Preparing a randomized pop health intervention trial:

Lessons from a South African-Canadian partnership
to improve HIV and Tuberculosis prevention and
care for health workers

Yassi A, O’Hara LM, Engelbrecht MC, Rau A, Uebel K,
Nophale LE, Bryce EA, Spiegel JM (and others)

Dr. Annalee Yassi, MD, MSc, FRCPC
Tier 1 Canada Research Chair, Professor, School of Population and Public Health
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Outline

• WHY this topic (& why HCWs? Why S.A?)
• WHAT we wanted to accomplish
• HOW we approached our task
• The 8 considerations:
  1. Build relationships and shared ownership;
  2. Conduct feasibility study;
  3. Build receptor/partner capacity;
  4. Create an information system;
  5. Conduct additional feasibility/pilot studies;
  6. Get all onside, with a view to scale-up;
  7. Refine a detailed protocol; and
  8. Address the ethical issues.
• Conclusion
Why this topic?

- **Biomedical and clinical research:** understand disease dynamics and inform development of therapeutic and diagnostic modalities
- **Population health research:** develop and implement solutions to reduce burden of disease, minimize health inequities and inform knowledge and practice to improve the overall health of populations
- Although *pop health research is quite complex*, preliminary steps to initiating a *clinical* trial are well described, but *equivalent guidance* for RCT of *pop health is lacking.*

Why Focus on Healthcare workers for HIV and TB?

- ILO (2005): in the absence of *increased access* to treatment, an estimated 74 million workers will be *lost to the workforce due to HIV/AIDS* by 2015
- Despite existence of clinical guidelines re prevention, diagnosis, treatment and care, *health workers are not obtaining the access to the HIV and TB services* they need
- *Stigma and discrimination* remain problematic
Background: Crisis in HHR

Figure 1.2 Distribution of health workers by level of health expenditure and burden of disease, by WHO region

Data sources: [3, 16, 19].
Occupational hazards in health care

• Back injuries
  – Heavy lifting and frequent bending or twisting when moving patients

• Shiftwork
  – Changing shifts and working at night disrupts natural rhythms, contributing to digestion problems, heart disease, and sleep problems.

• Violence
  – when dealing with angry, stressed patients or those suffering from dementia

• Other issues for healthcare workers include radiation, chemicals, noise, etc..

• And of course, infectious diseases

The New England Journal of Medicine

Tuberculosis among Health Care Workers

Dick Menzies, M.D., Anne Fanning, M.D., Lilian Yuan, M.D., and Mark Fitzgerald, M.B.


• There has been consistent evidence (for more than 20 years) that workers involved in autopsies and cough-inducing procedures are at high risk for TB.
Included **43 studies**

- Stratified pooled estimates for countries with **low** (<50 cases/100,000 population), **intermediate** (50-100/100,000 pop), and **high** (>100/100,000 pop)

- For TB, estimated **incident rate ratios** were 2.4 (95% CI 1.2-3.6), 2.4 (95% CI 1.0-3.8), and 3.7 (95% CI 2.9-4.5), respectively.

**→ HCWs: almost 4 times higher risk for TB!**

- Sound **TB infection control measures** should be implemented in all health care facilities with patients suspected of having infectious TB.

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**MDR-TB and HCWs**

(23 XDR-TB and 208 MDR-TB HCWs in KZN)

**Results:** Annual Incidence in Hospital Admissions (per 100,000)

<table>
<thead>
<tr>
<th></th>
<th>HCWs</th>
<th>General Population</th>
<th>Incidence Rate Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR-TB</td>
<td>64.8</td>
<td>11.9</td>
<td>5.46</td>
</tr>
<tr>
<td>XDR-TB</td>
<td>7.2</td>
<td>1.1</td>
<td>6.69</td>
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</table>
“Put your own oxygen mask on first before you help another passenger”

- Healthcare workers need to be empowered, by their organization, to consider their own safety as paramount to the safety of the organization.

- HCWs have to put their own health and safety needs before the needs of the patient.

- By doing so it will result in better health and safety for workers and patients alike.

Why South Africa? The Global TB Epidemic

Source: WHO, 2010
South Africa

• ~18% of the adult (15-49 years) population is HIV+

• TB incidence rate: 993 (819–1182) per 100,000 population (compared to 4.5 per 100,000 in Canada) (i.e. ~ 200X the risk)

The risk of getting TB is 26 times greater in HIV positive people and TB is the main cause of death in people with HIV.

Incidence

South Africa has 0.7% of the world’s population but 28% of the world’s patients co-infected with HIV and TB. 75% of TB patients are HIV positive.

The graph shows the link between HIV prevalence and TB Incidence in South Africa. The incidence of TB (red line) went up as HIV infections increased (yellow line).
International Consensus: New Guidelines Needed:

**Compile existing clinical and policy guidelines, and new evidence, into a coherent set of interdependent recommendations to improve access for health workers to HIV and TB services**

**Systematic Evidence Review**

- **Extensive literature review**, related studies, existing initiatives to assess relevance, feasibility & affordability
- **Identifying synergies and ensuring complementary advantages vs. duplications**
- **Referring to existing guidelines** on universal precautions, PEP, TB infection control, occupational safety and health mgt systems, etc.
- **Further country survey** covering all WHO regions (17 countries) to complement in-depth situation analysis of 5 African countries
- **Related work by regions, partners & countries**
- **Formal Systematic Review** (guided by PICOT questions)
Largely based on values:
- Worker rights
- Human rights
- Gender equity
- Cost
- Feasibility
- Advantages vs. disadvantages

• only 1 workplace RCT to date; and that wasn’t in the healthcare sector.
• RCT needed: to evaluate whether strengthening occupational health units to implement the new WHO-ILO-UNAIDS guidelines *in-house* *in the health care sector* - can really be effective, and if so, what determines successful outcomes

Objective of this presentation

- To outline considerations needed to guide implementation of RCTs in population health, based on a RCT we are conducting focused on healthcare workers in South Africa.

So... We now

Describe the steps that led to this large collaborative RCT launched in South Africa

...what we did, the challenges encountered, and what we learned...

To derive

- An eight-step approach combining our own experience with insights from ethicists, feminist researchers, indigenous and post-colonial perspectives as well as standard guidelines for intervention research.
1. Build relationships and shared ownership;
2. Conduct feasibility study;
3. Build receptor/partner capacity;
4. Create an information system;
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6. Get all onside, with a view to scale-up;
7. Refine a detailed protocol; and
8. Address the ethical issues.

1- Build relationships and shared ownership of the project
Ensured we understood the local history, to the extent possible

- Garnered support from the national and provincial levels of government
- …and worked together on plans for next steps
II.

What we did…

We visited several hospitals and met with OHN personnel.

Choice of Pelonomi Hospital as pilot site for the integrated program

1. Functional health and safety committees
2. Strong occupational health department
3. Electronic occupational health information system already in use
4. Provincial and academic support
5. Managerial support
6. Positive climate for change
• Listened, learned, .... And obtained support from frontline and senior healthcare managers, provincial decision-makers, unions and representatives of front-line workers
• Trust was not instantaneous.
  – well-described North-South power dynamics
  – legacy of racial politics
  – questionable ethical practices in research in the past, compounding
    – labour-management power dynamics.

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2- Conduct feasibility study

• Employed questionnaires, workplace assessments, and discussion groups at our pilot hospital to obtain baseline data.

• Workshops allowed us to learn about South Africa’s legal framework for health and safety protection and about health and safety conditions in healthcare, and share basic occupational health and infection control principles.

Participants explored five case studies: addressed needlestick injuries and stigma of HIV, back injury from heavy lifting, latex allergy from glove use, patient violence, and occupational exposure to tuberculosis.
Results:

• weaknesses in infection control knowledge, and suggested the need for improved training
  

• Learned that intervention research to improve access of health workers to HIV and TB prevention and care would indeed be welcomed

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3- Build receptor/partner capacity

• A user-friendly workplace assessment field guide was developed to help recognize hazards in the hospital environment.

• Role-play and pictorial guided orientation were used for training due to complex political, cultural and environmental factors. (O’Hara LM, Bryce EA, Scharf S, Yassi A. Innovative training for occupational health and infection control workplace assessment in healthcare. American Journal of Health Education. January/February 2012. 43(1): 57-61.)

Online Training Tools
Demonstrations (as time permits)

- Protect Patti
  [http://innovation.ghrp.ubc.ca/ProtectPatti/](http://innovation.ghrp.ubc.ca/ProtectPatti/)

- Basic Infection Control
  [http://innovation.ghrp.ubc.ca/InfectionControlEnglish/](http://innovation.ghrp.ubc.ca/InfectionControlEnglish/)

- Training for Infection Control Practitioners
  [http://innovation.ghrp.ubc.ca/WPATICP/](http://innovation.ghrp.ubc.ca/WPATICP/)

- JOHSC Resource -
  [www.innovation.ghrp.ubc.ca/johsc/](http://www.innovation.ghrp.ubc.ca/johsc/)

Build receptor/partner capacity cont’d

- A training program: to build capacity in occup health and infection control, needed for day-to-day practice as well as for implementing the envisioned RCT
Lessons learned

• Considerable guidance and assistance was necessary throughout the project designs, implementations and evaluations --- as participants had very little understanding of “research”.

• Very little computer skills (many had no access; many had no emails; considerable implications for data collection, as well as accessing literature)
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4- Create an information system to support the population health intervention

• Building upon a system used in British Columbia, Canada, the Occupational Health and Safety Information System - “OHASIS” was developed collaboratively by Canadians and South Africans to track occupational health indicators
Occupational Health and Information System

Challenges continue.... (alas, the digital divide)
Lessons from trying to implement an information system

http://www.biomedcentral.com/1472-6947/12/84


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5- Conduct additional feasibility and pilot studies

- Trainees from the certificate programme conducted 7 projects in their workplaces
  - Investigating TB infection control practices in the medical outpatient department at Pelonomi Hospital
  - Reducing the risk of DOTS supporters acquiring TB during home visits in Bloemfontein and Welkom
  - Creating a safe environment for patients and staff in the bronchoscopy theatre at Universitas Academic Hospital
  - Improving utilization of workplace HIV/AIDS programme for healthcare workers at Pelonomi Hospital
  - Improving reporting of blood and body fluid exposures in the workplace in Thebe District Hospital
  - Establishing an effective system to prevent, identify and treat TB in employees at Universitas Hospital
  - Improving infection control and safety practices in the Central Laundry: baseline assessment, intervention, and evaluation

How HIV affects their lives

“We live this [HIV] every day and there isn’t any household that does not have an HIV infected family member. I lost a member [my brother] in 2004, the one and only to this HIV. He was married and then their first born died within the first year and then, [in] 2001, the wife had a baby and within the second month of having that baby, she died. Fortunately, that child is HIV negative.”

-Nurse, TB Coordinator

An OH nurse reported that out of the 60 new employees that arrived at her hospital about “25 of them are HIV + that we know of.”

That’s almost 42%!"
ESTABLISHING AN EFFECTIVE SYSTEM TO PREVENT, TEST and TREAT TUBERCULOSIS in HEALTHCARE WORKERS

If you are a healthcare worker, you have a right to be confidentially tested, and if needed, treated, for tuberculosis, free of charge.

If you have been coughing for more than two weeks...
ask your supervisor for a permission slip to go to the Occupational Health Clinic for an assessment.

In addition to free confidential testing and treatment, you may be eligible for workers compensation benefits.

FOR MORE INFORMATION contact any of the following:
Me Sidyiyo: 0738724278; Mr Nkhatho: 0835327764; Me Moliko: 0828360230;
Me Langfoot: 0836025519; Me Kololo: 0727377903;
Me Benson: 0820909069; Mr Phandle: 0711264652

O hohola beke tse pedi kapa ho feta? Batla thuso. Hoes vir twee weke en meer? Kry help

• The team also conducted a large workforce baseline study (~ 1000 workers) in three in regional hospitals
  ✓ TB screening among healthcare workers is low
  ✓ few staff obtain vaccination against influenza
  ✓ health and safety practices are not well implemented
    (e.g. needles are recapped and hands are not always washed between patients)

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6- Get all stakeholders onside, with a view to scale up

- Results presented to all stakeholders at a research day, attended by representatives from the hospitals – including CEOs, provincial health department executive, and local unions
...as well as national and international leaders (if we want scale up)

- Special visits to each facility to discuss findings with hospital management
- A situational analysis of the occupational health units across the province regarding their staffing and current TB and HIV programs
- Several additional meetings and presentations where stakeholders offered input
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7- Develop and refine a detailed protocol

RCT protocol was finalised:
• ~9400 HCWs in Free State hospitals
Sample size calculation:
( ie=.02, ic=.03*, m=350, t=2, cv=0.25, alpha=.05, power=.080)
• revealed that we need 12 clusters of at least 350 in both experimental and control sites, followed for 2 years.
• All 26 occ health units in Free State (with the exception of the pilot hospital.
• paired and randomised

*based on past experience at Pelonomi (30 new TB cases last year in HCWs)
Control OHUs

Intervention OHUs

Preventive workplace assessments, follow-ups & health surveillance
- Routine workplace assessments of TB infection control
- Health worker with TB: periodic general medical examination including TB screening and offer of HIV test

TB and HIV testing
- Free TB testing
- Free confidential HIV counselling and testing
- Access to confidential CD4 counts

TB treatment and prophylaxis
- Free confidential monthly TB treatment
- Free Isoniazid Preventative Therapy for 6 months if HIV positive

HIV treatment
- HIV positive staff referred to ART clinics in hospital or in local clinic or private doctors
- HIV positive staff able to access treatment in the OHU

Stigma reduction and TB and HIV awareness campaign
- No campaign
- Stigma reduction workshops with managers, H&S cttee
- Awareness campaign reTB symptoms and availability of free confidential TB and HIV testing and treatment at OHU
- Distribution of TB symptom self-check cards to all HCWs
- Senior management messaging with the theme “zero stigma, zero new infections and zero TB and HIV deaths amongst health care workers”

<table>
<thead>
<tr>
<th>Dem.</th>
<th>TB and HIV testing</th>
<th>TB and HIV treatment</th>
<th>Overall health outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>#tested for TB</td>
<td>#initiating/transferred in for TB treatment</td>
<td>deaths amongst staff number of staff employed at hospital total sick leave (including incapacity leave) days taken number of staff taking any sick leave Job categories of staff taking sick leave</td>
</tr>
<tr>
<td>Sex</td>
<td># tested for HIV</td>
<td>#initiating/ transferred in for IPT</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td># positive TB</td>
<td># initiating and transferred in for ART</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td># positive HIV</td>
<td># cured of TB,</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td># CD4 counts</td>
<td># completing TB tx,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td># died on TB tx or defaulted</td>
<td></td>
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</tbody>
</table>

Demographics, testing and treatment data: “RCT Module” of OHASIS at 2 study sites. Other study sites will collect identical information on paper. Forms will be collected and centrally entered by an appointed research team member. Health outcome data will be obtained from PERSAL (HR database).
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8- Consider the ethical issues and obtain ethics approval

- Methods to maintain confidentiality were carefully considered
- Ethics approvals obtained at Canadian institution, University of British Columbia (UBC) and South African institution (UFS)
- Should take a wider view of “ethics”

New ethical questions

Social and cultural equity of the project:

Respect for the values, knowledge, and culture of the population/community that is involved in the project
YES [ ] NO [ ]
Comments:.................................................................
.................................................................
.................................................................

Strengthening of local and/or personal capacities of those who are involved in study to deal with the problem that is being addressed.
YES [ ] NO [ ]
Comments:.................................................................
.................................................................
.................................................................

Conclusions

• Just as in clinical trials, there are pre-conditions that must be met before launching a definitive population health RCT

• Strong RCTs can be developed to evaluate complex population health interventions, if proper attention is paid to ensuring that necessary conditions are satisfied
The Way Forward --- discussion*

*practicum opportunities available