Prospective Evaluation of Two Oral Fluid HIV Rapid Tests in Mozambique

Sena, Cynthia; Raposo, Cristiana; Correia, Delita; Jav, Hesh; Sobod, Darius; Penso, Lisa; Feresi, Bharat; National Institute of Health, Mozambique; Centers for Disease Control and Prevention (CDC), Mozambique; CDC, USA

Background
In Mozambique it is estimated that there are currently around 1.8 million people living with HIV. With a prevalence of about 15% in people aged 15 to 49, Mozambique is one of the countries most affected by HIV. Even with expansion of Counseling & Testing (C&T) services, national coverage is low and does not reach all communities, particularly remote areas. Availability of oral fluid (OF) based rapid tests in Mozambique may permit expansion of testing while reducing the biohazard associated with finger prick or venous blood draw. The use of Oral Fluid testing for HIV antibody testing has been researched since the 1980’s and has recently been suggested as an alternative to the use of blood samples. We tested two colloidal gold immunochromatography rapid tests: OnQuick Advance® and Chewba DP®.

Objectives

To evaluate the performance, feasibility and acceptability of oral fluid based HIV testing using the OnQuick® Advance test and the CHEMBO DP® rapid HIV 1/2 antibody test.
To compare the oral fluid based testing to the current national HIV testing algorithm of 2 blood based tests (Determine followed by UniGold™)

Methods

Enrollment
From May to August 2009, volunteers 18 years or older seeking CT services at two health facilities in Maputo City were invited to participate.
Written informed consent was obtained, and pre-test counseling given to all participants.
Testing
Participants received oral results for the two oral HIV tests according to company-specified procedures.
Thirty minutes were allowed between oral swabs since there is no validated time interval between the administration of the two OF tests.
The order of the OF tests was reversed halfway through the study to reduce bias.
During the 30 minute interval between oral fluid tests, the participants completed pre-tested acceptability questionnaires on the test and were given counseling in health according to national protocols for CT in health units.
All participants were also tested using the standard dried blood spot HIV tests according to national guidelines (serial testing using Determine and UniGold tests).

Results

Participants
A total of 1,676 people participated.
58.7% of participants were men.
Average age was 32 (range 18-76)

Test results

<table>
<thead>
<tr>
<th></th>
<th>Oral Fluid Test</th>
<th>Whole Blood Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Fluid Tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OnQuick</td>
<td>316</td>
<td>1157</td>
</tr>
<tr>
<td>Chewba DP®</td>
<td>317</td>
<td>1157</td>
</tr>
<tr>
<td>Whole Blood Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Determine</td>
<td>537</td>
<td>1157</td>
</tr>
<tr>
<td>UniGold</td>
<td>517</td>
<td>1157</td>
</tr>
</tbody>
</table>


Acceptability results
Based on the “intention to use” question, the finger prick tests are more acceptable among 1,620 respondents questions (49.9%).

Conclusions

Oral Fluid testing with DP® and OnQuick showed superior performance in accurately diagnosing HIV infection when examined individually or in an algorithm, in comparison to the current Mozambican national algorithm using whole blood.
Preference for oral fluid tests was nearly equal to that of finger prick tests, with women tending towards a preference for oral fluids and men tending towards a preference for finger stick.
Use of OF tests can further simplify HIV rapid testing while permitting expansion of testing in a variety of settings.

Limitations

Study was performed under ideal conditions of close training and supervision, the performance on the tests on a large scale is unknown.
Concerns exist over perception of population of oral fluid based tests for HIV considering concurrent messaging that HIV is not found in and cannot be transmitted by saliva.

Next Steps

The results of this study were promising, but many doubts and hurdles remain.
Further discussion among the Ministry of Health, study investigators, and other stakeholders is needed to decide the next steps regarding use of oral fluid based HIV tests in Mozambique.

Acknowledgements
We thank all collaborating institutions that participated in the success of this study:
MDH - National Institute of Health
IDP/LOGO
PSI
ICF
Maputo City Health Directorate
Maputo Military Hospital
1º June Health Faculties

Contact
Della Correia
Counseling and Testing / PMTCT Study Advisor
Centers for Disease Control and Prevention (CDC), Mozambique
Address: JAT Complex 4, 4th Floor
Ave Zedequias Monguella, 267
Maputo, Mozambique
Phone: (+258) 21 314 747 / (+258) 84 303 5329
Email: della.correia@mo.cdc.gov

[Diagram showing test performance and comparison between OnQuick and DP test results]

[Table showing test performance and comparison between OnQuick and DP test results]

Preference of HIV test type for future use among study participants:
- Among women, oral fluid testing was the preferred choice for future testing (52.0% of women preferred oral fluid).
- Among men, finger prick testing was more popular (57.5% of men preferred finger prick).

Conclusion
- The onQuick + DP® tests had an overall sensitivity of 99.8% and specificity of 99.3%.

OnQuick Advance®
Determine
UniGold™
Chewba DP®
- Men preferred oral fluid
- Women preferred finger prick