“Business Unusual- Finding and Testing the HIV Unawares
The case of HIVSmart!

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HIVSmart!
Its Journey from Innovation to Implementation in four sub populations & Impact.
Disclosure Statement

- I have no conflicts of interest with industry

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MY IMPLEMENTATION RESEARCH PROGRAM AT MCGILL IS ON POINT OF CLINICAL CARE (POCT) TECHNOLOGIES FOR HIV AND STBBI

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Inspired by the quote from ~ William H Foege, MD

“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.”
**HIV self-testing research in our lab since 2006-2007**

**Will an Unsupervised Self-Testing in Health Care Workers of South Africa Pilot Feasibility Study**
Nitika Pant Pai1,2, Tarannum Behlim2, Lameze Abrahams3, Sabrina Pillay3, Anke Binder3, Roni Deli-Houssein3, Nora Engle1,2

HIV self-testing research in our lab since 2006-2007

**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 Pai1, Madhavi Bhargava1, Lawrence Joseph1, Jigyasa Sharma2, Sabrina Pillay3, Bhatavdi Bhalram1, and Pierre-Paul Tellier1

**Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review**
Nitika Pant Pai1, Jigyasa Sharma2, Sudmita Shinkumar2, Sabrina Pillay3, Caroline Vadhia1, Lawrence Joseph1, Keeran Dheka1, Rosanna W. Peeling4

**What do Key Stakeholders Think About HIV Self-Testing in Canada? Results from a Cross-Sectional Survey**
N. Pant Pai1, M. Smallwood1, D. Galate1, N. Laczynski1, A. Muston1, C. Gaydou1, C. Johnston1, M. Steben1, T. Wong1, N. Engel1, J. Kim1

**Are we ready for home-based, self-testing for HIV?**

**HIV self-testing strategy: the middle road**

**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 Pai1, Bhavwan Bhan1, Sudmita Shinkumar2, Jigyasa Sharma2, Christiane Cama2, Gillian Lamb2, Rosemary Reing2, Lawrence Joseph1

**Empowering patients and public**
Dr Nitika Pant Pai is revolutionising the diagnosis of infectious diseases with a focus on HIV. Here, she discusses her work and its implications, and highlights the importance of collaboration and open-access science publishing.
Structure of my talk

1. Context: HIV Self-testing & challenges
2. Process Innovation: HIVSmart!
3. Insights & Recommendations
HIV self-testing is a self screening process whereby an end user (self-tester) performs an HIV self-test on his/her own, proactively collects his/her own sample (blood or oral), interprets, records and seeks linkages to counselling and care. (WHO HIV ST Guidelines 2016; Pant Pai, PLoS Med 2013)

- Non reactive self-test results are considered negative.
- Reactive or preliminary positive self-test results require a confirmation with a lab test.
2018: Where Are We?
HIV Self-testing as an alternative strategy to reach 30% of people with undiagnosed HIV infection

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 testing.

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.

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.

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.
Global Momentum on Self-testing

- United States, United Kingdom, France, Italy, The Netherlands, Latvia, Spain
  - Have approved self-tests for sale
- Kenya, Brazil, China, South Africa
  - Have guidelines for HIV self-testing
- 44+ countries have HIV self-testing policies in development
Self-testing Strategies

2 KINDS OF STRATEGIES

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

Facilitated/Supervised/Assisted self-testing
With the aid of counsellors or educators in a supervised setting, where the self-testing process is conducted by the participant in a kiosk.
Evidence: Self-testing studies to date globally

- **250+** studies on HIV Self testing (HIVST) worldwide (ongoing and published)
- **12+ RCTs** proven evidence of HIVST uptake, expands access, increases knowledge of sero-status, increases frequency of testing.
- **9+** studies on HIV self-testing’s cost-effectiveness
- **50+** reviews/editorials/commentaries on benefit of HIV self-testing
Issues: Challenges & Opportunities

- HIV ST Service delivery models:
  - scale up of self-tests and implementation in real life.

- Integration of HIVST
  - existing HIV testing programs and services
  - Aligned to UNAIDS 9—90-90 Targets

- Innovations: Process and product (support self-testing processes and linkages to care; blood based)
  - Interpretation and storage of self-test results
  - Initiation of linkages to treatment and retention for self test pos
  - Linkages to services for self test neg- pre-exposure prophylaxis, medical circumcision, partner notification & others.

- Linkage of HIVST to care data are weak-
Can process innovations impact HIV self-testing? If so, how?
HIVSmart! process innovation
Journey began in 2006

A global digital strategy for smart cities!
HIVSmart!: An integrated smartphone, tablet, web and cloud based HIV self-testing solution

- Smartphone, tablet based /internet based Application and database solution (Android/Iphone/Ipad/Android pads)
- Engages, informs individuals to self-screen, self-stage, self-conduct, interpret self-tests, Store result, and call with confidential lines to counselling and care
- links/retains self-testers in counselling/care
- Currently available for oral self-test & is being adapted for blood self tests.
- Developed in Canada, tested & evaluated in South Africa and Canada, scale up globally.

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HIVSmart! App is not on the market, but can be downloaded.

What else can HIVSmart! do?

- **End user:**
  - HIPAA compliant,
  - coded and anonymized information
  - Easy to use, convenient

- **Providers:**
  - LINKS to counsellors & clinics

- **Health Systems:**
  - Synergizes with existing databases and solutions

Above: home screen of the HIVSmart! app

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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

Nitika Pant Pai1,2,*, Tarannum Behlim3, Lameze Abrahams3, Caroline Vadnais3, Sushmita Shivkumar3, Sabrina Pillay3, Anke Binder3, Roni Deli-Houssein3, Nora Engel3, Lawrence Joseph3, Keertan Dheda3

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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.
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.

The HIVSmart! self-testing study

Investigators:
Dr. Réjean Thomas
Dr. Nitika Pant Pai

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Will HIVSmart! work for at risk populations in Montreal?
Will it help them complete self-testing and improve linkages to care?

- Self-tests are not yet approved in Canada
- Supervised self-testing at a community clinic La Actuel;
  - 510 MSMs; cross-sectional
- Smart tablet application (English and French) was provided to the clinic attendees along with self-tests in a kiosk
- Self-tests conducted on site but unsupervised to simulate a home environment
- Linkages to counselling and operationalized in the same day

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Results presented at the IDSA Conference 2017

- 450 MSM
  - >18 years of age, unknown sero-status
  - Average age 33 years, 84% high school or beyond, 52% tested 6 mo
- Impact:
  - Linkage: 100%
  - Usability: 98%
  - Referral: 94%
  - Accurate interpretation: 91%
- Acceptability: 98%
- Feasibility: 92%

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2015-2018
HIVSmart! Transition to Scale Study
in South African Township Populations

Department of Science & Technology, South Africa
South Africa MRC SHIP program
2017: HIVSmart! Platform developed
Portable, convenient, platform and device agnostic, global strategy
ENGAGES, INFORMS, CONDUCTS, RETAINS
Multi lingual- Xhosa, Afrikaans, Zulu, Swahili, French, English

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HIVSMART! TRANSITION TO SCALE STUDY IN TOWNSHIPS OF SOUTH AFRICA 2015-2018/2019

- Question
  - Will HIVSmart! oral HIV ST allow choice, increase referrals, detect new infections and increase linkages to care?

- Populations
  - 3000 At risk un-tested young adults and adults >18 yrs

- Study design
  - Offered a choice of unsupervised HIV self-testing in homes or private spaces, or supervised HIV self-testing (in clinics),
  - Cohort study
  - Concurrent follow up of conventional testing (ConvHT) in geographically separated clinics.

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HIV ST Action Points: Insights & Recommendations

- Scale up and sustainability of HIV self-testing
  - Rapid scale up in fast track cities; we need to synergize HIV self-testing within existing programs
  - Expand functionality of programs and improve integration with clinics offering ART and services.
  - Service delivery solutions to secondary distribution of self-test kits require an action plan from access to retention
  - NEED to Incorporate innovations within country programs
  - Data on scale up, impact, costs and cost-effectiveness are needed.
Key messaging for HIV ST
Self-testing is a middle road

- Self-testing is a middle road to engagement of populations who are not traditionally served by conventional methods
  - anonymous private testing, and expanded access!
  - USP of convenience, confidentiality, affordability, and non-invasiveness
  - Little evidence of self-harm or domestic abuse consequent to self-tests
  - **Does not stand to replace conventional testing**
  - If we synergize our energies, and initiate timely treatment, we can expand the full benefits of HIV ST with expanded access, timely linkages to care to reduce transmission in communities.

- We need to adapt the HIV ST strategies to unique sub-populations and most importantly, to their socio-cultural context and think scale.
Recommendations!

1. Rapid availability and approvals of quality assured and approved self-tests (Oral or Blood based)
2. Affordable self-tests (for the world!)
3. Synergistic collaborations between stakeholders, and effective communications to think scale up!
4. Implementation of policies
5. Public private partnerships for counselling
6. Innovations and payment systems
7. Business models re-think and models for counselling
8. **Scale up and sustainability of HIVST within existing HIV testing/treatment programs:**
9. **Different implementation models:** Pharmacies, community based organizations, outreach clinics, mobile vans, vending machines, private clinic kiosks, hospital based kiosks, web based HIVST, App based HIV ST.
FOR IMMEDIATE RELEASE

IAPAC, RI-MUHC, SYMPACT-X Announce Partnership to Implement HIVSmart!™ Self-Testing App in High HIV Burden Fast-Track Cities
McGill researcher develops new HIV self-testing app ‘HIVSmart’

November 28, 2017 | Science & Technology | by Odéane Mariscal

Human Immunodeficiency Virus (HIV) is one of the deadliest viruses in the world and has claimed over 35 million lives to date. Recently, Nitika Pant Pai, Associate Professor at the McGill Department of Medicine and researcher at The Research Institute of McGill University Health Centre has helped develop a new app called HIVSmart! designed to reduce the spread of this lethal virus. HIV attacks human CD4 T-cells—a type of white blood cell that usually protects us from disease. Without these immune cells, HIV patients are defenseless against other infections and succumb to illnesses that healthy patients would otherwise be able to fight off.

Nitika Pant Pai of Montreal plans to ‘reverse innovate’ her HIVSmart app, trying it out first in Canada later extending it to the developing world.

The Research Institute of the McGill University Health Centre

App puts process of AIDS testing in the palm of your hand

Ask Nitika Pant Pai about her work on a new self-test for HIV/AIDS and she’ll tell you: an app for that.

Canada’s Top Medical Doctoral University 2018: McGill University

Leading innovation on artificial intelligence, HIV and neuroscience attracts students from 140 countries to McGill’s campus in the heart of Montreal

Jennifer Goldberg

Williams to Arcade Fire’s Win Butler and singer-songwriter Leonard Cohen. The school has also produced more Rhodes Scholars (142) and Nobel laureates (12) than any other university in Canada.

MORE: Canada’s Top Medical/Doctoral Schools 2018

McGill is lauded for its superior Ph.D. programs and medical school. Some of its alumni’s more notable accomplishments include mapping the brain’s motor cortex, inventing Plexiglas and discovering that atoms are divisible. Today’s researchers continue that groundbreaking tradition with innovations in green chemistry, food science and computer science. In September, the Research Institute of the McGill University Health Centre (RI-MUHC) announced its role in implementing HIVSmart, a cloud-based app that facilitates HIV self-testing and care in high-risk cities worldwide. Further, scientists from the Douglas Mental Health University Institute’s Translational Neuroimaging Laboratory recently used artificial intelligence and big data to recognize the signs of dementia two years before its onset. Also in the field of AI, McGill has a strong connection to Facebook’s first Canadian AI lab; Joëlle Pineau, an associate professor of computer science, was recently tapped to head up the Montreal facility.
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"Be the change you wish to see in the world."

~Mahatma Gandhi
For HIVSMART!& results of HIVST projects, please contact us at

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