Feasibility of supervised Self-Testing using an Oral Fluid-based HIV Rapid Testing method among pregnant women in Rural India

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Where are we with HIV testing?

Between 2010 and 2014, 600 million adults (ages 15+) received HIV testing in 122 LMICs.

Reaching the first “90” is the most problematic: Too few taking the test

- Half of people with HIV unaware of status
- Only 44% pregnant women take the test in low and middle-income countries
- Feasibility studies are required on new testing approaches

HIV Testing: Pregnant Women In India

**Burden**
- HIV testing significant for early identification
- Only 37% pregnant women knew their HIV status
- 29 million women give birth every year
- Estimated 14000 HIV+ babies born annually

**Barriers**
- HIV-related stigma
- Low awareness
- High pregnancy burden
- Social barriers
- Lack of trained workers
- Long distance

**Potential Solution**
Supervised HIV self-testing using a rapid diagnostic test (non-invasive)
Objectives of the Study

To conduct supervised HIV self-testing using OraQuick® HIV antibody test among pregnant women in rural hospital settings of India to assess:

- Acceptability
- Concordance
- Feasibility of self-testing supervised by community health workers (CHWs)
Methodology

**Study design:** Cross-sectional study, conducted between August 2014 and January 2015

**Study setting:** Kasturba Rural Hospital, Mahatma Gandhi Institute of Medical Sciences, Wardha

**Study Procedures**

- **Orientation of Healthcare workers:** Objectives, protocol and procedures for OraQuick® test by the instruction guide
- **Recruitment:**
  - **Inclusion Criteria**
    - Pregnant women (>18 years of age)
    - First trimester of pregnancy and Registered for ANC with the hospital
    - Informed Consent
  - **Exclusion Criteria**
    - Bleeding gums/periodontal diseases
    - Abnormal vital signs
    - Incapacitation to give consent

- **Pre- & Post Test Counselling:** Consentig women provided pre and post test counselling
Recruitment of Participants

Assessed for eligibility (n=350)
- Excluded (n=148)
  - Missed ANC appointment (n=70)
  - Aged under 18 years (n=26)
  - Had chronic conditions (n=28)
  - Gum disease or oral ulcer (n=24)
  - Declined to participate (n=0)

Included in study (n=202)
- Performed self-testing intervention with OraQuick® kit (n=202)
- Participated in in-depth interviews (n=35)
- Received confirmatory testing at government operated ICTC (n= 202)

Confirmed negative (n=200)
- Confirmed positive cases (n=2)
  - Referred to ART centre (n=2)
  - Initiated on ART (n=2)
Procedure of Supervised Self-Testing:

- Self-testing by OraQuick® kit explained by CHW using pictorial representation
- Women performed test under supervision of CHW
- Test results observed and interpreted first by participants and then by CHW independently
- Results confirmed by government-run Integrated Counselling and Testing Centres (ICTC) at the hospital
- Post-test counselling and linkage to appropriate care
Data Collection and Analysis

Ethical consideration

- Ethical approval obtained
- Privacy and confidentiality were maintained

Data collection

- Semi-Structured questionnaire
- Observation schedule (for the health workers)
- In-depth interviews

Analysis

- Statistical analyses: IBM SPSS Statistics V.22
- Qualitative data translated and transcripts analyzed through an inductive approach
Operational definitions

Acceptability
Proportion of uptake (%) = 
no. of those who chose to self-test  
no. of those who were offered to testing

Sensitivity and specificity parameters
Index test: Self-test result interpreted by CHW
Reference standard test: Confirmatory tests done for HIV at the ICTC

Concordance
Agreement between the test result interpretation by participant and a CHW
Quantified as percentage agreement and with the Cohen’s Kappa (k) inter-rater agreement

Feasibility
Assessed by the ‘documented completion of self-testing and counselling processes
Results: Acceptability

- 100% pregnant women accepted the test
- 83.7% preferred oral compared to blood-based HIV tests
- 96% reported to recommend this test to other people
- 96% thought the test kits should be sold in public outlets

“I liked the test as it took little time for the testing process and it gave result very quickly” (Interview, 23-year-old pregnant woman, Parvani village)

“I didn’t have to give blood for testing, which reduced my fear and trouble” (Interview, 23-year-old pregnant woman, Pula village)
Concordance

- 98% concordance
- Kappa; k= 0.566, p<0.001

Inter-rater agreement between users and supervisors

<table>
<thead>
<tr>
<th>Inter-rater agreement</th>
<th>Supervisor result</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>User result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>197</td>
</tr>
<tr>
<td>Invalid</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>199</td>
</tr>
</tbody>
</table>

Sensitivity and Specificity

- 100% sensitivity and specificity for 201 tests
- As per CHW interpretation, two HIV positive and 199 HIV negative
- Results confirmed by ICTC
- One oral test deemed invalid by the supervisor and excluded
Feasibility

- All participants prepared test kit correctly with assistance
- 92.6% took the sample and did the test correctly
- 15% required assistance in swabbing gums; 3 did incorrectly
- 94.6% read and interpreted results correctly
- 95.5% participants reported being confident of performing test correctly
<table>
<thead>
<tr>
<th>Issue/coding concept</th>
<th>Major theme</th>
<th>Minor theme</th>
<th>Implications for program and research</th>
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</thead>
<tbody>
<tr>
<td><strong>Understanding self-testing the procedure</strong></td>
<td>Clarity of test instructions</td>
<td>Literacy levels</td>
<td>Catering for illiterate populations e.g. use of pictorials</td>
</tr>
<tr>
<td><strong>Acceptance and performance of the test</strong></td>
<td>Time-efficiency</td>
<td>Availability of self-test kits</td>
<td>Some participants did not wait for required 20 minutes</td>
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<td></td>
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<td>Non-invasiveness</td>
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<td>Convenience</td>
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<td></td>
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<td>Pain less</td>
<td></td>
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<tr>
<td><strong>Interpreting the result</strong></td>
<td>Clarity of instructions</td>
<td>Visual aids</td>
<td>Interventions focussing on invalid and other incorrect results</td>
</tr>
<tr>
<td><strong>Barriers to and fear of self-testing</strong></td>
<td>Fear of incorrect results</td>
<td></td>
<td>Emphasis that oral testing is a screening test critical in increasing uptake</td>
</tr>
</tbody>
</table>
Conclusion

→ Oral Fluid-based HIV Rapid Testing is Acceptable and Feasible

→ May provide a viable solution in resource constrained settings

→ Can utilize CHWs, rather than formally trained staff nurses

→ Ora-Quick has concordance with ICTC results in field settings

→ May strengthen implementation of Option B+ Strategy

→ Can be a useful strategy for screening in high pregnancy burden settings

→ Policy restrictions on HIV supervised self-testing

→ Further evidence needed to scale-up programmes
Way Forward.....

New HIV testing services guidelines launched in July 2015

New recommendations

1. Trained lay providers testing (*new recommendation*)

2. HIV self-testing (*implementation and monitoring*)

Currently, we are exploring use of rapid oral fluid based HIV testing by Community Health Workers (CHWs) among pregnant women as ‘point of care’ screening