



# CAN SMART APPS PLUG THE SERVICE DELIVERY GAP? RESULTS FROM INDIA, CANADA, SOUTH AFRICA

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**“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*



“Imagination is more important than knowledge. Knowledge is limited. Imagination encircles the world.”

-Albert Einstein



# Structure of my talk



1

INNOVATIONS: PRODUCTS, PROCESSES AND  
POINT OF CARE TECHNOLOGIES.

2

*FIELD EVALUATION OF AiDESMART!  
APP IN INDIA*

3

*FIELD EVALUATION OF HIVSMART!!  
CANADA SOUTH AFRICA*



# HEALTH INNOVATIONS

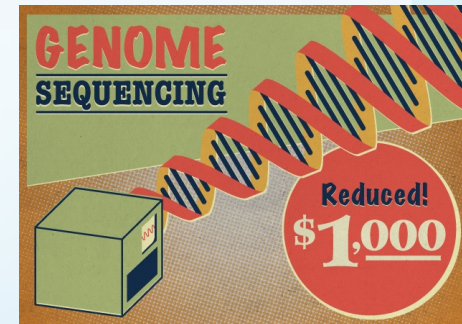
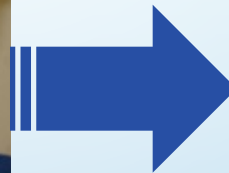
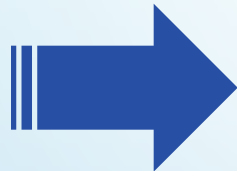
**•Innovation: Successful creation and delivery of a new product or service**



THE DOCTOR IS IN: The Swasthya Slate health tablet provides multiple diagnostics and decision support systems for frontline health workers in India.  
COURTESY OF UTSAV SHARMA

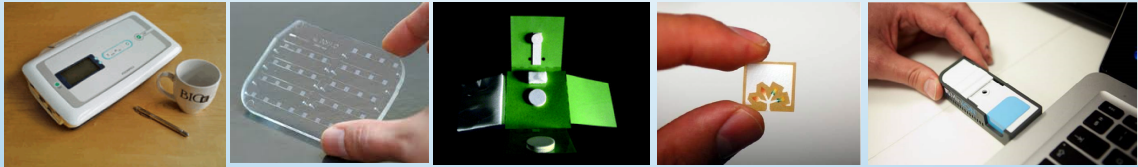
**Innovations: Product or Processes**

# PRODUCT INNOVATIONS IN HIV: POC DEVICES FOR LAB FOR HOMES





# POINT OF CLINICAL CARE (POC) TESTS RAPIDLY ACCURATELY SCREEN FOR HIV STI



# POCT Game changers!



*Current Pharmacogenomics and Personalized Medicine*, 2013, 11, 000-000

1

Editorial Article

## Point-of-Care Technologies and their Global Health Applications

Nitika Pant Pai<sup>1,2,\*</sup> and Tarannum Behlim<sup>2</sup>

<sup>1</sup>Department of Medicine, McGill University, Montreal, Quebec, Canada; <sup>2</sup>Division of Clinical Epidemiology, McGill University and Health Centre, Montreal, Quebec, Canada

**Keywords:** Global health application, diagnostics and development studies, impact, low and middle income countries, personalized medicine, point-of-care tests.





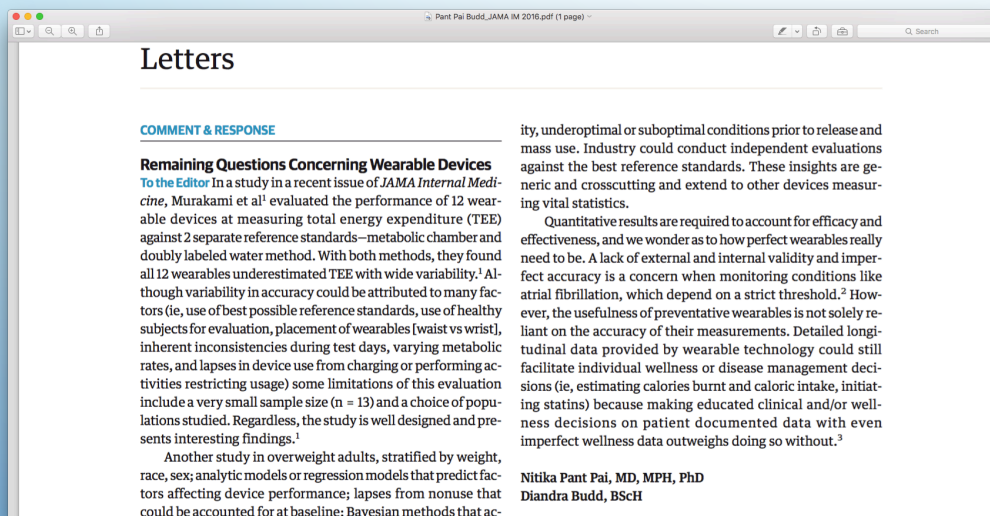
# PROCESS INNOVATIONS

- PROCESSES-
  - IMPACT SERVICE DELIVERY, BUSINESS MODELS, DISTRIBUTION CHANNELS
- HEALTH SERVICE DELIVERY (ACCESS TO CARE, EFFICIENCY OF CARE, IMPLEMENTATION OF A NOVEL STRATEGY)
  - 1. NOVEL WEB PLATFORM CONNECTS EVERY PROVIDER IN A REGION.
  - 2. SMS BASED REPORTING OF CD4 COUNT TO A REGIONAL LAB
  - 3. MAMA CARE TEXTING SERVICE TO PREGNANT WOMEN



# WHY ARE FIELD EVALUATIONS OF PRODUCT OR PROCESS INNOVATIONS IMPORTANT?

- MURAKAMI ET AL: JAMA INTERNAL MEDICINE. ACCURACY OF WEARABLE DEVICES IN ESTIMATING TOTAL ENERGY EXPENDITURE: COMPARISON OF METABOLIC CHAMBER AND DOUBLY LABELLED WATER METHOD





*“TO TURN CARING INTO  
AN ACTION, WE NEED  
TO SEE A PROBLEM,  
FIND A SOLUTION, AND  
DELIVER IMPACT.”*

*BILL GATES*



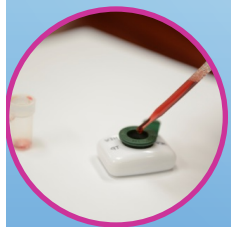
# FIELD EVALUATION INDIA

## Problem:

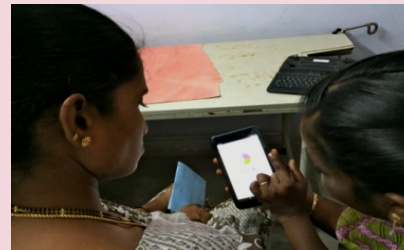
Conventional screening precipitates losses to follow up;  
12% get screened for all infections throughout pregnancy

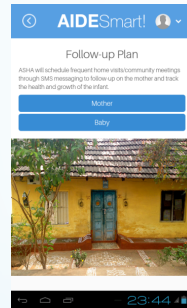


Missed opportunities to screen rural pregnant women for HIV STI  
Anemia in early pregnancy



**Solution:** Train front line professionals to offer rapid multiplex (simultaneous screening for infections and anemia with POCT), closer to their homes.





## QUESTION:

Will An App based Multiplexed point of care screening strategy expedite early, timely, high quality, early pregnancy screening for STBBI's/Anemia in pregnant women, so as to impact clinical outcomes in them and their infants?

# RESULTS



- THE SMARTAPP-BASED MULTIPLEXED POCT STRATEGY

- **IDENTIFIED NEW INFECTIONS**, FEASIBLE TO OPERATIONALIZE WITH A HIGH PATIENT ACCEPTABILITY.





#### Feedback from Patients

*"This project has helped me to detect the infections in me. I came to know how HepB is transmitted from mom to baby. I didn't get tested for Hep B anywhere outside. If I was not tested here, it would have created a problem for my baby."*

*"This project was very useful because from our village all medical facilities are far but now I got tested here in my village. If not, we wouldn't have got tested."*

*"It was useful and it was free. So we got tested or else we can't afford to get these tests done. Now my baby and I are fine."*



# Background work



**AJG** The American Journal of GASTROENTEROLOGY

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

Sushmita Shivkumar, MS<sup>1,2</sup>, Rosanna Peeling, PhD<sup>3</sup>, Yalda Jafari, MS<sup>4</sup>, Lawrence Joseph, PhD<sup>5</sup> and Nikita Pant Pai, MD, MPH, PhD<sup>6\*</sup>

**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-HBcAg 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/ng>

*Am J Gastroenterol* advance online publication, 28 May 2012; doi:10.1038/ajg.2012.141

**Annals of Internal Medicine**  
Established in 1927 by the American College of Physicians

**Annals of Internal Medicine**

**Accuracy of Rapid and Point-of-Care Screening Tests for Hepatitis C: A Systematic Review and Meta-analysis**

Sushmita Shivkumar, MS, Rosanna Peeling, PhD, Yalda Jafari, MS, Lawrence Joseph, PhD, and Nikita Pant Pai, MD, MPH, PhD

**Background:** 170 million people 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 studies.

**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 (serum, plasma, or oral fluid) or test type (POCT or RDT). Sensitivity was similarly high in POCTs of whole blood (86.9% [95% CrI: 94.5% to 99.8%]) and

serum or plasma (86.9% [CrI: 84.8% to 89.6%]), followed by RDTs of serum or plasma (86.4% [CrI: 88.2% to 99.8%]) and POCTs of oral fluid (87.1% [CrI: 84.1% to 90.6%]). Specificity was also high in POCTs of whole blood (99.5% [CrI: 97.5% to 99.9%]) and serum or plasma (99.7% [CrI: 99.3% to 99.9%]), followed by RDTs of serum or plasma (98.6% [CrI: 94.9% to 99.6%]) and POCTs of oral fluid (98.2% [CrI: 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 fluid. 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;157:568-566.  
For author affiliations, see end of text.

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<sup>1</sup>, Rosanna W. Peeling<sup>2</sup>, Sushmita Shivkumar<sup>3</sup>, Christiane Claessens<sup>4</sup>, Lawrence Joseph<sup>5</sup>, Nikita Pant Pai<sup>6\*</sup>

**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 standard tests, their underused global uptake, (ii) RDTs only, 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 pooled tests were: i) Determine, 80.6% (80.6, 82.1), ii) SD Bioline, 87.0% (72.9, 94.0), iii) Veriflex, 85.1% (72.8, 92.5), and iv) Syphilack, 74.8% (56.8, 88.4), while specificities were: i) Syphilack, 99.1% (96.3, 100), ii) Veriflex, 96.4% (91.0, 99.2), iii) SD Bioline, 95.6% (89.9, 99.3), and iv) Determine, 94.1% (86.2, 97.6). In whole blood samples, sensitivities were: i) Determine, 86.2% (77.26, 91.70), ii) SD Bioline, 84.0% (78.81, 92.61), iii) Syphilack, 74.6% (61.4, 82.1), and iv) Veriflex, 74.2% (51.02, 83.66), while specificities were: i) Syphilack, 96.0% (88.9, 99.96), ii) Veriflex, 95.4% (91.22, 99.98), iii) SD Bioline, 97.9% (92.54, 99.31), and iv) Determine, 95.8% (92.42, 97.74).

**Conclusions:** Rapid and POC, serological tests reported sensitivity and specificity estimates comparable to laboratory based serological tests, in resource limited settings, where access to laboratory is limited and where risk of patients, both to follow up and to high the introduction of these tests has already been limited 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:** Dr. William Cameron, University of Ottawa, Canada

**Received:** January 15, 2012; **Accepted:** December 12, 2012; **Published:** February 28, 2013

Editorial

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## Rapid hepatitis C tests: better than the gold standard?

Expert Rev. Med. Diagn. 13(1), 221–223 (2013)

**Nikita Pant Pai**  
Department of Medicine, Division of Clinical Epidemiology, McGill University and Montreal General Hospital, Montreal, Quebec, Canada

**Kimberly Sollis**  
Department of Clinical Immunology, London School of Hygiene and Tropical Medicine, London, UK

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**“The true value of a diagnostic test lies beyond high-test performance. Point-of-care tests can be said to be better than the gold standard if they can reach more at-risk populations, identify more cases and lead to more cases being treated than laboratory-based tests.”**

The WHO estimated that 170 million people worldwide are infected with the hepatitis C virus (HCV) (i). This is likely an underestimate, as data on chronic HCV infections are limited to some areas of the world (i). The true burden of HCV is likely comparable to that of hepatitis B virus infections (200 million) and considerably higher than the WHO estimates of 34 million people living with HIV and 36 million with syphilis (ii,iii). HCV is prevalent in men who have sex with men (MSM), injection drug users and those who are immunosuppressed, such as transplant and blood transfusion recipients (iv). An estimated 10 million individuals are coinfect

National control programs have developed guidelines for the screening of at-risk populations (v). In the USA, it is estimated that 95–50% of infected individuals are not aware of their serostatus. Studies showed that HIV-positive MSM are at higher risk than HIV-negative MSM of HCV infection (vi). This highlights the need for routine screening initiatives, especially in HIV-positive MSM. Highly sensitive and specific enzyme immunoassays and RNA detection assays are commercially available, but the test must be performed in a laboratory facility, requiring patients to return to the testing site to receive results. Studies in the USA showed that approximately half



# Background work: Are POC tests accurate? Field evaluations

Open Access Research

## BMJ Open Will a quadruple multiplexed point-of-care screening strategy for HIV-related co-infections be feasible and impact detection of new co-infections in at-risk populations? Results from cross-sectional studies

Nitika Pant Pai,<sup>1,5</sup> Rachita Dhurat,<sup>2</sup> Martin Potter,<sup>3,4</sup> Tarannum Behlmi,<sup>5</sup> Geneviève Landry,<sup>4</sup> Caroline Vadnais,<sup>5</sup> Camilla Rodrigues,<sup>6</sup> Lawrence Joseph,<sup>7</sup> Anjali Shetty<sup>8</sup>



Special Report

EXPERT REVIEWS

### Multiplexed testing for HIV and related bacterial and viral co-infections at the point-of-care: *quo vadis?*

Expert Rev. Med. Diagn. 15(4), 463-469 (2015)

Nitika Pant Pai<sup>1,2</sup> and Jana Daher<sup>3</sup>

Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>2</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>3</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>4</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>5</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>6</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>7</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada; <sup>8</sup>Department of Medicine, 1450E University Avenue, Centre for Global Health and Infectious Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada

**Keywords:** HIV and co-infections • multiplexed • point-of-care tests • simultaneous testing

EDITORIAL

FUTURE MICROBIOLOGY

### Multiplexed point-of-care assays for HIV and co-infections for resource constrained settings: a perspective



Nitika Pant Pai\*

"The impact of multiplexing is very context specific and is therefore heavily dependent on the point of placement in the care pathways."



# HIVSMART!

A GLOBAL DIGITAL STRATEGY

**FIELD EVALUATIONS IN CANADA & SOUTH AFRICA**

**HIVSMART** About

**Be Smarter than HIV.**

Learn. Assess. Diagnose. Connect. Get care.  
We imagined something unique.  
Everything is possible.  
Start now!

Available on the **App Store** **ANDROID APP ON Google play**

ALLOWED	NOT ALLOWED
Drinking water	Eating
	Drinking (other than water)
	Chewing gum

**Find Local Resources** **Download for Free** **Stage Your Risk** **Learn About HIV** **Link to Care**

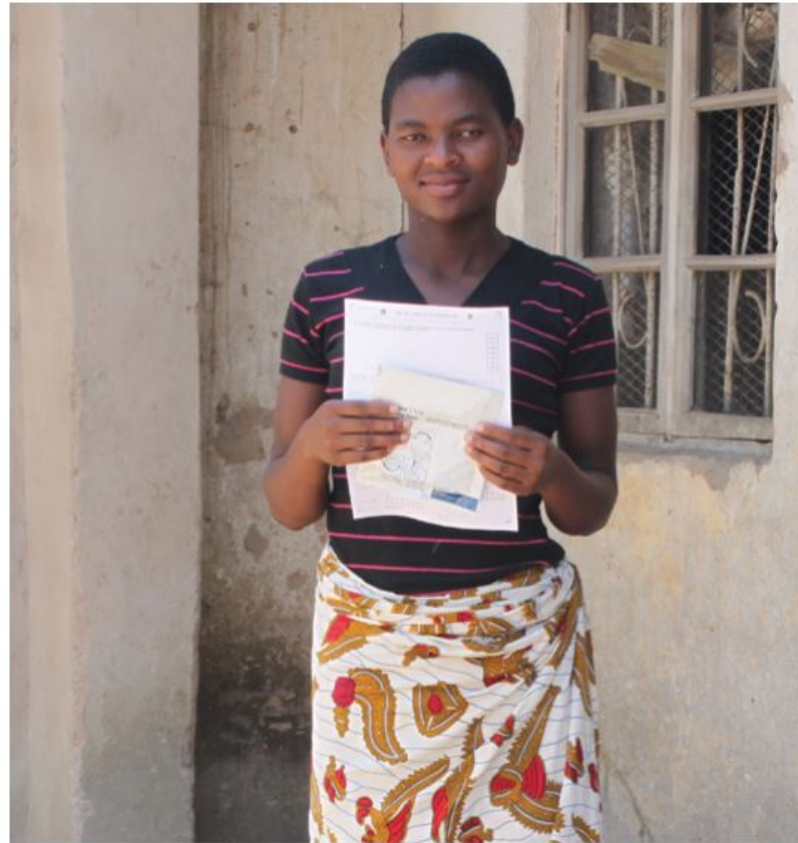
**HIVSMART**

# FDA APPROVED IN HOME ORAL HIV SELF TEST JULY 2012



Global momentum  
on self testing

A short technical update on self-testing for HIV



# WHY HIV SELF TESTING?

## PROBLEM: CONVENTIONAL TESTING

- INDIVIDUALS WORLDWIDE ARE UNWILLING TO SEEK TESTING IN HEALTH CARE FACILITIES- 40%-50% DO NOT KNOW THEIR HIV SEROSTATUS
- SOCIAL VISIBILITY
- LACK OF CONFIDENTIALITY
- LONG WAIT TIMES TO TEST RESULTS
- STIGMA AND DISCRIMINATION
- DELAY IN RECEIPT OF RESULTS
- DELAY IN LINKAGES TO TREATMENT



# HIV SELF TESTING



## NEED

- **CONFIDENTIAL**
- **CONVENIENT**
- **PERSONALIZED AND AFFORDABLE**
- **ACCESS, CONNECTS, AND LINKS TO CARE**
- **OFFERS TIME AND COST SAVINGS**

# 2012-2015 CONCERNS WITH SELF TESTS

- WHAT ABOUT ACCURACY OF SELF TESTS?
- CAN SELF TESTING OCCUR WITHOUT ERRORS?
- CONCERNS ABOUT INCREASES IN RISK BEHAVIOR POST RECEIPT OF A NEGATIVE TEST?
- WHAT ABOUT SELF HARM, FORCED TESTING AND ADVERSE EFFECTS?





# Oral tests are Accurate enough to be considered as self tests Self testing is Acceptable Preferred more likely to result in partner testing



## 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 (Orapack 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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See OnlineCor  
DOI:10.1016/S1473-3099(12)70900-0  
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OPEN ACCESS Freely available

PLOS MEDICINE

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

Nitika Pant Pai<sup>1</sup>\*, Jigyasa Sharma<sup>2</sup>, Sushmita Shivkumar<sup>1</sup>, Sabrina Pillay<sup>1</sup>, Caroline Vadnais<sup>1</sup>, Lawrence Joseph<sup>2</sup>, Keertan Dheda<sup>3</sup>, Rosanna W. Peeling<sup>4</sup>

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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.

Pant Pai N, Balram B, Shivkumar S, Martinez-Cajas JM, Claessens C, Lambert G, Peeling RW, Joseph L. 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. *Lancet Infectious Diseases*. 2012, 12(5): 373-380

# 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.



## 2015-- MOMENTUM AND SUPPORT



- **IAS VANCOUVER 2015-**
  - UNAIDS DAI- SELF TESTING-DEMOCRATIZATION OF TESTING?
- **IAS DURBAN 2016**
  - UNAIDS DAI- HIV SELF TESTING AS AN INNOVATIVE STRATEGY
  - PRE EXPOSURE PROPHYLAXIS AS A TOOL
  - UNAIDS HIV 90-90-90 (90% TESTED; 90% TREATED; 90% RETAINED)
- **WHO RECOMMENDATIONS 2016**
  - IN FAVOR OF SELF TESTING DEC 1, 2016
  - VERY NEEDED FOR THE FIRST 90- GETTING EVERYONE TO KNOW THEIR STATUS

## HIV TESTING SERVICES

WHO RECOMMENDS  
HIV SELF-TESTING

DECEMBER 2016



## Reaching people with undiagnosed HIV

HIV self-testing (HIVST) is an empowering and innovative way to reach more people with HIV and help achieve the first of the United Nation's 90–90–90 targets – for 90% of all people with HIV to know their status by 2020. Expanded use of HIVST can contribute to these global targets by reaching first-time testers, people with undiagnosed HIV or those at ongoing risk who are in need of frequent retesting.

**HIV self-testing** is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

Source: WHO 2015.

HIVST has been shown to be an empowering, discreet and highly acceptable option for many users, including key populations, men, young people, health workers, pregnant women and their male partners, couples and general population groups.

HIVST represents another forward step in line with efforts to increase patient autonomy, decentralize services and create demand for HIV testing among those unreached by existing services.



UNITAID STAR Project Zimbabwe. © UNITAID/Eric Gauss

## HIV self-testing strategy

The result of a single rapid diagnostic test (RDT) is not sufficient to make an HIV-positive diagnosis. HIVST requires self-testers with a reactive (positive) result to receive further testing from a trained provider using a validated national testing algorithm.



## THE BLOG

Featuring fresh takes and real-time analysis from  
HuffPost's signature lineup of contributors



**Nitika Pant Pai** [Become a fan](#)



Physician, Clinical Epidemiologist, Innovator, Social  
Entrepreneur, Poet, Artist

HIV Self-Testing Can Help End  
The AIDS Epidemic

Posted: 12/01/2016 6:20 am EST | Updated: 12/01/2016 6:20 am EST

# CONCERNS WITH SELF TESTS 2015- 2017



## ○ SELF TESTING

- WHAT ABOUT **LINKAGES** TO CARE POST TEST?
- WHAT ABOUT INTERPRETATION OF SELF TESTS?
- WHAT ABOUT **INNOVATIONS** TO SUPPORT THE PROCESS?
- WHAT ABOUT **PUBLIC HEALTH IMPACT, COST EFFECTIVENESS?**
- WHAT ABOUT SUSTAINABILITY?





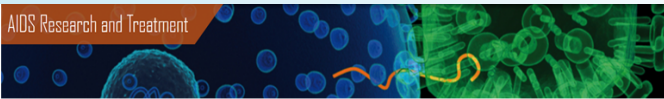
*“CAN PROCESS  
INNOVATIONS IMPACT SELF  
TESTING? IF SO, HOW?.”*

# Field testing: background work

## Self testing in Canada



AIDS Research and Treatment



### 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,<sup>1,2</sup> Madhavi Bhargava,<sup>2</sup> Lawrence Joseph,<sup>3</sup> Jigyasa Sharma,<sup>1</sup> Sabrina Pillay,<sup>2</sup> Bhairavi Balram,<sup>1</sup> and Pierre-Paul Tellier<sup>4</sup>

<sup>1</sup> Department of Medicine, McGill University, Montreal, QC, Canada H3A 1A1

<sup>2</sup> Division of Clinical Epidemiology, McGill University and Health Centre, Montreal, QC, Canada H3A 1A1

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**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.

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## Retrovirology: Research and Treatment

### Perspective on HIV Self-testing in North America: A Tale of Two Countries—US and Canada

Nitika Pant Pai

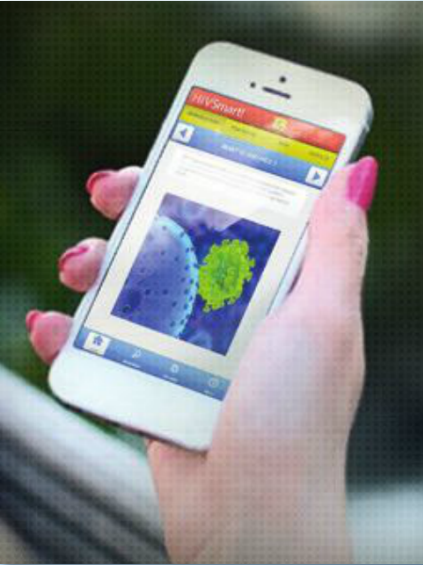
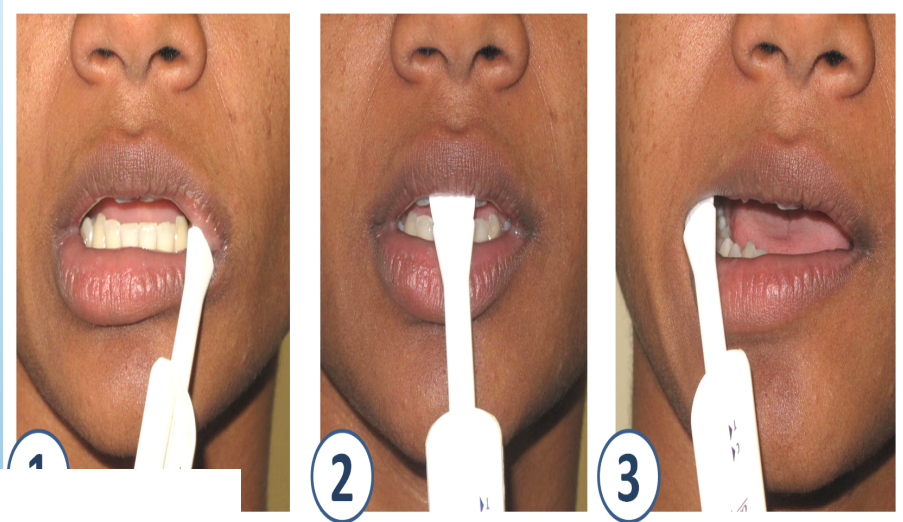
Division of Clinical Epidemiology, Department of Medicine, McGill University and Health Centre, West Montreal, Quebec, Canada.

Pant Pai N, Bhargava M, Joseph L. Will an Unsupervised Self-Testing Strategy Be Feasible to Operationalize in Canada? Results from a Pilot Study in Students of a Large Canadian University. *Aids Research and Treatment*. 2014



# HIVSMART!

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# INNOVATION



## Health Care Professionals

OPEN ACCESS Freely available online



### Will an Unsupervised Self-Testing Strategy for HIV Work in Health Care Workers of South Africa? A Cross Sectional Pilot Feasibility Study

Nitika Pant Pai<sup>1,2</sup>, Tarannum Behlim<sup>2</sup>, Lameze Abrahams<sup>3</sup>, Caroline Vadnais<sup>2</sup>, Sushmita Shivkumar<sup>2</sup>, Sabrina Pillay<sup>2</sup>, Anke Binder<sup>3</sup>, Roni Deli-Houssein<sup>2</sup>, Nora Engel<sup>4</sup>, Lawrence Joseph<sup>5</sup>, Keertan Dheda<sup>3</sup>

1 Department of Medicine, McGill University, Montreal, Canada, 2 Division of Clinical Epidemiology, Department of Medicine, McGill University and Health Centre, 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 Global Health, Department of Health, Ethics and Society at Maastricht University, Maastricht, The Netherlands, 5 Department 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



# An innovative unsupervised self- testing strategy



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The ASAP Program Sponsors congratulate the three ASAP Award Recipients:

1. Global Collaboration to Fight Malaria
2. **HIV Self-test Empowers Patients**
3. Visualizing Complex Science





## FURTHER FIELD TESTING OF AN APP OPTIMIZED STRATEGY IN CANADA

- **QS; WILL AN APP OPTIMIZED HIV SELF TESTING STRATEGY WORK FOR AT RISK POPULATION? WILL IT HELP THEM COMPLETE SELF TESTING AND IMPROVE LINKAGES TO CARE?**
- SELF TESTING STUDY 2015-2017
- SUPERVISED SELF TESTING AT A COMMUNITY CLINIC; 450 MSMS; CROSS SECTIONAL;
- SELF TESTS AND TABLET APPLICATION (**ENGLISH AND FRENCH**) PROVIDED TO THE CLINIC ATTENDEES ALONG WITH SELF TESTS;
- SELF TESTS CONDUCTED ON SITE BUT UNSUPERVISED TO SIMULATE A HOME ENVIRONMENT;
- LINKAGES OPERATIONALIZED THE SAME DAY

## ARE YOU...

- ✓ Male
- ✓ 18 years or older?
- ✓ Sexually active with men?
- ✓ Interested in trying out an innovative HIV self-testing strategy?

### To make an appointment, please contact:

Laurence Desjardins  
Sexologist, Research Assistant  
514-524-3642 x 273  
Laurence.Desjardins@lactuel.ca

Participants will be compensated for their time.



Investigators:  
Dr. Réjean Thomas  
Dr. Nitika Pant Pai



Centre universitaire de santé McGill  
McGill University Health Centre

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# The HIVSmart! self-testing study

## STUDY INFORMATION

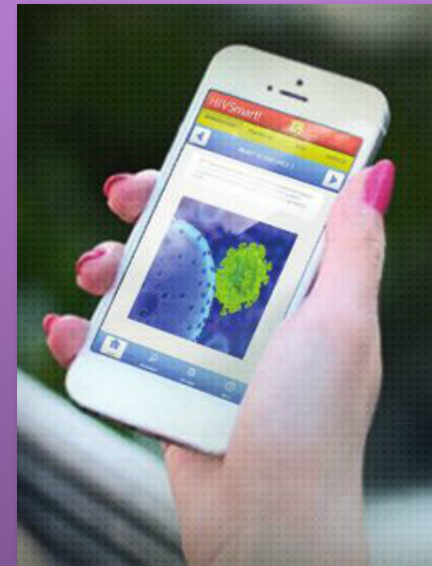


Image: International Innovation 2014

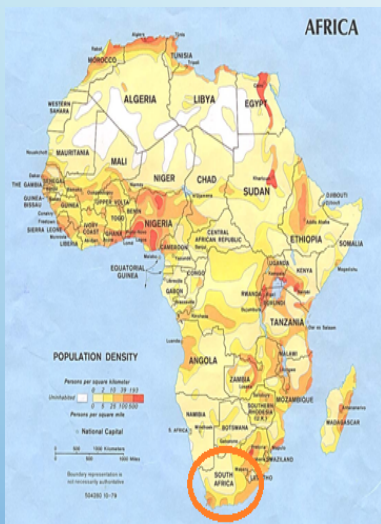


# HIVSmart! Transition to scale in South Africa co-funded by Govts of Canada and South Africa



**Department of Science & Technology,  
South Africa**

**South Africa MRC SHIP program**





# TRANSITION TO SCALE STUDY IN SOUTH AFRICA 2015-2018

- QUESTION:
- IN TOWNSHIP POPULATIONS OF SOUTH AFRICA, WILL AN APP OPTIMIZED SELF TESTING STRATEGY HELP DETECT NEW INFECTIONS, IMPROVE ACCESS, AND IMPROVE LINKAGES TO CARE FOR HIV ?

## POPULATIONS

- 3000 AT RISK UN-TESTED YOUNG ADULTS AND ADULTS >>18 YRS



# THANK YOU COLLEAGUES, MENTORS, COLLABORATORS, STUDENTS TRAINEES, PATIENTS, AND STUDY STAFF AND SPONSORS




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- DR RACHEL BAGGALEY,WHO., DR ROSANNA PEELING LSE, DR JOHN KIM, NATIONAL LABS
- LAB STAFF AND TRAINEES AND STUDENTS: JANA, MEGAN, CAROLINE, RONI, AMIT ANNA, MORGAN, SHAILLY, AMIT, FRUZZINA, SUSHMITA, ROHIT, BHAIRAVI, TIAGO, SEAN, AND OTHERS.

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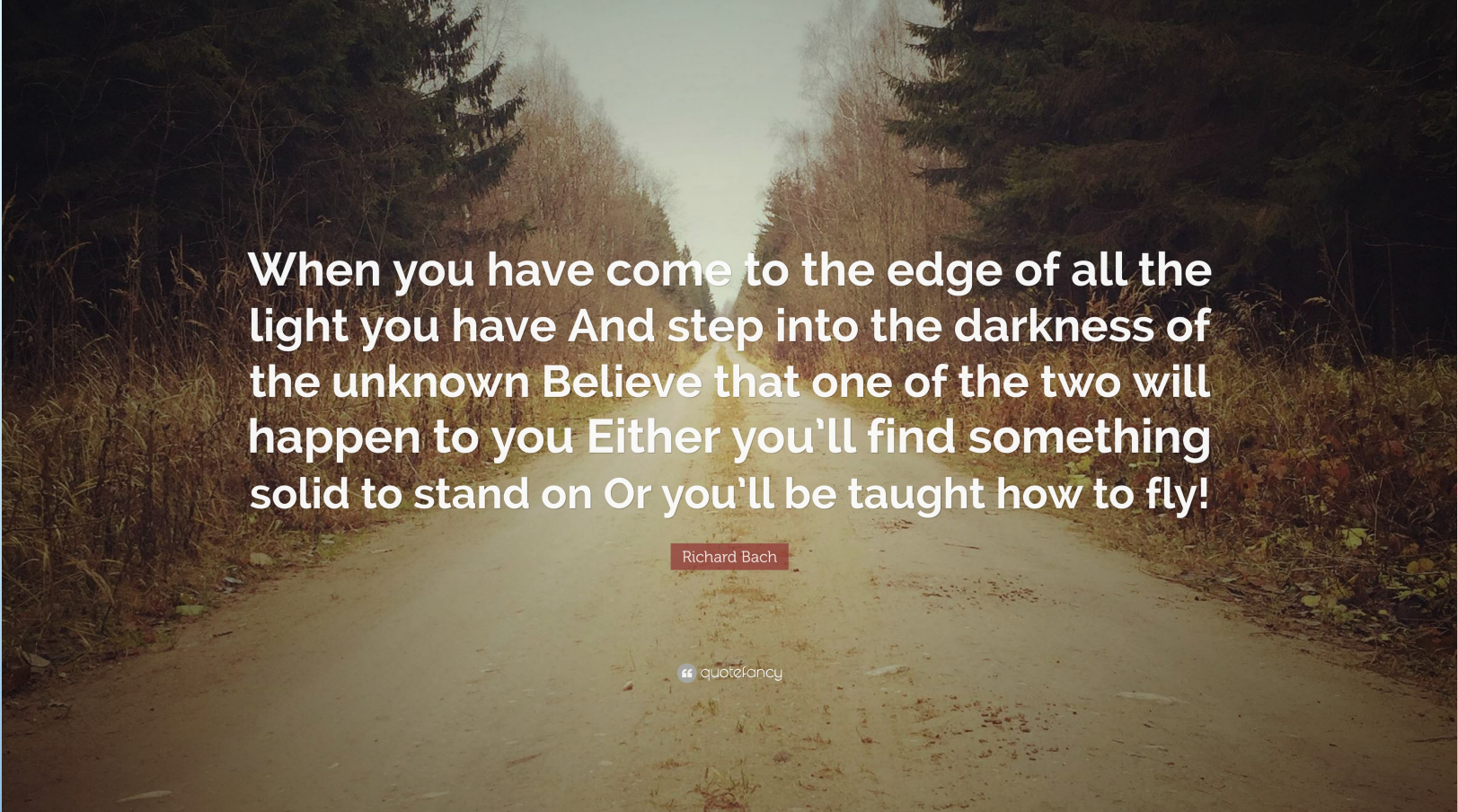


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**When you have come to the edge of all the  
light you have And step into the darkness of  
the unknown Believe that one of the two will  
happen to you Either you'll find something  
solid to stand on Or you'll be taught how to fly!**

Richard Bach

quote fancy