Assess the use of Maryland updated guidelines for appropriate treatment of culture-negative tuberculosis patients, Maryland, 2014-2016

By Audrey Garman
BA/MHSC candidate
TB Treatment

• ATS/CDC recommends 6 months treatment for TB (2 months 4-drug, 4 months continuation)

• The ATS/CDC allows short-course treatment TB (2 months 4-drug, 2 months continuation) for culture-negative pulmonary cases.
  
  o Patients with HIV or extrapulmonary site of disease, and children who have negative cultures are excluded from this regimen
PHASE student Yohhei Hamada conducted a study of culture-negative pulmonary TB cases from 2010 to 2013.

He conducted a literature review to develop a definition for “uncomplicated” culture negative pulmonary TB to be used in Maryland.

In May 2014 a Memorandum was released including the exclusion criteria.

It was also announced at several statewide meetings.
Maryland Exclusion Criteria for Short-Course Treatment

1. HIV infection
2. Children <15 years of age
3. Extrapulmonary tuberculosis
4. Diabetes mellitus
5. End-stage renal disease (ESRD)
6. Malignancy
7. Receiving immunosuppressive therapy
8. Lung cavitation
9. Extensive pulmonary lesions
10. Anti-TB treatment initiated before sample collection
11. Known exposure to fluoroquinolones (FQs) or other antibiotics active against TB for 7 days or more within one month, or any exposure within one week prior to specimen collection for culture
Purpose

• Review Cases 2014 through 2016
• Check to see if there has been improvement
• Analyze LHD adherence to new policies
• Improve treatment for culture-negative TB cases in Maryland
Review of TB Cases in Maryland

- 349 cases of TB that had “completed treatment” between 2014 and 2016
- 13 cases of TB that had completed treatment in 175 days
- 5 LHDs containing the 13 cases of TB
# Case Characteristics

*Patients Reviewed (n=13)*

## Age at Diagnosis (Years)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-24</td>
<td>1</td>
<td>7.7%</td>
</tr>
<tr>
<td>25-44</td>
<td>4</td>
<td>30.7%</td>
</tr>
<tr>
<td>45-64</td>
<td>5</td>
<td>38.5%</td>
</tr>
<tr>
<td>65+</td>
<td>3</td>
<td>23.1%</td>
</tr>
</tbody>
</table>

**Analysis**

- Mean: 51.8
- Median: 49
- Range: 21-88

## Sex

<table>
<thead>
<tr>
<th>Gender</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>6</td>
<td>46.2%</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>53.8%</td>
</tr>
</tbody>
</table>
## Case Characteristics

*Patients Reviewed (n=13)*

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>3 (23.1%)</td>
</tr>
<tr>
<td>Black</td>
<td>7 (53.8%)</td>
</tr>
<tr>
<td>White</td>
<td>1 (7.7%)</td>
</tr>
<tr>
<td>White, Hispanic</td>
<td>2 (15.4%)</td>
</tr>
</tbody>
</table>
## Findings

### Days of Treatment

<table>
<thead>
<tr>
<th></th>
<th>Patients with &lt;120 days tx (n=1)</th>
<th>Patients with ≥120 days tx (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD)</strong></td>
<td>115</td>
<td>131.1 (6.71)</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>115</td>
<td>132</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>115</td>
<td>123-146</td>
</tr>
</tbody>
</table>

### Break From Tx Guidelines

<table>
<thead>
<tr>
<th>Condition</th>
<th>Patients with &lt;120 days tx (n=1)</th>
<th>Patients with ≥120 days tx (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrapulmonary</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Positive Sputum Culture</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Pulmonary Cavitation</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Bilateral Disease</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>&lt; 8 Weeks PZA</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Staff’s Conclusion

- 6 (46%) Inappropriate Regimen
- 4 (31%) Acceptable Treatment
- 2 (15%) Not Adequate Treatment
- 1 (8%) NEDSS Error
Noteworthy Cases

- Two patients not included in final analysis due to data entry error in NEDSS
- One patient’s chart said LTBI but had not been corrected in the surveillance system
- Six patients had a previous history of TB treatment
- One patient that only had 53% DOT and likely insufficient treatment, but due to NEDSS error was pulled from analysis
- One case was a LHD’s first vDOT patient
Observations in Progress from 2014 to 2017

• 2009 to 2013
  o 55 cases less than 175 days
  o 833 cases total “completed treatment”
  o 6.60%

• 2014 to 2016
  o 13 cases less than 175 days
  o 349 cases total “completed treatment”
  o 3.72%

• OR=1.8, CI=1-3.4, p=0.05
Observations in Progress from 2014 to 2017

<table>
<thead>
<tr>
<th>Category</th>
<th>2014 Study</th>
<th>2017 Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;120 days</td>
<td>6/19 (31.6%)</td>
<td>1/11 (9.1%)</td>
</tr>
<tr>
<td>Children &lt;15 yrs</td>
<td>1/19 (5.3%)</td>
<td>0/11 (0%)</td>
</tr>
<tr>
<td>&lt;80% DOT</td>
<td>2/19 (10.5%)</td>
<td>0/11 (0%)</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>2/19 (10.5%)</td>
<td>2/11 (18.1%)</td>
</tr>
<tr>
<td>Extrapulmonary</td>
<td>2/19 (10.5%)</td>
<td>2/11 (18.1%)</td>
</tr>
</tbody>
</table>
Policy and the Future of TB Control

• The decrease in patients being treated for less than 175 days
• Continuing the conversation about proper culture-negative TB treatment
• The LHD reports
• Additional memos to LHDs
• Data accuracy for reporting
  o Meetings
  o Conferences
• Future projects
• Meeting with clinicians
Acknowledgements

• Center Chief: Nancy Baruch
• TB Consortium and Program Epidemiologist: Wendy Cronin
• Epidemiologists: Lisa Paulos (preceptor) and Alexandra Pyan (alternative preceptor)
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• Secretary: Towanda Williams
• PHASE Organizers: Beth Resnick and Paulani Mui
• Past PHASE Students: Yohhei Hamada and Jun Sugihara
• CTBCP PHASE Desk-Buddy: Marianne Henry


7. TB Physicians/Nurse Practitioner’s Meeting. Presented at Maryland Department of Health and Mental Hygiene, Baltimore, MD; May 16th, 2014.

