HIV Self-Testing: Assessment Of The Usability Of The Australian Rapid Atomo Galileo Device

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Background

Undiagnosed HIV Australia 10% globally 40%

Diagnosis = access to ART = better outcomes + less transmission

Self-testing is an additionally method to provide access to HIV testing

Via oral swab (less sensitive to early infection) or pin prick blood test

HIV testing doubles where self-testing is available

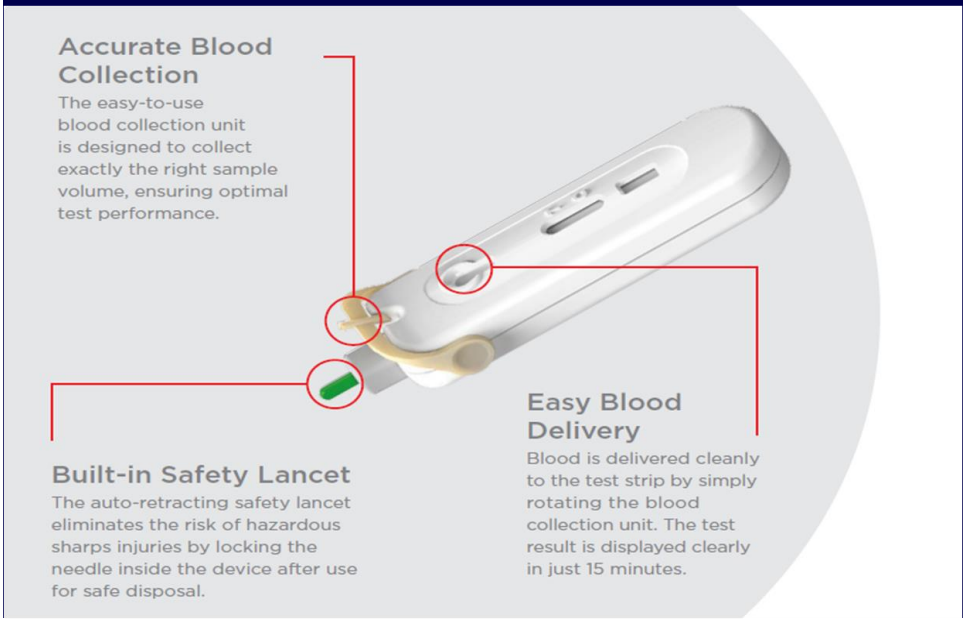
Benefits of Self-testing

- Increase testing uptake and diagnosis of HIV infection
- Access to testing to existing and harder to reach communities
- Increased confidentiality
- Increased convenience, Rapid results
- Autonomy and empowerment
- Potential to remove the stigma surrounding HIV
- Less resource intensive from the healthcare system perspective

Risks of Self-testing

- Greater potential for inaccurate results
- Psychological danger when decoupling testing and counseling
- Greater difficulty ensuring referral and linkage to care
- Potential unethical use of HIV self-testing
- Self-testing as justification for unprotected sex
- Concern for safe disposal of biohazard material
- Uncoupling with STI testing

ATOMO: Galileo Method



Study Aims

To assess the performance of the Atomo Galileo HIV self-test in the hands of typical self-test users vs. stand of care laboratory serology

To assess the usability of the Atomo Galileo self-test in the hands of typical self-test users

Study Hypotheses

1. That the specificity of the Atomo HIV Self Test compared with laboratory serology will be at least 95%

2. That the invalid test rate of the Atomo HIV Self Test will be less than 2%

3. That the proportion of participants able to successfully complete the six critical steps in the Atomo HIV Self Test procedure will be at least 90%

4. That the specificity of the Atomo HIV Self Test when used in the laboratory compared with laboratory serology will be at least 99%

Inclusion/Exclusion:

INCLUSION CRITERIA

Attending health clinic or community-based testing study sites
Aged 18 years or more
Requesting HIV testing and/or in whom HIV testing is indicated
Willing and able to give their own informed consent
Willing to participate in and comply with the study procedures

EXCLUSION CRITERIA

People known to be HIV positive
People in whom HIV testing is not indicated or not appropriate
People not fluent in English in whom provision of informed consent or compliance with the study procedures may be problematic
People who have participated in the study previously

Study methods:

Prospective observational study.

Patients attending Holdsworth House Medical Practice in Sydney September 2016 to May 2017

Demographic data was recorded.

Following an instructional four minute video, participants performed the ATOMO self-test with access to a visual instruction aid, whilst the performance of the testing was assessed by trained study coordinators.

There was an option to repeat the test once if participant perceived they'd made a mistake

Study methods: Critical 6 steps

There 6 critical steps of testing that were assessed by trained study coordinators:

1. Removal of sterility tab
2. Lancet-prick finger
3. Administration of sufficient blood to tube
4. Flipping tube to well
5. Ensuring blood moved into well
6. Buffer application

Concurrent plasma 4th-generation Siemens ADVIA Centaur XPT Immunoassay System was performed.
Optional rapid Allere testing was available to participants.

Participants were asked to interpret a mock test result

Results:

521 adult participants

98% Male

93% MSM

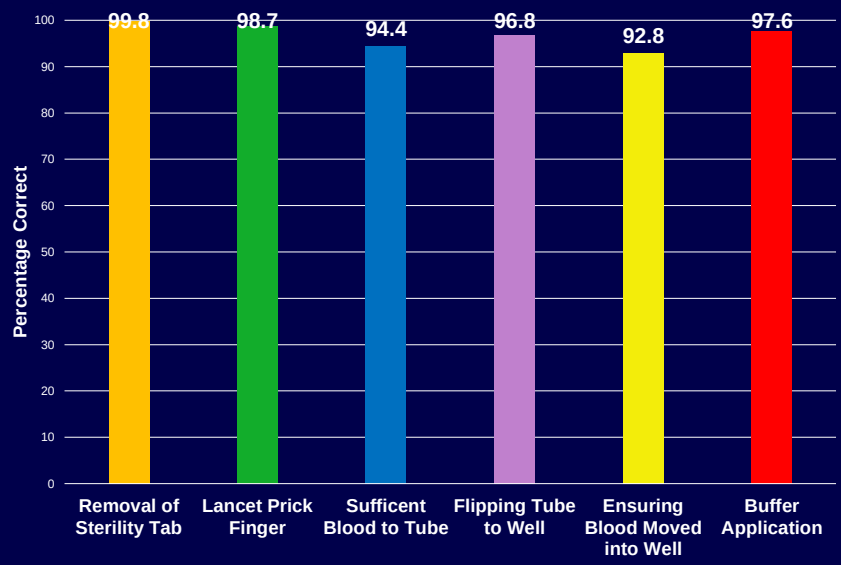
83% white, 8% Asian, 2% Hispanic, 1% indigenous

91% spoke English as primary language

78% had HSC or higher education

49% were receiving PrEP

Results: Critical Steps



Results:

Average critical step usability was 96.8%.
Correct performance of all critical steps 1-6 was 88.7%.

Concordance of self-test with laboratory HIV testing results was 99.8%.
Concordance of self-test with coordinator repeat of self-test was 100%

Additional steps of washing hands, checking test expiry date and massaging finger pre-test were conducted in 87.2%, 44.9% and 84.2% of participants respectively.
Interpretation of mock test result by participant was correct in 95.5%

Ease of use of self-test was rated by 76% as ≥8/10.

Conclusions:

There was a high level of usability of the ATOMO self-test by Australian participants.

HIV self-testing could provide a viable additional option to access of HIV testing in the community.

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