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Public Health Ethics: A Case in Infectious Disease Prevention and Control

Webinar | January 24, 2017

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Presented by:

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To ask questions during the presentation

Please use the chatbox at any time.

Please note that we are recording this webinar, including the chat, and we will be posting this on the NCCHPP’s website.
Your presenters today

Dr. Nitika Pant Pai
McGill University, McGill University Health Centre

Dr. Mohammad Khan
Medical Health Officer Kelsey Trail Health Region Saskatchewan

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Olivier Bellefleur
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This PowerPoint was developed with significant contributions throughout by the NCCID’s Geneviève Boily-Larouche. Thank you Geneviève!
Declaration of real or potential conflicts of interest

Presenters:
Dr. Nitika Pant Pai, Dr. Mohammad Khan, Olivier Bellefleur and Michael Keeling

I have no real or potential conflict of interest related to the material that is being presented today.
The National Collaborating Centres for Public Health

National Collaborating Centre for Infectious Diseases
Centre de collaboration nationale des maladies infectieuses
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Centre de collaboration nationale des déterminants de la santé
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National Collaborating Centre for Healthy Public Policy
Montréal-Québec, QC | www.ncchpp.ca
What you said...

• The results from our questionnaire, in brief:

- Infectious disease & point of care testing

- Public health ethics
Our goals today:

• Introduce **Point of Care testing (POCT)** and discuss its potential in the Canadian context,

• Use an ethics framework to help us to identify the **ethical issues** that arise in a case study involving the use of POCT to expand the HIV testing offering, and

• Provide you with additional **resources** on POCT and on public health ethics.
Let’s start with a problem...

In many rural and northern settings in Canada, people have limited access to HIV testing due to stigma and discrimination, geographical challenges (including sub-optimal or no laboratories), a limited testing offering, and population migration.

While HIV diagnosis is clearly essential for preventing its spread and in its management for infected individuals and populations, access to effective and timely testing is limited.
What to do? How to decide?

Numerous factors can be involved in framing, motivating, influencing, informing and justifying our responses to a problem.

- Blind spots/biases
- Feasibility
- Supervisor’s directive
- Values
- Cost-effectiveness
- Legal/regulatory environment
- Institutional culture/norms
- Acceptable to public/decision makers
- Professional standards
- Social status/privilege
- Scientific + other evidence
- Ethics: analysis
- Analysis of the ‘problem’
- Your suggestions?

These are just a few among many. All of these are important and call for critical attention.
...here is one response

Point-of-Care HIV testing in rural and northern Saskatchewan\(^1\)
(a fictional pilot project)

- In order to improve access to HIV testing for rural, northern and Indigenous populations, three Saskatchewan Health Regions have collaborated to introduce a pharmacy-based Point-of-Care HIV testing pilot project.

- Goals of the project
  - Expand access in remote regions
  - Offer testing in settings with extended opening hours, and no appointment required
  - Offer more testing options not involving general practitioners and hospital settings
  - Prevent “lost to follow-up” situations by providing rapid results

\(^1\)Case developed by the NCCID’s Geneviève Boily-Larouche.

Project Development – Steps

1) Identifying and engaging partners
   • University researchers.
   • Three rural/northern health regions and one urban health region with POCT experience for training and technical support.
   • Rural and northern pharmacists.
   • Consulted and engaged local CBOs, Tribal Councils, Indigenous leaders, STBBI nurses, local GPs and Ministry of Health.

2) Preparation and implementation
   • Quality Assurance (QA) Program
   • Trained pharmacists and staff – HIV knowledge, counselling, testing, QA, data collection and reporting
   • Ensured facilities’ readiness and privacy
   • Mechanisms to link to confirmatory tests, care, and reporting to MOH

3) Evaluation
   • Data: offer/acceptance rates, testing volumes, yield, demographic, first time/return testers, # of +ve/-ve, invalid or indeterminate tests, pharmacist/client satisfaction
   • Success criteria: feasibility for pharmacists, acceptability to clients, reach compared to other protocols, cost-effectiveness data.

Images:
https://commons.wikimedia.org/wiki/File:Red_Ribbon.svg
At first glance, should you support this program?

Hmmm. Maybe?

YES! NO!
Why point of care?

Nitika Pant Pai, MD., MPH., PHD
Associate Professor
McGill University, Montreal
Email: nitika.pai@mcgill.ca
Structure of my talk

1. 2017 and the need for POC (Point of care)
2. The Point of POC
3. HIV in Canada and the role of POC
2017: Entering the brave new world of diagnostics!

- Real-time data
- Personalized data
- Connectivity (from your mobile to your doctor’s laptop)
- At point of clinical care (POC), at home, pharmacies, outreach settings
Mobile smartphone has emerged as a powerful new diagnostic POC tool!
Wearable Health Technologies

wellness or treatment, adherence, monitoring and communication of results to the providers in real time.

Real-time glucose monitoring

http://www.medtronicdiabetes.com/res/img/misc/guardian-introducing.png
Wearable Health Technologies: 
*Fitbit, iWatch, OMwear* record sleep, vital signs

http://www.nuubo.com/
Tablet is a health technology assistant

it wirelessly communicates with an Android tablet and includes a bag of plug-and-play sensors that measure blood pressure and levels of blood sugar and hemoglobin, conduct electrocardiography (EKG) tests, etc.

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

http://www.the-scientist.com/?articles.view/articleNo/33761/title/A-Dime-a-Dozen/
IMAGINE 2025: TRICORDER!!

What is point of care? 
And what are the five points to be kept in mind.

• What are
  • its definitions, criteria?
  • Or, spectrum of its use?
  • essential conditions for its functioning?
  • What needs to be improved? Is technology enough?
  • Where lies ahead in its envisioned implementation in Canada?
Many POC Devices
Point 1: point of clinical care

- Point of care technologies
  - POCT Tools for an accurate diagnosis
  - POC—at the point of clinical care—near to the patient
  - Notion is to bring the test process closer to the patient, so that the patient, physician can hasten Dx/ Rx process, and expedite patient care.
  - First proposed—Emergency, ICU settings
    - (CABG, Hb, Cardiac markers)
    - First definitions were lab definitions
Point 2: Goal of POCT
Rapid Clinical Action In Any Setting!

• POCT: tools to help with
  • a rapid action, faster decision making, faster triage, rapid confirmation, reduce professional time, increase the number of people screened, increase the number of new infections detected, and, increase the numbers linked to treatment or the next step in the clinical pathway.
  • **Ultimately the focus of POCT must be: clinical action**
Clinical action is important because

*Treatment (Clinical Action plan) is what really matters –
tangible clinical impact/ public health impact
Disease burden/ reducing transmission…

Rapid, clinically actionable results
Change in provider’s decisions
Correct treatment or management choices
Improved patient outcomes or public health benefits

on the spot; in the same clinical encounter; while the patient waits; at least on the same day
Clinical action entails a Rapid completion of the “test and treat” loop in the same clinical encounter is the ‘job-to-be-done’

*Treatment can be: start drugs, stop drugs, modify drugs, refer, order more tests, discharge, admit, etc.
In global context, goal oriented definition of POCTs 2015

“POCT can also be viewed as Testing that will result in a clear, actionable, management decision (e.g. referral, initiation of confirmatory test, start of treatment), within the same clinical encounter (e.g. day).”

POCT criteria:
POCT have moved from the ER to the field: a move to ASSURED, to a broader criteria

Popular view: product oriented

<table>
<thead>
<tr>
<th>ASSURED</th>
<th>(保证)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affordable</td>
<td>(价格适宜)</td>
</tr>
<tr>
<td>Sensitive</td>
<td>(灵敏)</td>
</tr>
<tr>
<td>Specific</td>
<td>(特异)</td>
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<tr>
<td>User-friendly</td>
<td>(容易使用)</td>
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<tr>
<td>Rapid/Robust</td>
<td>(快速/可靠)</td>
</tr>
<tr>
<td>Equipment-free</td>
<td>(无仪器)</td>
</tr>
<tr>
<td>Deliverable</td>
<td>(易储运)</td>
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</tbody>
</table>

Panel 3: Suggested revised criteria for an ideal diagnostic point-of-care test in resource-limited settings
- Allows a quick clinical decision
- Can be used at the clinical point-of-care by health workers
- Affordable (low average cost per test)
- Rapid (provides result during a clinic visit or within a reasonable waiting time)
- Acceptable test efficacy (likelihood ratio times patient notification rate)
- Cost effective

Diagnostic point-of-care tests in resource-limited settings
Point 3: POCT:
A Rapid turnaround time (TAT) is key to efficiency of care

Example 1: HIV test/treat cascade

- At every step of the test and treat cascade, about 25% patients get lost to follow up!
  - A newly diagnosed patient into care (25%), from staging to ART initiation (25%), from ART initiation to treatment retention (25%) and from treatment retention to adherence (25%)
  - With an action plan linked point of care test/treat strategy, losses to follow up could be reduced (50%! Or even more! (75%)
  - In South Africa, it takes 1 week–3 weeks to get a confirmatory result, and 3 weeks to 6 weeks to get linkage to counselling and 6 weeks to 12 weeks to get initiated on treatment, provided CD4/VL tests are available at the clinics.

- 90-90-90 UNAIDS 90-90-90 targets.
Rapid TAT varies in contexts, and settings and infections?
Example 2: In TB In India, for example, it can take 8 days before TB treatment is started after sputum smear is read +ve
Rapid TAT: 
if we can eliminate at least one return visit.

“Ultimately, the diagnosis-treatment gap will only be closed by rapid point-of-care diagnostic assays that can be used during the patient’s first clinic visit to permit immediate treatment decisions…”

Lawn S et al.

“Providing Xpert at point of care had important advantages. Results were available the day of the clinic visit, allowing immediate treatment initiation and eliminating the need for a return visit. This reduced the cost borne by patients…” [Van Rie et al. IJTLD 2013]
Point 4: POCT technologies are a “spectrum” cover a variety of settings, users, products (i.e. 5 Target Product Profile’s)

http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001306

Pai M et al. Microbe 2015
Ultimately, big or small, **the technology is a tool** in the process and pathway to clinical care.

Test developers seem to believe that smaller the device or portability = POC technology

Portability may help, does not guarantee POCT implementation

The technology should be implemented to allow a rapid completion of the test and treat loop in any one of the 5 TPPs
POC TECHNOLOGY alone is not enough!

POC testing is a TOOL in the spectrum of care

- Technology does not define a POC test nor determine its use at the POC.
- It is the successful USE at the point-of-care that defines a diagnostic process as POC testing.
- So, we need POC testing programs, rather than POC tests

POCT program = technology + enabling healthcare system

POCT program = technology + sustainable business models*

*courtesy: Peter Small

Point-of-Care Diagnostic Testing in Global Health: What Is the Point?
The main goal of such testing is to inform caregivers in ways that lead rapidly to their starting correct treatments for patients.

Madhukar Pai, Marzieh Ghiasi, and Nitika Pant Pai
Point 5: Essential conditions for POCT to thrive

• Product development, evaluation and approvals
• Enabling environment: allows POCT culture to thrive
  • QA/QC protocols, periodic checks, procedures, staff, devices
  • Training of professionals, proficiency testing, certification
  • Quality /reliability of test results
  • Data management, interpretation, reading results, storage
• Integration of results in clinical care
  • Communication of results, storage of results
  • Action plans, and record of action Clinical action- cost savings
• Sustainable Business models: Enabling and disruptive, patient friendly
  • Who pays, how much, sustainable models, scale up, services are maintained over time for patients and their communities.
Why do we think POC use will benefit Canada?

• New infections are on the rise
  • PHAC 2011 estimates 71,300 (58,600-84,00) HIV infection
  • 25% unaware of their serostatus

• HIV Burden concentrated in MSMs, IDUs, Aboriginal populations

• Estimated cost of HIV infection: $4 billion
HIV in Canada and the role of POC

- Late presentation is an economic burden
- 2001-2005, 64% of newly diagnosed progress to AIDS in a year
- 54% of new HIV present with low CD4 counts
- In Alberta, 71% newly dx in 2009 were immunosuppressed, 38% had advanced HIV
- INSPQ data revealed that 16% of those tested positive, had advanced HIV infection
How can POCT help?

- If integrated with health care services, POCT’s can reach out to the communities, provide rapid test results and expedite counselling and treatment.
- If approved in Canada, Self tests can help individuals know their HIV status in the comfort of their own home.
- If used by outreach settings, Multiplexed POCT’s can help detect multiple HIV associated infections (HCV, HBV, syphilis, CT, GC) in a rapid turnaround time.
- Early detection, timely linkage, can help save lives and help timely treatment can help reduce transmission of new infections over time.
We can be totally zen

Do not dwell in the past, do not dream of the future, concentrate the mind on the present moment.

~ Buddha ~
Or be prepared to embrace the POCT induced change?

“There are three constants in life: change, choice & principles”.

Stephen Covey
Point of Care Technologies (POCT); versatile, impactful, sustainable and game changers

Point of Care Tests as tools to impact Global Health

Game changers

Biosurveillance
Screening & triage
Expand access to Primary Care
Community Engagement

Empowerment & Proactivity

Behaviour change in providers

Sustainable Business Models

Integrated & Synergistic Innovations

Teaching Diagnostics

"It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change".

Charles Darwin
Acknowledgements:
Genevieve NCCID, Michael and Olivier of NCCHPP Participants

Fonds de recherche Santé
Québec

Bill & Melinda Gates Foundation
Questions? Comments?

Next:
An ethical dimension in decision making

‘Questions’ Photo credit: Derek Bridges. Flickr.com
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Why should we take an interest in public health (PH) ethics?

Because to act with professionalism in this situation, one must know:

• What Point-of-Care testing is, how it works, and whether it is a viable option for improving health outcomes for remote and northern communities.
• Lessons and best practices for successful implementation.

But we also need to:

• Pay attention to the direct and indirect effects that our decisions have on communities, groups, individuals and ourselves.
• Recognize the values that are being promoted and those that are being diminished.
• Be able to deliberate about options, make decisions, and justify them.

Ethics can help you to do these!
What can we use to help us think about ethical issues in public health?

- Nothing
- Intuitions
- Ethical theories
- Codes of ethics
- Values
- Frameworks
- Principles
- Cases
There are also different levels to consider...

**Macro**

At the level of public policy or population health
(e.g., policy promoting equitable, population-wide access to diagnostic technologies)

**Meso**

At the level of organizations or groups
(e.g., training and support for community pharmacists to perform tests)

**Micro**

Between one or a few individuals
(e.g., before, during and after tests... every intervention is different, and important!)

Each perspective reveals different ethical issues - every level is important
What can we use to help us think about ethical issues in public health?

- Codes of ethics
- Values
- Frameworks
- Principles
- Cases
- Ethical theories
- Intuitions
- Nothing
Ethics frameworks for public health

• A framework is a guide that can help professionals to adopt an ethical perspective – no prior expertise in ethics is required.

• Alas, it will only help to guide you – the work is still up to you (especially the critical thinking) and so are the decisions.

• Many frameworks exist (see the resources at the end of this presentation).
Let’s discuss our case with the help of the framework by Nancy Kass

**Case:**

- 3 Health Regions leading pilot project in Saskatchewan
- Expand access to testing through pharmacist-administered POCT
- Eliminate delays in obtaining test results and expand testing opportunities
- Data collection and research dimension

**The framework:**

**Its goal:**

“to help public health professionals consider the ethics implications of proposed interventions, policy proposals, research initiatives, and programs” (2001, p. 1777).


Our adapted summary is available at: [http://www.ncchpp.ca/docs/2016_eth_frame_kass_En.pdf](http://www.ncchpp.ca/docs/2016_eth_frame_kass_En.pdf)

**Its structure:**

- 6 questions
1. What are the public health goals of the proposed program?

The ultimate health goal(s)

Reduce morbidity and mortality caused by the presence and/or the spread of HIV in remote and northern communities.

(A key to realizing this goal is to increase access to testing, as this can lead to earlier access to treatment and reduced transmission.)
1. What are the public health goals of the proposed program?

2. How effective is the program in achieving its stated goals?

The “greater the burdens posed by a program” (liberty, costs, etc.) the stronger the evidence should be.

The program is intended to do this:
- Increase testing rates
- Individuals aware of results
- Confirmatory testing
- Transmissions
- Treatment and care
- Mortality
- Morbidity

Main points on effectiveness:
- Accuracy of POCT procedure is comparable to lab testing.
- Questions about access, uptake, follow-up, resources, support. Context is everything.
- Promising results from other Canadian pilots, BC for example, but none in SK.
1. What are the public health goals of the proposed program?
2. How effective is the program in achieving its stated goals?
3. What are the known or potential burdens of the program?
   What are the risks
   to privacy and confidentiality?
   to liberty and self determination?
   to justice?
   to individuals’ health?
1. What are the public health goals of the proposed program?
2. How effective is the program in achieving its stated goals?
3. What are the known or potential burdens of the program?
4. Can burdens be minimized? Are there alternative approaches?

“[W]e are required, ethically, to choose the approach that poses fewer risks to other moral claims, such as liberty, privacy, opportunity, and justice, assuming benefits are not significantly reduced” (p. 1780).
1. What are the public health goals of the proposed program?
2. How effective is the program in achieving its stated goals?
3. What are the known or potential burdens of the program?
4. Can burdens be minimized? Are there alternative approaches?

5. Is the program implemented fairly?
   Is there a fair distribution of benefits and burdens?
   Will the program increase or decrease inequalities?
   Should the program be universal?
   Should it target certain populations?
   Is there a risk of stigmatizing certain groups?
Kass (6/6)

1. What are the public health goals of the proposed program?
2. How effective is the program in achieving its stated goals?
3. What are the known or potential burdens of the program?
4. Can burdens be minimized? Are there alternative approaches?
5. Is the program implemented fairly?

6. How can the benefits and burdens of a program be fairly balanced?

“[T]he greater the burden imposed by a program, the greater must be expected public health benefit”.

the more that “burdens are imposed on one group to protect the health of another...the greater must be the expected benefit”

Balancing these calls for a democratic, equitable process.
Now, we’ll ask again: Should you support this program?

Hmmmm.

Maybe?

YES!  NO!
Questions and discussion
To learn more about POCT

More KT resources
- BCCDC POCT Program: http://www.bccdc.ca/our-services/programs/point-of-care-rapid-hiv-testing
- International Innovation: HIVSmart!: a smart solution to HIV healthcare

More events
- NCCID: Follow-up webinar with Dr. Pai in April, more details to come
- McGill Summer Institute: Global Health Diagnostics Course Spotlight

More scientific articles on POCT

Open Access

Journal articles
- Pai et al. Point-of-Care Technologies and their Global Health Applications, Current Pharmacogenomics and Personalized Medicine, 2013, 11, 000-000.
To learn more about POCT (2)

More scientific articles on community pharmacy-based models for POCT services

*Open Access*


*Journal articles:*


More scientific articles on self-testing

*Open Access*

Some NCCHPP resources on public health ethics

http://www.ncchpp.ca/708/Repertoire_of_Frameworks.ccnpps

http://www.ncchpp.ca/127/publications.ccnpps?id_article=1525

http://www.ncchpp.ca/127/Publications.ccnpps?id_article=1527

http://www.ncchpp.ca/127/Publications.ccnpps?id_article=1517

http://www.ncchpp.ca/128/presentations.ccnpps?id_article=1553

http://www.ncchpp.ca/127/Publications.ccnpps?id_article=1426
Acknowledgements and thanks

NCCHPP and NCCID wish to thank:

**Dr. Nitika Pant Pai** – McGill University and McGill University Health Centre

**Dr. Mohammad Khan** – Kelsey Trail Health Region

for sharing their time and expertise with us.

We also wish to thank:

**Dr. Deborah Kelly** – Special Advisor, Practice Innovation, Memorial University of Newfoundland

**Alexandra Musten** – REACH/Ontario Coordinator

**Susanne Nasewich** – Registered Nurse, HIV Strategy Coordinator in Regina Qu’Appelle Health Region

For their precious advice during the preparation of this webinar.
Evaluation and continuing education credits

- We will send you an email with a link to an evaluation form for this webinar.

- In order to receive continuing education credits, you will have to fill out the evaluation form.

- To obtain continuing education credits, once you have filled out the evaluation form, you can click on a link that will take you to another form requesting your credits. Your evaluation form responses will remain confidential and will not be connected to your request for continuing education credits.
Thank you for joining us

This subject interests you?

Please note that the NCCID is planning a follow-up webinar in which Dr. Pant Pai will go into greater depth on POCT and its promise in Canada. To learn more, visit the NCCID’s website or contact one of us by email.

Visit NCCID’s ([http://nccid.ca/](http://nccid.ca/)) and NCCHPP’s ([www.ncchpp.ca](http://www.ncchpp.ca)) websites for more resources.

Or, write to us:
– Geneviève Boily-Larouche at NCCID ([Genevieve.Boily-Larouche@umanitoba.ca](mailto:Genevieve.Boily-Larouche@umanitoba.ca))
– Olivier Bellefleur at NCCHPP ([olivier.bellefleur@inspq.qc.ca](mailto:olivier.bellefleur@inspq.qc.ca))
– Michael Keeling at NCCHPP ([michael.keeling@inspq.qc.ca](mailto:michael.keeling@inspq.qc.ca))