B-waivers in Maryland: An Evaluation of Diagnostic Outcomes

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration
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Center for TB Control and Prevention
TB Waiver Classification

• A – Active, Infectious pulmonary TB
  • Most TB cases are required to complete treatment before entry to the U.S.

• B1 – Noninfectious pulmonary TB
  • CXR consistent with TB, smears and cultures are negative

• B1 – Noninfectious extrapulmonary TB

• B2 – LTBI Evaluation needed
  • TST positive, CXR normal
  • Usually children under 15 years old

• B3 – TB contact evaluation
Maryland TB B Waiver Epidemiology

• 2008-2012:
  • TB case rate
    • 1,639/100,000 among B1 waivers
    • 664/100,000 among B2 and B3 waivers
  • Latent TB Infection rate
    • 45% diagnosed with LTBI (Class 2)
      • 43% among immigrants
      • 52% among refugees

• 2012-2015:
  • TB Case rate
    • 1,398/100,000 among B1 Waivers
Background

• Review of TB follow-up worksheets during data entry revealed:
  • Misclassifications of assigned outcome diagnoses
  • Insufficient test results to permit accurate diagnosis

• How much of a problem was this?
  • Decided to review the data to assess the degree of misclassification and incomplete US evaluation among B-waivers
Outcome Definitions

• Question D3 on TB follow-up worksheet

• D3. Diagnosis
  • Class 0 – No TB exposure, not infected
  • Class 1 – TB exposure, no evidence of infection
  • Class 2 – TB infection, no disease
  • Class 3 – TB, active disease
    • (Pulmonary, Extrapulmonary, Both sites)
  • Class 4 – TB, inactive disease
Study Definitions

• Misclassification: Patient test results did not meet CDC-defined criteria for the diagnosis assigned

• Incomplete evaluation: Patient history or test information was inadequate to permit a final diagnosis
Methods

• Study approach: Retrospective

• Study population:
  • All persons with a TB class B waiver
  • Arrived in Maryland between 2013-2014
  • Final outcome diagnosis was available

• Variables used for analysis:
  • Demographic information
  • Pre-immigration testing and treatment
  • US test results
  • Final outcome diagnosis

• Evaluated outcomes by diagnostic class:
  • Algorithm to assess for misclassification and incomplete evaluation
Methods
Algorithm for Each Diagnostic Class

- All B Waivers
- All B1 Waivers

  LTBI testing

  Chest Radiograph

  Sputum Collected

  • Evaluation Complete
  • Not misclassified
Results: Study Population

- 683 B-waiver arrivals to Maryland for 2013-2014 in EDN system

- 518 had an outcome diagnosis for analysis
  - B1: 317, 61%
  - B2: 191, 37%
  - B3: 7, 1.4%
  - Missing: 3, 0.6%
Maryland B Waivers
2013-2014
Sex: All B Waivers

- Female: 47%
- Male: 52%
- Missing: 1%
Age: All B Waivers

- 0-4: 4.5%
- 5-14: 27.5%
- 15-24: 5.5%
- 25-44: 22.0%
- 45-64: 31.0%
- 65+: 14.5%
- Missing: 0.0%
Country of Birth

- Philippines: 33%
- Burma: 11%
- Ethiopia: 7%
- Bhutan: 6%
- Cameroon: 5%
- Vietnam: 4%
- China: 4%
- All Other Countries: 30%
Diagnostic Class

- Class 0: no infection, no exposure
  - 174 cases
- Class 1: Hx of exposure, no infection
  - 47 cases
- Class 2: LTBI
  - 190 cases
- Class 3: TB disease
  - 4 cases
- Class 4: Inactive TB
  - 103 cases
## Results: Misclassification

### All B Waivers

<table>
<thead>
<tr>
<th>Class</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 0 (n = 174)</td>
<td>8 (5%)</td>
<td>14 (30%)</td>
</tr>
<tr>
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<td>13 (7%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Class 2 (n = 190)</td>
<td>0</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Class 3 (n = 4)</td>
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</tr>
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### B1 Waivers

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<tbody>
<tr>
<td>Class 0 (n = 103)</td>
<td>4 (4%)</td>
<td>12 (40%)</td>
</tr>
<tr>
<td>Class 1 (n = 30)</td>
<td>12 (40%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Class 2 (n = 89)</td>
<td>10 (11%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Class 3 (n = 4)</td>
<td>3 (3%)</td>
<td>29 (9%)</td>
</tr>
<tr>
<td>Class 4 (n = 91)</td>
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Results: Misclassification

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<tr>
<th>All B Waivers</th>
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OR: 7.9, CI 3.7,16.7 for Class 1 (TB exposure, no infection) to be misclassified

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## Results: Incomplete Evaluation

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**OR: 1.8, CI: 1.1, 2.9** for Class 2 (LTBI) to be incompletely evaluated

### B1 Waivers

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LTBI testing = 182
US testing = 124
Neg = 5
No testing = 15
Hx Prev. Pos., No US testing = 43
US testing = 124
Neg = 5
CXR = 162
No = 5
Yes = 157
No Interpretation = 2

Key
- Incomplete Evaluation
- Misclassification

Definition of Class 2 diagnosis
- Positive TST or IGRA
- No clinical or radiographic evidence of TB
- Negative microscopy and bacteriology results
- No previous history of TB disease

Comp TB Tx Overseas = 8
Class 2 = 190
Definition of Class 2 diagnosis

- Positive TST or IGRA
- No clinical or radiographic evidence of TB
- Negative microscopy and bacteriology results
- No previous history of TB disease
Limitations

• Chart reviews were not conducted which would have allowed for:
  • Assessing for the presence or absence of TB symptoms
  • Review of the chest radiograph report
  • Review for risk factors
  • Review of the Clinician notes
  • Document reporting errors on TB follow-up worksheet
Conclusions

- TB class B1 waiver arrivals were less likely than B2 or B3 waiver arrivals to be appropriately classified and evaluated (P=0.03)
- Among outcome diagnostic groups:
  - Patients diagnosed as **Class 1** (TB exposure, no infection) were less likely to be appropriately classified compared to patients in other diagnostic classes
  - Patients diagnosed as **Class 2** (LTBI) were less likely to be appropriately evaluated compared to patients in other diagnostic classes
Conclusions (cont’d)

• Resources developed:
  • Guidelines for evaluation steps for all arrivals with a TB class B waiver
  • Table to clarify definitions of CDC diagnosis classes
Prevention and Health Promotion Administration

http://phpa.dhmh.maryland.gov