Sexual risk behaviour predicts more frequent use of HIV self-testing: early findings from the FORTH trial


Australasian HIV & AIDS Conference 2015
September 17, 2015

Disclosure of Interest Statement

• Self-test kits were purchased from OraSure Technologies Inc. (Bethlehem, PA, USA)

Background

• More than 70% of new HIV diagnoses in Australia occur in gay and bisexual men (GBM)
• Higher-risk GBM test at less than the recommended frequency (3-6 monthly) (Sydney Gay Periodic Survey)
• Barriers (Prestage, Sex Health 2012; Conway, J Int AIDS Soc 2015)
  – Difficulties with appointments
  – Lack of time
  – Cost and inconvenience
• 63-67% likely to test more often if self-testing available (Bavinton 2013; Chen 2010)

Availability of HIV self-tests

• 2014: Australian regulations changed
• 2015: TGA provided guidance on acceptable performance
  – Sensitivity: ≥99.5% whole blood, ≥99% oral fluid
  – Specificity: ≥99%
  ‘assessed on a case-by-case basis and will depend on how well the manufacturer has mitigated any risks and demonstrated that the overall benefits of the product outweigh any residual risks associated with its use.’
• No self test kits approved for sale in Australia
• Self-tests commercially available in the US, UK, France

Orasure OraQuick

• Second generation test
• Oral fluid specimens
• Results in 20-40 minutes
• Untrained users
  – Sensitivity: 91.7% (84.2-96.3)
  – Specificity: 99.9% (99.9-100.0)
• Screening test

Randomised trial of HIV self-testing

• 2013-2015 ‘FORTH’
• Two arms
  – Intervention: self-tests + clinic tests
  – Control: clinic tests
• Primary objective
  – Compare HIV testing frequency
• Secondary objectives
  – Compare STI testing frequency
  – Acceptability
FORTH participants and recruitment

- 350 HIV-negative GBM at increased risk of HIV
  - >5 partners, or
  - Condomless anal intercourse in previous 3 months
- 300 frequent testers (tested <2 yrs)
- 50 infrequent testers (tested ≥2 yrs or never)
- Recruitment
  - Sydney and Melbourne sexual health clinics
  - ACON aTEST, Victorian AIDS Council
- Promotion: Facebook, Grindr, posters and postcards at recruitment sites

FORTH follow-up

- 12-months
- Baseline survey: Demographics, risk behaviour, past clinic HIV testing
- 3-monthly surveys: Risk behaviour, number of current clinic and HIV self-tests
- Up to three reminders via email or SMS
  - One week apart
  - Final SMS asking the total number of HIV tests
- ~90% response rate

FORTH self-kit supply

- Four self-test kits at baseline
- Manufacturer-supplied step-by-step instructions and a web-link to an instructional video
- Able to request additional kits, one at a time
- Maximum of 12 kits in one year

PRELIMINARY ANALYSIS

- Intervention arm only (n=182)
- Self-testing only (not clinic testing)
- Follow-up
  - 12 months: 138 (75%)
  - 6 or 9 months: 42 (25%)
- Multivariate logistic regression
- Cross sectional analysis
- Baseline factors associated with >average number of self-tests in 12 months

Participant characteristics (n=182)

<table>
<thead>
<tr>
<th></th>
<th>FORTH intervention (n=182)</th>
<th>GCPS (%) (n=4670)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>36 (11.1)</td>
<td>35 (11.8)</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>62%</td>
<td>68%</td>
</tr>
<tr>
<td>University degree</td>
<td>52%</td>
<td>56%</td>
</tr>
<tr>
<td>&gt;10 male partners in past 6 months</td>
<td>50%</td>
<td>22%</td>
</tr>
<tr>
<td>Condomless anal intercourse with casual partners in past 6 months</td>
<td>59%</td>
<td>21%</td>
</tr>
<tr>
<td>Any group sex in past 6 months</td>
<td>58%</td>
<td>32%</td>
</tr>
<tr>
<td>Mean gay social engagement score* (SD, range)</td>
<td>4.3 (1.5, 0-7)</td>
<td>4.3 (1.5, 0-7)</td>
</tr>
<tr>
<td>≥3 HIV tests in past 12 months</td>
<td>35%</td>
<td>22%</td>
</tr>
</tbody>
</table>

How self-tests were used

<table>
<thead>
<tr>
<th></th>
<th>Participants n=182</th>
<th>Self-tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>To test themselves</td>
<td>159 (87%)</td>
<td>481</td>
</tr>
</tbody>
</table>

*Sum of scores for 'gay friends' and 'time spent with gay men' questions
### How self-tests were used

<table>
<thead>
<tr>
<th>Participants</th>
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</tr>
</thead>
<tbody>
<tr>
<td>n=182</td>
<td></td>
</tr>
<tr>
<td>To test themselves</td>
<td>159 (87%)</td>
</tr>
<tr>
<td>≥3 tests</td>
<td>86 (47%)</td>
</tr>
</tbody>
</table>

Mean number of self-test per person: 3

<table>
<thead>
<tr>
<th>Participants</th>
<th>Self-tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=182</td>
<td></td>
</tr>
<tr>
<td>To test someone else (e.g. partner)</td>
<td>47 (26%)</td>
</tr>
</tbody>
</table>

### Outcome: ≥3 HIV self-tests

<table>
<thead>
<tr>
<th>Category</th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV clinic tests last 12 months</td>
<td>OR (95% CI)</td>
<td>p</td>
</tr>
<tr>
<td>&lt;3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>2.36 (1.26-4.43)</td>
<td>0.007</td>
</tr>
<tr>
<td>Condomless anal intercourse with casual partners in past 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2.21 (1.21-4.04)</td>
<td>0.010</td>
</tr>
<tr>
<td>Number of partners last 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥10</td>
<td>1.86 (1.03-3.36)</td>
<td>0.038</td>
</tr>
</tbody>
</table>

Other co-variables: age, country of birth, ethnicity, employment status, education, area of residence, sex with regular partners, in past 6 months, group sex, gay social engagement

### Conclusions

- Higher risk GBM used self-tests frequently
- Free supply of up to 12 self-tests
- Men who reported condomless anal intercourse with casual partners used more self-tests
- Need to raise awareness about longer window period of OraQuick self-test
- About a quarter of men tested partners - interviews
- FORTH final analysis late 2015
Acknowledgements

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**FORTH investigators/recruitment staff**
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- Centre for Social Research in Health, UNSW Australia: Martin Holt
- Kirby Institute, UNSW Australia: Garrett Prestage, Andrew Grulich, John Kaldor, Benjamin Bavinton, Damian Conway, Handan Wand, Phillip Keen

**FORTH study participants**

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**TGA requirements:**

- **Proposed TGA requirements:**
  - Sensitivity: ≥99.5% whole blood, ≥99% oral fluid
  - Specificity: ≥99%

- However, it is recognised that the same level of sensitivity and specificity may not be achieved in a self-testing environment.

- The suitability of these studies will be assessed on a case-by-case basis and will depend on how well the manufacturer has mitigated any risks and demonstrated that the overall benefits of the product outweigh any residual risks associated with its use. Demonstration of the benefit of a test and effectiveness of risk mitigation measures in the self-testing environment may be supported by a documented review of relevant published literature.

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**Thank You**

Email: Rguy@kirby.unsw.edu.au