The Effectiveness of TB Infection Control Strategies in High HIV/TB Burden Settings
Eltony Mugomeri, Africa University, Zimbabwe
A Webber Training Teleclass

The effectiveness of TB infection control strategies in high HIV/TB burden settings: The case of isoniazid preventive therapy in Lesotho

Eltony Mugomeri, DHSc
Department of Health Sciences, Africa University, Zimbabwe

Hosted by Joseph Kaunda
Alberta Health Services, Canada

Global TB Hot Spots, 2016

Global Tuberculosis Report (2017)

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HIV/TB syndemic in sub-Saharan Africa

Global Tuberculosis Report (2017)

- PLHIV in SSA largest reservoir of TB globally (74% of all annual infections). (Hermans et al, 2016).
- How effective is universal IPT (all HIV+) in high HIV/TB burden settings?

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HIV/TB syndemic in sub-Saharan Africa

- PLHIV in SSA largest reservoir of TB globally (74% of all annual infections) (Hermans et al, 2016).
- How effective is universal IPT (all HIV+) in high HIV/TB burden settings?

Provision of IPT to PLHIV, 2005-2014

- WHO recommended 6 month IPT course for PLHIV in 2004.
- Slow uptake of IPT common in SSA where needed most.
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**Efficacy of IPT in clinical trials**

- **Comstock (1999)**

![Graph showing efficacy of IPT in clinical trials](image)

- **Optimum course IPT (Clinical Trials)**
  - 36 months IPT = 3 yrs protection (Martinson et al, 2009 [S.Africa]; Samandari et al, 2011 [Botswana]).
  - 6 months IPT = 6 months protection (Rangaka et al, 2014) in S. Africa where IPT reduced TB incidence by 60% in HIV+ adults with no history of TB.
  - Rifampicin & pyrazinamide?
  - How effective is universal IPT?

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Universal IPT for latent TB

<table>
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<tr>
<th>Cost-Effectiveness of isoniazid preventive therapy among HIV-infected patients clinically screened for latent tuberculosis infection in Dar es Salaam, Tanzania: A prospective Cohort study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grace A. Shayo, Derek Chitama, Candida Moshiro, Said Aboud, Muhammad Bakari and Ferdinand Mugusi</td>
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**Abstract**

*Background:* One of the reasons why isoniazid preventive therapy (IPT) for Tuberculosis (TB) is not widely used in low income countries is concerns over cost of excluding active TB. We analyzed the cost-effectiveness of IPT provision in Tanzania having ruled out active TB by a symptom-based screening tool.

*Conclusion:* IPT should be given to HIV-infected patients who screen negative to symptom-based TB screening questionnaire. Its cost-effectiveness supports government policy to integrate IPT to HIV/AIDS care and treatment in the country, given the availability of budget and the capacity of health facilities.

Reactivation of persistent latent infection is a challenge

<table>
<thead>
<tr>
<th>The timing of tuberculosis after isoniazid preventive therapy among gold miners in South Africa: a prospective cohort study</th>
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<tbody>
<tr>
<td>Sabine M. Hermans, Alison D. Grant, Violet Chihota, James J. Lewis, Emilia Vynnycky, Gavin J. Churchyard and Katherine L. Fielding</td>
</tr>
</tbody>
</table>

- The durability of protection by IPT was lost within 6–12 months in this setting with a high HIV prevalence and a high annual risk of M. tuberculosis infection.
- The observed rate of reinfection was higher than the modelled rate [1.3/100 pyrs, vs 2.2/100 pyrs (95 % CI, 1.8–2.7)], suggesting that reactivation of persistent latent infection plays a role in the rapid return to baseline TB incidence.
Barriers included stigma, limited knowledge about TB among contacts, insufficient time and space in clinics for counselling, mistrust of health center staff among index patients and contacts, and high travel costs for lay health workers and contacts.

The most important facilitators identified were the personalized and enabling services.

The use of a behavioral theory and a validated implementation framework provided a comprehensive approach for systematically identifying barriers to and facilitators of TB contact investigation.

Poor contact investigations remains a barrier to TB infection control

TB infection control in healthcare facilities remains a concern

Results: The observational study showed that none of the clinics had a tuberculosis infection control plan. No clinic was consistently screening patients for cough. Twelve facilities (60 %) consistently provided masks to patients who were coughing. Ventilation in the waiting areas was assessed to be inadequate in 60 % of the clinics while four clinics (20 %) possessed N-95 respirators. Findings from the focus group discussions showed weak managerial support, poor funding, understaffing, lack of space and not wanting to be seen as stigmatizing against tuberculosis patients as barriers that hindered the implementation of TB infection control measures.
Effective IPC governance is needed in some countries

Eltony Mugomery M Tech
Department of Pharmacy, Faculty of Health Sciences, National University of Lesotho, Maseru, Lesotho

Key Words
Infection control practice, infection prevention and control committees, infection prevention and control governance

Background: The implementation of the core components of infection prevention and control (IPC) programs supported by the World Health Organization faces severe challenges, particularly in developing countries. Given that hospital IPC committees are the key implementers of IPC, there is a need to evaluate their effectiveness. This study qualitatively evaluated the effectiveness of IPC committees in the southern African country of Lesotho with the aim of identifying themes for policy discussion on improving IPC practice in the country.

Methods: Data gathering was conducted through open interviews with purposely selected key informants - IPC committee members and relevant officials in the Ministry of Health, whereas data analysis was based on grounded theory.

Results: Despite their commitment, IPC committees were largely ineffective because of 5 major barriers, namely poor sense of competence, administrative constraints, inadequate financial support, role uncertainty, and negative staff attitudes. Poor IPC governance was found to be a central barrier to the effectiveness of IPC committees in Lesotho.

Conclusions: The impact of this study is that effective IPC governance is key to improving the IPC program in Lesotho. Effective leadership with the necessary competencies is needed to meet the IPC program in the country.

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Lesotho’s HIV/TB situation

- HIV+ = 23.5% (adults) & TB incidence = 852 per 100,000 (WHO, 2016);
- > 700 per 100,000 alongside S. Africa & Swaziland
- 74% of TB+ co-infected with HIV (WHO, 2014).
- TB incidence & notification rates, Lesotho?
Lesotho’s HIV/TB situation

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- TB incidence & notification rates, Lesotho?

TB incidence & notification rates, Lesotho? (2000-2013)

Lesotho’s HIV/TB situation

Poor TB treatment outcomes persist

TB treatment outcomes (2016) by category (a) and overall (b) (n = 812).

Trends in diagnostic techniques and factors associated with tuberculosis treatment outcomes in Lesotho, 2010–2015

Eltony Mugomery, Birat S Bekel, Charles Malbriak and Clemente Tarirar
Southern African Journal of Infectious Diseases, 33:1, 18-23,
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Diagnostic techniques for TB in Lesotho

- Smear microscopy
- GeneXpert MTB/RIF
- Chest Xray

Trends in diagnostic techniques and factors associated with tuberculosis treatment outcomes in Lesotho, 2010–2015
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Study sampling criteria

- Stratified systematic random sampling
- PLHIV (2004 – 2016) from eight district hospitals (three in sparse & five in densely inhabited districts).

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Data Collection

- HIV-positive children, adolescents, adults, geriatric & pregnant in 2 cohorts (Before & after IPT launch.) NB. Lesotho launched IPT in 2011.

- Discrete-time survival data (6-month intervals).

Data Abstraction Tool

Microsoft Access Relational Database Tool (SQL patient profiling)

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Sample size

Total sample size = 4322
Transfer-in=118
Past TB =337
TB at enrolment / TB within 1 month after enrolment =3185
6 months follow up /died before IPT launch =131
Insufficient Information =99
Final cohort=2955

Analysis?

Sample size

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Transfer-in=118
Past TB =337
TB at enrolment / TB within 1 month after enrolment =3185
6 months follow up /died before IPT launch =131
Insufficient Information =99
Final cohort=2955

Analysis
- Cox’s proportional hazard regression model for TB occurrence in Stata®

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Rate of initiation on IPT

- 68.8% of 2,955 sample had received IPT by study exit time (Dec 2016).
- IPT initiation was 20.6 per 100 person-years, with 135 (6.6%) defaults.
- Slow IPT initiation?

Overall cumulative IPT uptake, 2011-2016

Rate of initiation on IPT

- 68.8% of 2,955 sample had received IPT by study exit time (Dec 2016).
- IPT rate of initiation was only 20.6 per 100 person-years, with 135 (6.6%) defaults.
- Slow IPT initiation: Children/adolescents, higher population density and longer duration of ART>=5 years
- Overall TB incidence rate was 2.0 per 100 person-years in 12 208 person-years. (No previous TB)
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Rate of initiation on IPT

- The rate of IPT implementation remains slow.
- Using national coverage statistics, as is the current practice globally, may be misleading.
- More bioinformatics tools and skills are needed to improve this.
- Currently, data on rate IPT initiation is scarce, with only Brazil reporting such data – the rate of initiation in that country was 20.0 per 100 person-years in 2014 (Dowdy et al., 2014)

IPT uptake: sub Saharan Africa overview

- National coverage for IPT in 15 of the 30 high HIV/TB burden countries ranged from 1% in Swaziland to 53% in South Africa (WHO, 2018).
- Other countries in sub Saharan Africa with IPT coverage higher than 30% include Ethiopia (45%) and Nigeria (39%).
- Sierra Leone (22%), Zambia (18%), Namibia (15%) and Angola (13%). Notably, IPT coverage in many sub Saharan countries, including Botswana, Malawi, Ghana and Uganda, was unknown in 2017 (WHO, 2018)
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Data table: Cox proportional hazards model for initiation of IPT by patient characteristics in Lesotho

<table>
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Data table (Cont.)

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*Predictors insignificant when controlled for baseline WHO clinical Stage, duration of ART, district category and adherence to ART; WHO=World Health Organization, ART=Antiretroviral therapy, Fatal=patient status at study exit time, N=number of patients, PLHIV=People living with HIV; # denotes interaction of term

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- Age group, district category and duration of ART emerged as the most significant predictors of IPT initiation.

Comments:
- Patients enrolled on ART after IPT was launched have a higher initiation rate in this setting. This disparity therefore needs to be addressed.

- Patients in the sparsely populated districts [Odds ratio (OR)=1.6] and males [OR=2.1] had significantly (p<0.005) higher rates of defaulting IPT compared to those in the densely populated districts and females, respectively.

Comments:
The high rates of defaulting IPT in the sparsely inhabited districts is evidence to the need to improve the monitoring of this programme.

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Implementation of IPT in Lesotho

Seven health system challenges to implementation of IPT in Lesotho:
- Decentralisation of HIV services;
- Monitoring and evaluation systems;
- Service delivery;
- Supply chains;
- Health workforce;
- Health system financing;
- Health information systems.

Observation: Implementation of complex health interventions need a ‘health systems’ approach.

Benchmarks for evaluating the effectiveness of health interventions

Level IV: Adaptation – the extent to which the IPT intervention has been applied to and adapted to the local context

Level III: Sustainability – the extent to which the practice can be maintained and monitored

Level II: Reach – the extent IPT covers the intended target population

Level I: Effectiveness – the extent the practice achieves the desired outcomes

Source: Author

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Better monitoring strategies needed to improve TB screening and IPT uptake

IPT side effects still a problem

Miss-diagnosis of TB persists

Side effects

IPT defaulting?

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IPT treatment outcomes

A. Misdiagnosed TB in the previous 66
   Yes 27.1%
   No 72.9%
   n = 246

B. HIV side effect = also SA6
   Yes 27.1%
   No 72.9%
   n = 1,033

C. HIV side effect = peripheral neuropathy
   Yes 25.6%
   No 74.4%
   n = 1,033

D. Ever stopped IPT due to side effect
   Yes 13.5%
   No 86.5%
   n = 2,033

E. Ever defaulted IPT
   Yes 3.5%
   No 96.5%
   n = 2,033

F. Developed TB after receiving IPT
   Yes 3.5%
   No 96.5%
   n = 246

Misdiagnosis of TB persists

Side effects

IPT defaulting

- Patients in the sparsely populated districts (aOR=1.6] and males (aOR=2.1] had significantly
(p<0.005) higher rates of defaulting IPT compared to those
in the densely populated districts and females, respectively.

TB after IPT?

Time to TB event in IPT-exposed cohort

Thirty-nine (15.9%, n = 246) patients developed TB after IPT

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Time to TB event in IPT-exposed cohort

Thirty-nine (15.9%, n = 246) patients developed TB after IPT

Effectiveness of IPT in Lesotho

TB incidences per 100 person-years by timing of IPT:
- IPT before ART (1.7),
- IPT after ART (1.8),
- no IPT (2.6),
- IPT within one year of ART commencement (1.3) &
- IPT 3-5 years after ART initiation (2.3).

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Effectiveness of IPT in Lesotho

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Predictor variables for TB event

- A. Period enrolled into HIV care
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: 2011-2016 vs. 2006-2010

- B. District category
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: Dense, Sparse

- C. Baseline WHO clinical stage
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: Stage I, Stage II/III

- D. Gender
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: Female, Male

- E. Median viral load
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: low/very low, high/very high

- H. Duration on pre-ART
  - Cum. TB event vs. Follow-up time (Years)
  - Comparison: <2 years, >2 years

Figure 5.4 Cumulative occurrence of first TB event by predictor variable (A-D)

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**Significant Predictor variables for TB event**

Based on Wilcoxon’s log-rank test & Kaplan-Meier survival plots (Categorical) and Cox regression analysis (Continuous)

- Gender,
- baseline WHO clinical stage,
- district category
- Time to IPT relative to ART commencement (Continuous variable)

**Table 5.3** Cox’s proportional hazards model of the effect of IPT on the occurrence of TB in PLHIV in Lesotho

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Outcome</th>
<th>Total TB incidence per 100 PY</th>
<th>Unstratified model 2004-2016</th>
<th>Model stratified by period of enrolment 2004-2016</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Unadjusted</td>
<td>p-value</td>
<td>Adjusted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR (95% CI)</td>
<td></td>
<td>Adjusted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unadjusted</td>
<td>p-value</td>
<td>Adjusted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR (95% CI)</td>
<td></td>
<td>Adjusted</td>
</tr>
<tr>
<td>Enrollment period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011-2016</td>
<td>1.745</td>
<td>1.96 (1.31-2.96)</td>
<td>0.007</td>
<td>1.92 (1.33-2.83)</td>
</tr>
<tr>
<td>2004-2010</td>
<td>1.218</td>
<td>1.65 (1.06-2.55)</td>
<td>0.044</td>
<td>1.60 (1.07-2.39)</td>
</tr>
<tr>
<td>Time to IPT/ART</td>
<td>2.055</td>
<td>1.47 (1.06-2.03)</td>
<td>0.024</td>
<td>1.10 (0.70-1.71)</td>
</tr>
<tr>
<td>Baseline WHO stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>1.049</td>
<td>1.0 (1.0)</td>
<td>0.004</td>
<td>1.0 (1.0)</td>
</tr>
<tr>
<td>II</td>
<td>1.319</td>
<td>1.47 (1.06-2.03)</td>
<td>0.024</td>
<td>1.10 (0.70-1.71)</td>
</tr>
<tr>
<td>III</td>
<td>515</td>
<td>1.65 (1.06-2.55)</td>
<td>0.044</td>
<td>1.60 (1.07-2.39)</td>
</tr>
<tr>
<td>IV</td>
<td>171</td>
<td>1.47 (1.06-2.03)</td>
<td>0.024</td>
<td>1.10 (0.70-1.71)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.942</td>
<td>1.0 (1.0)</td>
<td>0.004</td>
<td>1.0 (1.0)</td>
</tr>
<tr>
<td>Male</td>
<td>1.033</td>
<td>1.47 (1.06-2.03)</td>
<td>0.024</td>
<td>1.10 (0.70-1.71)</td>
</tr>
<tr>
<td>District population density</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sparsely</td>
<td>1.042</td>
<td>1.0 (1.0)</td>
<td>0.004</td>
<td>1.0 (1.0)</td>
</tr>
<tr>
<td>Densely</td>
<td>1.913</td>
<td>1.47 (1.06-2.03)</td>
<td>0.024</td>
<td>1.10 (0.70-1.71)</td>
</tr>
</tbody>
</table>

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Increasing time to IPT by one six-month interval increased the risk of contracting TB by between 6% and 59%, depending on the cohort.

**Table 5.3** Cox’s proportional hazards model of the effect of IPT on the occurrence of TB in PLHIV in Lesotho

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Outcome</th>
<th>Unstructured model</th>
<th>Model stratified by period of enrolment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2004-2010</td>
<td>2004-2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total TB incidence</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>per 100 PV</td>
<td>p-value</td>
</tr>
<tr>
<td>Time to IPT/ART</td>
<td>2011-2010</td>
<td>1.16 (1.06-1.27)</td>
<td>0.001</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td>Male, Female</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.03 (0.88-1.21)</td>
<td>0.67</td>
</tr>
<tr>
<td>District population density</td>
<td></td>
<td>1.12 (1.08-1.17)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR (95% CI)</td>
<td>p-value</td>
</tr>
</tbody>
</table>

**CONCLUSION**

*Time to IPT relative to ART commencement is an important determinant

Ethiopia study: IPT-before-ART (aHR = 0.18, 95% CI = 0.08–0.42) better than simultaneously with ART (aHR = 0.20, 95% CI = 0.10–0.42) (Yardaw et al, 2014)

High risk of reinfection in certain settings

Compared to no IPT, combined IPT and ART reduces the risk of contracting TB by 37% (HR = 0.63, 95% CI 0.41-0.94) (Rangaka et al. 2014) in S.A;
- 60% (HR = 0.40; 95% CI 0.18 - 0.87) (Ayele et al, 2015) in Ethiopia;
- Six months IPT = six months protection? (Rangaka et al, 2014) in S. Africa.

Booster doses needed

Brazil: Six-month IPT course reduces the risk of contracting TB for at least seven years? Golub et al. (2015)
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-Thank You-

Acknowledgements
- D. Olivier and W. M.J. van den Heever
- Central University of Technology, Free State, SA
- National University of Lesotho, Maseru, Lesotho

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Speaker: Juliana Munro, Clinical Nurse Specialist, Infection Prevention & Control, Canterbury District Health Board, New Zealand

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Speaker: Prof. Didier Pittet, University of Geneva Hospitals, and Dr. Pierre Parneix, Hôpital Pitié Salpétrière, CHU de Bordeaux, France

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