Evaluating the Classification of Congenital Syphilis Investigations in NYC, 2012

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Background – Congenital Syphilis

• Congenital Syphilis (CS)  
  – Occurs in infants whose mothers have untreated syphilis during pregnancy  
  – When contracted in utero, syphilis can result in stillbirth, perinatal death, prematurity, and a range of developmental abnormalities  
  – CS can be prevented: women with syphilis must be adequately treated early in pregnancy

Background – Case Definitions

• CDC/CSTE develops standard surveillance case definitions  
  – Promotes consistent approach to case classification and reporting across health departments  
• CS surveillance case definition is complex  
  – CDC developed a schematic in the 1980’s to assist health departments with case classification (known as the ‘old CDC algorithm’)

Background – Need for a New Algorithm

• 2012 evaluation of 349 CS case investigations in Louisiana found poor correspondence between the CDC surveillance case definition and the old CDC algorithm *  
  – CDC case definition allows for an infant to be classified as a CS case even without maternal data  
  – Old CDC algorithm requires maternal data to classify an infant as a CS case  
  – Old CDC algorithm classified many more infants as cases compared to the CDC case definition

New CDC Algorithm

- CDC developed a new algorithm (2013)
  - New CDC algorithm classifies infants according to the CDC case definition, i.e. allows for infant to be classified as a case even without maternal data

Objective

- To determine the impact of using the new CDC algorithm on classification of 2012 infant investigations in NYC as cases/non-cases

Methods – Study Population

- NYC infants born in 2012 who were the subject of a syphilis case investigation
- Women with reactive syphilis serologies who were known to be pregnant between June 1, 2011 and December 31, 2012
- Deduplicated and linked investigations of mother and baby
- 166 investigations made up the final study population*

Analytic Approach – 1

- We evaluated each CS investigation conducted in NYC in 2012 using:
  1. CDC surveillance case definition
  2. Old CDC algorithm
  3. New CDC algorithm
  4. NYC case classification (based on CDC case definition)
- Using the CDC case definition as the gold standard, we calculated sensitivities and specificities of each classification method

*there were no lab-confirmed cases in NYC in 2012
Analytic Approach – 2

- Abstracted maternal and infant data using the same abstraction form as the Louisiana evaluation
- One reviewer classified all investigations using the 3 methods (NYC case classification was already documented)
- 2nd reviewer examined all investigations classified as CS cases by the CDC case definition, and 10% sample of remaining investigations
- Complex cases were discussed and classification assigned by consensus

Results – 1

<table>
<thead>
<tr>
<th>CDC CASE DEFINITION</th>
<th>NYC CLASSIFICATION</th>
<th>OLD ALGORITHM</th>
<th>NEW ALGORITHM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Cases</td>
<td>Non-cases</td>
<td>Cases</td>
</tr>
<tr>
<td>Cases</td>
<td>8</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Non-cases</td>
<td>158</td>
<td>0</td>
<td>158</td>
</tr>
<tr>
<td>Total</td>
<td>166</td>
<td>4</td>
<td>162</td>
</tr>
</tbody>
</table>

Results – 2

<table>
<thead>
<tr>
<th>Classification method</th>
<th>Sensitivity*</th>
<th>Specificity*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old CDC algorithm</td>
<td>87.5% (7/8)</td>
<td>60.7% (96/158)</td>
</tr>
<tr>
<td>New CDC algorithm</td>
<td>100% (8/8)</td>
<td>100% (158/158)</td>
</tr>
<tr>
<td>NYC classification</td>
<td>50% (4/8)</td>
<td>100% (158/158)</td>
</tr>
</tbody>
</table>

*Calculated using the CDC surveillance case definition as the Gold Standard

Results – Old CDC Algorithm

- Over-counted: only 10% (7/69) of the investigations the old CDC algorithm classified as cases, were cases by CDC case definition
- Under-counted: 1 infant missed by the old CDC algorithm had clinical evidence of CS (abnormal long bone films), however, mother was adequately treated
Results – NYC Classification

- NYC CS classification was based on the CDC case definition; however, NYC missed 50% (4/8) of cases that met CDC case definition in 2012
  - 2 infants had clinical evidence of CS (abnormal long bone films, elevated CSF); however, there was evidence of adequate maternal treatment
  - 2 other infants; mothers had inadequate treatment, unclear why they were not classified as cases?

Limitations

- Information in surveillance system was the only data source
  - Did not access prenatal or delivery records
- Investigations deemed non cases by NYC not documented as well as cases
  - Unclear if missing tests were negative or not done
- Complex interpretations
  - Different reviewers may interpret complicated investigations differently than our study team

Conclusion

- Using the old CDC algorithm, many CS investigations were classified as cases that did not meet the CDC case definition
- NYC correctly identified all the non-cases, but missed half of the cases
- New CDC algorithm matched perfectly with the CDC case definition

As a result ...

- In-service of NYC staff involved with CS investigations will be conducted
- All pregnant women with reactive syphilis serologies are investigated, including interaction with providers and birth outcomes monitored
- Improved documentation of CS investigations, including those deemed non cases
- Reevaluate 219 reported cases in NYC from 2000 to 2011 using the old and new algorithm
Acknowledgements

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• CDC/Louisiana study team

Case Definition

Syphilis Stillbirth: A fetal death that occurs after a 20-week gestation or in which the fetus weights >500g and the mother had untreated or inadequately treated* syphilis at delivery

Probable: a condition affecting an infant whose mother had untreated or inadequately treated* syphilis at delivery, regardless of signs in the infant, or an infant or child who has a reactive treponemal test for syphilis and any one of the following:
- Any evidence of congenital syphilis on physical examination
- Any evidence of congenital syphilis on radiographs of long bones
- A reactive cerebrospinal fluid (CSF) venereal disease research laboratory (VDRL)
- An elevated CSF cell count or protein (without other cause)
- A reactive fluorescent treponemal antibody absorbed-19S-IgM antibody test or IgM enzyme-linked immunoassay test

Confirmed: a case that is laboratory confirmed

*Inadequate treatment consists of any nonpenicillin therapy or penicillin administered <30 days before delivery.

Laboratory criteria for diagnosis: Demonstration of T. pallidum by darkfield microscopy, fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material