3-4 MAY 2018

2018 CONTROLLING THE HIV EPIDEMIC S U M M I T

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

Nitika Pant Pai, MD, MPH, PhD

Associate Professor, Department of Medicine, McGill University
Division of Clinical Epidemiology & Infectious Diseases
McGill University Health Centre







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



Disclosure Statement

- I have no conflicts of interest with industry
- My research program has been supported by grants from the CIHR, FRQS, NIH, Grand Challenges Canada, South African Medical Research Council, Department of Science & Technology South Africa & The Bill & Melinda Gates Foundation.















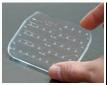


MY IMPLEMENTATION RESEARCH PROGRAM AT MCGILL IS ON POINT OF CLINICAL CARE (POCT) TECHNOLOGIES FOR HIV AND STBBI



















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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



OPEN @ ACCESS Freely available online

Will an Unsupervised Self-Testing High- and Low-Risk Populations: A Systematic Review in Health Care Workers of South Af Nitika Pant Pail*, Jigyasa Sharma², Sushmita Shivkumar¹, Sabrina Pillay¹, Caroline Vadnais¹, **Pilot Feasibility Study**

Sabrina Pillay², Anke Binder³, Roni Deli-Houssein², Nora Engel

1 Department of Medicine, McGill University, Montreal, Canada, 2 Division of Clinical Epidemiology Montreal, Canada, 3 Lung Infection and Immunity Unit, Division of Pulmonology and UCT Lung Institut Molecular Medicine, University of Cape Town, Cape Town, South Africa, 4 Global Health, Department of Netherlands, 5 Department of Epidemiology, Biostatistics & Occupational Health, McGill University, M

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PLOS MEDICINE

Supervised and Unsupervised Self-Testing for HIV in

Lawrence Joseph², Keertan Dheda³, Rosanna W. Peeling⁴

1 Division of Clinical Enidemiology, McGill University Health Centre, Department of Medicine, McGill University, Montreal, Canada, 2 Department of Enidemiology Biostatistics and Occupational Health, McGill University, Montreal, Canada, 3 Lung Infection and Immunity Unit, Division of Pulmonology and UCT Lung Institu Nitika Pant Pai 1,2 *, Tarannum Behlim², Lameze Abrahams³, Ca Tropical Medicine, London, United Kingdom

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.

AIDS Behav DOI 10.1007/s10461-017-1764-z

ORIGINAL PAPER

What do Key Stakeholders Think About HIV Self-Testing in Canada? Results from a Cross-Sectional Survey

N. Pant Pai¹ · M. Smallwood¹ · D. Gulati² · N. Lapczak¹ · A. Musten³ · C. Gaydos⁴ · C. Johnston⁵ · M. Steben⁶ · T. Wong⁷ · N. Engel² · J. Kim⁸

JDS 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, 1,2 Madhavi Bhargava, Lawrence Joseph, Jigyasa Sharma, Sabrina Pillay, 2 Bhairavi Balram,1 and Pierre-Paul Tellier4

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The BMJ

Nitika Pant Pai: HIV self-testing can help end the AIDS epidemic

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

THE LANCET Infectious Diseases

Head-to-head comparison of accuracy of a rapid point-of-care (1) 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,

HIV self-testing strategy: the middle road

Expert Rev. Mol. Diagn. 13(7), 639-642 (2013)

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 it implications, and highlights the importance of collaboration and open-access science publishing

18-05-04



Structure of my talk

Context: HIV Self-testing & challenges

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Process Innovation: HIVSmart!

3 Insights & Recommendations



What is HIV Self-testing (HIV ST)?

- ► 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?



World Health Organization



HIV TESTING SERVICES

WHO RECOMMENDS HIV SELF-TESTING

DECEMBER 2016



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 20

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.

2018-05-02018-05-04





- 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 selftesting policies in development





Self-testing Strategies

2 KINDS OF STRATEGIES

Unsupervised/Unassisted self-testing:

Participants understand pretest 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 selftesting process is conducted by the participant in a kiosk.





- 250+ studies on HIV Self testing (HIVST) worldwide (ongoing and published)
- 12+ RCTs proven evidence of HIVST uptake, expands access, increases knowledge of serostatus, increases frequency of testing.
- 9+ studies on HIV self-testing's cost-effectiveness
- 50+ reviews/editorials/commentaries on benefit of HIV self-testing





OPEN access Freely available o

PLOS MEDICINE

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

Nitika Pant Pai¹*, Jigyasa Sharma², Sushmita Shivkumar¹, Sabrina Pillay¹, Caroline Vadnais¹, Lawrence Joseph², Keertan Dheda³, Rosanna W. Peeling⁴

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

Assessment of the Potential Impact and Costeffectiveness of Self-Testing for HIV in Low-Income Countries

Valentina Cambiano, Deborah Ford, Travor Mabugu, Sue Napierala Mavedzenge, Alec Miners, Owen Mugurungi, Fumiyo Nakagawa, Paul Revill, and Andrew Phillips

Johnson CC et al. Journal of the International AIDS Society 2017, 20:21594 http://www.jiasociety.org/index.php/jias/article/view/21594 | https://doi.org/10.7448/IAS.20.1.21594



Review article

Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis

Cheryl C Johnson^{1§}, Caitlin Kennedy², Virginia Fonner³, Nandi Siegfried^{1,4}, Carmen Figueroa¹, Shona Dalal¹, Anita Sands⁵ and Rachel Baggaley¹

⁵Corresponding author: Cheryl C Johnson, Department of HIV, World Health Organization, 20 Avenue Appia, Geneva 1201, Switzerland. Tel: +41 22 791 4335. (Johnsonc@who.int)

RESEARCH ARTICLE

A Finger-Stick Whole-Blood HIV Self-Test as an HIV Screening Tool Adapted to the General Public

Thierry Prazuck¹*, Stephen Karon¹, Camelia Gubavu¹, Jerome Andre², Jean Marie Legall³, Elisabeth Bouvet⁴, Georges Kreplak⁵, Jean Paul Teglas⁶, Gilles Pialoux⁷

- 1 Department of Infectious Diseases, Centre Hospitalier Régional, Orléans, France, 2 HF Prevention, Trappes, France, 3 Aides, Paris, France, 4 Department of Infectious Diseases, Hôpital Universitaire Bichat Claude Bernard, Paris, France, 5 Centre de Biologie du Chemin Vert (CBCV), Paris, France, 6 INSERM INED, U822, Hôpital Kremlin Bicêtre, Le Kremlin-Bicêtre, France, 7 Department of Infectious Diseases, Hôpital Tenon, Paris, France
- * thierry.prazuck@chr-orleans.fr

2018-05-04





- ► 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.

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Linkage of HIVST to care data are weak-

2018-05-04



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.













Above: home screen of the HIVSmart! app

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



2009-2011

FIELD TESTING: FIRST PROTOTYPE OF HIVSMART! WAS EVALUATED IN MONTREAL





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 Jigyasa Sharma, ¹ Sabrina Pillay, ² Bhairavi Balram, ¹ and Pierre-Paul Tellier⁴

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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.

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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



2011-2013 SECOND PROTOTYPE

WEB HIVSMART! FOR HEALTH CARE PROFESSIONALS WAS EVALUATED IN SOUTH AFRICA







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^{1,2}*, Tarannum Behlim², Lameze Abrahams³, Caroline Vadnais², Sushmita Shivkumar², Sabrina Pillay², Anke Binder³, Roni Deli-Houssein², Nora Engel⁴, Lawrence Joseph⁵, Keertan Dheda³

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.



BOLD IDEAS FOR HUMANITY."

An innovative unsupervised selftesting strategy



ARE YOU...

- ✓ Male
- √18 years or older?
- Sexually active with men?
- ✓ Interested in trying out an innovative HIV selftesting 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





The HIVSmart! self-testing study

STUDY INFORMATION









THIRD PROTOTYPE HIVSMART! APP EVALUATED IN 2015-2017

IN MONTREAL IN MSM POPULATIONS FROM LA ACTUEL



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%;





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

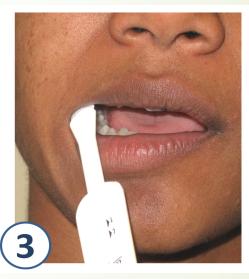
Portable, convenient, platform and device agnostic, global strategy ENGAGES, INFORMS, CONDUCTS, RETAINS

Multi lingual- Xhosa, Afrikaans, Zulu, Swahili French, English















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.

















- 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 selftest 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.

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2018-05-04



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!

- Rapid availability and approvals of quality assured and approved selftests (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.

2018-05-04









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!'

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 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 defenceless 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 Cana later extending it to the developing world.

The Research Institute of the McGill University Health Centre

App puts process of AIDS testing in the palr vour hand

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



INNOVATION

© Copyright UNE APPLICATION POUR DÉPISTER LE VIH



The Story of HIVSmart!

A Canadian Integrated Innovation for HIV Self-Testing to Help End the HIV Epidemic

by Dr. Nitika Pant Pai



EDUCATION HUB

OUR ARCHIVES THE CANADA PROJECT CONTACT

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

October 11, 2017

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.

Acknowledgements & Thanks











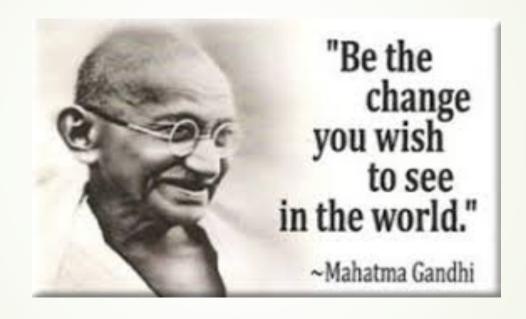








- -Dr Jose Zuniga, President, & IAPAC Staff.
- -Dr Peter Singer, CEO, Grand Challenges Canada
- -Dr Professor Keertan Dheda UCT, South Africa
- -Dr Costas Karatzas of the RI MUHC, Canada
- -Dr Ali Esmail, & Dr Suzette Pretorius, UCT South Africa
- -Marietjie Pretorius & Maria Engel, UCT South Africa
- -Dr Nora Engel, Maastricht University, Netherlands
- -Dr Alice Anne Zwerling, U of Ottawa, Canada
- -Dr Paramita Saha Choudhuri, McGill University
- --Students, staff, trainees of UCT, McGill, MUHC RI.
- --Study participants from South Africa and Canada.



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

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