

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

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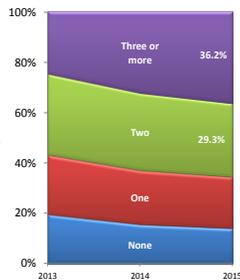


Disclosure of Interest Statement

- 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*)



Sydney Gay Periodic Survey
HIV tests in last year
(‘high risk’ men)

Availability of HIV self-tests

- 2014: Australian regulations changed
- 2015: TGA provided guidance on acceptable performance
 - Sensitivity: $\geq 99.5\%$ whole blood, $\geq 99\%$ oral fluid
 - Specificity: $\geq 99\%$

‘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 ‘FORTH’

- 2013-2015
- 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)

	FORTH intervention (n=182)	GCPS (%) (n=4670)
Mean age in years (SD)	36 (11.1)	35 (11.8)
Born in Australia	62%	68%
University degree	52%	56%
>10 male partners in past 6 months	50%	22%
Condomless anal intercourse with casual partners in past 6 months	59%	21%
Any group sex in past 6 months	58%	33%
Mean gay social engagement score* (SD, range)	4.3 (1.5, 0-7)	4.3 (1.5, 0-7)
≥3 HIV tests in past 12 months	35%	22%

*Sum of scores for 'gay friends' and 'time spent with gay men' questions

How self-tests were used

	Participants n=182	Self-tests
To test themselves	159 (87%)	481

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To test someone else (e.g. partner)	47 (26%)	76

How self-tests were used

	Participants n=182	Self- tests
To test themselves	159 (87%)	481
≥3 tests	86 (47%)	
Mean number of self-test per person	3	
To test someone else (e.g. partner)	47 (26%)	76
Given to someone else	20 (11%)	25

Outcome: ≥3 HIV self-tests

Category	Univariate		Multivariate	
	OR (95% CI)	p	AOR (95% CI)	p
HIV clinic tests last 12 months				
<3	1			
≥3	2.36 (1.26-4.43)	0.007	2.13 (1.11-4.08)	0.022
Condomless anal intercourse with casual partners in past 6 months				
No	1			
Yes	2.21 (1.21-4.04)	0.010	2.04 (1.09-3.82)	0.027
Number of partners last 6 months				
<10	1			
≥10	1.86 (1.03-3.36)	0.038	1.45 (0.78-2.71)	0.245

Other co-variables: age, country of birth, ethnicity, employment status, education, area of residence, sex with regular partner(s) 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

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FORTH study participants

Thank You



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EXTRA SLIDES

TGA requirements:

- Proposed TGA requirements:
 - Sensitivity: $\geq 99.5\%$ whole blood, $\geq 99\%$ oral fluid
 - Specificity: $\geq 99\%$

TGA requirements:

- **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