Development and Clinical Use Case of a Urine Tenofovir Adherence Test
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[Background]
- Pre-exposure prophylaxis (PrEP) effectively prevents HIV infection when taken consistently.
- Poor adherence limits PrEP’s effectiveness.
- Current adherence monitoring methods are limited.
- A Liquid Chromatography Mass Spectrometry (LC-MS/MS) urine test for Tenofovir (TFV) was developed and used clinically.
- This poster describes:
  1. Early adherence results using the LC-MS/MS test.
  2. Ongoing efforts to develop a point-of-care (POC) urine test for TFV.

[Objectives]
1. To evaluate initial results from utilization of novel adherence monitoring test.
2. To develop a prototype POC urine test for TFV to assess non-adherence within the last 48 hours.

[LC-MS/MS Test]
**Methods**
- Urine samples were collected from PrEP patients in Broward County, Florida.
- The LC-MS/MS test quantified levels of the TFV in urine.
- Adherence results were reported to providers and patients through an online portal.
- De-identified data was collected for quality improvement purposes.

**Results**
- Over ten weeks, samples from 271 individuals were tested.
- Participants ranged from 20-69 years old with an average age of 35.2 years old.
- Urine TFV testing demonstrated:
  - 14 individuals were non-adherent in the previous 7-10 days.
  - 17 individuals were inconsistently adherent in the previous 7-10 days.
  - 11.4% of individuals and 22.2% of women were sub-optimally adherent.

[POC Test]
**Methods**
- The antibody performance in the ELISA format showed 100% sensitivity and 94.67% specificity to TFV (Table 1).

**Results**
- An initial dose response curve was developed for the LFIA prototype (Figure 1).

**Table 1: Results from antibody’s performance in ELISA format**

<table>
<thead>
<tr>
<th>Antibody (+)</th>
<th>LC-MS (+)</th>
<th>LC-MS (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody (+)</td>
<td>50</td>
<td>8</td>
</tr>
<tr>
<td>Antibody (-)</td>
<td>0</td>
<td>140</td>
</tr>
</tbody>
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**Figure 1: Nitrocellulose strip demonstrating dose response curve**

[Conclusions]
1. **LC-MS/MS:**
   - For the first time, an objective adherence test was used commercially in a clinic setting.
   - PrEP navigators and specific counselling were targeted to those individuals with sub-optimal adherence.

2. **POC:**
   - A POC LFIA could promote adherence and patient engagement to PrEP.
   - This performance may also be applicable to monitoring first line ART adherence, especially in resource-limited settings.

[References]