Implementation RESEARCH PROGRAM WITH Point-of-care tests for HIV and co-infections

EVALUATION AND INNOVATION IN INDIAN, SOUTH AFRICAN AND CANADIAN HEALTH SYSTEMS

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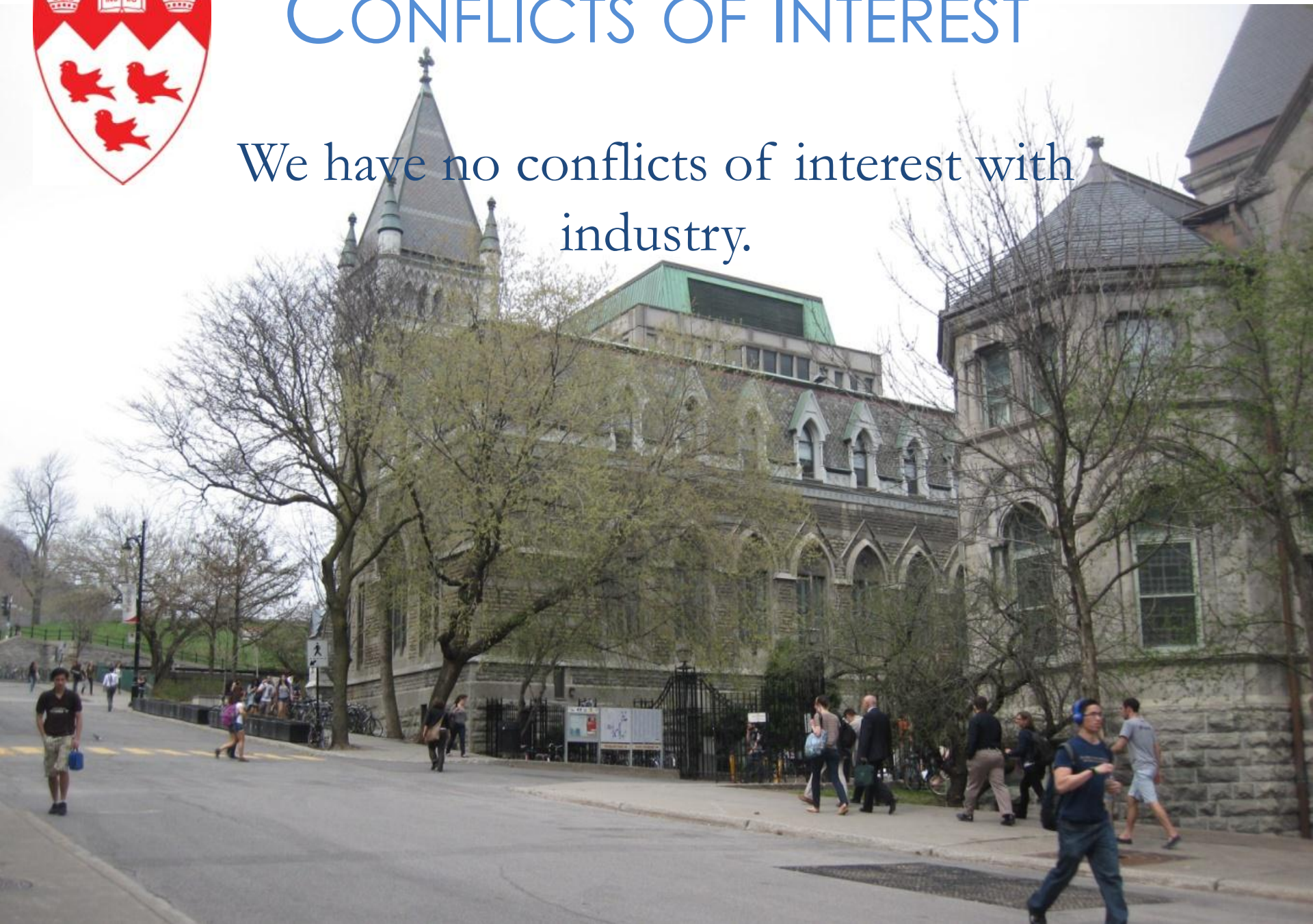
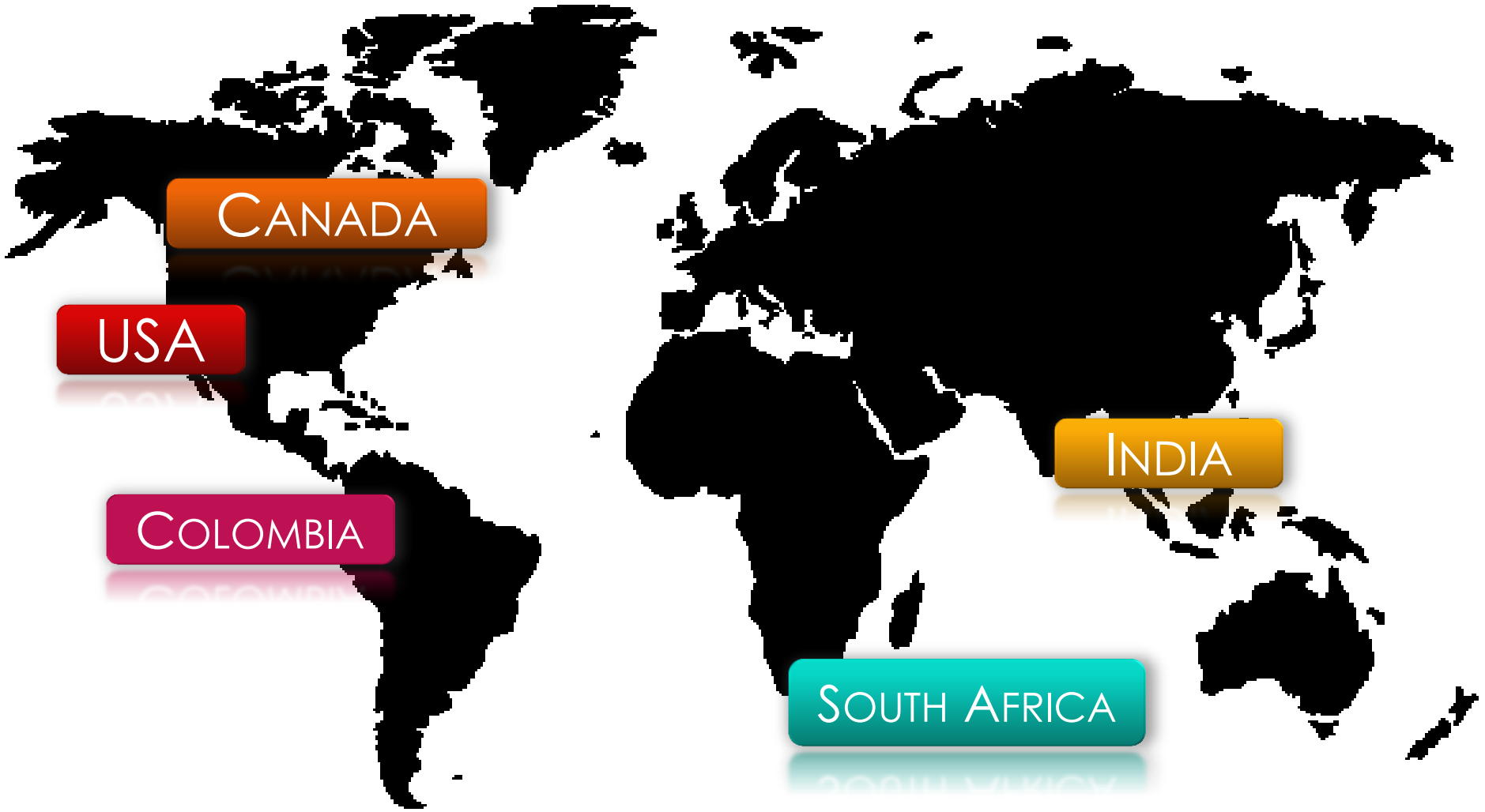
Conflicts of Interest

We have no conflicts of interest with industry.



Point-Of-Care Tests

1. Program on POCTs
2. Background work
3. Multiplex /Self testing


CANADA
USA
COLOMBIA
INDIA
SOUTH AFRICA

“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

Vision and Mission

Vision:

Innovative, expedited public health screening strategies with point-of- care tests(POCTs) for marginalized populations

Mission:

Impact public health, global public policy

New methodologies and evidence

POCT-generations

Study I: Oral test accuracy

- India's HIV epidemic was at its peak; debate
  - Inadequate screening of at risk population
- Screening by conventional methods;
  - Finger stick based POC tests;
  - No data on accuracy of Oral tests from rural settings
  - Sevagram, Rural Indian hospital India

OPEN ACCESS Freely available online

PLOS one

Evaluation of Diagnostic Accuracy, Feasibility and Client Preference for Rapid Oral Fluid-Based Diagnosis of HIV Infection in Rural India

Nitika Pant Pai[1]*, Rajnish Joshi[2], Sandeep Dogra[3], Bharati Taksande[2], S. P. Kalantri[2], Madhukar Pai[4], Pratibha Narang[2], Jacqueline P. Tulsky[5], Arthur L. Reingold[6]

1 Immunodeficiency Service, Montreal Chest Institute, McGill University Health Center, Montreal, Canada, 2 Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra, India, 3 Acharya Shri Chander College of Medical Sciences, Jammu, India, 4 Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada, 5 Department of Internal Medicine, University of California at San Francisco, San Francisco, California, United States of America, 6 Division of Epidemiology, University of California at Berkeley, Berkeley, California, United States of America

Sn=100 (95%CI:98,100)
Sp=100(95%CI 99,100)
Preference 87% first time

Table 2. Diagnostic accuracy of the OraQuick HIV-1/2 rapid test performed on oral mucosal fluid specimens

	ELISA+Western Blot positive	ELISA+Western Blot negative	Total
Oral fluid test positive	146	0	146
Oral fluid test negative	0	304	304
	146	304	450

Sensitivity = 100% (95% CI 98, 100)
Specificity = 100% (95% CI 99, 100)
Positive predictive value = 100%
Negative predictive value = 100%
Positive likelihood ratio = NA
Negative likelihood ratio = 0
doi:10.1371/journal.pone.0000367.t002

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Study II: Oraquick II: Pregnant women in labour

Problem

- About 50% women presented "unregistered"
- HIV testing not offered round-the-clock
- ART was ineffectively delivered
- **Last** window of opportunity to prevent HIV transmission

Labour room

Impact

OPEN ACCESS Freely available online

PLoS MEDICINE

Impact of Round-the-Clock, Rapid Oral Fluid HIV Testing of Women in Labor in Rural India

Nitika Pant Pai[1*], Ritu Barick[2], Jacqueline P. Tulsky[3], Poonam V. Shivkumar[2], Deborah Cohan[3], Shriprakash Kalantri[2], Madhukar Pai[4], Marina B. Klein[1], Shakuntala Chhabra[2]

1 Division of Infectious Diseases and Immunodeficiency Service, Montreal Chest Institute, McGill University Health Center, Montreal, Canada, **2** Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra, India, **3** Positive Health Program, Division of Internal Medicine, University of California San Francisco, San Francisco, California, United States of America, **4** Department of Epidemiology and Biostatistics, McGill University, Montreal, Canada

Funding: This study was in part supported by the Canadian HIV Trials Network. NPP is supported by a fellowship from the Canadian HIV Trials Network (CTN). CTN had no role in the design, conduct, analysis, interpretation of data, manuscript preparation, nor in the decision to submit this manuscript for a publication.

Competing Interests: Deborah Cohan has an investigator-initiated research award from Pfizer Pharmaceuticals.

Academic Editor: David Celentano, Johns Hopkins University, United States of America

Citation: Pai NP, Barick R, Tulsky JP, Shivkumar PV, Cohan D, et al. (2008) Impact of round-the-clock, rapid oral fluid HIV testing of women in labor in rural India. PLoS Med 5(5): e92. doi:10.1371/journal.pmed.0050092

ABSTRACT

Background

Testing pregnant women for HIV at the time of labor and delivery is the last opportunity for prevention of mother-to-child HIV transmission (PMTCT) measures, particularly in settings where women do not receive adequate antenatal care. However, HIV testing and counseling of pregnant women in labor is a challenge, especially in resource-constrained settings. In India, many rural women present for delivery without any prior antenatal care. Those who do get antenatal care are not always tested for HIV, because of deficiencies in the provision of HIV testing and counseling services. In this context, we investigated the impact of introducing round-the-clock, rapid, point-of-care HIV testing and counseling in a busy labor ward at a tertiary care hospital in rural India.

Methods and Findings

After they provided written informed consent, women admitted to the labor ward of a rural teaching hospital in India were offered two rapid tests on oral fluid and finger-stick specimens (OraQuick Rapid HIV-1/HIV-2 tests, OraSure Technologies). Simultaneously, venous blood was

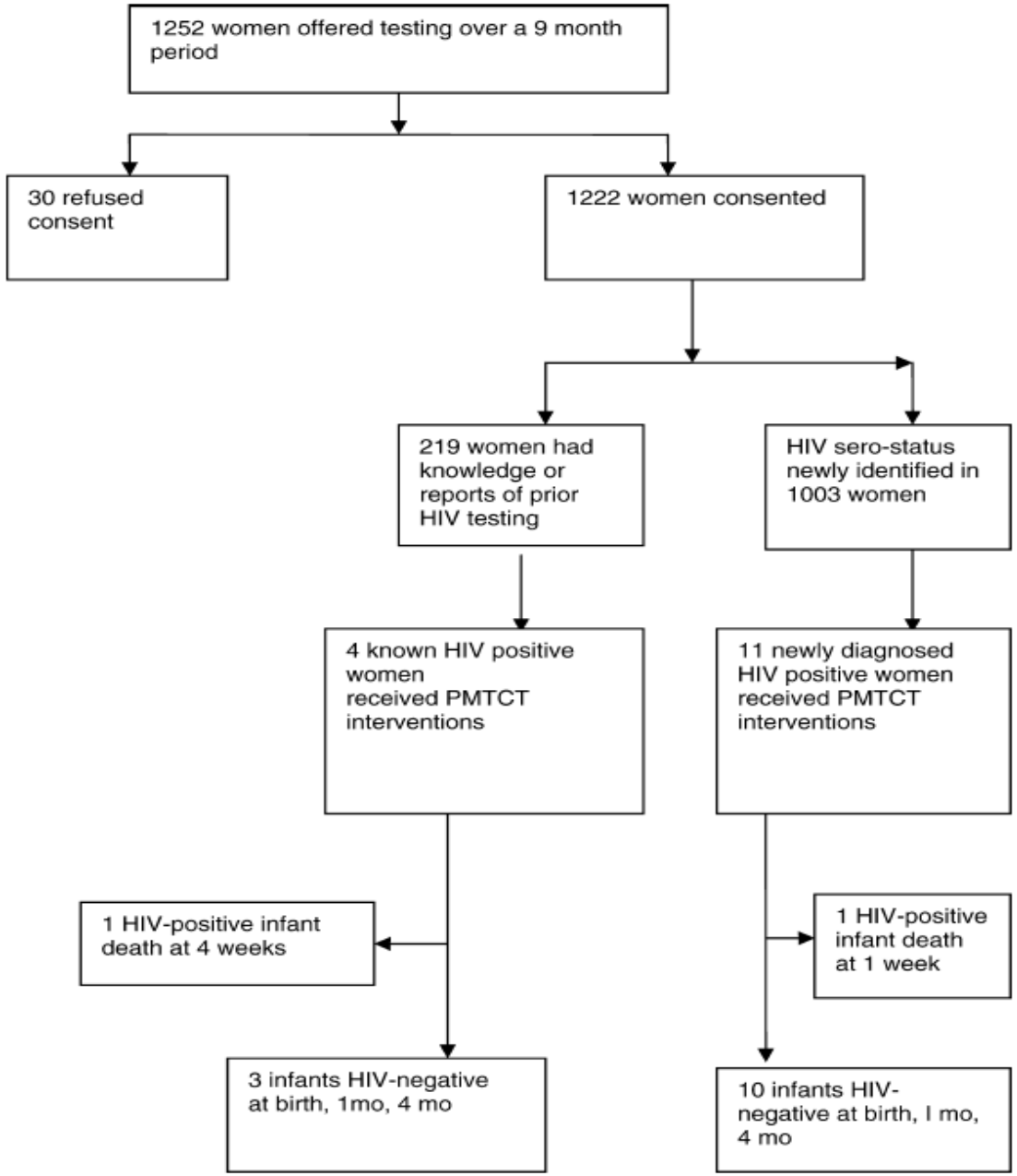

Figure 1. Flow of Participants Through the Study
doi:10.1371/journal.pmed.0050092.g001

Tropical Medicine and International Health doi:10.1111/j.1365-3156.2006.01812.x

VOLUME 12 NO 2 PP 1–12 FEBRUARY 2007

Rapid point-of-care HIV testing in pregnant women: a systematic review and meta-analysis

Nitika Pant Pai[1], Jacqueline Peterson Tulsky[2], Deborah Cohan[3], John M. Colford, Jr[1] and Arthur L. Reingold[1]

1 *McGill University Health Centre, Division of Infectious Diseases & Immunodeficiency Service, Montreal Chest Institute, QC Canada*
2 *Positive Health Program at San Francisco General Hospital, University of California, San Francisco, CA, USA*
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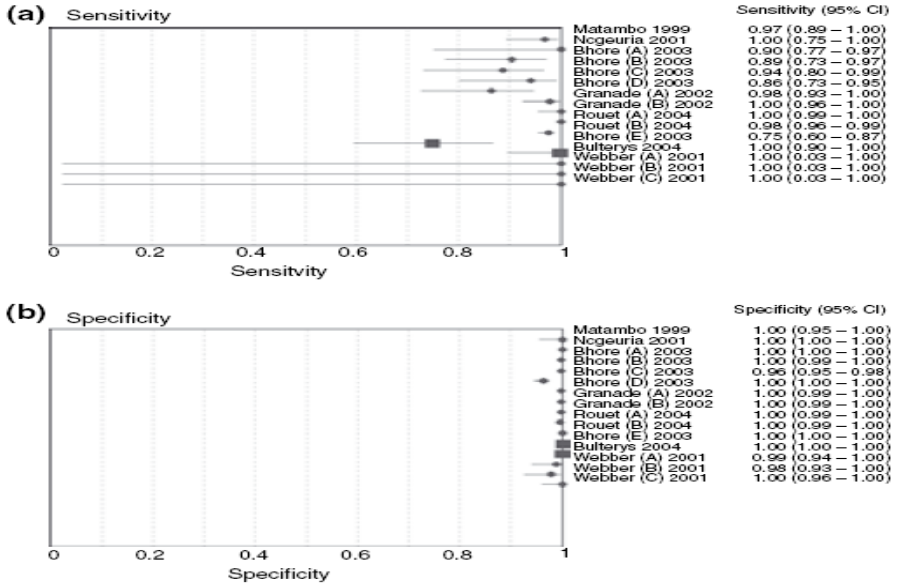

Figure 2 Forest plot of sensitivity and specificity for blood-based and oral rapid HIV tests. The point estimates of sensitivity and specificity for each study are shown as solid circles and squares with error bars (95% confidence intervals). Solid squares represent oral rapid tests and solid circles represent blood-based rapid tests.

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Oral fluid-based rapid HIV testing: issues, challenges and research directions

'... it is hoped that detection of (HIV-infected) individuals with high-quality, rapid, accurate point-of-care oral HIV tests will enable provision of early, timely and highly effective ART or expedite triage to care and prevention.'

Expert Rev. Mol. Diagn. 7(4), 325–328 (2007)

Study III: CIHR-CTN SP 243 trial: Montreal

Simultaneous Timed Triple Screening (SiTTS) strategy (2009-2011)

with POC tests for HIV, Hepatitis B and Syphilis in early pregnancy

International Journal of STD & AIDS

The Royal Society of Medicine Journals

ORIGINAL RESEARCH ARTICLE

Simultaneous triple point-of-care testing for HIV, syphilis and hepatitis B virus to prevent mother-to-child transmission in India

N P Pai MD MPH PhD*, **J Kurji** MSc†**, **A Singam** MD‡**, **R Barick** MD‡, **Y Jafari**§, **M B Klein** MD MSc*, **S Chhabra** MD‡ **and P Shivkumar** MD‡

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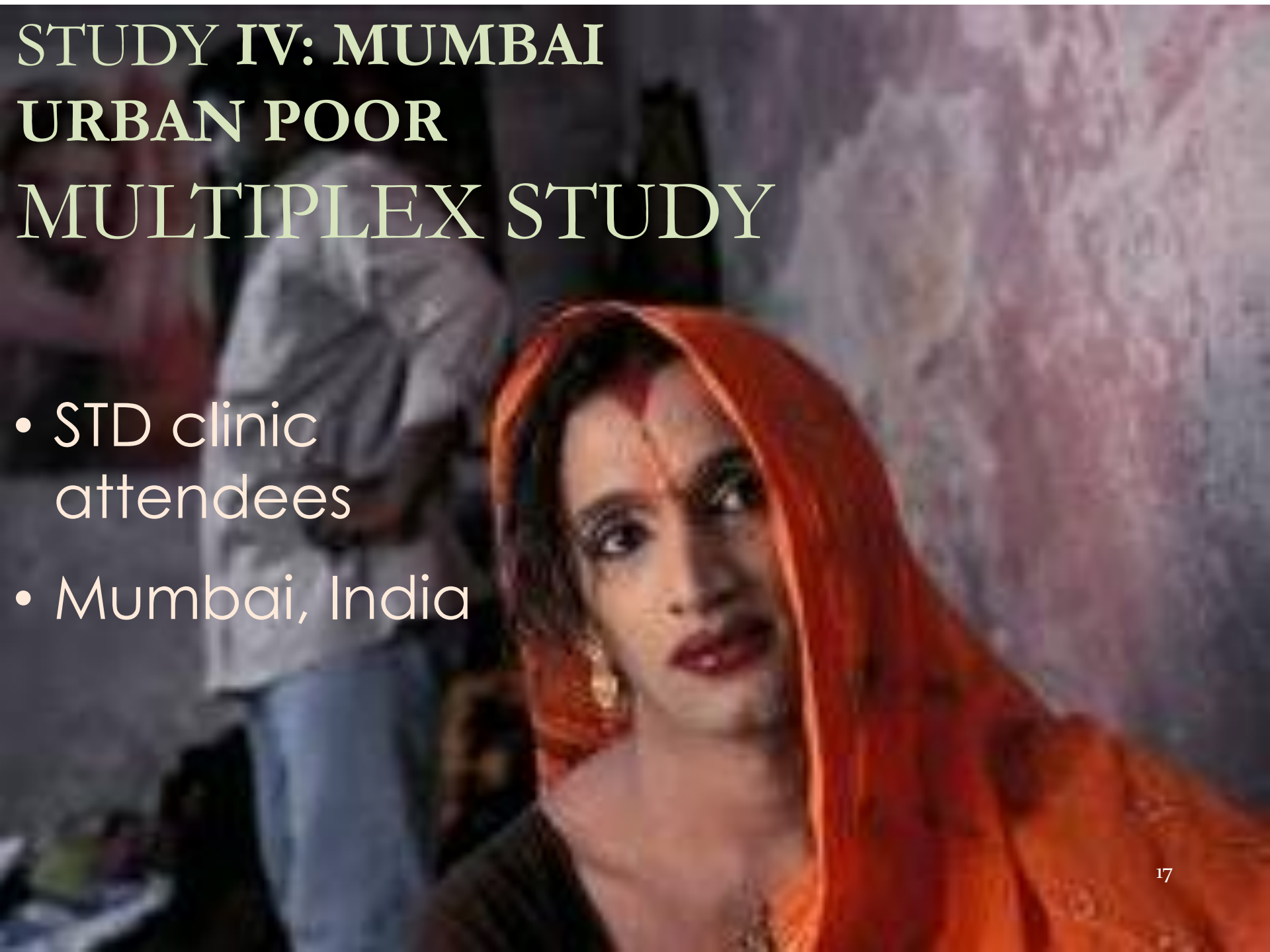
Summary: An innovative simultaneous triple point-of-care (STPOC) screening strategy for syphilis, hepatitis B and HIV with Determine® tests was offered to pregnant women presenting for antenatal care and evaluated for feasibility and preference in rural India. Of 1066 participants approached, 1046 consented, of which 1002 (96.0%) completed the strategy. Only 9% reported any history of testing in their current pregnancy. With STPOC screening, 989 women (98.7%) tested negative and 13 had preliminary positive results for infection. The total time taken was 45 minutes per participant. Mothers and infants were provided prophylaxis/treatment for HIV, syphilis and hepatitis B, with interventions initiated within 3–5 days. STPOC was preferred by 99.3% (95%CI: 98.8–99.8%) of participants, facilitated early simultaneous screening for the three infections, timely initiation of prophylaxis/treatment and was feasible in this rural setting. These data suggest that multiplexed STPOC screening for syphilis, hepatitis B and HIV in pregnancy would be desirable for women in rural India.

Keywords: HIV, syphilis, hepatitis B, point-of-care test, screening, pregnancy, antenatal care, rural, India

DOI: 10.1258/ijsa.2011.011139. *International Journal of STD & AIDS* 2012; **23**: 319–324

Study IV & V : Comparative evaluation of Multiplex testing strategy in Canada & India

STUDY **IV: MUMBAI URBAN POOR** MULTIPLEX STUDY



- STD clinic attendees
- Mumbai, India

STUDY **V:**
MULTIPLEX STUDY: MONTREAL

- Injection drug users
- Community Clinics
- Montreal, Canada

MULTIPLEX COMPARATIVE TABLE

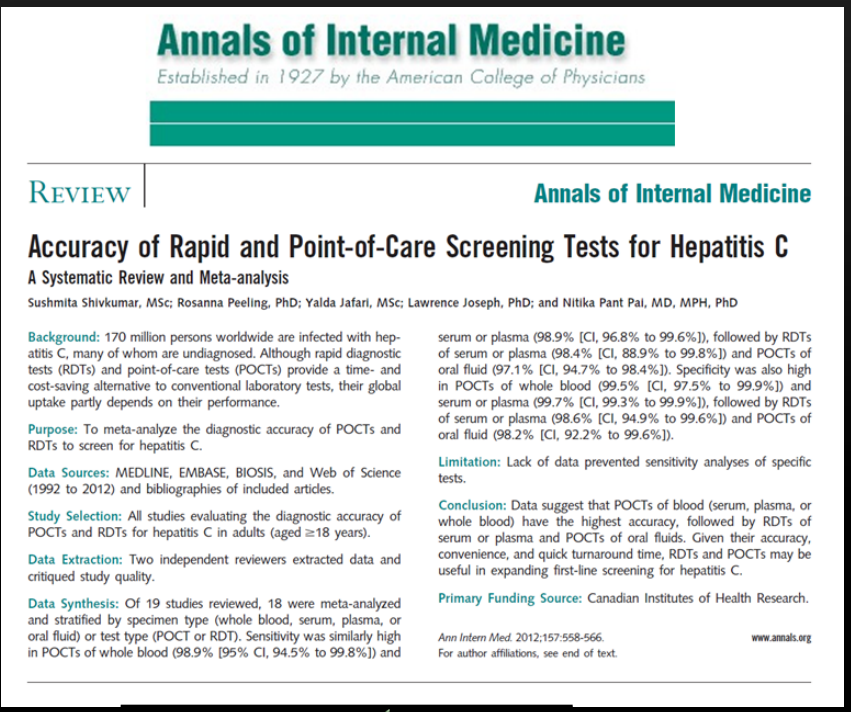
CATEGORY	MUMBAI	MONTREAL
Population	375 STI clinic attendees	109 IDU
Demographics		
•Gender	83% males	67.9% males
•Age (mean)	31.2 years	
History of testing		
•HIV	48%	96.3%
• HBV	1.62%	83.8%
•HCV	1.89%	94.3%
• Syphilis	2.7%	58.7%
Sensitivity		
•HIV	100% [95%, CI: 94.8, 100]	100% [95%, CI: 47.3, 100]
•HBV	13.3% [95%, CI: 6.6, 23.2]	n/a
•HCV	50% [95%, CI: 1.26, 98.74]	80.4% [95%, CI: 66.1, 90.6]
•Syphilis	86.1% [95%, CI: 70.5, 95.3]	100% [95%, CI: 22.4, 100]

CATEGORY	MUMBAI	MONTREAL
Specificity		
•HIV	99.7% [95%, CI: 98.3, 100]	100% [95%, CI: 97.2, 100]
•HBV	99.3% [95%, CI: 98.5, 99.9]	100% [95%, CI: 97.3, 100]
•HCV	99.7% [95%, CI: 98.5, 100]	85.3% [95%, CI: 73.8, 93.0]
•Syphilis	85.2% [95%, CI: 80.9, 88.8]	98.1% [95%, CI: 93.3, 99.8]
Prevalence		
•HIV	14.9% (56)	3.7% (4)
•HBV	20% (75)	n/a
•HCV	0.5% (2)	43% (46)
•Syphilis	9.87% (37)	1.9% (2)
Concordance		
•HIV	99.7% (κ = 0.99)	n/a
•HBV	98.9% (κ = 0.79)	n/a
•HCV	100% (κ = 1)	n/a
•Syphilis	97.3% (κ = 0.92)	n/a
Preference	61%	n/a

Evidence from other studies?

Meta-analyses

CIHR funded
POC tests for Hepatitis C, Hepatitis B, Syphilis:
F 1000 citation



Annals of Internal Medicine

Established in 1927 by the American College of Physicians

REVIEW | Annals of Internal Medicine

Accuracy of Rapid and Point-of-Care Screening Tests for Hepatitis C

A Systematic Review and Meta-analysis

Sushmita Shivkumar, MSc; Rosanna Peeling, PhD; Yalda Jafari, MSc; Lawrence Joseph, PhD; and Nitika Pant Pai, MD, MPH, PhD

Background: 170 million persons worldwide are infected with hepatitis C, many of whom are undiagnosed. Although rapid diagnostic tests (RDTs) and point-of-care tests (POCTs) provide a time- and cost-saving alternative to conventional laboratory tests, their global uptake partly depends on their performance.

Purpose: To meta-analyze the diagnostic accuracy of POCTs and RDTs to screen for hepatitis C.

Data Sources: MEDLINE, EMBASE, BIOSIS, and Web of Science (1992 to 2012) and bibliographies of included articles.

Study Selection: All studies evaluating the diagnostic accuracy of POCTs and RDTs for hepatitis C in adults (aged ≥18 years).

Data Extraction: Two independent reviewers extracted data and critiqued study quality.

Data Synthesis: Of 19 studies reviewed, 18 were meta-analyzed and stratified by specimen type (whole blood, serum, plasma, or oral fluid) or test type (POCT or RDT). Sensitivity was similarly high in POCTs of whole blood (98.9% [95% CI, 94.5% to 99.8%]) and serum or plasma (98.9% [CI, 96.8% to 99.6%]), followed by RDTs of serum or plasma (98.4% [CI, 88.9% to 99.8%]) and POCTs of oral fluid (97.1% [CI, 94.7% to 98.4%]). Specificity was also high in POCTs of whole blood (99.5% [CI, 97.5% to 99.9%]) and serum or plasma (99.7% [CI, 99.3% to 99.9%]), followed by RDTs of serum or plasma (98.6% [CI, 94.9% to 99.6%]) and POCTs of oral fluid (98.2% [CI, 92.2% to 99.6%]).

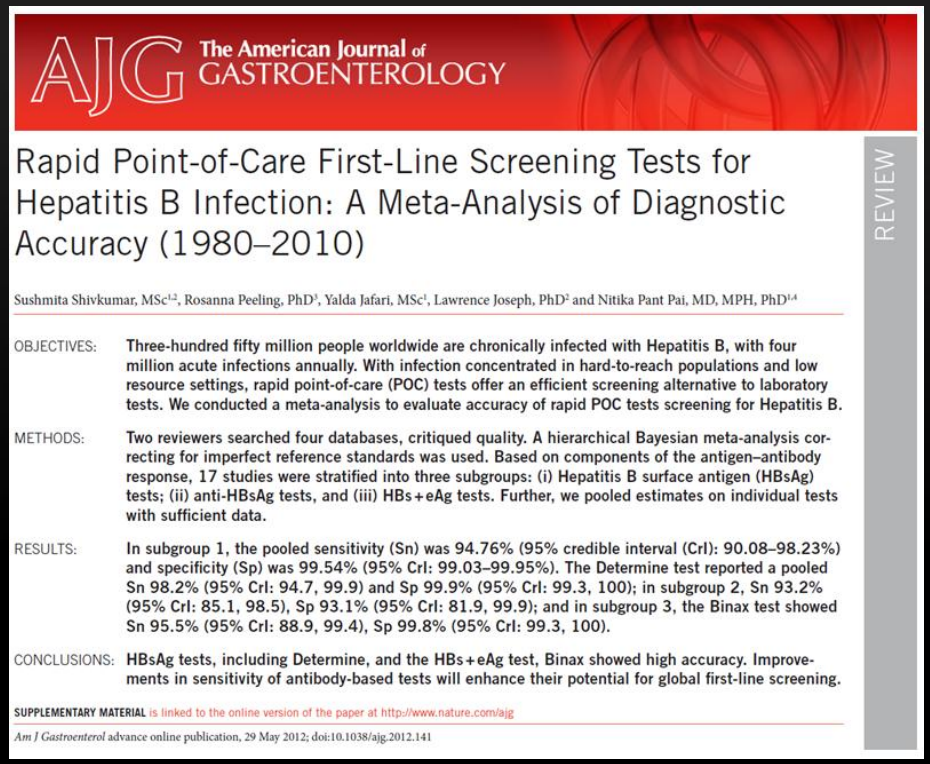
Limitation: Lack of data prevented sensitivity analyses of specific tests.

Conclusion: Data suggest that POCTs of blood (serum, plasma, or whole blood) have the highest accuracy, followed by RDTs of serum or plasma and POCTs of oral fluids. Given their accuracy, convenience, and quick turnaround time, RDTs and POCTs may be useful in expanding first-line screening for hepatitis C.

Primary Funding Source: Canadian Institutes of Health Research.

Ann Intern Med. 2012;157:558-566. www.annals.org

For author affiliations, see end of text.



AJG The American Journal of GASTROENTEROLOGY

REVIEW

Rapid Point-of-Care First-Line Screening Tests for Hepatitis B Infection: A Meta-Analysis of Diagnostic Accuracy (1980–2010)

Sushmita Shivkumar, MSc[1,2], Rosanna Peeling, PhD[3], Yalda Jafari, MSc[1], Lawrence Joseph, PhD[2] and Nitika Pant Pai, MD, MPH, PhD[1,4]

OBJECTIVES: Three-hundred fifty million people worldwide are chronically infected with Hepatitis B, with four million acute infections annually. With infection concentrated in hard-to-reach populations and low resource settings, rapid point-of-care (POC) tests offer an efficient screening alternative to laboratory tests. We conducted a meta-analysis to evaluate accuracy of rapid POC tests screening for Hepatitis B.

METHODS: Two reviewers searched four databases, critiqued quality. A hierarchical Bayesian meta-analysis correcting for imperfect reference standards was used. Based on components of the antigen–antibody response, 17 studies were stratified into three subgroups: (i) Hepatitis B surface antigen (HBsAg) tests; (ii) anti-HBsAg tests, and (iii) HBs+eAg tests. Further, we pooled estimates on individual tests with sufficient data.

RESULTS: In subgroup 1, the pooled sensitivity (Sn) was 94.76% (95% credible interval (CrI): 90.08–98.23%) and specificity (Sp) was 99.54% (95% CrI: 99.03–99.95%). The Determine test reported a pooled Sn 98.2% (95% CrI: 94.7, 99.9) and Sp 99.9% (95% CrI: 99.3, 100); in subgroup 2, Sn 93.2% (95% CrI: 85.1, 98.5), Sp 93.1% (95% CrI: 81.9, 99.9); and in subgroup 3, the Binax test showed Sn 95.5% (95% CrI: 88.9, 99.4), Sp 99.8% (95% CrI: 99.3, 100).

CONCLUSIONS: HBsAg tests, including Determine, and the HBs+eAg test, Binax showed high accuracy. Improvements in sensitivity of antibody-based tests will enhance their potential for global first-line screening.

SUPPLEMENTARY MATERIAL is linked to the online version of the paper at http://www.nature.com/ajg

Am J Gastroenterol advance online publication, 29 May 2012; doi:10.1038/ajg.2012.141

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

OPEN ACCESS Freely available online

PLOS ONE

Are *Treponema pallidum* Specific Rapid and Point-of-Care Tests for Syphilis Accurate Enough for Screening in Resource Limited Settings? Evidence from a Meta-Analysis

Yalda Jafari[1], Rosanna W. Peeling[2], Sushmita Shivkumar[1], Christiane Claessens[3], Lawrence Joseph[1,4], Nitika Pant Pai[4]*

1 Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montréal, Canada, **2** London School of Hygiene and Tropical Medicine, London, United Kingdom, **3** Institut national de santé publique (INSPQ), Montréal, Canada, **4** Division of Clinical Epidemiology, Department of Medicine, McGill University and MUHC, Montréal, Canada

Abstract

Background: Rapid and point-of-care (POC) tests for syphilis are an invaluable screening tool, yet inadequate evaluation of their diagnostic accuracy against best reference standards limits their widespread global uptake. To fill this gap, a systematic review and meta-analysis was conducted to evaluate the sensitivity and specificity of rapid and POC tests in blood and serum samples against *Treponema pallidum* (TP) specific reference standards.

Methods: Five electronic databases (1980–2012) were searched, data was extracted from 33 articles, and Bayesian hierarchical models were fit.

Results: In serum samples, against a TP specific reference standard point estimates with 95% credible intervals (CrI) for the sensitivities of popular tests were: i) Determine, 90.04% (80.45, 95.21), ii) SD Bioline, 87.06% (75.67, 94.50), iii) VisiTect, 85.13% (72.83, 92.57), and iv) Syphicheck, 74.48% (56.85, 88.44), while specificities were: i) Syphicheck, 99.14% (96.37, 100), ii) Visitect, 96.45% (91.92, 99.29), iii) SD Bioline, 95.85% (89.89, 99.53), and iv) Determine, 94.15% (89.26, 97.66). In whole blood samples, sensitivities were: i) Determine, 86.32% (77.26, 91.70), ii) SD Bioline, 84.50% (78.81, 92.61), iii) Syphicheck, 74.47% (63.94, 82.13), and iv) VisiTect, 74.26% (53.62, 83.68), while specificities were: i) Syphicheck, 99.58% (98.91, 99.96), ii) VisiTect, 99.43% (98.22, 99.98), iii) SD Bioline, 97.95%(92.54, 99.33), and iv) Determine, 95.85% (92.42, 97.74).

Conclusions: Rapid and POC treponemal tests reported sensitivity and specificity estimates comparable to laboratory-based treponemal tests. In resource limited settings, where access to screening is limited and where risk of patients lost to follow up is high, the introduction of these tests has already been shown to improve access to screening and treatment to prevent stillbirths and neonatal mortality due to congenital syphilis. Based on the evidence, it is concluded that rapid and POC tests are useful in resource limited settings with poor access to laboratories or screening for syphilis.

Editor: D. William Cameron, University of Ottawa, Canada

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Point-Of-Care Tests

1. Program on POCTs
2. Background
3. Studies on self testing

Self Test Context

Worldwide, six out of ten **individuals do not know** their HIV sero-status

Conventional facility-based testing

- Visibility and lack of confidentiality
- Long wait times
- Delay in receipt of results and linkages to treatment
- Stigma and Discrimination

- **In North America**, **25 - 30%** are lost to follow up

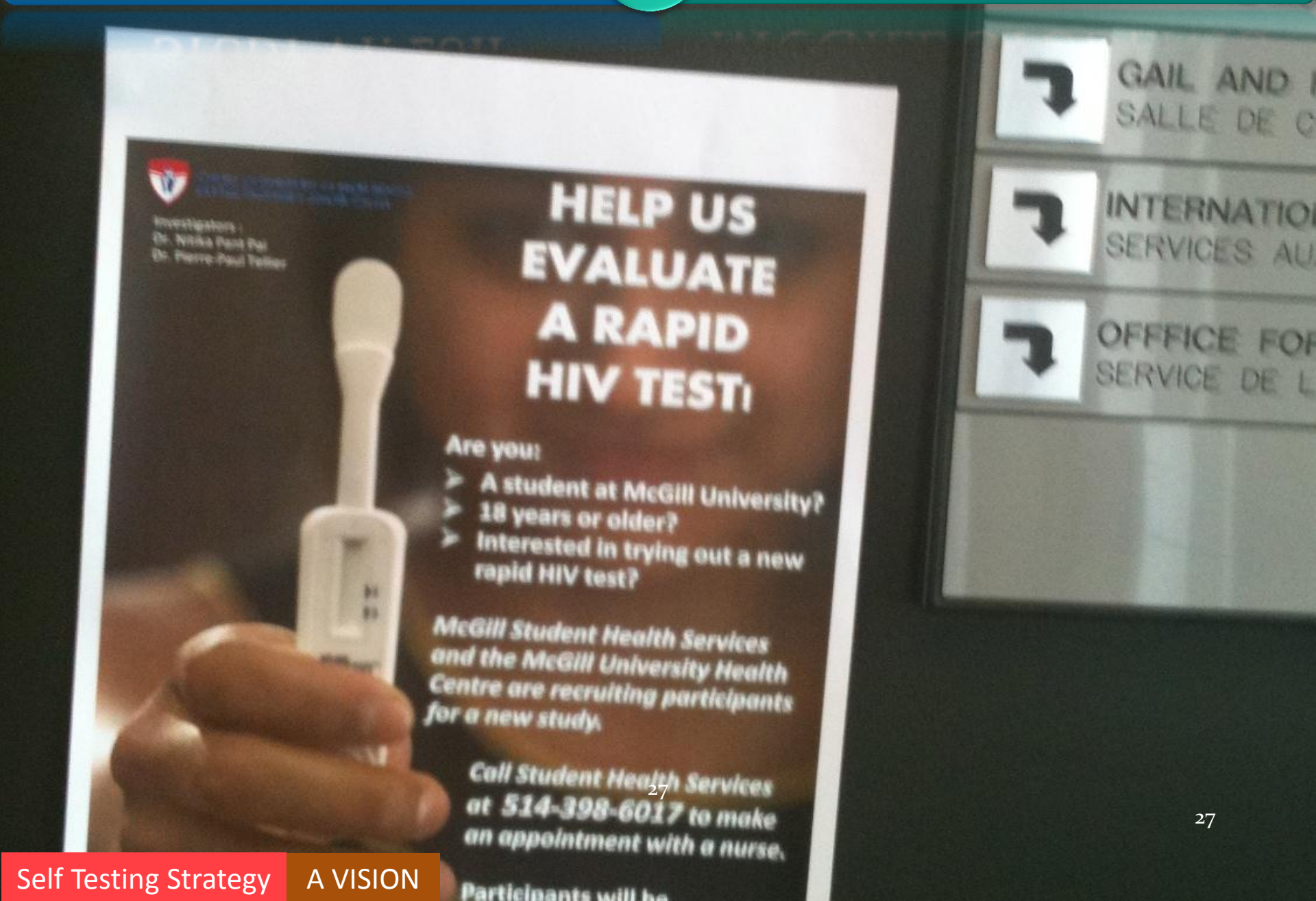
40% present late with AIDS

SELF TESTING

Grand Challenges Canada™
Grands Défis Canada™
BOLD IDEAS FOR HUMANITY.™

A. Privacy and confidentiality
B. Decreases stigma and discrimination

Study VI: 2011- McGill Students



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SELF TEST RESULTS

100% Agreement between student-led self testing and nurse-led POC test

81% preferred self-test over conventional lab-based testing

98% found self-tests convenient

84% oral self-tests non invasive and pain free

71% willingness to buy them over-the-counter

65% expressed willingness to follow up with lab-based confirmatory tests if self-tests were offered

Preferred post-test counseling options:

- Phone and internet: 43%
- Community clinics: 41%
- Pharmacies: 16%

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 infections will 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

MEDICINE

Bring HIV home test to Canada: experts

Synergistic Innovative HIV Self testing Strategy

- Highest HIV prevalence 5.3 million in the world! (22% of global HIV burden)
- Affected populations include:
  - Migrant workers, Young women
- A long history of AIDS denialism (1983-)
- About 50% of population do not seek facility-based testing –shame, stigma, discrimination, long wait times, delays in linkages to care
- A personalized tailored screening option.

CONCERNS

1. Can people self test without errors?
2. What about accuracy of these tests?

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.

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

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3099(12)7000

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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

TheScientist
MAGAZINE OF THE LIFE SCIENCES

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 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

THE TIMES OF INDIA Health & Fitness

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

Times LIVE

Saliva HIV test as accurate as blood screening

ANI Jan 25, 2012, 05:36PM IST

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.

0

Recommend

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

FDA approved in home oral HIV self test July 2012

Self Testing Strategy | A VISION

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Self Testing Strategy

A VISION

Centre universitaire de santé McGill
McGill University Health Centre
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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.

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Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review

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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, PsycINFO, 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.

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Home HIV test could help prevent spread: study

McGill researcher sees global impact

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Health Care Professionals

Grand Challenges Canada™
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BOLD IDEAS FOR HUMANITY.™

An innovative unsupervised self-testing strategy

ORAL HIV TESTS POC

Oral Test • Internet • Computers • Mobile Phone

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SELF TESTING: THE MIDDLE PATH

- An alternative that will expand the reach of conventional testing; engagement and improving access to testing marginalized communities; linked treatment solutions
- Non- judgemental, proactive, confidential; careful guided introduction; private;
- Each country requires its own strategic set ups, linkages, networks

POCT Barriers Project

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Policy Forum

Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries

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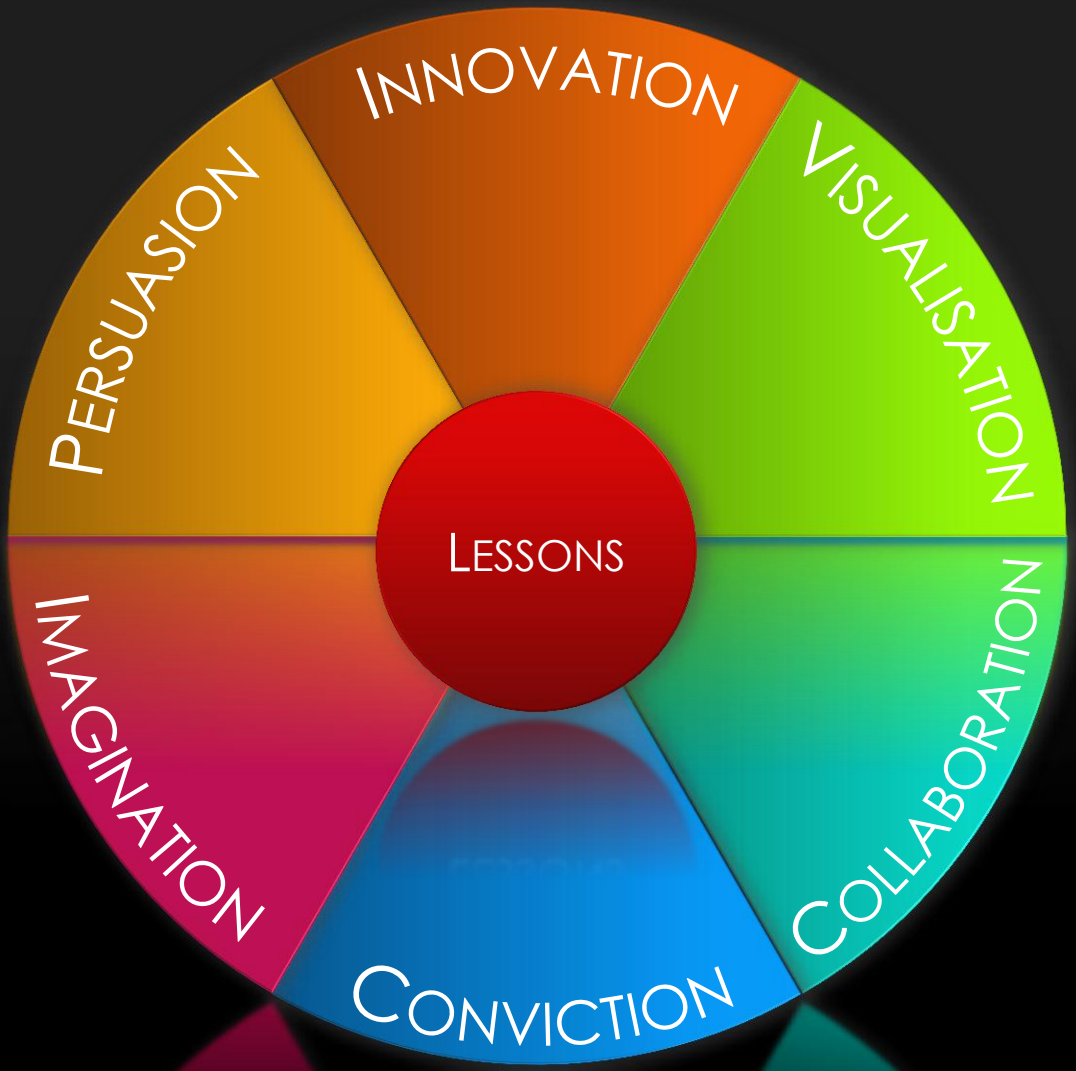

"There is no end to learning. When we feel that we have learned everything, it means that we have learned nothing."

- Kenosha Furuya

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