Completion of the Revised Congenital Syphilis Form

Jessica Frasure-Williams, MPH
Syphilis Elimination Coordinator
May 13, 2013   9-10AM

Call-in Information:
888-606-7149
65231#

Please mute your phones!
Training Series

Introduction and Protocol for Congenital Syphilis Surveillance in California

May 6, 2013 – 9-10AM

Completion of the Revised Congenital Syphilis Form

May 13, 2013 – 9-10AM

CalREDIE: Initiating, Monitoring and Entering Data for Congenital Syphilis

May 20, 2013 – 9-10AM
Overview of Training

• When to complete the California Congenital Syphilis Case Investigation and Report ("CS Form")
• Description and rationale for variables included in the form
Preventing and reporting cases.

WHEN TO COMPLETE THE CS FORM
Protocol Summary

- Confirm treatment for all cases in women of child-bearing age and infants
- Initiate FR for the following:
  - All female cases of child-bearing age
  - All females with an infant with a reactive STS
  - All infants with a reactive STS
- Conduct syphilis interviews and partner services for early cases
- Complete the revised CS form for the following:
  - Infants or stillborn fetuses of mothers who are inadequately treated
  - Infants with reactive STS and evidence of congenital syphilis
- Fax provider information sheets according to circumstances
- Close cases within 30 days of treatment verification or delivery
- Send closed cases to the CS Coordinator within 7 days.
Algorithm for Classifying CS Cases

1. **Does mother meet case definition for syphilis?**
   - **YES**
     - Did mother begin treatment 30 days or more prior to delivery and complete the treatment regimen appropriate for her stage?
     - **YES**
       - **Do you have lab or medical information for infant?**
         - **YES**
           - What is infant/child’s non-treponemal test result?
           - **YES**
             - Reactive/Unknown/Not Done
           - **NO**
             - **Non-reactive**
             - **Not a Case**
         - **NO**
           - **Not a Case**
     - **NO/Unknown**
     - Was this a fetal death meeting either of the following criteria:
       - Delivery after 20-week gestation
       - Birth weight >500 grams
     - **YES**
       - **Syphilitic Stillbirth**
     - **NO/Unknown**
   - **NO/Unknown**

2. **Does infant/child have a (+) darkfield or (+) DFA exam?**
   - **YES**
     - **Confirmed Case**
   - **NO/Unknown/Not Done**
   - **NO/Unknown/Not Done**

3. **Does infant/child have ANY one of the following:**
   - Physical signs of CS
   - Evidence of CS on long bone x-ray
   - Reactive cerebrospinal fluid VDRL (CSF-VDRL)
   - Elevated CSF cell count or protein (without other cause)
   - **YES**
     - **Probable Case**
   - **NO/Unknown/Not Done**

4. **Not a Case**
When to complete the CS Form

• Complete the CS form for Confirmed, Presumptive, or Syphilitic Stillbirths.
  – Infants or stillborn fetuses of mothers who are inadequately treated
  – Infants with reactive STS and evidence of congenital syphilis. Evidence includes
    • Physical signs of CS (footnote c)
    • Evidence of CS on long bone x-ray
    • Reactive cerebrospinal fluid VDRL (CSF-VDRL)
    • Elevated CSF cell count or protein (without other cause) (footnote d)
Why each data element is important.

RATIONALE
Rationale for Completing the Form

PART 1. MATERNAL INFORMATION
Header:
Mother and infant name and CalREDIE ID#, as well as the delivery hospital

**CASE ID No.**
The CS ID Number that is obtained from ICCR Headquarters.

**Rationale:** For reference when working the case.
1. Report date to HD:
Date when the first information about the infant came to the attention of the LHJ.

2, 3. Reporting State, County
The State (California) and county reporting the CS case. This should be the county of residence for the mother.

**Rationale:** Used for tracking CS reports by LHJ.
4-8. Residence Country, State, County, City, Zip Code: All residence information is for the residence of the MOTHER.

Rationale: Used for tracking CS morbidity by LHJ. Country information used to track imported CS from Mexico or other countries.
9-11. Mother’s Date of Birth, Ethnicity, and Race: Establishes mother’s demographics. Note that you can check all that apply for race.

**Rationale:** Used for describing mothers and assessing disparities in health.
12-14. Prenatal Care Access: Indicate whether mother had prenatal care within the US, outside the US, or not at all. Indicate the date of the first prenatal visit and number of prenatal visits.

**Rationale:** Used for tracking whether prenatal care was accessed in the U.S. Access to care is a potential point of intervention.
15-16. Non-Treponemal testing: Document RPR/VDRL testing and results in pregnancy, at delivery, or within 3 days of delivery.

**Rationale:** Used for assessing appropriate screening by medical providers. Results help DIS and managers assess whether mother is a new case of syphilis.
17-18. Additional testing: Indicate date of confirmatory testing (TP-PA, EIA), results and date of test. Indicate any additional testing done on lesions at delivery.

Rationale: Used for assessing appropriate confirmatory testing by medical providers. Positive tests of lesions classify the mother as a primary case of syphilis at delivery.
19-21. Mother’s Treatment:
Indicate when mother was last treated for syphilis, and whether that treatment was adequate.

**Rationale:** Required for classifying the infant as a CS case. Also, inadequate treatment may indicate a need for medical provider intervention.
19-21. Mother’s Treatment: Indicate when mother was last treated for syphilis, and whether that treatment was adequate.

**Rationale:** Required for classifying the infant as a CS case. Also, inadequate treatment may indicate a need for medical provider intervention.
Case Study #1: Sophia

• 27 year old mother, who is TP-PA+ with RPR of 1:16, diagnosed with late latent syphilis
• Previously treated for secondary syphilis (2009) with BIC x 1
• Last reported RPR of 1:2 in 2010
• First dose of BIC received 40 days before delivery
• Third dose of BIC received 26 days before delivery
• Treatment verified by medical provider
We don’t need a CS Form, but let’s complete this for practice...

**Did mother begin treatment 30 days or more prior to delivery and complete the treatment regimen appropriate for her stage?**

- **YES**
  - **Does mother meet case definition for syphilis?**
    - (footnote e)
  - **Do you have lab or medical information for infant?**
    - **YES**
      - **What is infant/child’s non-treponemal test result?**
        - **YES**
          - Reactive/Unknown/Not Done
        - **NO**
          - Non-reactive
    - **NO**
      - Non-a Case

- **NO/Unknown**
  - **Not a Case**

**Was this a fetal death meeting either of the following criteria:**
  - Delivery after 20-week gestation
  - Birth weight >500 grams

- **YES**
  - **Syphilitic Stillbirth**
- **NO/Unknown**

**Does infant/child have a (+) darkfield or (+) DFA exam?**

- **YES**
  - **Confirmed Case**
- **NO/Unknown/Not Done**

**Does infant/child have ANY one of the following:**
  - Physical signs of CS (footnote c)
  - Evidence of CS on long bone x-ray
  - Reactive cerebrospinal fluid VDRL (CSF-VDRL)
  - Elevated CSF cell count or protein (without other cause) (footnote d)

- **YES**
  - **Probable Case**
- **NO/Unknown/Not Done**

**STD Control Branch**
### MATERNAL INFORMATION

1. **Report date to health department:** [ ] Unk  
   **Mo.** / **Day.** / **Yr.**

2. **Reporting state:**  
   **CALIFORNIA**

3. **Reporting county:**

4. **Country of residence:**  
   (leave blank if USA)

5. **Residence state:** [ ] Unk

6. **Residence county:** [ ] Unk  
   (if case resides in a city health jurisdiction)

7. **Residence city:** [ ] Unk

8. **Residence zip code:** [ ] Unk

9. **Mother's date of birth:** [ ] Unk  
   **Mo.** / **Day.** / **Yr.**

10. **Mother's ethnicity:**  
    - [ ] Hispanic/Latina [ ] Unk  
    - [ ] Non-Hispanic/Non-Latina

11. **Mother's race:** (check all that apply)  
    - [ ] American Indian/Alaska Native  
    - [ ] Asian  
    - [ ] Black or African American  
    - [ ] Native Hawaiian or Other Pacific Islander  
    - [ ] White  
    - [ ] Unk

12. **Did mother have prenatal care?**  
    - [ ] Yes, at least once in US  
    - [ ] No (Go to Q15)  
    - [ ] Yes, outside of US [ ] Unk (Go to Q15)

13. **Indicate date of first prenatal visit:**  
    **Mo.** / **Day.** / **Yr.** [ ] Unk

14. **Indicate number of prenatal visits:** [ ] Unk

15. **Did mother have a non-treponemal test (e.g., RPR or VDRL) in pregnancy, at delivery, or within 3 days of delivery?**  
    - [ ] Yes  
    - [ ] No (Go to Q17)  
    - [ ] Unk (Go to Q17)

16. **Indicate dates and results of non-treponemal tests: (list the most recent first)**

<table>
<thead>
<tr>
<th>Date</th>
<th>Results</th>
<th>Titer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mo.</td>
<td>Day</td>
<td>Yr.</td>
</tr>
<tr>
<td>a.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. **Did mother have confirmatory treponemal test result (e.g., EIA, TP-PA)?**  
   If so, when was the test performed?  
   - [ ] Yes, reactive  
   - [ ] Yes, nonreactive  
   - [ ] No test  
   [ ] Titer: Mo. / Day / Yr.

18. **Did mother have darkfield or direct fluorescent antibody (DFA) exam of lesions at delivery?**  
    - [ ] Yes, positive  
    - [ ] No test of lesions  
    - [ ] Yes, negative  
    - [ ] No lesions present

19. **Before this delivery, when was mother last treated for syphilis?**  
    - [ ] Before pregnancy (Go to Q20)  
    - [ ] No treatment (Go to Q22)  
    - [ ] During pregnancy (Go to Q21) [ ] Unk (Go to Q22)

20. **Before pregnancy, was mother's treatment adequate?**  
    - [ ] Yes, adequate: treatment appropriate for stage  
    - [ ] Unk (Go to Q22)  
    - [ ] No, treatment not appropriate for stage (Go to Q22)

21. **During pregnancy, was mother's treatment adequate?** (Footnote a)  
    - [ ] Yes, adequate: penicillin-based treatment appropriate for stage  
    - [ ] No, inadequate: penicillin-based treatment not appropriate for stage  
    - [ ] No, inadequate: penicillin-based treatment begun < 30 days before delivery  
    - [ ] No, inadequate: non-penicillin-based treatment  
    - [ ] Unk
Rationale for completing the form.

PART 2. INFANT INFORMATION
### 22-27. General information about the infant:

Indicate date of delivery, vital status, date of death if applicable, sex, birth weight, and estimated gestational age.

**Rationale:** Provides basic information about the infant, including information required for classifying stillborn infants as syphilitic stillbirths.
28-29. Infant non-treponemal and treponemal testing:
Indicate whether the infant has serum or cord-blood tested, the dates of tests, and results.

**Rationale:** Provides specific laboratory data for the infant for case classification. Infant serum is more informative than cord-blood.
30. Signs of CS:
Indicate whether the infant has signs of congenital syphilis, including condyloma lata, snuffles, syphilitic skin rash, hepatosplenomegaly, jaundice/hepatitis, pseudo paralysis, and edema. Consult a clinician if unclear about signs.

Rationale: Signs of CS are important for understanding true burden of clinical CS.
### Laboratory Confirmation: Did the Infant/child have a darkfield exam or DFA-TP?

| Yes, positive | Yes, negative | No test | Unk |

#### Rationale:
Positive darkfield exam or DFA-TP are required to classify an infant as a confirmed CS case.
32-34. Infant Evaluation:
Indicate results of long bone X-rays, CSF-CDRL, CSF cell count or CSF protein test.

**Rationale:** Evidence of syphilis from one of these tests may be required for classifying an infant as a probable case.
35. **Infant Treatment:**

Indicate treatment for the infant, if received.

**Rationale:** Ensures treatment to prevent future complications of congenital syphilis. STD Control Officer may consider whether further follow-up with the medical provider is needed.
36. CS Case Classification:
Using the algorithm, classify the case as Not a case (form not required), a Confirmed case, a Syphilitic stillbirth, or a Probable case.

**Rationale:** Provides final classification for cases.
REPORTING OF STDs DOES NOT REQUIRE PATIENT CONSENT AND IS NOT SUBJECT TO THE REQUIREMENTS OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA). HIPPA ALLOWS DISCLOSURE OF THIS INFORMATION TO PUBLIC HEALTH FOR THE "PURPOSE OF ... PUBLIC HEALTH SURVEILLANCE, PUBLIC HEALTH INVESTIGATIONS, AND PUBLIC HEALTH INTERVENTIONS..." 45 CFR 164.512(b)(1)

RETURN COMPLETED FORM TO THE CDPH STD CONGENITAL SYPHILIS COORDINATOR VIA SECURE EMAIL TO cpacs@cdph.ca.gov OR FAX TO 916.440.5949

Case Study #2: Isabella

- Adopted – no information on mother
- 3 month-old female with RPR of 1:8
- Lumbar puncture results:
  - WBC count = 3 WBC/mm$^3$
  - CSF protein = 58 mg/dL
- No long bone X-ray available
Did mother begin treatment 30 days or more prior to delivery and complete the treatment regimen appropriate for her stage?

- YES
- NO/Unknown

Was this a fetal death meeting either of the following criteria:

- Delivery after 20-week gestation
- Birth weight >500 grams

- YES
- NO/Unknown

Does infant/child have a (+) darkfield or (+) DFA exam?

- YES
- NO/Unknown/Not Done

What is infant/child’s non-treponemal test result?

- RPR 1:8
  - Reactive/Unknown/Not Done

Does infant/child have ANY one of the following:

- Physical signs of CS (footnote c)
- Evidence of CS on long bone x-ray
- Reactive cerebrospinal fluid VDRL (CSF-VDRL)
- Elevated CSF cell count or protein (without other cause) (footnote d)

- YES
- NO/Unknown/Not Done

WBC count = 3 WBC/mm³
CSF protein = 58 mg/dL
### Part II: INFANT INFORMATION

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>22. Date of delivery</td>
<td>01/17/2013</td>
</tr>
<tr>
<td>23. Vital status:</td>
<td>Alive (Go to Q25)</td>
</tr>
<tr>
<td></td>
<td>Born alive, then died</td>
</tr>
<tr>
<td></td>
<td>Stillborn (Go to Q26) (Footnote b)</td>
</tr>
<tr>
<td></td>
<td>Unk (Go to Q25)</td>
</tr>
<tr>
<td>24. Date of death</td>
<td>/ / Yr.</td>
</tr>
<tr>
<td>25. Sex: Male, Female, Unk</td>
<td>Female</td>
</tr>
<tr>
<td>27. Estimated gestational age (in weeks)</td>
<td>38</td>
</tr>
<tr>
<td>28. Did infant/child have a reactive non-treponemal test for syphilis?</td>
<td>Serum</td>
</tr>
<tr>
<td>29. Did infant/child have a reactive treponemal test for syphilis?</td>
<td>Serum</td>
</tr>
<tr>
<td>30. Did the infant/child have any classic signs of congenital syphilis?</td>
<td>X No, asymptomatic infant/child</td>
</tr>
<tr>
<td>31. Did the infant/child have a darkfield exam or DFA-TP?</td>
<td>X No test</td>
</tr>
<tr>
<td>32. Did the infant/child have long bone X-rays?</td>
<td>X No X-rays</td>
</tr>
<tr>
<td>33. Did the infant/child have a CSF-VDRL?</td>
<td>X No test</td>
</tr>
<tr>
<td>34. Did the infant/child have a CSF cell count or CSF protein test?</td>
<td>X One or both elevated</td>
</tr>
<tr>
<td>35. Was the infant/child treated?</td>
<td>X Yes, with Benzathine penicillin x 1</td>
</tr>
<tr>
<td>36. Classification</td>
<td>Probable case (A case identified by the above algorithm, which is not a confirmed case or syphilitic stillbirth)</td>
</tr>
</tbody>
</table>

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**Reporting of STDs does not require patient consent and is not subject to the requirements of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA allows disclosure of this information to public health for the "purpose of... public health surveillance, public health investigations, and public health interventions..." 45 CFR §164.512(b)(1).**

**Return completed form to the CDPH STD Congenital Syphilis Coordinator via secure email to cpaas@cdph.ca.gov or fax to 916.440.5949 CDPH 9049 (4/2013)**

(CS Case Report 4/4/2013)
SUMMARY
Summary

• Complete the CS form for Confirmed, Presumptive, or Syphilitic Stillbirths.
  – Infants or stillborn fetuses of mothers who are inadequately treated
  – Infants with reactive STS and evidence of congenital syphilis
• Use of the CS form for non-cases is optional, to be determined by local program managers.
• Forms should be submitted to the Congenital Syphilis Coordinator within 7 days of case closure.
Case Closure, Case Review and Documentation

Mother Adequately Treated

- Within 30 days of treatment confirmation

Mother Inadequately Treated

- Within 30 days of treatment confirmation, stillbirth or delivery

- Front line supervisors should review all cases prior to submission.

- The following should be submitted to the Congenital Syphilis Coordinator within 7 days of case closure:
  - California CS Case Investigation and Report
  - Copy of the FR for mother and infant
  - Reactor history printed from the local reactor database
  - For early cases: copies of the FRs for partners and IR for mother

- Notify ICCR headquarters if you request a CS ID Number and the infant is subsequently determined not to be a case.

CONGENITAL SYPHILIS COORDINATOR:
cpacs@cdph.ca.gov or fax to 916.440.5949
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CalREDIE: Initiating, Monitoring and Entering Data for Congenital Syphilis
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Thank You!

California Department of Public Health
- Michael Samuel
- Denise Gilson
- Romni Neiman
- Edwin Lopez
- George Camarillo
- Heidi Bauer

County of San Diego
- Heidi Aiem
- Debra Lopez-Devereaux

Contact Information

PRESENTER INFORMATION:
Jessica Frasure-Williams
Syphilis Elimination Coordinator
Jessica.Frasure@cdph.ca.gov

SUBMIT ALL FORMS TO:
Congenital Syphilis Coordinator
cpacs@cdph.ca.gov or
tax to 916.440.5949
Surveillance Case Definition for Congenital Syphilis (CS)

• A **confirmed case** of CS is an infant or child in whom *Treponema pallidum* is identified by darkfield microscopy, direct fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material.

• A **presumptive case** of CS is either of the following: any infant whose mother had untreated or inadequately treated syphilis at the time of delivery, regardless of the findings in the infant or child; any infant or child who has a reactive treponemal test for syphilis and any one of the following:
  – evidence of CS on physical examination;
  – evidence of CS on long bone X-ray;
  – reactive CSF-VDRL;
  – elevated CSF cell count or protein (without other cause);

• A **syphilitic stillbirth** is defined as a fetal death in which the mother had untreated or inadequately treated syphilis at the time of delivery of either a fetus after a 20-week gestation or a fetus weighing >500g.

*Established by the Coalition of State and Territorial Epidemiologists*
Adequate treatment for syphilis in pregnant females

<table>
<thead>
<tr>
<th>Stage of syphilis</th>
<th>Treatment</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary, Secondary, and Early Latent</td>
<td>BIC x 1</td>
<td>Administered 30 days or more prior to delivery</td>
</tr>
<tr>
<td>Late Latent and Latent of Unknown Duration</td>
<td>BIC x 3</td>
<td>First dose administered 30 days or more prior to delivery, AND all doses received</td>
</tr>
</tbody>
</table>

Pregnant women allergic to penicillin should be treated with penicillin after desensitization. There are no alternative regimens for syphilis treatment in pregnancy.

Definition: Syphilitic Stillbirth

- fetal death in which the mother had untreated or inadequately treated syphilis at the time of delivery of either
  - a fetus after a 20-week gestation or
  - a fetus weighing >500g
Definition: Confirmed Case

- positive darkfield or special stains in the specimens from
  - lesions
  - placenta
  - umbilical cord, or
  - autopsy material
Definition: Probable Case

• inadequate treatment in the *mother*, regardless of infant results, OR

• reactive non-treponemal test in the *infant* plus one of the following:
  – evidence on physical exam,
  – evidence on long bone X-ray,
  – reactive CSF-VDRL, OR
  – elevated CSF cell count or protein (without other cause)

<table>
<thead>
<tr>
<th>Age of infant/neonates</th>
<th>Elevated CSF White Blood Cell Count</th>
<th>Elevated CSF Protein Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤30 days old</td>
<td>&gt;15 WBC/mm³</td>
<td>&gt;120 mg/dL</td>
</tr>
<tr>
<td>days old</td>
<td>&gt;5 WBC/mm³</td>
<td>&gt;40 mg/dL</td>
</tr>
</tbody>
</table>