Evaluating and enhancing pharmacy reporting for tuberculosis surveillance, Arizona, 2011

August 2\textsuperscript{nd}, 2012
Arizona Department of Health Services
2012 Arizona Infectious Disease Training and Exercise,
Arizona State University – Tempe, Arizona

Jason Matthew Lempp, MPH
CDC/CSTE Applied Epidemiology Fellow
Arizona Department of Health Services (ADHS)
Office of Infectious Disease Services
Tuberculosis Control Program
Infectious Disease Reporting in AZ

- Clinical Suspicion or Diagnoses
- Local Health Departments
- Counties and Tribes
- Laboratory Testing
- Self-reporting Facilities or Individuals
- TUBERCULOSIS

Health and Wellness for all Arizonans
Tuberculosis (TB)

• Infection with *Mycobacterium tuberculosis* bacteria
  – typically pulmonary (lungs)

• Highly transmittable
  – aerosolized droplet nuclei from respiratory secretions

• 2nd leading cause of infectious disease mortality, worldwide\(^1\)

CDC: http://phil.cdc.gov/phil/details.asp
Tuberculosis Classifications

**Pulmonary TB**
Common; respiratory infection; highly infectious

**Extra Pulmonary TB (EPTB)**
Bacilli disseminated to other body areas; less infectious

**Active TB Disease** - Reportable

*also:*
Latent tuberculosis infection (LTBI)
non-communicable/dormant infection with *M. tuberculosis*
2011 Tuberculosis Rates

255 Cases in 2011

AZ: 4.0 cases per 100,000
US: 3.4 cases per 100,000

High Morbidity State

2011 County TB Rates per 100,000

- 0
- 0.1 – 2.0
- 2.1 – 3.4 < National Average
- 3.5 – 10.0
- 10.1 – 15.3

Legend

Major Population Centers

Health and Wellness for all Arizonans

azdhs.gov
Why Pharmacy Reporting for TB?

- Remember:
  - Important to catch all cases - transmission
  - Coordinate care with local health jurisdictions
  - High relapse rate from incomplete therapy $^3$

Easy to identify TB prescription medications ...
Pharmacy Reporting

• TB has specialized multi-drug therapy
• 6 months to 9 months for susceptible TB
• AZ Administrative Code = Legal Requirement

**Initial prescription for two or more of the listed drugs:**

- Rifampin (any)
- Pyrazinamide
- Streptomycin
- Isoniazid
- Ethambutol

Report to Public Health
Also Caught by Pharmacy Reports...

- **Nontuberculous *Mycobacterium* (NTM) infections**
  - Often treatment includes reportable anti-TB drugs
  - *M. avium* among immunocompromised

- **TB suspected, empirically treated – later ruled-out**
  - *Nocardia* infection
  - Valley Fever – common in AZ

- **LTBI – same drugs but often fewer**

Coccidioidomycosis Chest Radiograph
Evaluation Goals

1) Is Arizona pharmacy reporting complete?

2) Are there unreported cases of TB?

3) Are reporting requirements accurate to identify TB?
Pharmacy Reports & Timeline

- **2009**
  - January 1, 2009
  - September 1, 2009
  - December 31, 2009

- **2010**
  - September 1, 2010
  - September 30, 2010
  - October 1, 2010

- **2011**
  - September 30, 2011

**Key Points**:
- **22 Pharmacy Reports Received 2009**
- **31 Pharmacy Reports Received 2010**
- **53 Pharmacy Reports Received 2010/2011 Study Period**
- **2010/2011 Evaluation Period**
- **“ROUTINE”**

**Timeline**:
- Pilot Pharmacy Evaluation
- 2010/2011 Evaluation Period
"Routine" Pharmacy Reporting

- **53** Routine reports received

- **22 (41.5%)** Valid prescriptions

- **31 (58.5%)** Records excluded*
  - Out-of-state pharmacies dispensing within AZ (ex: Dept. of Corrections)

  *Given appropriate public health follow-up, excluded from this surveillance evaluation

- **7 TB (31.8%)**
- **9 NTM (40.9%)**
- **6 Other (27.3%)**
Pharmacy Reports & Timeline

HOW MANY REPORTS SHOULD WE EXPECT?

- 22 Pharmacy Reports Received 2009
- 31 Pharmacy Reports Received 2010
- 53 Pharmacy Reports Received 2010/2011 Study Period
- 31 Pharmacy Reports Received 2010/2011 Evaluation Period

Contacted pharmacies for additional retrospective prescriptions from 2010/2011

"ANNUAL"

"ROUTINE"
2011 Pharmacy Evaluation

Total Pharmacies (N = 1257)
Arizona Board of Pharmacy (September 15\(^{th}\), 2011)

Inclusion criteria
Licensed commercial or hospital pharmacies registered in AZ (Independent, Chain, Hospital, etc.)

Exclusion criteria
Public health jurisdiction pharmacies (Counties)
Non-Arizona pharmacies licensed to distribute in AZ
“Annual” Report Template

Template for annual report response by mail or email

<table>
<thead>
<tr>
<th>Pharmacy Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Pharmacy</td>
</tr>
<tr>
<td>Address</td>
</tr>
<tr>
<td>Pharmacy Primary Contact</td>
</tr>
</tbody>
</table>

Prescription records maintained by (circle one): Paper, Electronically, Both

No Multi-drug prescriptions for anti-tuberculosis medications filled from 10/1/2010 to 9/30/2011

- Patient: demographics, contact information, medications
- Prescribing physician: contact information
**Evaluation Plan**

**ROUTINE**
- ALL reports received during study period

**ANNUAL**
- Reports received through retrospective data request

**Pharmacy Exclusions**

**Prescription Exclusions**

**Valid prescriptions**

**Not reported in Annual**

**Routine records confirmed in Annual Reports**

**Patient Outcomes**

**Database Matching**
- Matched Records
- Unmatched Records

**Efficacy of Routine Reporting**

**Analysis**

**Physician Follow-up**
Annual Pharmacy Responses

Responding Pharmacies (n = 1041)  Non-responding Pharmacies (n = 216)

Phoenix Area  82.8%
Annual Pharmacy Response Results

1257 Pharmacies Contacted
1041 (82.8%) Pharmacies Responded
242 (23.2%) Pharmacies Reporting Valid Patient Prescriptions
216 (17.2%) No Response

799 (76.8%) with No Multi-Drug Prescriptions
731 – Indicated none
68 – Invalid prescriptions
Annual Patient Prescription Records

310 Pharmacies reporting any prescriptions

516
Total prescription records

146 (28.3%) Records excluded
20 – All prescriptions out of range
34 – Monotherapy
92 – Multiple drugs, different dates

370 (72.1%) Valid prescriptions *

* Individuals can be repeated as reported prescriptions from separate pharmacies.
Received Reports: Results

**Routine Reporting**
- Received 53 reports.
- 31 excluded.
- 22 valid prescriptions.
- 6 (27.3%) not reported in Annual.
- 16 (72.7%) records confirmed in Annual Reports.

**Annual**
- Received 516 reports.
- 146 excluded.
- 370 valid prescriptions.

**Database Matching**
- 95.7% incomplete.

Reports received include:
- **Routine**: 53
- **Annual**: 516

Valid prescriptions include:
- **Routine**: 22
- **Annual**: 370
Record Matching: Databases

Electronic Report of Verified Case of Tuberculosis (eRVCT)
• Report date (date case was alerted to public health, State or County)

ADHS TB Control’s “in-house” case management (Suspect)
• Report date (date lab is received by ADHS)

ADHS “Stop TB AZ Registry” for LTBI and Contacts (STAR)
• Service origin date (for cases), date client identified by case (for contacts) or presented for services (targeted testing)

ASPHL Laboratory Information Management System (LIMS)
• Test completed date
# Record Matching: Results

## Probabilistic Matching Identified

<table>
<thead>
<tr>
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<th>ERVCT</th>
<th>SUSPECT</th>
<th>STAR</th>
<th>LIMS</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>58</td>
<td>161</td>
<td>23</td>
<td>117</td>
</tr>
<tr>
<td></td>
<td>199 / 370 records</td>
<td>53.8%</td>
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<td></td>
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</table>

## Deterministic Matching Identified

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<th>STAR</th>
<th>LIMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>52</td>
<td>157</td>
<td>17</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>183 / 370 records</td>
<td>49.5%</td>
<td></td>
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## Total Matches Identified

<table>
<thead>
<tr>
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<th>SUSPECT</th>
<th>STAR</th>
<th>LIMS</th>
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</thead>
<tbody>
<tr>
<td>Unique</td>
<td>0</td>
<td>70</td>
<td>3</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>181</td>
<td>23</td>
<td>118</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<td>60</td>
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<td>23</td>
<td>118</td>
</tr>
</tbody>
</table>

**Total Matches Identified**: 206 / 370 records  55.7%

**Matched Records**
### Evaluation Outcome Definitions

<table>
<thead>
<tr>
<th><strong>TB</strong></th>
<th>Active Tuberculosis Disease: pulmonary TB extra-pulmonary TB <em>(as confirmed by laboratory culture or medical diagnoses)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LTBI</strong></td>
<td>Latent Tuberculosis Infection: non-infectious</td>
</tr>
<tr>
<td><strong>NTM</strong></td>
<td>Non-tuberculous <em>Mycobacterium</em> infection</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Patients treated for TB, then TB ruled-out</td>
</tr>
</tbody>
</table>
Patient Outcomes: Diagnoses

- 206 (55.7%) Matched Records
  - 133 Not TB
    - 5 – LTBI
    - 111 – NTM
    - 17 – Other
  - 73 TB
- 370 Valid Annual reports received
  - 164 (44.3%) Unmatched (Manual Follow-up)
    - 148 Not TB
      - 11 – LTBI
      - 104 – NTM
      - 33 – Other
    - 5 TB
  - 11 Lost FUP (6.7%)

97.0% Overall Confirmed Diagnoses
## Previously Unreported TB Cases

<table>
<thead>
<tr>
<th>Report Date</th>
<th>Age/Sex</th>
<th>Tests Performed (result)</th>
<th>Site of Infection</th>
<th>Risk Factors</th>
<th>Therapy (Start) [Complete]</th>
<th>Case Management</th>
<th>Annual Prescription (date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/14/11*</td>
<td>63/F</td>
<td>TST (+); Node Smear (+); Node Culture (+)</td>
<td>Extra-pulmonary TB (EPTB)</td>
<td>Diabetes mellitus, Immunosuppression (non-HIV/AIDS)</td>
<td>(5/24/11) [1/1/2012]</td>
<td>Totally self-administered</td>
<td>RIF, INH, ETH (5/24/11)</td>
</tr>
<tr>
<td>11/24/11</td>
<td>41/M</td>
<td>TST (-); Brain Smear (+); Brain Culture (+)</td>
<td>EPTB Brain</td>
<td>Homelessness, Non-injecting drug use, Alcohol</td>
<td>(2/5/10) [3/16/2012]</td>
<td>Tx extended-improper case management DOT 110 weeks</td>
<td>INH, PZA, ETH (3/13/11)</td>
</tr>
<tr>
<td>12/30/11</td>
<td>56/F</td>
<td>TST (+); Node Smear (+); Node Culture (+)</td>
<td>EPTB Lymphatic</td>
<td>Foreign born in 10 years in US</td>
<td>(6/16/11) [3/01/2012]</td>
<td>Totally self-administered</td>
<td>RIF, INH, ETH (3/2/11)</td>
</tr>
<tr>
<td>12/31/11</td>
<td>37/F</td>
<td>IGRA (-); Node Smear (+); Node Culture (+)</td>
<td>EPTB Lymphatic</td>
<td>Foreign born &gt; 10 years in US</td>
<td>(3/10/11) [12/30/11]</td>
<td>Totally self-administered</td>
<td>RIF, INH, PZA, ETH (2/24/11)</td>
</tr>
<tr>
<td>2010†</td>
<td>32/M</td>
<td>Smear (-); Culture (+)</td>
<td>EPTB Lymphatic</td>
<td>Pneumovirus - etc.</td>
<td>(4/18/11) [12/4/2011]</td>
<td>Not managed</td>
<td>RIF, INH (1/2/11)</td>
</tr>
</tbody>
</table>

* Positive smear reported to local health department. Patient not followed-up due to negative culture result.
† Colorado case appropriately reported RVCT in 2010

TB, tuberculosis; NIDU, non-injection drug use; EPTB, extra-pulmonary tuberculosis; HIV/AIDS, human immunodeficiency virus/acquired immune deficiency syndrome; RIF, rifampin; INH, isoniazid; PZA, pyrazinamide; ETH, ethambutol

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**Health and Wellness for all Arizonans**

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**CSTE APPLIED EPIDEMIOLOGY FELLOWSHIP**

azdhs.gov
Patient Outcomes: Diagnoses

370
Valid Annual reports received

206 (55.7%)
Matched Records

133 Not TB
5 – LTBI
111 – NTM
17 – Not TB

73 TB

164 (44.3%)
Unmatched (Manual Follow-up)

148 Not TB
11 – LTBI
104 – NTM
33 – Not TB

5 TB

78 TB
(21.1%)

281 Not TB
(75.9%)

11 Lost FUP
(3.0%)
Analysis: Medication Quantity

- Arizona requires reporting for 2 or more TB drugs
- Compare active TB versus “Not TB” to identify differences in prescription quantities

<table>
<thead>
<tr>
<th></th>
<th>TB - 78</th>
<th>Not TB - 281</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Drugs</td>
<td>21 (26.9%)</td>
<td>216 (76.9%)</td>
</tr>
<tr>
<td>3+ Drugs</td>
<td>57 (73.1%)</td>
<td>65 (23.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>TB</th>
<th>Not TB</th>
</tr>
</thead>
<tbody>
<tr>
<td>3+ Drug</td>
<td>57</td>
<td>65</td>
</tr>
<tr>
<td>2 Drug</td>
<td>21</td>
<td>216</td>
</tr>
<tr>
<td></td>
<td>78</td>
<td>281</td>
</tr>
</tbody>
</table>

Fisher’s exact $p < 0.001$

TB is significantly associated with 3+ drug prescriptions
Positive Predictive Value

Routine reporting:

7 TB Confirmed / 22 Reports Received = 31.8%

7 TB Confirmed / 11 3+ Drug Reports = 63.6%

Annual Reporting:

78 TB Confirmed / 370 Reports Received = 21.1%

57 TB Confirmed / 122 3+ Drug Reports = 46.7%
PPV Significance Testing

Annual Reporting:
PPV ≥ 3 Drug = 46.7 (37.9-55.6)
PPV ≥ 2 Drug = 21.7 (17.5-26.0)

Relative PPV (PPV₃/PPV₂) = 2.150
95% CI: 2.134 – 2.167

*Interpretation*⁴:
The lower bound of the 95% CI is well above 1, and therefore PPV₃ is significantly greater than PPV₂
“Unfound” TB Cases using PPV$_3$

20 AZ TB cases with pharmacy reports for 2 drugs

Physician Reported  | AZ Public Health Lab  | Commercial Labs  | Local Health Jurisdiction

55%  | 75%  | 60%  | 45%

At least 3 reports: 45%
At least 2 reports: 40%
Single other report: 15%

ZERO “unfound” TB case would have gone unreported to public health.
Conclusions

Under-reporting of reportable prescriptions

Annual resubmission of all reportable prescriptions

✓ Increase awareness of reporting requirements, adherence and case catchment

Unreported TB can be found through pharmacy reporting

Develop educational resources for extra-pulmonary TB reporting

✓ Outreach to physicians and laboratories to ensure TB case catchment

Predictive value improved with more specific drug reporting

Reporting for only 3+ anti-TB medication prescriptions

✓ Improve reporting simplicity, accuracy, timeliness and reduce reporting burden
Future Directions

- Collaborations with Arizona’s 4 largest pharmacy chains (~50% of total facilities) to establish routine electronic record pulls

- Similar Routine/Annual system could be adapted to other diseases with sentinel drugs
Thank You

Office of Disease Integration and Services

Carla Chee – Office Chief
Ayesha Bashir – Deputy TB Control Officer (former)
Julia Skinner – HIV Capacity Building Epidemiologists

ADHS CSTE Mentors

Cara Christ – Medical Director and Bureau Chief, TB Control Officer
Shoana Anderson – Deputy Bureau Chief

Office of Infectious Disease Services

Jessica Rigler – Acting Office Chief OIDS (former)
References


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Introduction

TB in Arizona

2009: 232 cases
(3.52 vs 3.8* per 100,000)

2010: 282 cases
(4.41 vs 3.6* per 100,000)

2011: 255 cases
(4.00 vs 3.4* per 100,000)

*US Rates by reported by CDC

TB Reporting in Arizona

- Physicians
  - Suspected or confirmed diagnoses of TB
- Laboratorians
  - Positive *M. tuberculosis* cultures
- Pharmacists
  - Rx for anti-TB drugs
- Local Health Jurisdictions

*US Rates by reported by CDC²
Pharmacy Response

Response Rate: 82.8%

<table>
<thead>
<tr>
<th>Arizona counties</th>
<th>No. of Pharmacies</th>
<th>No. of Responses (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apache</td>
<td>4</td>
<td>3 (75.0)</td>
</tr>
<tr>
<td>Cochise</td>
<td>25</td>
<td>19 (76.0)</td>
</tr>
<tr>
<td>Coconino</td>
<td>26</td>
<td>20 (76.9)</td>
</tr>
<tr>
<td>Gila</td>
<td>12</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>Graham</td>
<td>6</td>
<td>4 (66.7)</td>
</tr>
<tr>
<td>Greenlee</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>La Paz</td>
<td>5</td>
<td>3 (60.0)</td>
</tr>
<tr>
<td>Maricopa</td>
<td>805</td>
<td>684 (85.0)</td>
</tr>
<tr>
<td>Mohave</td>
<td>40</td>
<td>25 (62.5)</td>
</tr>
<tr>
<td>Navajo</td>
<td>16</td>
<td>12 (75.0)</td>
</tr>
<tr>
<td>Pima</td>
<td>193</td>
<td>167 (86.5)</td>
</tr>
<tr>
<td>Pinal</td>
<td>46</td>
<td>39 (84.8)</td>
</tr>
<tr>
<td>Santa Cruz</td>
<td>8</td>
<td>6 (75.0)</td>
</tr>
<tr>
<td>Yavapai</td>
<td>43</td>
<td>35 (81.4)</td>
</tr>
<tr>
<td>Yuma</td>
<td>27</td>
<td>17 (63.0)</td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td><strong>1257</strong></td>
<td><strong>1041 (82.8)</strong></td>
</tr>
</tbody>
</table>

Arizona Counties (number of responses)

- **≤ 59%**: Greenlee (0 responses)
- **60-69%**: Mohave (25), La Paz (3), Pinal (39), Santa Cruz (6), Yuma (17)
- **70-79%**: Cochise (19), Pima (167), Navajo (12), Yavapai (35)
- **≥80%**: Maricopa (684), Apache (3), Mohave (25), Yavapai (35), La Paz (3), Cochise (19)

Health and Wellness for all Arizonans
Annual Records Demographics

- Individuals (N = 351)
- 92.0% Arizona residents (323/351)
  - 17 States + Mexico (CA, CO, DE, HI, ID, IL, KS, MO, MT, NJ, NM, NV, OR, SD, TX, WA, WI)

<table>
<thead>
<tr>
<th>Arizona counties</th>
<th>No. of Patients (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apache</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Cochise</td>
<td>8 (2.5)</td>
</tr>
<tr>
<td>Coconino</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Gila</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Graham</td>
<td>3 (0.9)</td>
</tr>
<tr>
<td>Greenlee</td>
<td>0</td>
</tr>
<tr>
<td>La Paz</td>
<td>0</td>
</tr>
<tr>
<td>Maricopa</td>
<td>206 (63.8)</td>
</tr>
<tr>
<td>Mohave</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Navajo</td>
<td>5 (1.5)</td>
</tr>
<tr>
<td>Pima</td>
<td>50 (15.5)</td>
</tr>
<tr>
<td>Pinal</td>
<td>23 (7.1)</td>
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<tr>
<td>Santa Cruz</td>
<td>6 (1.9)</td>
</tr>
<tr>
<td>Yavapai</td>
<td>11 (3.4)</td>
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<tr>
<td>Yuma</td>
<td>4 (1.2)</td>
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<tr>
<td><strong>Totals:</strong></td>
<td><strong>323</strong></td>
</tr>
</tbody>
</table>

Age Distribution (n = 336)

- [Graph showing age distribution with categories and frequency counts]
Age Distribution

Annual Record Individual Age Distribution (n = 336)

25 - 44 years old: Arizona’s largest TB age group
≥ 3 Drug Reports

2 Drug Reports

All TB cases

Single Prescriptions

N_1 = 65

N_2 = 0

N_3 = 216

N_4 = Unk

N_5 = 57

N_6 = 0

N_7 = 21

N_8 = Unk

Reference 5
**COMPARISON OF 2 POSITIVE PREDICITIVE VALUES**

<table>
<thead>
<tr>
<th>Relative Positive Predictive Value</th>
<th>A = ≥ 3 Drug Reports</th>
<th>N₁</th>
<th>65</th>
</tr>
</thead>
<tbody>
<tr>
<td>B = ≥ 2 Drug Reports</td>
<td>N₂</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>D = TB disease</td>
<td>N₃</td>
<td>216</td>
<td></td>
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</table>

PPV A = ≥ 3 Drug PPV

\[
\frac{N₅ + N₆}{N₁ + N₂ + N₅ + N₆} = 0.4672131
\]

PPV B = ≥ 2 Drug PPV

\[
\frac{N₅ + N₇}{N₁ + N₃ + N₅ + N₆} = 0.2172702
\]

Relative positive predictive value

\[rPPV = \frac{PPV A}{PPV B}\]

\[\text{Natural Log } rPPV = 0.7656438\]

Variance of rPPV = \(σ^2P\)

\[= 0.0057209\]

\[\frac{1}{(N₅ + N₇)(N₅ + N₆)} \times \left[ N₆(1 - PPVB) + N₅(PPVB - PPV₁) + 2(N₇ + N₃)PPVA \times PPVB + N₇(1 - 3PPVA) \right] \times \frac{1}{N} = 0.005721\]

95% Confidence Intervals of rPPV

\[\log_{10} rPPV \pm Z_{1-α/2} \times \sqrt{\frac{σ^2P}{N}}\]

\[= 0.773468 \text{ exponentiated} = 2.167269\]

\[-0.75782 \text{ exponentiated} = 2.133619\]

Relative positive predictive value = 2.15 (2.13-2.17)

The lower bound of the 95% confidence interval is well above 1 and therefore PPV A is significantly higher than PPV B.
“Lost” Cases using PPV$_3$

21 TB cases not reported by annual 3+ drug reporting:

- 11/15 had positive ASPHL specimens submitted
  - 4 remaining = 3 individuals; All Symptomatic
    - 2/3 EPTB Patho/Cyto Cx (+) Commerical lab
    - 1/3 Sp Smear (-); Cx (-); MD Dx

- 6 Remaining:
  - 1 Lung Structure; Cyto Smear (+); Commercial lab Cx (+)
  - 1 Nervous System; Smear/Cx (-); DOC;
  - 2 Pulm; Related children, Contact Investigation; CXR Ab
  - 1 Osteo-articular TB reported in 2004, on Tx for life
  - 1 Colorado TB Case – not in any AZ state DB