Integrating tobacco cessation with reduced harmful drinking and TB/HIV treatment adherence in South Africa: PROLIFE Implementation feasibility

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Introduction

• South Africa 3rd highest number of incident tuberculosis (TB) cases in the world
• 65% TB-HIV co-infection
• Tobacco smoking in SA (2007): 33% for men, 9.5% for women
• TB smokers more likely food-insecured, low-SES individuals with alcohol drinking problem
• Nearly a quarter (24%) of all tuberculosis deaths in SA attributable to smoking
TB and Tobacco Control

Collaboration between
- WHO Tobacco Free Initiative (TFI)
- WHO Stop TB! Department (STB)
- International Union Against Tuberculosis and Lung Diseases (The Union)

Smoking cessation and Alcohol counselling recommended in:
- SA National TB Management Guideline 2014
- However, generally not implemented but there was recent treatment adherence counselling as a pilot intervention.

“to integrate tobacco control and respiratory care services in Primary Health Care (PHC) settings”
Context

• The re-engineering of PHC in SA involving the deployment of ward-based outreach team of community workers led by a nurse provides unique opportunity for using lay health workers who may be DOTS in supporting integration of smoking cessation with treatment adherence.

• However, until our study started in 2012 no study had explored use of non-professionals to deliver smoking cessation within TB treatment facility using RCT design.
Organisation of TB services

• Nurse delivered
• HIV care usually delivered in parallel fashion but under one roof
  ➢ Considerable additional work load for TB nurse (referrals for HIV counselling and HIV/CD4 testing, ART initiation)
• LHCWs working in majority of TB/HIV services (HIV testing & drug adherence counselling, TB service support)
Motivational Interviewing - Intervention

• Directive, client-centred counselling or communication style

• Helps clients to explore and resolve ambivalence to change

• Works on “motivation to change” and “confidence to change”

• Motivation may improve self-efficacy to change multiple risk behaviours

• 5 principles: (a) expressing empathy, (b) developing discrepancy, (c) avoiding argumentation (d) rolling with resistance and (e) supporting self-efficacy
For all TB patients coming for their first TB treatment visit, ask:

“Do you currently smoke tobacco (cigarettes/cigars/cigarillos/hubbly bubbly)?”

If patient says YES, give the following brief advice:

“Tobacco smoking is extremely harmful for your health. If you stop smoking now, your TB will heal better and you will have a lower risk of getting TB again in the future. You will also reduce your risk of heart disease and cancer and protect your children against TB. As a professional nurse, I advise to give up smoking in the interests of your health.”

“Go kgoga motsoko go kotsi thata mo bophelong ba gago. Fa o tlogela go kgoga gona jaanong, bolwetsi ba gago ba mafatlha (TB) bo tla folo botoka gape le wena o tla ba le kotsi e ko tlase ya go fuma BA gape mo nakong e tlang. Mme gape o tla fokotsa kotsi ya gore o be le malwetse a pelo, kankere le go sireletsa bana ba gago kgatlhanong le TB. Nna ke le mooki yoo naleng tsebo, ke go eletsa go tlogela go kgoga mo kgatlhegong ya bophelo ba gago”

All patients who smoke tobacco, should also receive a smoking cessation booklet.
Motivational Interviewing (MI) Training

Pocket card for each participant.

SPIRIT OF MI:
COLLABORATION, EMPATHY, EVOCATION,
RESPECT FOR CHOICE AND CONTROL, KEEPING DIRECTION

ENGAGING
- Open questions, affirmation, reflection, summaries (OARS)

FOCUSING
- Agenda mapping
- Asking permission

EVOKING
- Evoking change talk
- Responding to sustain talk
- Evoking hope and confidence

PLANNING
- Setting clear goal
- Collaborative plan

OARS Information exchange
Newly registered adult TB patients at 6 clinics (N=2411)

Baseline questionnaire (N=1926)

Current smoker (N=421)

Excluded:
- < 18 yrs (247)
- Too ill to/language (49)
- No consent (57)
- >1 month Rx (49)
- Other (11)

MI (n= 205)
4-week follow-up (FU n=169)
Analysed: 205

Control (n=204)
4-week follow-up (FU n=168)
Analysed: 204

3-month follow-up (FU n=163)
Analysed: 205

6-month follow-up (FU n=152)
Analysed: 205

Follow-up

Allocation

Enrolment

RCT RESULTS (Louwagie et al 2014)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tobacco use status (N=1904)</strong></td>
<td></td>
</tr>
<tr>
<td>Current tobacco smokers</td>
<td>21.9%</td>
</tr>
<tr>
<td>Ever smokeless tobacco use</td>
<td>4.3%</td>
</tr>
<tr>
<td><strong>First Episode of TB (N=1879)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87.0%</td>
</tr>
<tr>
<td><strong>Pulmonary TB (N=1895)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>92.1%</td>
</tr>
<tr>
<td><strong>HIV positive (N=1803, excluding unknown HIV status)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87.1%</td>
</tr>
<tr>
<td><strong>On antiretroviral treatment (if HIV positive, N=1570)</strong></td>
<td></td>
</tr>
<tr>
<td>Not on ARV</td>
<td>45.5%</td>
</tr>
<tr>
<td>Yes</td>
<td>22.9%</td>
</tr>
<tr>
<td>Unknown</td>
<td>31.6%</td>
</tr>
<tr>
<td><strong>Problem drinking (N=1895)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>19.4%</td>
</tr>
<tr>
<td><strong>Illicit drug use (N=1882)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.1%</td>
</tr>
</tbody>
</table>
Sustained 6-month smoking abstinence

<table>
<thead>
<tr>
<th></th>
<th>Motivational Interviewing n (%)</th>
<th>Control n (%)</th>
<th>RR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-reported abstinence</td>
<td>44/205 (21.5)</td>
<td>19/204 (9.3)</td>
<td>2.29 (1.34;3.92)</td>
</tr>
<tr>
<td>Biochemically verified abstinence</td>
<td>24/83 (28.9)</td>
<td>11/83 (13.3)</td>
<td>2.33 (1.08;4.51)</td>
</tr>
</tbody>
</table>

*Multilevel analysis with facility as random effect.
Predictor models show HIV-infected individuals we no less successful, but dependent smokers are less successful only in the first months.

<table>
<thead>
<tr>
<th>Predictor</th>
<th>1-month 7-day PPA</th>
<th>1-month 7-day PPA</th>
<th>3-month sustained abstinence</th>
<th>6-month sustained abstinence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low nicotine-dependence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI) Motivational</td>
<td>3.01 (1.74;5.21)</td>
<td>0.62 (0.17;2.32)</td>
<td>2.23 (1.28;3.89)</td>
<td>2.69 (1.49;4.86)</td>
</tr>
<tr>
<td><strong>High nicotine-dependence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI) Motivational</td>
<td>0.62 (0.17;2.32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Self-efficacy</strong></td>
<td>1.03 (1.01;1.06)</td>
<td>1.08 (1.01;1.14)</td>
<td>1.03 (1.00;1.05)</td>
<td>-</td>
</tr>
<tr>
<td><strong>HIV status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive vs. negative</td>
<td>3.58 (1.31;9.78)</td>
<td>0.31 (0.06;1.65)</td>
<td>3.73 (1.11;12.58)</td>
<td>3.17 (0.93;10.77)</td>
</tr>
<tr>
<td>Unknown vs. negative</td>
<td>2.24 (0.54;9.22)</td>
<td>0.31 (0.02;5.67)</td>
<td>4.01 (0.90;17.94)</td>
<td>4.03 (0.89;18.21)</td>
</tr>
</tbody>
</table>
Feasibility of implementation of integrated complex intervention

• Used Normalisation Process Theory (NPT) as a conceptual framework to inform a planned implementation design for an effectiveness and cost-effectiveness evaluation in three provinces (n=40 clinics) as part of feasibility for scaling
Normalisation Process Theory (NPT)

- NPT offers an explanation of the work of implementation, embedding, and integration – focusing on the agentic contribution of individuals and groups.
- to explain how practices are routinely embedded in their organizational and professional contexts
- to explain the routine embedding of practices by reference to the role of four generative mechanisms (constructs):
  - Coherence – (Value to users/stakeholders, belief of demand, shared beliefs of purpose and relationship with other practices),
  - Cognitive participation – (Initiation, legitimisation, enrolment)
  - Collective action - (Operationalise practice, allocate tasks, execution in support of practice)
  - Reflexive monitoring – (Individual & group’s appraisal of practice’s worth to form knowledge about effect)
the structure of NPT/defining constructs and constraints

• NPT assumes that these four constructs representing generative mechanisms are the means by which social goals are achieved and, in turn, are foci of contests and conflicts

• NPT assumes that individual and collective contributions are interdependent

• NPT mechanisms are constrained (and released) by the operation of;

• norms (notions of how beliefs, behaviours, and actions should be accomplished); and

• Conventions/Processes (how beliefs, behaviours, and actions are practically accomplished)

Source: May & Finch 2010
**PROLife = MI plus SMS — IMB model**

- 31* first MI complete
- 17 second MI complete
- 12 third MI complete
- 12 TB participant exit interviews complete
- 9 LHW interviews complete
- 12 Clinic and TB Program managers interviews

**439** TB SMS messages sent
**165** Tobacco related messages
**131** Alcohol related messages

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**KEY MESSAGES**

1. Tuberculosis (TB) is caused by bacteria that is transmitted through coughing, spitting

2. TB mainly affects the lungs but can spread to other parts of the body including bones, joints, the heart, brain and kidneys

3. TB is curable with a combination of four drugs (RIFAFOUR)

4. Treatment must be taken daily for at least 6 months

5. **If TB patients continue to smoke, they may die or not recover from TB**

6. Support from a family member or friend is essential to ensure that treatment is taken correctly and completed

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**KEY MESSAGES**

1. There’s no safe level of drinking alcohol. At least both men and women shouldn’t regularly drink more than 14 units a week

2. Excessive drinking damages one’s health, family relationships, friendships and livelihoods

3. Alcohol damages one’s liver and body’s defenses against infections such as TB and HIV

4. **Cutting down on alcohol helps people recover faster from TB**

5. **Heavy alcohol drinking will make people forget to take their TB and HIV medication and they will stay sick longer**

6. It is best to stop drinking alcohol while patients are on TB medication. But if they do drink, they should drink a very minimal amount

7. It is normal for patients to be nervous about reducing their drinking. They shouldn’t panic. They should talk to their family, friends, and other people. They will get support
### SMS Messages schedule over 3 sessions over 12 weeks

<table>
<thead>
<tr>
<th>MI SESSION</th>
<th>WEEK</th>
<th>DAY</th>
<th>TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Remember to cover your mouth when you cough; this prevents TB germs from spreading in the air. For a complete cure, you will need to take TB medicines daily for at least 6 months.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Take your TB medicines always at the same time, like when you brush your teeth. This will help you remember.</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1</td>
<td>It is normal for TB medicines to cause side effects. Common ones include nausea, stomach pains, vomiting, orange urine, joint aches, and skin rash.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>If you have any problems or concerns about your medication, do not stop. Consult your TB nurse or doctor. They have tips to help you take your pills.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Keep windows open around you. If possible. Fresh air helps reduce TB germs.</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1</td>
<td>If you stop taking your medicines or don’t take them correctly, you can pass TB germs on to others.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Ask a family member or friend to help you remember taking TB medicines.</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5</td>
<td>Do take your TB medicines in full dose, even when you feel good. It is the only way to kill TB germs.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Adopt a healthy lifestyle. Reduce your chances of ever developing TB again.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MI SESSION</th>
<th>WEEK</th>
<th>DAY</th>
<th>TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>9</td>
<td>4</td>
<td>Alcohol damages your liver and your body’s protection against infection such as TB and HIV.</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1</td>
<td>Cutting down on alcohol will help you recover faster from your TB.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Heavy alcohol drinking can make people forget to take their TB medication and they stay sick longer.</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>1</td>
<td>Drinking less saves you money. Think about what extra money could buy you and your family.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>Stopping drinking alcohol while you are on TB medication is best. But if you do drink, drink less.</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>1</td>
<td>It is normal to be nervous when reducing your drinking, it helps to talk to your family, friends, or other people to support you.</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td>If you struggle to reduce your drinking, help is at hand. Talk to your nurse or another health professional. You are not alone.</td>
</tr>
</tbody>
</table>

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### ALCOHOL USE

**Intermediate (Secondary outcomes)**
- Tobacco cessation
- Spumon conversion
- In problem drinking
- Adherence to TB drugs

**Final (Primary outcomes)**
- TB treatment failure
- TB deaths
- Successful TB treatment

**Prolife intervention**
- Tobacco
- Alcohol
- TB and ARV

**HIV or and on ART:**
- ART adherence
- HIV status unknown

**HIV or and not on ART:**
- ART care seeking
- Acceptance of counselling and testing for HIV

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**University of York**

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**saMRC**

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Exit interviews of 12 who completed three MI sessions

<table>
<thead>
<tr>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated very helpful</td>
<td>92%</td>
</tr>
<tr>
<td>Now drink less</td>
<td>50%</td>
</tr>
<tr>
<td>Now smoke less</td>
<td>58%</td>
</tr>
<tr>
<td>Quit smoking</td>
<td>41.7%</td>
</tr>
<tr>
<td>Know more about smoking &amp; TB</td>
<td>83%</td>
</tr>
<tr>
<td>Know more about alcohol &amp; TB</td>
<td>91.7%</td>
</tr>
<tr>
<td>Now more adherent to TB meds</td>
<td>100%</td>
</tr>
</tbody>
</table>
## Preliminary findings – NPT framework

<table>
<thead>
<tr>
<th>Generative mechanism</th>
<th>Process constraints/release</th>
<th>Normative constraints/release</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coherence</strong></td>
<td>Immediate components</td>
<td>Organizational components</td>
</tr>
<tr>
<td>Factors that promote or inhibit mobilization of practice (practice objects)</td>
<td>- Patients perceived its helpful - Patients more likely open to LHW - Default and adherence problems* - Several TB Patients will need assistance to quit difficult habit of problem drinking &amp; smoking (demand)</td>
<td>Similar to ‘mum connect’ and recent past pilot of national adherence strategy - Will improve TB Rx outcomes - Alcohol and smoking compromises TB Rx and adherence (shared belief)</td>
</tr>
<tr>
<td><strong>Cognitive participation</strong></td>
<td>- Counselling is already happening but not consistently &amp; not integrated (Initiation constraint) - Aligns with DoH healthy lifestyle campaign (legitimacy) - TB management guideline</td>
<td></td>
</tr>
<tr>
<td>Factors that promote or inhibit participation in a practice (practice actors)</td>
<td>- LHW fills role of unavailable psychologists &amp; Social workers - LHW could help as tracers - Work with ward-teams (Interactional work)</td>
<td>- Supported by program &amp; clinic managers who expressed commitment (policy &amp; practice sponsors)</td>
</tr>
<tr>
<td><strong>Collective action</strong></td>
<td>- LHW are trained &amp; have clear role/tasks allocated (Skill-set work) - Referrals to Ministries for social devt &amp; Home affairs to alleviate poverty and documentation (contextual integration)</td>
<td></td>
</tr>
<tr>
<td>Factors that promote or inhibit enacting the practice (practice work)</td>
<td></td>
<td></td>
</tr>
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</table>

**Reflective monitoring**
Conclusion and recommendations

• LHCWs-delivered MI doubled success thus need to do:
  o Tobacco cessation (integrated with other services)
  o Adherence counselling (TB meds and/or ARV)
  o Other: alcohol, nutritional support

• Promoting smoking cessation in TB settings and among HIV infected patients has the potential to be scaled and address inequity in TB-related mortality.

• Integration best at structural legitimation and at level of practice through development of new protocols
MI Training
Acknowledgments

- TB and district managers, TB nurses, LHCW's and K Kodi
- KNCV Tuberculosis foundation (Grant 12.402.2/MvdW/U.10.0696/cal)
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