ORAL VS. FINGER STICK FOR HIV: A META-ANALYSES

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Self Testing Strategy A VISION

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CONFLICTS OF INTEREST

We have no conflicts of interest with industry.

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ARE WE READY TO SELF TEST FOR HIV?

? QS?

- Why self test?
- Should we?
- What does it mean for the world?
- Is there a global momentum for self testing strategies?
- Which test? Evidence from a meta-analyses.
- What is the evidence from Montreal and South Africa?

IN HOME HIV TEST

OVER THE COUNTER SELF TEST HIV

- On May 12, 2012, the US FDA's BPA committee approved the first over the counter HIV test.
- FDA's approval on July5th 2012
- This is a momentous step forward in the history of HIV/AIDS
- In a few months, self tests for HIV will be available over the counter at Walgreens, CVS and pharmacies in US.

***

SELF TESTING: WHY?

60% of individuals are unaware of their serostatus

25- 30% testers are lost to follow up

About 40% present late with an AIDS diagnosis.

A self-test is an in-vitro test on self-collected samples

(i.e., finger stick blood, venous blood, urine, oral swab) for screening or monitoring disease.

SELF-TEST: ADVANTAGES

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A) **privacy** of their home, ensuring complete **confidentiality**

B) Empowers **pro-activity** in health care and personal decisions making

C) Decreases **stigma and visibility**

D) **Early** knowledge of sero-status;

E) Encourages early linkages to treatment and possible reduction in HIV transmission

F) Partner testing and partner notification.

BUT WHAT ABOUT ACCURACY ?

META-ANALYSES ORAL VS FINGER STICK

THE LANCET Infectious Diseases

Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis

Nitika Pant Pai, Bhairavi Balram, Sushmita Shivkumar, Jorge Luis Martinez-Cajas, Christiane Claessens, Gilles Lambert, Rosanna W Peeling, Lawrence Joseph

Summary

Background The focus on prevention strategies aimed at curbing the HIV epidemic is growing, and therefore screening for HIV has again taken centre stage. Our aim was to establish whether a convenient, non-invasive, HIV test that uses oral fluid was accurate by comparison with the same test with blood-based specimens.

Methods We did a systematic review and meta-analysis to compare the diagnostic accuracy of a rapid HIV-antibody-based point-of-care test (Oraquick advance rapid HIV-1/2, OraSure Technologies Inc, PA, USA) when used with oral versus blood-based specimens in adults. We searched five databases of published work and databases of five key HIV conferences. Studies we deemed eligible were those focused on adults at risk of HIV; we excluded studies in children, in co-infected populations, with self-reported inferior reference standards, and with incomplete reporting of key data items. We assessed the diagnostic accuracy of testing with oral and blood-based specimens with bivariate regression analysis. We computed positive predictive values (PPVs) in high-prevalence and low-prevalence settings with Bayesian methods.

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FLOW CHART

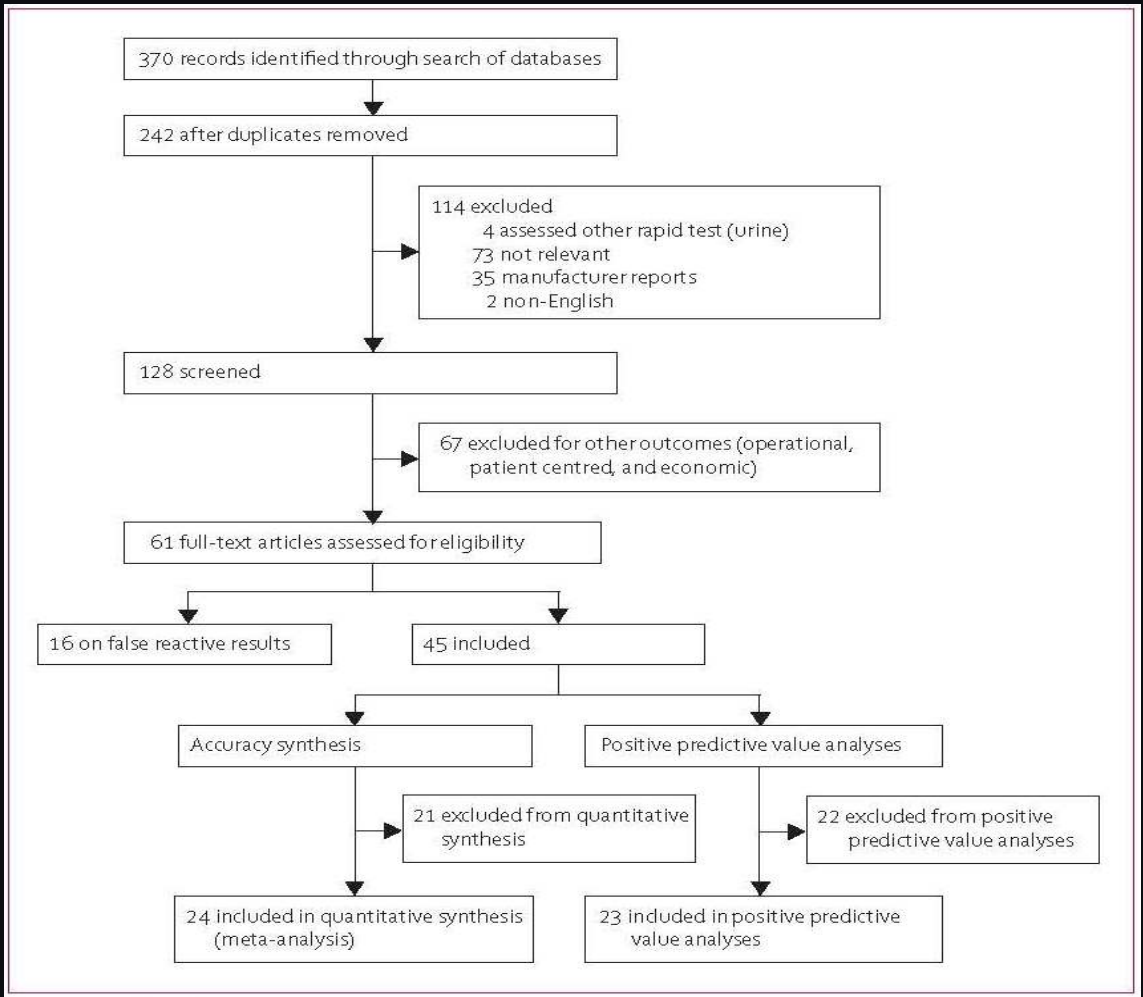


Figure 1: Study selection

PRIMARY OBJ: Accuracy

- Subgroup 1 head to head comparisons oral vs. finger stick
- Subgroup 2 oral only
- Subgroup 3 finger stick only

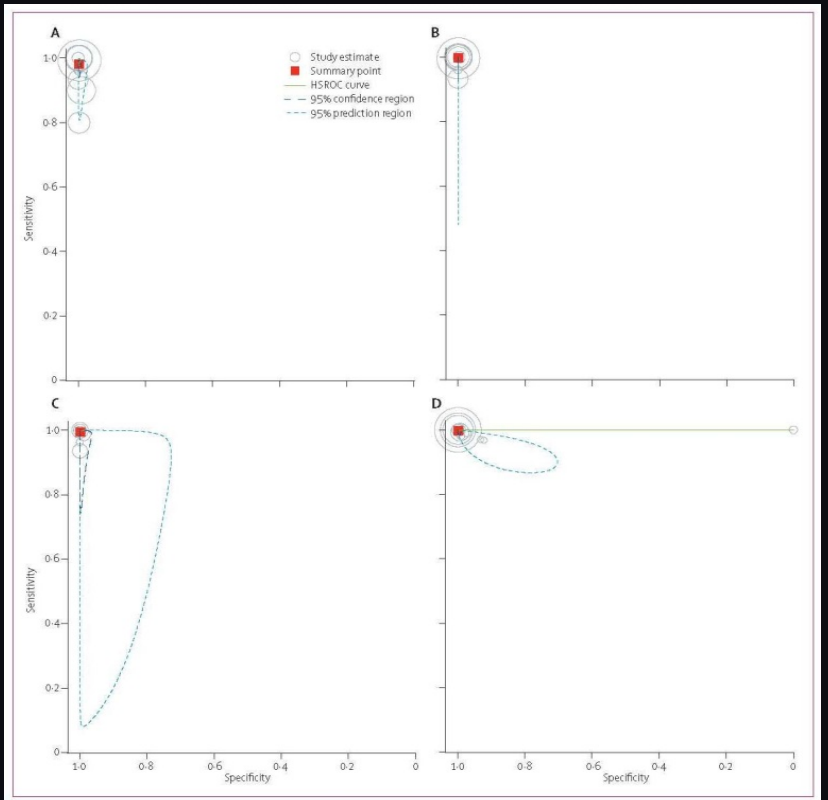


Figure 2: HSROC curves for each subgroup
Curves for studies with oral mucosal transudate within-study comparisons (A), finger-stick blood within-study comparisons (B), oral mucosal transudate samples only (C), and finger-stick blood samples only (D). HSROC=hierarchical summary receiver operating characteristic.

PRIMARY OBJ: ACCURACY

	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Log (diagnostic odds ratio)
Subgroup 1a (oral mucosal transudate within study; n=10)	98·03% (95·85–99·08)	99·74% (99·47–99·88)	383·37 (183·87–799·31)	0·019 (0·009–0·040)	9·87
Subgroup 1b (whole blood within study; n=10)	99·68% (97·31–99·96)	99·91% (99·84–99·95)	1105·16 (633·14–2004·37)	0·003 (0·001–0·034)	12·75
Subgroup 2 (oral mucosal transudate only; n=6)	99·43% (95·28–99·93)	99·86% (99·22–99·98)	721·65 (126·84–4105·76)	0·006 (0·001–0·050)	11·75
Subgroup 3 (whole blood only; n=17)	99·8% (99·07–99·93)	99·78% (99·27–99·93)	466·96 (137·42–1586·76)	0·003 (0·001–0·009)	11·78

n refers to a datapoint (one set of true positive, false positive, false negative, and true negative).

Table 1: Pooled estimates of accuracy across studies

PRIMARY OBJECTIVE: INTERPRETATION

Our first subgroup—the main subgroup of interest— containing studies with both oral and whole-blood comparisons:

Pooled sensitivity was greater for whole-blood than oral

Pooled specificity was similar

COMPARISON OF OUR FINDINGS

manufacturer's claims
(sensitivity 99·3%, 95% CI 98·4–99·7; specificity 99·8%, 99·60–99·89)

only the pooled specificity estimates from our study were close to the manufacturer.

Discrepancy in sensitivity estimates from the manufacturer's estimates --?carefully controlled laboratory settings of serum panels.

Implementation research: study settings, study designs, populations, prevalence, and variable quality control procedures

optimism bias.

Implications accuracy

the lower sensitivity in oral mucosal transudate vs.blood specimens
→lower quantity of HIV antibodies
-> low titre of HIV antibodies - acute HIV infection pre seroconversion;

oral testing might miss more acute HIV infections than tests with blood specimens because of its lower sensitivity.

Cautious
oral test as a first-line screening test to detect early HIV infection in settings with low HIV prevalence.

SECONDARY OBJ: PPV IN SAMPLES; BY PREVALENCE

	Positive predictive value (95% credible interval)
Blood group (n=32)	
High-risk populations (n=10)	98·50% (93·10–99·79)
Low-risk populations (n=22)	97·65% (95·48–99·09)
Overall	98·03% (96·38–99·08)
Oral mucosal transudate group (n=31)	
High-risk populations (n=11)	98·65% (85·71–99·94)
Low-risk populations (n=20)	88·55% (77·31–95·87)
Overall	94·88% (87·66–98·4)

n refers to one set of true positives and false positives.

Table 2: Pooled estimates of positive predictive value

Point estimates and 95% credible intervals for PPV provided similar estimates for blood and oral specimens in high-prevalence settings

By contrast, in low prevalence settings, PPV estimates were higher for blood than oral specimens.

DISCUSSION AND IMPLICATIONS

- In high prevalence performance of the test in blood and oral specimens was similar in settings
- In low prevalence settings, the test was inferior in oral compared with blood specimens.

- The use of a single oral test in low-prevalence settings could lead to a higher number of false positives than blood tests.

- National screening program impede widespread implementation of HIV testing

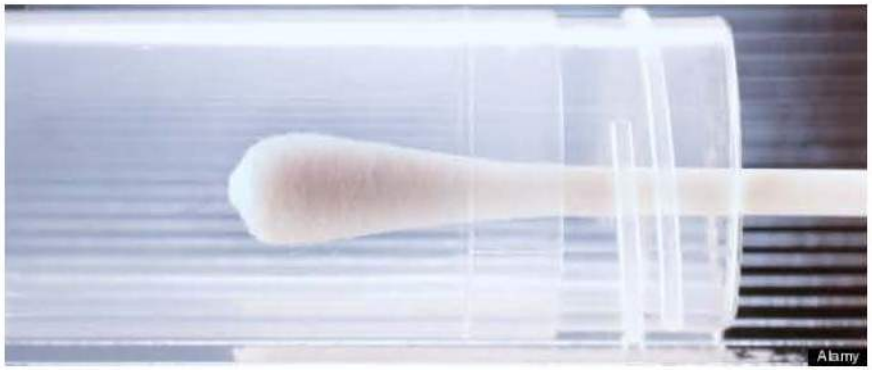
OUR FINDINGS IN CONTEXT

- Self tester has a high self-perception of risk recent exposure and window period initial self test is negative,
- he/she must seek immediate further confirmatory testing with advanced tests at a referral center of choice.

TheScientist
MAGAZINE OF THE LIFE SCIENCES

HUFF POST BLACKVOICES
CANADA

Saliva HIV Test As Effective As Blood Test: Study



First Posted: 01/30/2012 3:12 pm Updated: 01/30/2012 3:58 pm

Despite advances in the treatment of HIV, one huge challenge still lingers in the medical community: getting people tested in

The stigma associated with being tested and potentially exposed in a public clinic has prompted scientists at the Research Inst
University Health Centre to evaluate the efficacy of an oral HIV self-test, a method they believe can serve as an effective but
alternative to clinical testing.

Compared to a traditional blood screening, the saliva test OraQuick HIV1/2, the only oral fluid test approved for use in a heal
Food and Drug Administration, was 99 percent accurate in detecting HIV antibodies in high-risk populations and about 97 pe
populations, according to study findings published in the journal *The Lancet Infectious Diseases*.

To evaluate this saliva test's potential for worldwide use, researchers analyzed real-life field research data from five global da
groups include injection drug users, men who have sex with men, and people who have unprotected sex

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Saliva Legit for HIV Testing

A quick spit test is as good as blood for detecting HIV, and could encourage self-testing initiatives in the US and Africa.

By Megan Scudellari | January 25, 2012

OraQuick HIV test

A pain-free, non-invasive saliva test is as accurate as a traditional blood test to diagnose infections of the human immunodeficiency virus (HIV), according to a new meta-analysis published yesterday (January 24) in *The Lancet Infectious Diseases*. The test could be a solution for countries that

strategies for HIV.

Pooling data from five wor

international team of resea

HIV-1/2, a saliva test sold

Times LIVE

Saliva HIV test as accurate as blood screening

ANI Jan 25, 2012, 05:36PM IST

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Recommend

Tags: saliva test | saliva | McGill University | HIV

Researchers including one of an Indian origin have revealed that saliva test used to diagnose the human immunodeficiency virus (HIV), is comparable in accuracy to the traditional blood test.

A new study led by the Research Institute of the McGill University Health Centre (RI-MUHC) and McGill University found that the saliva HIV test, OraQuick HIV1/2, had the same accuracy as the blood test for high-risk populations.

(Saliva HIV test as accurate as blood screening (Thinkstock photos/Getty Images))

Home › HIV Special Report › Article ›

Oral HIV test results found to be less reliable

HARRIET MCLEA | 24 January, 2012 00:22

A new study on oral HIV tests has added fire to the debate on whether self-testing should be allowed in South Africa.

A NEW study on oral HIV tests has added fire to the debate on whether self-testing should be allowed in South Africa.

The study, which compared the accuracy of testing for HIV using cheek and gum tissue (oral mucosal transudate) to blood tests, was

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So can we use this test for self testing?

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SELF TESTING STRATEGIES

2 KINDS OF STRATEGIES

Unsupervised self testing:
3 studies (Katz 2012, Kalibala 2011, Orasure 2012)

Facilitated or supervised self testing:
with aid of counselors, educators, HCW

SELF TEST EVIDENCE

About 16 studies evaluated self testing strategies worldwide

Variable study populations	• At risk • General populations • Health care workers
Settings	• 69% in developed • 31% in developing settings
Countries	•Singapore •US •Canada •Malawi •Kenya •India
Study designs	•1 RCT •1 cohort •6 surveys •2 qualitative surveys •1 mixed methods •Others cross sectional observational

SELF TESTING STRATEGIES: EVIDENCE?

Uptake	•Kenya - 78% •US/UK/Canada - 87-90%-99% •Malawi - 92%-95%
Tendency	•Lower in marginalized 20-30% •Higher in general (85-91)
Concordance	•High •Kappa: 0.28-0.97
Specimen preference	•Oral 90% •Cost preference varied between •5-20$ in NA •7-13 Singapore
Difficulties in testing	•Test performance – 2% •Test interpretation – 5% •Test conduct were performed incorrectly – 17%
Illiterate	•Required greater assistance (Choko 2011)

SELF TESTING

Pre-test counselling	•Considered essential in all studies •Preferences varied across contexts and settings: Anonymous person vs. phone, internet varied with literacy, and access
Post-test counselling	•Function of ease, preference and access •North America: homeless face to face, •Malawi: face to face by unknown individuals •Kenya: Phone based preference high. •Educated populations Canada preferred internet and phones
Linkages	•Intention to follow up in positives: 75% to 88% •Negatives follow up: documentation poor!

SOUTH AFRICA : AN IMPLEMENTATION RESEARCH PROJECT

An integrated innovative* self-testing strategy

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HIV IN SOUTH AFRICA

- Prevalence: 5.3 million (2007)
- Accounts for 17% of global infection
- Affected populations include:
  - Sex Workers
  - Adolescents
  - Migrant workers
  - Young women

WILL SELF-TESTING BE PREFERRED BY STUDENTS OF MCGILL UNIVERSITY?

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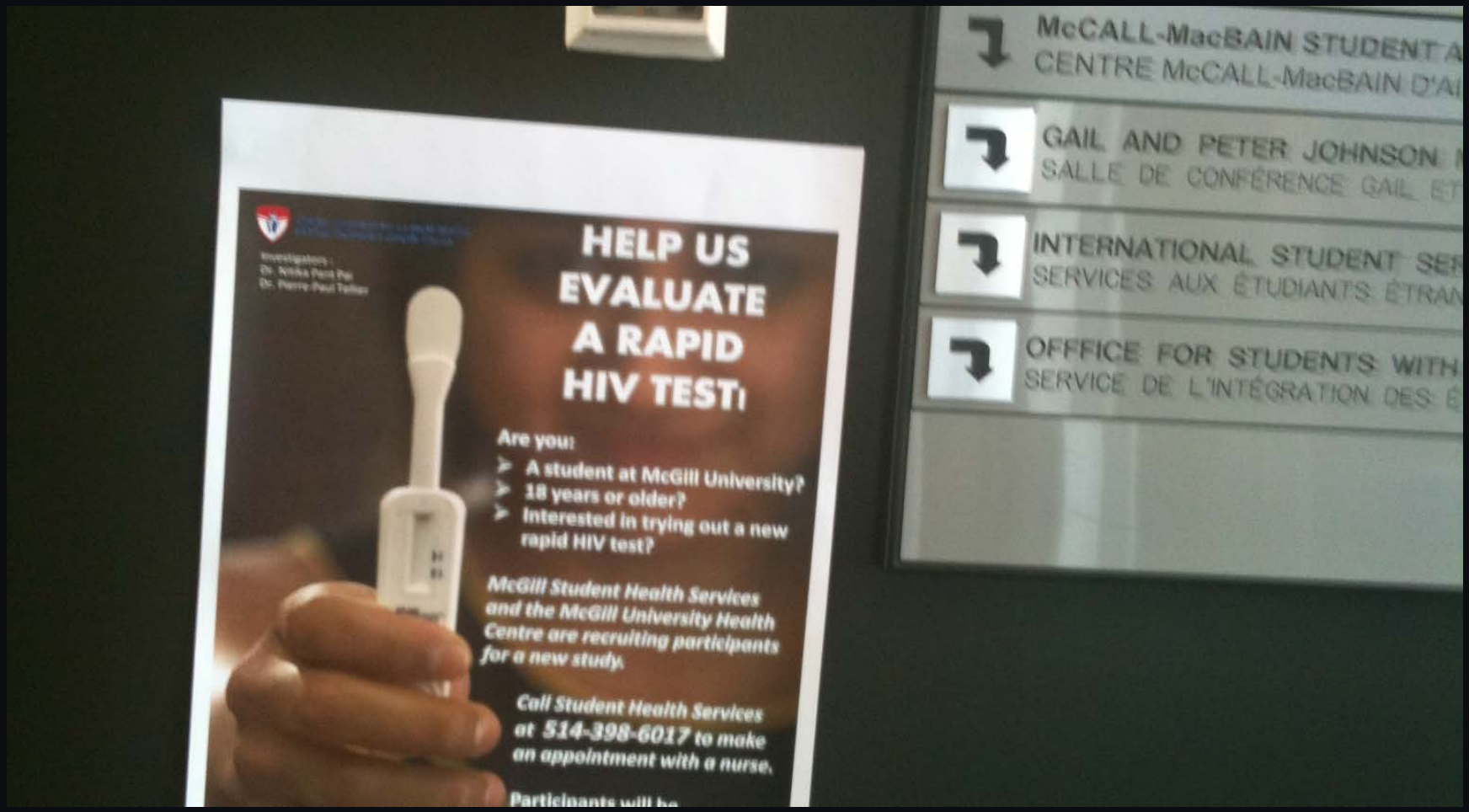
SUPERVISED SELF TESTING STRATEGY MONTREAL STUDENTS MCGILL



RESULTS

- 100% Agreement between self test by students and nurse performed poc test
- 81% students preferred self-test over conventional lab-based testing
- 98% students found self-tests convenient
- 84% oral self-tests to be non invasive and pain free
- 71% expressed willingness to buy them over-the-counter
- 65% expressed willingness to follow up with lab-based confirmatory tests if self-test offered were over-the-counter
- Preferred post-test counseling options:
  - phone and internet: 43%
  - community clinics: 41%
  - Pharmacies: 16%

MONTREAL STUDY CONCLUSION

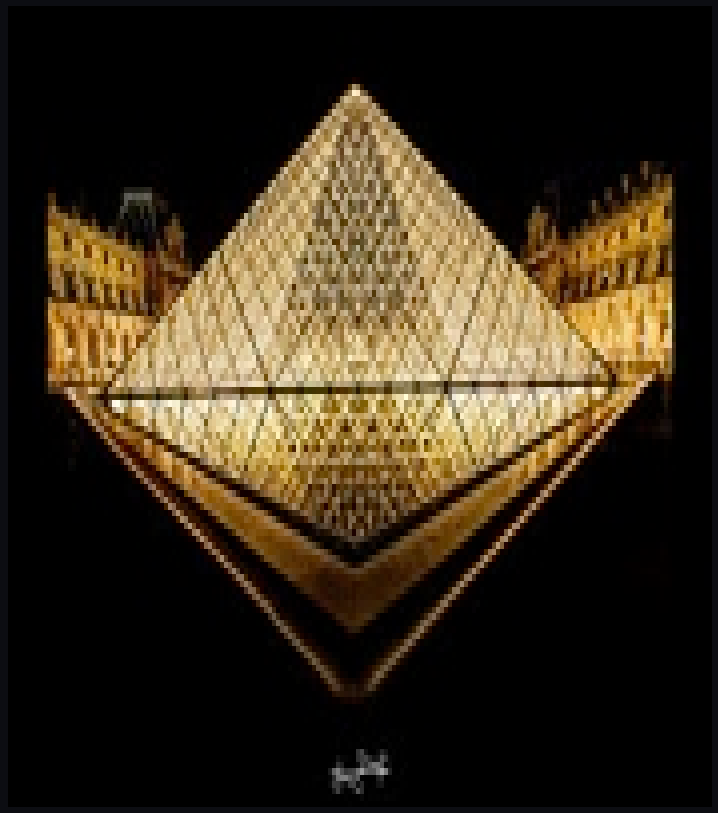
High concordance, acceptability and preference for self testing, attributed to convenience, non invasiveness and time savings.

Preference for personalized counseling via phone or internet followed by in person counseling and confirmatory test at community clinics/hospitals

Concerns expressed for timely counseling and linkages, costs and accuracy of tests.

FINALLY

Self-testing and counseling -an alternative paradigm that will complement and expand the current repertoire of testing and counseling to reach 60% untested!—
one of the magic bullets!



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BOLD IDEAS FOR HUMANITY.

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CIHR IRSC
Canadian Institutes of Health Research
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MERCI!

- *“There is no end to learning.*
- *When we feel that we have learned everything, it means*
- *that we have learned nothing.”*

- *Kenosha Furuya*