EVALUATING THE USE OF AN EVIDENCE-BASED TEST FOR TUBERCULOSIS SCREENING

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Tuberculosis (TB)

- Caused by *Mycobacterium tuberculosis*
- TB is spread via droplet nuclei
- The best way to stop transmission is to:
  - Isolate infectious persons
  - Provide effective treatment to infectious persons as soon as possible

## Latent TB Infection vs. TB Disease

<table>
<thead>
<tr>
<th>Latent TB Infection (LTBI)</th>
<th>TB Disease (in the lungs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inactive</strong>, contained tubercle bacilli in the body</td>
<td><strong>Active</strong>, multiplying tubercle bacilli in the body</td>
</tr>
<tr>
<td>TST or blood test results usually positive</td>
<td>TST or blood test results usually positive</td>
</tr>
<tr>
<td>Chest x-ray usually <strong>normal</strong></td>
<td>Chest x-ray usually <strong>abnormal</strong></td>
</tr>
<tr>
<td>Sputum smears and cultures <strong>negative</strong></td>
<td>Sputum smears and cultures may be <strong>positive</strong></td>
</tr>
<tr>
<td><strong>No symptoms</strong></td>
<td><strong>Symptoms</strong> such as cough, fever, weight loss</td>
</tr>
<tr>
<td><strong>Not infectious</strong></td>
<td><strong>Often infectious</strong> before treatment</td>
</tr>
<tr>
<td><strong>Not a case of TB</strong></td>
<td><strong>A case</strong> of TB</td>
</tr>
</tbody>
</table>

Estimated TB incidence rates, 2015

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Reported Tuberculosis (TB) Cases
United States, 1982–2015*

*As of June 9, 2016. Centers for Disease Control
TB Case Rates,* United States, 2015

*Cases per 100,000 population; as of June 9, 2016. Centers for Disease Control
Percentage of Foreign-Born Persons Among TB Cases, United States,* 2005 and 2015

2005

2015

* As of June 9, 2016. Centers for Disease Control
Assessment

- In 2012, California reported the highest number of tuberculosis (TB) cases in the United States – Largest groups are Foreign born (79%) and homeless (5.9%)
In December 2012, CDC identified a TB homeless outbreak in Los Angeles County.
Los Angeles County

- 10 million residents
- 88 cities
- 4,000 square miles
- 14 Public Health Centers
- ~165 Public Health Nurses (generalist)
- Investigate over 3,000 TB suspects
Homeless in Los Angeles County

- 39,463 (2013) homeless
- L.A. second to New York City in homeless
- Nationwide decline of homeless, but an increase in LA County
Assessment

Current practice in LA County 2012:

• Using TST as the only method for screening for TB

• Since 1907 Tuberculin Skin Test (TST) has been the test of choice for TB screening

• New technology offered an evidence based practice alternative to TST called IGRA
Screening for TB: Tuberculin Skin Test
Tuberculin Skin Test (TST)

- **Advantages**
  - Using it since 1907
  - Intradermal
  - Low cost

- **Disadvantages**
  - Return visit for reading
  - Lacks accuracy
  - Interacts with BCG vaccine and other mycobacterium (that are not TB)
Technology Advancing Medicine

- In 2001 a new blood test was developed to screen for TB

**Interferon-Gamma Release Assay (IGRA)**

Blood test that is specific to Mycobacterium Tuberculosis

2 vendors:
- Quantiferon (QFT) Gold
- TSPOT
Screening for TB: Interferon-Gamma Release Assay
IGRA Test

• Advantages
  – No return visit necessary
  – Accuracy
  – Does not interact with BCG vaccine or other mycobacterium
  – Lower cost in the long run

• Disadvantages
  – Higher cost for test (lower cost on the long run!)
  – Venipuncture
  – Incubation or laboratory processing is necessary
Evidence Based

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>QFT</td>
<td>TSPOT</td>
</tr>
<tr>
<td>Schlager &amp; Burzynski (2010)</td>
<td>76%</td>
<td>88-90%</td>
</tr>
<tr>
<td>Menzies, Madhukar &amp; Comstock (2007)</td>
<td>76%</td>
<td>88%</td>
</tr>
<tr>
<td>Sadatsafavi et al. (2010)</td>
<td>64.2%</td>
<td>50%</td>
</tr>
<tr>
<td>Diel et al. (2011)</td>
<td>100%</td>
<td>98%</td>
</tr>
</tbody>
</table>

**Sensitivity**: True Positive Ability to yield a positive result when person actually has that condition

**Specificity**: True Negative Ability to yield a negative result when the person does not have that condition
CDC Recommendations

Using an IGRA in the following populations:

• Persons who have received BCG (either as a vaccine or for cancer therapy); and

• Persons from groups that historically have poor rates of return for TST reading.

• For those 5 years old or older

**GOAL:** Screen contacts, homeless and foreign born with IGRA
Plan

• February 2013 Policy Implementation to use IGRA in the *clinics* only using QFT
  – Field Testing for Contact Investigation
    • Integral part of stopping the spread of TB
    • Key role of public health departments
    • Occur in the field setting (home, workplace, schools, etc.)

• In February 2014 expanded the policy to include IGRA testing in the *field* using TSPOT

• *Evaluate*
Implementation

QFT in Clinic 2013 → QFT Pilot Test in Field → Decision Made TSPOT → Policy Training → TSPOT in Field 2014
Evaluation

1. Compared TB Control data for
   • Contact investigation screening completion rates
   • Latent TB infection rate

2. Cost Analysis
   • Cost
   • Cost impact analysis

3. Track usage of IGRA in the field
## Results: Screening Completion

Screening completion includes:
- Negative TST or IGRA
- Positive TST or IGRA and Negative CXR

<table>
<thead>
<tr>
<th></th>
<th>Number of TB Cases Investigated</th>
<th>Number of Contacts Screened</th>
<th>Percent completed Screening</th>
<th>LTBI Positivity Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan to June 2013</td>
<td>178</td>
<td>3223</td>
<td>3146</td>
<td>97.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan to June 2014</td>
<td>143</td>
<td>1383</td>
<td>1337</td>
<td>96.6%</td>
</tr>
</tbody>
</table>
Results: Latent TB Infection Rate

2013 and 2014 Latent TB Infection Rates Comparison

CDC ESTIMATE 5-10%

$X^2 (1, N= 3731) = 31.85, p= .0000$
## Results: Cost-Analysis

### LTBI Screening Cost in the field

<table>
<thead>
<tr>
<th>ITEM</th>
<th>TST</th>
<th>IGRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>0.28</td>
<td>46.50</td>
</tr>
<tr>
<td>PHN Time 15 min visit 1</td>
<td>13.28</td>
<td>13.28</td>
</tr>
<tr>
<td>PHN Time 15 min visit 2</td>
<td>13.28</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Screening Total</strong></td>
<td>$26.84</td>
<td>$59.78</td>
</tr>
</tbody>
</table>

### LTBI Treatment Cost for 9 month course

<table>
<thead>
<tr>
<th>ITEM</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xray 1 view</td>
<td>5.60</td>
</tr>
<tr>
<td>Radiology Technician 15 min</td>
<td>7.32</td>
</tr>
<tr>
<td>Radiologist MD 15 min</td>
<td>56.25</td>
</tr>
<tr>
<td><strong>Xray Total</strong></td>
<td>$69.17</td>
</tr>
<tr>
<td>INH 300mg x9 mos</td>
<td>18.90</td>
</tr>
<tr>
<td>B6 50mg x9 mos</td>
<td>2.70</td>
</tr>
<tr>
<td><strong>Prescription Total</strong></td>
<td>$21.60</td>
</tr>
<tr>
<td>Baseline Liver Function test x1</td>
<td>7.50</td>
</tr>
<tr>
<td>Follow up AST/ALT x9</td>
<td>2.20</td>
</tr>
<tr>
<td>RN blood draw 10 min</td>
<td>8.10</td>
</tr>
<tr>
<td>MD visit 15 min x1</td>
<td>24.41</td>
</tr>
<tr>
<td>RN visit 15 min x9</td>
<td>109.37</td>
</tr>
<tr>
<td>Clerk 10 min x9</td>
<td>28.53</td>
</tr>
<tr>
<td><strong>Clinic Visits for 9 months Total</strong></td>
<td>$180.11</td>
</tr>
<tr>
<td><strong>TOTAL COSTS FOR 9 MOS LTBI TX</strong></td>
<td>$270.88</td>
</tr>
</tbody>
</table>
Results: Cost Impact Analysis

<table>
<thead>
<tr>
<th></th>
<th>TST</th>
<th>IGRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>26.84</td>
<td>59.78</td>
</tr>
<tr>
<td>9 month LTBI Treatment</td>
<td>270.88</td>
<td>270.88</td>
</tr>
<tr>
<td>Screening Total</td>
<td>$297.72</td>
<td>$330.76</td>
</tr>
</tbody>
</table>

For 1,000 contacts screened, there is an estimated cost savings of $21,288.78.

<table>
<thead>
<tr>
<th>1,000 Contacts Screened</th>
<th>TST</th>
<th>IGRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTBI RATE</td>
<td>21.7%</td>
<td>13.1%</td>
</tr>
<tr>
<td># Estimated Contacts with LTBI</td>
<td>217</td>
<td>131</td>
</tr>
</tbody>
</table>
Results: Usage of IGRA

2014 IGRA Usage in the Field

- IGRA Training
- Educational Training
- Policy

IGRA Tests

TB Cases

January
February
March
April
May
June
July
August
September
October
November
December

IGRA Tests

TB Cases
IGRA USAGE IN FIELD SETTING BY SITE JAN-DEC 2014

- SITE A: 21
- SITE B: 0
- SITE C: 55
- SITE D: 38
- SITE E: 20
- SITE F: 900
- SITE G: 482
- SITE H: 334
- SITE I: 233
- SITE J: 580
- SITE K: 101
2014 IGRA Usage in the Field by Sites
with Less than 100 tests

<table>
<thead>
<tr>
<th>Site</th>
<th>Jan</th>
<th>Feb</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
</tr>
</thead>
<tbody>
<tr>
<td>SITE A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>SITE B</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SITE C</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>31</td>
</tr>
<tr>
<td>SITE D</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>SITE E</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>20</td>
</tr>
</tbody>
</table>
Innovation Adoption Lifecycle

- 2.5% Innovators
- 13.5% Early Adopters
- 34% Early Majority
- 34% Late Majority
- 16% Laggards
We don’t do it that way here

I haven’t drawn blood in a long time

Can I draw blood without a doctor’s order?

The field is not a safe area for me to draw blood

Can we go in pairs to draw the blood?

Is it within our scope of work to draw blood?
T-SPOT®.TB Tests per Month
January 2014 - March 2016
The T-SPOT®.TB Test Results per Month
January 2016 – December 2016

<table>
<thead>
<tr>
<th>Month</th>
<th>Total Resulted Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2016</td>
<td>514</td>
</tr>
<tr>
<td>Feb 2016</td>
<td>384</td>
</tr>
<tr>
<td>Mar 2016</td>
<td>447</td>
</tr>
<tr>
<td>Apr 2016</td>
<td>436</td>
</tr>
<tr>
<td>May 2016</td>
<td>512</td>
</tr>
<tr>
<td>Jun 2016</td>
<td>569</td>
</tr>
<tr>
<td>Jul 2016</td>
<td>578</td>
</tr>
<tr>
<td>Aug 2016</td>
<td>463</td>
</tr>
<tr>
<td>Sep 2016</td>
<td>528</td>
</tr>
<tr>
<td>Oct 2016</td>
<td>455</td>
</tr>
<tr>
<td>Nov 2016</td>
<td>350</td>
</tr>
<tr>
<td>Dec 2016</td>
<td>499</td>
</tr>
</tbody>
</table>
Benefits of IGRA

- Less false positives!!
- Reduce unnecessary exposure to patient:
  - Chest x-ray
  - LTBI treatment with INH
- More accurate results!!
Lesson Learned

- Change is not easy
- A policy does not mean nurses will change their practices
- Training does not mean nurses will change their practices
- Looking at overall data doesn’t mean everyone has adopted the change
- Cost-analysis are important in the evaluation of changes in nursing practice
- The outcomes of the patient should drive change
Screen for TB with an IGRA