
<td>Store DBS card on drying rack with blood spots facing up and dry the DBS card at room temperature overnight, or for a minimum of 3 hours. Dispose of used and leftover materials per local protocol, including remaining blood.</td>
</tr>
<tr>
<td>11</td>
<td>The cards will be dry once the color of the blood changes from bright red to dark red. After the DBS card dries, insert it into the sealable plastic bag with the desiccant and humidity indicator.</td>
</tr>
<tr>
<td>12</td>
<td>Insert the sealed plastic DBS bag and the lab requisition form in the envelope provided and mail the envelope immediately, or within 3 days.</td>
</tr>
</tbody>
</table>
Successes on PrEP and HIVDR Monitoring

- Collaboration with partners and MOH
- Directly trained service providers in 10 highest HIV incidence counties
- Collaborated with partners to further train County and sub-County AIDS Coordinators
- Distributed flowcharts, job aids and specimen collection kits to clinics
- Ongoing specimen collection and testing!
Challenges and Responses

1. Training
   - Limited funds
   - Inconsistent cascade of training
     - Response: Train High HIV incidence counties

2. Testing difficulties
   - Stock out of lab testing reagents
     - Response: Expand to allow plasma-based testing and add in back-up lab

3. Missed seroconversions
   - Facilities unaware of protocol and/or seroconverters lost to follow-up
     - Response: Ongoing communication, track within the national database
Lessons Learned

- Collaborate with the National PrEP Program for wide-level commitment to protocol implementation

- Engage implementing partners to support cascade of training

- Regular calls with partners, County and sub-County AIDS Coordinators

- Mechanisms in place so that every local health facility is aware of program and collects sample at time of seroconversion

- Dedicated personnel to closely coordinate monitoring activities
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Q&A