Implementation Science for Quality Improvement

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Learning Objectives

Participants will be able to:

• Understand key principles of implementation science relevant to the improvement of TB services and care

• Cite examples of their application to TB services and care
  • Case Study: Implementation of Xpert MTB/RIF testing in Uganda

• Identify opportunities where implementation science can be harnessed to improve TB knowledge and care in their own settings
Implementation Science

- Study of **methods or strategies to promote** the systematic uptake of proven interventions into routine clinical practice. In this context, it includes the study of **influences** on the **behavior** of patients, providers, and organizations in either healthcare or population settings.
  
  --- *Implementation Science Journal*

- Study of **methods to promote** the integration of research findings and evidence into healthcare **policy and practice**. It seeks to understand the **behavior** of healthcare professionals and other stakeholders as a key variable in the sustainable uptake, adoption, and implementation of evidence-based interventions.
  
  --- *NIH Fogarty International Center*

- Study of processes used in the implementation of initiatives and **contextual factors** that affect these initiatives. The basic intent is to understand not only what is and is not working, but **how and why** implementation is going right or wrong, and testing **approaches** to improve it.
  
  --- *World Health Organization*
Common themes across definitions

- Implementation science involves
  - Understanding behavior
  - Developing strategies to change behavior
  - Engaging stakeholders

Increase speed, quantity and quality of evidence uptake
Logic Model
Use of theory/frameworks in implementation science

- “Theory without empirical research is empty; empirical research without theory is blind” -- Immanuel Kant

1. Identify determinants of behavioral/environmental risk factors
2. Create a causal model of the problem
3. Specify determinants being targeted for change
4. Select intervention methods to match targets
5. Inform evaluation of implementation strategy
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Uganda Context

• Among global leaders in Xpert scale-up
  • >200 GeneXpert devices (hub-and-spoke model)
  • >400,000 Xpert MTB/RIF cartridges

• Unresolved questions
  • How well are Xpert referral networks functioning?
  • What is the quality of TB diagnostic care within Xpert referral networks?
  • What policy changes and co-interventions can further enhance Xpert implementation?
Xpert Performance Evaluation to facilitate Linkage to TB care (XPEL TB)

AIMS

• To quantify gaps in TB diagnosis at health centers linked to Xpert testing sites

• To identify modifiable barriers to high-quality TB diagnostic services
  • Provider-level
  • Patient-level
  • Health system-level

• To develop and test a theory-driven intervention to improve the quality of TB diagnostic services
Aim 1: “Define quality gap”

• Study setting
  • 24 health centers (spokes) linked to 16 Xpert testing sites (hubs)
  • Selected based on 2015 NTLP case notification data

• Study design: Prospective cohort study

• Participants: All adults undergoing TB evaluation
Methods

• Data collection from routine data sources
  • Data sources: Presumptive TB register, TB laboratory register, Xpert requisition forms, TB treatment register

• GxAlert server data used to ensure complete capture of Xpert results
Quality of TB diagnostic evaluation

<table>
<thead>
<tr>
<th>Indicator 1: Proportion referred for sputum-based TB testing</th>
<th>%</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator 2: Proportion completing recommended TB testing (if referred)</td>
<td>55%</td>
<td>13 – 80%</td>
</tr>
<tr>
<td>Indicator 3: Proportion treated within 14 days (if smear- or Xpert-positive)</td>
<td>73%</td>
<td>60 – 100%</td>
</tr>
<tr>
<td>Indicator 4: Cumulative probability of being diagnosed and treated</td>
<td>33%</td>
<td>4 – 77%</td>
</tr>
</tbody>
</table>

Davis JL, Katamba A et al. AJRCCM. 2011
Farr K, Nalugwa T et al. JC TUBE 2019
Utilization of Xpert testing

- 17% (365/2091) of patients referred for Xpert testing
  - 34% (267/779) of HIV-positive adults
  - 7% (98/1312) of HIV-negative adults

- <5% (14/365) of patients referred for Xpert as first-line test

- <50% (20/48) of Xpert-positive patients initiated treatment within 14 days
  - Median time-to-treatment: 7 days (IQR 1 – 17)

High coverage of Xpert testing services ≠ High quality care

Farr K, Nalugwa T et al. JC TUBE 2019
Aim 2: “Understand quality gap”

- Conceptual Model: Theory of Planned Behavior

Patient Factors
- Time/distance to access care
- Cost to access care

Health System Factors
- Physical Resources
- Material Resources

Intention to Follow ISTC

ISTC Adherence

Case Detection and Treatment

ISTC, International Standards for TB Care
Methods

• Data collection
  – Key informant interviews (N=22 staff at 6 health centers)
  – Field observation
  – Surveys (N=64 presumed TB patients at 6 health centers)

• Analysis
  – Qualitative data
    • Transcribe interviews and field notes
    • Apply standard coding scheme to identify recurring themes/sub-themes
  – Quantitative data: descriptive statistics
### Aim 2 Summary: Barriers to high-quality TB evaluation

<table>
<thead>
<tr>
<th>PRECEDE framework</th>
<th>Recurring themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predisposing factors</strong></td>
<td></td>
</tr>
<tr>
<td>(Knowledge, attitudes, beliefs, intention)</td>
<td>• Time and resource constraints (i.e., high workload) → low self-efficacy&lt;br&gt;• Belief that TB evaluation is not urgent</td>
</tr>
<tr>
<td><strong>Enabling Factors</strong></td>
<td></td>
</tr>
<tr>
<td>(Factors that if addressed make it easier to initiate the desired behavior)</td>
<td>• Failure of patients to return after initial visit (due to time and costs)&lt;br&gt;• Inconsistent/delayed specimen transport to Xpert testing sites&lt;br&gt;• Inability to track and follow-up patients&lt;br&gt;“When they have a cough for more than 2 weeks they are sent to the lab. But the problem is they get the first sample and sometimes, actually most times they don’t bring the second sample.”</td>
</tr>
<tr>
<td><strong>Reinforcing Factors</strong></td>
<td></td>
</tr>
<tr>
<td>(Factors that if addressed make it easier to continue the desired behavior)</td>
<td>• Lack of communication and coordination among staff&lt;br&gt;• Insufficient oversight from NTP&lt;br&gt;“...Actually at times we have met but we don’t meet [regularly], only when we realize there is a problem that’s when we communicate and say why is this happening, then we try to rectify.”</td>
</tr>
</tbody>
</table>

Aim 3: “Improve quality gap”

Intervention design process:

- Evidence review
- Stakeholder consultation
- Feasibility

1. Prioritize barriers
2. Select interventions
3. Specify how interventions delivered
Theory-informed intervention components: XPEL TB strategy

1. **Onsite Xpert testing using GeneXpert Edge at health clinic**
   - Reduce workload, increase speed and accuracy of testing

2. **Clinic process redesign to facilitate same day testing and treatment of TB**
   - Address lack of urgency and failure of patients to return

3. **Regular feedback of quality metrics to health facility staff**
   - Improve communication, coordination and oversight
XPEL TB TRIAL DESIGN AND POPULATION

- **Objective:** To evaluate the effectiveness, implementation and costs/cost-effectiveness of the XPEL TB strategy at community health centers

- **Design:** Ultra-pragmatic, cluster-randomized, hybrid effectiveness implementation (Type 2) trial
  - 20 community health centers in Uganda (10 sites randomized to each arm)
  - Intervention arm: XPEL TB strategy
  - Control arm: Routine care (onsite microscopy + referral-based Xpert testing)

- **Population:** All adults evaluated for pulmonary TB from Oct 2018 to Mar 2020
  - Patients with RIF resistance excluded from analysis

Reza T, Nalugwa T et al. Implement Sci 2020
XPEL TB TRIAL PROCEDURES

• Public randomization ceremony (restricted + stratified randomization using 2017 TB data)

• Waiver of informed consent to extract patient demographic and clinical data from photos of routine TB registers

• Minimal contact with health centers: initial training visit + quarterly site visits to resolve data queries and conduct nested sub-studies

Reza T, Nalugwa T et al. Implement Sci 2020
RESULTS: PRIMARY OUTCOME

- Cluster-level analysis using negative binomial regression models

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>Unadjusted GMR</th>
<th>Adjusted GMR*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number treated for confirmed TB within 14 days</td>
<td>340</td>
<td>218</td>
<td>1.56 (1.16-2.09)</td>
<td>1.56 (1.21-2.02)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

* Adjusted for: Randomization strata, number of patients treated for confirmed TB within 14 days in 12-month pre-trial period

Katamba A et al. Union Lung Health Conference 2020
RESULTS: SECONDARY OUTCOMES

- Tested per national guidelines

**Same-day outcomes**
- Diagnosed with confirmed TB
- Treated for confirmed TB

14-day outcomes
- Diagnosed with confirmed TB
- Treated for confirmed TB

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted Geometric Mean Ratio</th>
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<tbody>
<tr>
<td>Diagnosed with confirmed TB</td>
<td>1.85 (1.22, 2.83)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>1.89 (1.41, 2.54)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>2.38 (1.58, 3.58)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>1.90 (1.22, 2.96)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>1.27 (0.97, 1.66)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>1.54 (1.19, 1.99)</td>
</tr>
<tr>
<td>Treated for confirmed TB</td>
<td>1.46 (1.02, 2.09)</td>
</tr>
</tbody>
</table>

*Graph showing adjusted geometric mean ratios for different outcomes.*
CONCLUSIONS

• Scale-up of novel diagnostics alone is unlikely to significantly increase case detection or improve patient outcomes

• The XPEL TB strategy (onsite Xpert testing + implementation supports)
  • increased 14-day TB diagnosis and treatment by 56%
  • improved quality metrics at each step along the TB diagnostic evaluation cascade of care

• Analysis of implementation and health economic outcomes is ongoing

• National TB programs should consider scaling-up decentralized Xpert testing to close the case detection gap

• Implementation science-based methods are useful for designing and evaluating health system interventions to improve quality of care
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