Utilizing real-time adherence monitoring devices among HIV+ pregnant and postpartum women: Challenges encountered in the Uganda WiseMama study

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Conflict of Interest Disclosure

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has no real or apparent
conflicts of interest to report.
Background

• HIV prevalence in Uganda:
  – 8.2% among women of childbearing age
  – 7.3% in general population, 6.3% for men.

• WHO’s Option B+ initiative: provision of lifelong ART to all HIV+ pregnant women.
  – Option B+ is current standard of care in Uganda
  – High retention in HIV care and ART adherence are critical for success (women’s health and elimination of mother-to-child transmission (MTCT) of HIV)

• Obstacle: HIV+ pregnant and postpartum women (PPPW) face particular challenges related to retention in care and adherence.
Previous research and real-time feedback

• Real-time wireless pill containers (WPC)
  – Web-linked medication container that sends electronic signal to central server at each opening
  – Allows reminders to be sent at specific times

• Patient experience with WPC
  – Feasible/acceptable in Uganda (Haberer et al 2010)
  – Feasible/acceptable in southern China (2013)
  – WPC-based triggered reminders + data-informed counseling improved ART adherence in China (CATS)
Given the need for adherence support among PPPW, our main study question…

Could real time reminders (via WPC) combined with data-informed counseling improve ART adherence in this vulnerable population?
WiseMama RCT: Ongoing

Feasibility component:

Primary Objective

- Assess the feasibility and acceptability of use of real-time monitoring devices among pregnant and postpartum women
**WiseMama Study Overview**

- **Enrolled ART-naïve pregnant women N=165**
  - **Mityana District Hospital N=81**
    - WPC Given
    - Randomized n=66
    - 15 withdrawn
  - **Entebbe Grade B Hospital N=84**
    - WPC Given
    - Randomized n=66
    - 18 withdrawn

Pre-intervention phase
Methods: Enrollment

- 165 ART-naïve pregnant women, >18 years, attending 2 antenatal clinics (ANC):
  - Entebbe Grade B Hospital
  - Mityana District Hospital
- Once daily regimen: (tenofovir, 3TC, efavirenz)
- Subjects given a WPC for daily use with one HIV medication for ~8-10 months total
Methods: Data Collection

• Monitored subjects’ adherence using WPC for 1 month (pre-intervention period).
• Investigated all adherence lapses $\geq 48$ hours via phone follow-up with women and WPC website.
• Surveys administered at enrollment and Month 1 clinic visit (end of pre-intervention period).
• After pre-intervention period, women randomized to intervention (reminders + counseling) or control (usual care).
Methods: Data analysis

• Lapse causes
  – categorized as behavioral or technical
  – further subcategorized based on subject explanation or data from WPC website

• Experiences with device (Month 1 Survey)
  – Proportions calculated for quantitative questions
  – Open-ended questions analyzed by theme

• Adherence to ART (as measured by WPC) calculated for the one month pre-intervention period
### Characteristics at baseline (N=165)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%) or Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>25.1 (5.6)</td>
</tr>
<tr>
<td>Married</td>
<td>118 (74.2)</td>
</tr>
<tr>
<td>Education level completed</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>65 (40.6)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>83 (51.9)</td>
</tr>
<tr>
<td>First pregnancy</td>
<td>44 (29.0)</td>
</tr>
<tr>
<td>Multiparous women, previous pregnancies</td>
<td>2.5 (1.8)</td>
</tr>
<tr>
<td>Someone else knew status at enrollment</td>
<td>62 (38.8)</td>
</tr>
<tr>
<td>Disclosed to husband/partner at enrollment</td>
<td>41 (26.1)</td>
</tr>
<tr>
<td>Completed pre-intervention period</td>
<td>132 (80.0)</td>
</tr>
<tr>
<td>Adherence, pre-intervention period (%)</td>
<td>76.0 (24.9)</td>
</tr>
</tbody>
</table>
# Reasons for Signal Lapses

<table>
<thead>
<tr>
<th>Category</th>
<th>N</th>
<th>% in category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total signal lapses</strong></td>
<td>179</td>
<td></td>
</tr>
<tr>
<td><strong>Behavioral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intentional nonuse - side effects</td>
<td>21 (40.2)</td>
<td></td>
</tr>
<tr>
<td>Fear of mixing meds</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>No Pills</td>
<td>3 (4.2)</td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>8 (11.1)</td>
<td></td>
</tr>
<tr>
<td>Fear of Disclosure</td>
<td>13 (18.1)</td>
<td></td>
</tr>
<tr>
<td>Inconvenience</td>
<td>14 (19.4)</td>
<td></td>
</tr>
<tr>
<td>Forgetting to take a dose</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Life event</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Lack of food</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>Forgot device</td>
<td>1 (1.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Technical</strong></td>
<td>58 (32.4)</td>
<td></td>
</tr>
<tr>
<td>Signal strength</td>
<td>41 (70.7)</td>
<td></td>
</tr>
<tr>
<td>Battery</td>
<td>4 (6.9)</td>
<td></td>
</tr>
<tr>
<td>Faulty device</td>
<td>9 (15.5)</td>
<td></td>
</tr>
<tr>
<td>Sim card</td>
<td>4 (6.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>49 (27.4)</td>
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</tbody>
</table>
WPC experience: Quantitative findings

- 98/126 (77%) found device “very easy” to use.
- 100/128 (78%) found it convenient to carry.
- 114/128 (89%) were “very positive” about real time monitoring.
- 30/126 (24%) worried about disclosure due to device.
- Reports of disclosure due to device: N=6 women.
WPC use: Positive experiences

• “The container is better than the normal pill container. Even if you carry it in public, people may not notice it’s a pill container.”

• “I have disclosed to my husband. In fact, he asked if he can also be given a device.”

• “Knowing I am being monitored makes me feel special because I know they care. That gives me the courage to take my medicine.”
WPC use: Negative responses

• “The blinking makes it difficult since I do not want people to know my status. When it blinks I am worried someone might begin asking questions.”

• “I keep it away from my husband. I fear him seeing it because I did not disclose to him.”

• “I had to hide it from my husband… I think he saw it and no longer wants to talk to me.”
Conclusions

• Behavioral and technical factors represented substantial challenges to real-time, web-linked monitoring of adherence among pregnant women attending two Ugandan clinics.

• Concerns about medication side effects and disclosure require further exploration.

• Before widespread use, technical issues require resolution.
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