Feasibility and Acceptability of Hair- and Dried Blood Spot-Derived ARV Biomarkers as Objective Measures of Treatment Adherence in South Africa

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ART adherence research and clinical care hampered by lack of objective measure of medication adherence

Current strategies: unannounced pill counts, electronic monitoring devices, pharmacy records
  ▶ **Do not** measure actual ingestion

Newer strategies: drug levels in hair and blood
  ▶ **Do** measure ingestion over the course of approx. several weeks
Two important aspects of objective measures of ART adherence should be that they
- impose minimal burden on patients/research participants and on healthcare systems
- be usable in a variety of settings (e.g., clinic, home)

Dried blood spot (DBS) and hair samples are
- Minimally invasive (DBS) or non-invasive (hair)
- Usually considered minimal risk
- Inexpensive to collect (i.e., materials and personnel)
- Suitable for repeated sampling/ongoing monitoring
How acceptable and feasible to patients are collecting hair and blood samples?

- How burdensome/painful are giving regular samples?
- Could collection occur at the clinic and at home?
- Could patients collect DBS by themselves?
- Are there concerns about the use of one’s blood and hair samples?
SETTING
Sub-sample of participants in the Masivukeni ART adherence RCT

- NIMH-funded RCT of a laptop-based, multimedia and interactive ART adherence intervention
- HIV+ adults initiating ART in Cape Town health clinics
- Monitored via Wisepill
Eligibility

- Enrolled in Masivukeni
- On first line ART regimen (e.g., Atroiza or Odimune containing tenofovir) for 1-2 months
- Attend 5 study visits, one month apart
- Provide hair and blood samples at each visit
PILOT METHODS

- At each monthly visit, nurse collected:
  - Finger-stick for DBS sampling
  - Hair sample (approx. 100 strands)
  - Brief survey

- R300 (≈$30) incentive for each study visit
PROCEDURE
RESULTS:
PARTICIPANT CHARACTERISTICS

- 30 participants enrolled
- Demographics
  - 90% women, 100% Black African
  - Mean age: 30 years (SD=5.25)
- 28 participants completed all 5 study visits; 2 completed 4 visits
- 148 total finger-stick and hair collection samples
- 148 completed surveys
RESULTS: PAIN FROM DBS

ANY PAIN FROM FINGER-STICK?

Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5
---|---|---|---|---
No. Participants
30% | 47% | 62% | 62% | 67%
RESULTS:
WILLINGNESS TO DO DBS REGULARLY

How willing would you be to do a finger-stick during regular clinic visits?

<table>
<thead>
<tr>
<th>Visit</th>
<th>Not very&quot; to &quot;Not at all willing&quot;</th>
<th>&quot;Somewhat willing&quot;</th>
<th>&quot;Willing&quot; to &quot;Very willing&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>40%</td>
<td>17%</td>
<td>63%</td>
</tr>
<tr>
<td>Visit 2</td>
<td>37%</td>
<td>21%</td>
<td>66%</td>
</tr>
<tr>
<td>Visit 3</td>
<td>50%</td>
<td>66%</td>
<td>47%</td>
</tr>
<tr>
<td>Visit 4</td>
<td>69%</td>
<td>33%</td>
<td>50%</td>
</tr>
<tr>
<td>Visit 5</td>
<td>33%</td>
<td>&quot;Not very&quot; to &quot;Not at all willing&quot;</td>
<td>&quot;Willing&quot; to &quot;Very willing&quot;</td>
</tr>
</tbody>
</table>

No. participants
RESULTS:
WILLING TO TO DBS AT HOME

Would you be willing to do finger-sticks at home, on your own?

No. Participants

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
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</thead>
<tbody>
<tr>
<td>10%</td>
<td>17%</td>
<td>31%</td>
<td>52%</td>
<td>53%</td>
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</tbody>
</table>

No Yes

HIV CENTER for Clinical and Behavioral Studies
at the New York State Psychiatric Institute and Columbia University
RESULTS:
CONFIDENCE DOING DBS BY SELF

How confident are you that you could do finger-sticks at home by yourself?

- "Not at all confident"
- ≥ "Somewhat Confident"

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<thead>
<tr>
<th>Visit</th>
<th>No. Participants</th>
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<tbody>
<tr>
<td>1</td>
<td>10%</td>
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<td>2</td>
<td>17%</td>
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<td>3</td>
<td>31%</td>
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<td>4</td>
<td>52%</td>
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<tr>
<td>5</td>
<td>47%</td>
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</table>
RESULTS: DBS ACCEPTABILITY AND FEASIBILITY

- What was it like for you to have your finger pricked and give blood samples today?
  - Most responses: “a little painful”, “slightly sore”, “wasn’t too bad”, “wasn’t painful”

- Throughout all visits, ≥ 90% of participants reported willingness to have a health worker come to their home to do finger-stick.
RESULTS:
WILLINGNESS TO GIVE HAIR REGULARLY

How willing would you be to give hair samples during your regular clinic visits?

Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5
---|---|---|---|---
57% | 57% | 76% | 93% | 97%

- "Willing" to "Very willing"
- "Somewhat willing"
- "Not very" to "Not at all willing"
RESULTS:
HAIR ACCEPTABILITY AND FEASIBILITY

- No one at any point reported experiencing any pain from the hair collection procedure

- What was it like for you to give a hair sample today?
  - Most responses: “fine,” and “okay”. One participant responded “a bit stressful,” another, “I’m just worried my hair isn’t growing quickly enough.”
No participant at any visit reported concerns about long-term storage and future use of their hair or blood samples.
CONCLUSIONS

- Finger-stick for DBS was acceptable to most patients and may be feasible in resource-limited settings.
- Hair samples were less acceptable than DBS, especially for regular and repeated collections.
- Repeated exposure to procedures appeared to increase willingness and confidence for DBS sample collection by the patient her/himself at home.
- Further studies might examine the setting of sampling, and potential barriers to more widespread use in clinical practice.
- Research is needed to evaluate the ability of tenofovir DBS to measure ARV adherence.
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