SELF TESTING FOR HIV, A GAME CHANGER, REALLY?

Nitika Pant Pai, MD, MPH, PhD

McGill University and McGill University Health Centre
Montreal, Quebec, Canada

Assistant Professor, Clinical Epidemiology & Infectious Diseases
Faculty of Medicine
Nitika Pant Pai

Has no financial relationships with any industry

Dr. Pant Pai’s research program on point of care for HIV and co-infections is supported by Operating Grants from the Canadian Institutes of Health Research (CIHR), Grand Challenges Canada (GCC) and the Bill & Melinda Gates Foundation
“There is something better than science. That is science with a moral compass. Science that contributes to the social equity. Science in the service of humanity.”

~ William H Foege, MD
After this presentation, you will be able to understand the following:

1. Need, benefits and concerns with HIV self testing
2. Global Evidence on self testing strategies
3. Gaps in the Evidence
4. Future research directions
NEED
Conventional facility based HIV testing faces barriers:

- Social Visibility, perceived stigma and discrimination
- Long wait times in clinics,
- Delay in receipt of results and linkages to treatment

Worldwide, six out of ten individuals do not know their HIV sero-status because of failure to access health facilities.

In North America, 25 - 30% tested in facilities are lost to follow up; 40% of individuals present late with an AIDS.

40% of individuals present late with an AIDS.
Perspective on HIV Self-testing in North America: A Tale of Two Countries—US and Canada
Nitika Pant Pai
Division of Clinical Epidemiology, Department of Medicine, McGill University and Health Centre, West Montreal, Quebec, Canada.

ABSTRACT: Long waiting time in clinics, loss of working days to obtain an HIV test result, fear of social visibility, perceived stigma, and discrimination, associated with facility-based HIV testing impede testing efforts. Not surprisingly, therefore, about 25% of Canadians and Americans with HIV continue to live unaware of their positive sero-status, and knowingly or unknowingly contribute to continued HIV transmission in their communities. To such individuals, self-testing for HIV, offers one potential, proactive, de-stigmatizing screening solution. Individuals can screen themselves in the comfort of their home or assisted by a health care professional, and combine it with remote on phone or in person expedited counseling. Self testing has the potential for expanded access, and offers a confidential private testing option, but high costs of currently approved self test, concerns about timely linkages to counseling and care, coupled with a lack of awareness and knowledge about self tests, in communities that desire it the most, stand as obstacles to its expansion. Will self-testing strategy, achieve its destiny of reaching the untested and of expanding access in a people-friendly convenient and affordable manner? Will it succeed in linking people to counseling and care in a timely manner? And, lastly, Will it also bring many more partners to self-test? In this perspective, we explore some of these questions, discusses potential ways in which self testing for HIV could be offered, accessed, expanded, operationalized within Canada and US, to help reach many more individuals that desire a self testing solution.

KEYWORDS: HIV Self testing, North America, Canada, US, perspective
IS THERE A PLACE FOR SELF TESTING IN THE CANADIAN HEALTH SYSTEM?

- Financial burden of treating HIV infected individuals 4 billion
- 64.2% of newly diagnosed advanced to AIDS in one year.
- New HIV infections cost CAD 3,175 per year (2,250-4,100)
- Direct health cost, economic and quality of life LOSS amounted to $14,453 per asymptomatic HIV-infected person, failure to detect and treat infected individuals at an early stage
- Anonymous testing offered by 10 Canadian Provinces
- No self tests currently approved in Canada

Self Testing Strategy | A VISION
BENEFITS
A. **Individual:**

1. Privacy and Anonymity
2. Convenience and Empowerment
3. Time savings
4. Reduces perceived Stigma and discrimination

B. **Population level:**

1. Promises Expanded Access (partner referrals)
2. Improved uptake (convenience, acceptability, preference)
3. Early Detection of new infections in undiagnosed and staging of sero-status (community)
1. Health care workers
2. Female sex workers
3. Sero-discordant couples
4. Youth
5. Men who have sex with men
FDA-approved in-home oral HIV self test
July 2012
A. Quality of testing and quality of self tests:
   1. Can people self test without errors?
   2. What about accuracy of self tests?

B. Timely initiation of linkages:
   1. Where, how, when of linkages to care post test?

C. Consequences of self testing:
   1. Self harm, forced testing, anxiety, increases in risk behavior post selftest? (Brown A, Aids Behavior 2014)

Reference: Realizing the potential for HIV self testing. Johnson et al Aids Behavior 2014
1. Scale up of self testing in under resourced settings (Johnson C, Aids Behavior 2014)

2. National policies on Self testing (Wong et al, Aids Behavior, 2014) USA, Kenya, France, UK

3. Is self testing ethical? (Scott A, Aids Behavior 2014; Allia s & Venter, Aids Behavior 2014)
WHAT IS THE EVIDENCE?
SELF TESTING STRATEGIES

2 Kinds of Strategies

Unsupervised self testing:
Participants understand pre test information, conduct and interpret self test, and call the counselor for post test linkages.

Facilitated or supervised self testing
with aid of counselors, educators in a supervised setting, where the self testing process is conducted by the participant in a kiosk.
Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review

Nitika Pant Pai, Jigyasa Sharma, Sushmita Shivkumar, Sabrina Pillay, Caroline Vadnais, Lawrence Joseph, Keertan Dheda, Rosanna W. Peeling

1 Division of Clinical Epidemiology, McGill University Health Centre, Department of Medicine, McGill University, Montreal, Canada, 2 Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada, 3 Lung Infection and Immunity Unit, Division of Pulmonology and UCT Lung Institute, Department of Medicine and Institute of Infectious Diseases and Molecular Medicine, University of Cape Town, Cape Town, South Africa, 4 London School of Hygiene and Tropical Medicine, London, United Kingdom

Abstract

**Background:** Stigma, discrimination, lack of privacy, and long waiting times partly explain why six out of ten individuals living with HIV do not access facility-based testing. By circumventing these barriers, self-testing offers potential for more people to know their sero-status. Recent approval of an in-home HIV self-test in the US has sparked self-testing initiatives, yet data on acceptability, feasibility, and linkages to care are limited. We systematically reviewed evidence on supervised (self-testing and counselling aided by a health care professional) and unsupervised (performed by self-tester with access to phone/internet counselling) self-testing strategies.

**Methods and Findings:** Seven databases (Medline [via PubMed], Biosis, PsychINFO, Cinahl, African Medicus, LILACS, and EMBASE) and conference abstracts of six major HIV/sexually transmitted infections conferences were searched from 1st January 2000–30th October 2012. 1,221 citations were identified and 21 studies included for review. Seven studies evaluated an unsupervised strategy and 14 evaluated a supervised strategy. For both strategies, data on acceptability (range: 74%–96%), preference (range: 61%–91%), and partner self-testing (range: 80%–97%) were high. A high specificity (range: 99.8%–100%) was observed for both strategies, while a lower sensitivity was reported in the unsupervised (range: 92.9%–100%; one study) versus supervised (range: 97.4%–97.9%; three studies) strategy. Regarding feasibility of linkage to counselling and care, 96% (n = 102/106) of individuals testing positive for HIV stated they would seek post-test counselling (unsupervised strategy, one study). No extreme adverse events were noted. The majority of data (n = 11,019/12,402 individuals, 89%) were from high-income settings and 71% (n = 15/21) of studies were cross-sectional in design, thus limiting our analysis.

**Conclusions:** Both supervised and unsupervised testing strategies were highly acceptable, preferred, and more likely to result in partner self-testing. However, no studies evaluated post-test linkage with counselling and treatment outcomes and reporting quality was poor. Thus, controlled trials of high quality from diverse settings are warranted to confirm and extend these findings.

Please see later in the article for the Editors’ Summary.
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 Lois 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.

Findings In a direct head-to-head comparison of studies, we identified a pooled sensitivity about 2% lower in oral

Funding Canadian Institutes for Health Research (CIHR KRS 102067).

www.thelancet.com/infection Published online January 24, 2012 DOI:10.1016/S1473-3099(11)70368-1

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

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 wish to adopt self-testing strategies for HIV.

Pooling data from five worldwide databases, an international team of researchers found that Oraquick HIV-1/2, a saliva test sold by Pennsylvania-based OraSure, is comparable in accuracy to the traditional blood test.

Saliva HIV test as accurate as blood screening

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.

Oral HIV test results found to be less reliable

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.
Effect of Optional Home Initiation of HIV Care Following HIV Self-testing on Antiretroviral Therapy Initiation Among Adults in Malawi: A Randomized Clinical Trial

Peter MacPherson, PhD; David G. Laloo, MD; Emily L. Webb, PhD; Hendramoorthy Maheswaran, MSc; Augustine T. Choko, MSc; Simon D. Makombe, DipClinMed; Anthony E. Butterworth, PhD; Joep J. van Oosterhout, PhD; Nicola Desmond, PhD; Deus Thindwa, MSc; Stephen Bertel Squire, MD; Richard J. Hayes, DSc; Elizabeth L. Corbett, PhD

**IMPORTANCE** Self-testing for HIV infection may contribute to early diagnosis of HIV, but without necessarily increasing antiretroviral therapy (ART) initiation.

**OBJECTIVE** To investigate whether offering optional home initiation of HIV care after HIV self-testing might increase demand for ART initiation, compared with HIV self-testing accompanied by facility-based services only.

**DESIGN, SETTING, AND PARTICIPANTS** Cluster randomized trial conducted in Blantyre, Malawi, between January 30 and November 5, 2012, using restricted 1:1 randomization of 14 community health worker catchment areas. Participants were all adult (≥16 years) residents (n = 16,660) who received access to home HIV self-testing through resident volunteers. This was a second-stage randomization of clusters allocated to the HIV self-testing group of a parent trial.

**INTERVENTIONS** Clusters were randomly allocated to facility-based care or optional home initiation of HIV care (including 2 weeks of ART if eligible) for participants reporting positive HIV self-test results.

**MAIN OUTCOMES AND MEASURES** The preplanned primary outcome compared between groups the proportion of all adult residents who initiated ART within the first 6 months of HIV self-testing availability. Secondary outcomes were uptake of HIV self-testing, reporting of positive HIV self-test results, and rates of loss from ART at 6 months.

**RESULTS** A significantly greater proportion of adults in the home group initiated ART (181/8194, 2.2%) compared with the facility group (63/8466, 0.7%; risk ratio [RR], 2.94; 95% CI, 2.10-4.12; P < .001). Uptake of HIV self-testing was high in both the home (5287/8194, 64.9%) and facility groups (4433/8466, 52.7%; RR, 1.23; 95% CI, 0.96-1.58; P = .10). Significantly more adults reported positive HIV self-test results in the home group (490/8194 [6.0%] vs the facility group, 278/8466 [3.3%]; RR, 1.86; 95% CI, 1.16-2.97; P = .006). After 6 months, 52 of 181 ART initiators (28.7%) and 15 of 63 ART initiators (23.8%) in the home and facility groups, respectively, were lost from ART (adjusted incidence rate ratio, 1.18; 95% CI, 0.62-2.25; P = .57).

**CONCLUSIONS AND RELEVANCE** Among Malawian adults offered HIV self-testing, optional home initiation of care compared with standard HIV care resulted in a significant increase in the proportion of adults initiating ART.

Research Article

Will an Unsupervised Self-Testing Strategy Be Feasible to Operationalize in Canada? Results from a Pilot Study in Students of a Large Canadian University

Nitika Pant Pai,1,2 Madhavi Bhargava,2 Lawrence Joseph,3 Jigyasu Sharma,1 Sabrina Pillay,2 Bhairavi Balram,1 and Pierre-Paul Tellier4

1 Department of Medicine, McGill University, Montreal, QC, Canada H3A 1A1
2 Division of Clinical Epidemiology, McGill University and Health Centre, Montreal, QC, Canada H3A 1A1
3 Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Montreal, QC, Canada H3A 1A2
4 McGill University Student Health Services, Montreal, QC, Canada H3A 0G3

Background. A convenient, private, and accessible HIV self-testing strategy stands to complement facility-based conventional testing. Over-the-counter oral HIV self-tests are approved and available in the United States, but not yet in Canada. Canadian data on self-testing is nonexistent. We investigated the feasibility of offering an unsupervised self-testing strategy to Canadian students. Methods. Between September 2011 and May 2012, we recruited 145 students from a student health clinic of a large Canadian university. Feasibility of operationalization (i.e., self-test conduct, acceptability, convenience, and willingness to pay) was evaluated. Self-test conduct was computed with agreement between the self-test performed by the student and the test repeated by a healthcare professional. Other metrics were measured on a survey. Results. Participants were young (median age: 22 years), unmarried (97%), and 47% were out of province or international students. Approximately 52% self-reported a history of unprotected casual sex and sex with multiple partners. Self-test conduct agreement was high (100%), so were acceptability (81%), convenience (99%), and willingness to pay (74%) for self-tests. Concerns included accuracy of self-tests and availability of expedited linkages. Conclusion. An unsupervised self-testing strategy was found to be feasible in Canadian students. Findings call for studies in at-risk populations to inform Canadian policy.

Copyright © 2014 Nitika Pant Pai et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTERNET, PHONE BASED SELF TESTING STRATEGY

© Pant Pai and McGill University 2013

Nitika Pant Pai1,2*, Tarannum Behlim2, Lameze Abrahams3, Caroline Vadnais2, Sushmita Shivkumar2, Sabrina Pillay2, Anke Binder3, Roni Deli-Houssein2, Nora Engel4, Lawrence Joseph5, Keertan Dheda3

1Department of Medicine, McGill University, Montreal, Canada, 2Division of Clinical Epidemiology, Department of Medicine, McGill University and Health Centre, Montreal, Canada, 3Lung Infection and Immunity Unit, Division of Pulmonology and UCT Lung Institute, Department of Medicine and Institute of Infectious Diseases and Molecular Medicine, University of Cape Town, Cape Town, South Africa, 4Global Health, Department of Health, Ethics and Society at Maastricht University, Maastricht, The Netherlands, 5Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Montreal, Canada

Abstract

Background: In South Africa, stigma, discrimination, social visibility and fear of loss of confidentiality impede health facility-based HIV testing. With 50% of adults having ever tested for HIV in their lifetime, private, alternative testing options are urgently needed. Non-invasive, oral self-tests offer a potential for a confidential, unsupervised HIV self-testing option, but global data are limited.

Methods: A pilot cross-sectional study was conducted from January to June 2012 in health care workers based at the University of Cape Town, South Africa. An innovative, unsupervised, self-testing strategy was evaluated for feasibility; defined as completion of self-testing process (i.e., self test conduct, interpretation and linkage). An oral point-of-care HIV test, an Internet and paper-based self-test HIV applications, and mobile phones were synergized to create an unsupervised strategy. Self-tests were additionally confirmed with rapid tests on site and laboratory tests. Of 270 health care workers (18 years and above, of unknown HIV status approached), 251 consented for participation.

Findings: Overall, about 91% participants rated a positive experience with the strategy. Of 251 participants, 126 evaluated the Internet and 125 the paper-based application successfully; completion rate of 99.2%. All sero-positives were linked to

HIVSMART! App: Android, iPhone

Self Testing Strategy A VISION
ASAP award winning HIVSmart! Self testing strategy


Awards were announced October 21 at the OA Week Kickoff Event, hosted by the Scholarly Publishing & Academic Resources Coalition (SPARC) and the World Bank.

The ASAP Program Sponsors congratulate the three ASAP Award Recipients:
- Global Collaboration to Fight Malaria
- HIV Self-test Empowers Patients
- Visualizing Complex Science
EVIDENCE GAP?

- Self testing strategies personalized, tailored to languages, suited to different contexts and populations needed (African, Asian, American, European) and settings (Pant Pai, PlosMedicine 2013; Johnson C, AIDS Behavior 2014;)

- Implementation science (program science approach) - efficient, innovate, integrated service delivery models needed.
Evidence Gap?

- Impact of HIV Self testing on the economics, new infections, linkages to care (data 3 studies: US, South Africa, Malawi)

- Impact of Innovation to improve testing quality (One study: South Africa)

- Modeling benefits/cost effectiveness needed (Cambiano Aids Behavior 2014; Katz D, STD, 2014)
CONCLUSION
Challenges

- Costs and Affordability?
- Quality control (and regulation of quality kits)
- Integration challenges within health systems for an efficient service delivery
- Oral and Blood based self tests.
- Oral fluid based tests in the testing algorithms to accommodate self testing
Self test: a game changer or middle road?
HIV self-testing strategy: the middle road


Nitika Pant Pai
Author for correspondence:
Division of Clinical Epidemiology,
Department of Medicine, Royal
Victoria Hospital, McGill
University Health Centre,
V Building, 687 Pine Avenue
West Montreal, Quebec,
Canada H3A1A1
Tel.: +1 514 934 1934 x44729
Fax: +1 514 934 8293
nitika.pa@mcgill.ca

Keertan Dheda
Department of Medicine and
UCT Lung Institute, University of
Cape Town, Cape Town, South
Africa

“A self-testing strategy will only be one of the several approaches to improve testing and counseling uptake for those individuals who prefer to test with a degree of privacy.”

HIV self-testing marks the beginning of a new era for infectious diseases testing. US FDA-approved self-tests are being sold in the USA with 1-800-linked counseling. Globally, many countries are considering their approval. This editorial discusses the nuances involved in the introduction of self-testing strategies.

Background
Over the past 30 years, several facility-based HIV testing initiatives, such as voluntary testing and counseling, provider-initiated, client-centered and antenatal clinic-based testing and coun-

Some unique advantages of self-testing are: (i) it provides individuals with the option of knowing their HIV status in the privacy of their home, ensuring complete confidentiality [3]; (ii) it empowers and promotes proactivity in healthcare and personal decisions regarding sexual practices [4]; (iii) it decreases visibility associated with tests done in public settings [3]; (iv) it provides an early knowledge of sero-status, which could potentially modify human behavior positively [5]; and (v) it may encourage early linkages to treatment and with it a possible reduction in HIV transmission

Keywords: counseling • HIV • self-tests • self-testing • strategies

www.expert-reviews.com
ACKNOWLEDGEMENTS

CIHR New Investigator Award 2010

Grand Challenges Canada Stars in Global Health Award 2011, 2013

CIHR grants (Self test modelling, and evaluation of strategy in MSM)

Global Health research award, McMaster University, 2012

Maude Abbott Research Excellence Award, McGill Univ. 2013

PLOS Google Wellcome trust Open Access ASAP Innovation award 2013
Which among the following need to be worked upon for an efficient implementation of self testing strategies?

a. Affordability and costs
b. Preference and Acceptability
c. Efficient service delivery
d. Quality
e. None of the above.
Future of self tests