ABSTRACT.  Background and Rationale. Diagnosis of congenital syphilis is problematic: infants with congenital syphilis are often asymptomatic, and signs in symptomatic infants are frequently subtle and nonspecific. Furthermore, there are no readily available diagnostic tests that provide a definitive diagnosis. Previously, the diagnosis of congenital syphilis was based on a complex set of clinical and laboratory criteria, and only infants with clinically apparent illness or laboratory findings indicating congenital syphilis were classified as cases and reported to health departments and the Centers for Disease Control and Prevention (CDC). To systematize diagnosis and case-reporting, the CDC developed a standardized surveillance case definition in 1988. This definition includes symptomatic infants as well as asymptomatic infants of mothers with untreated or inadequately treated syphilis during pregnancy. It is intended to be highly sensitive to better estimate the burden of disease in the community. Treatment guidelines for congenital syphilis are intentionally conservative and err on the side of overtreatment so that all potentially infected infants are treated. The congenital syphilis surveillance case definition is compatible with the American Academy of Pediatrics (AAP) and CDC treatment guidelines; thus, the number of infants identified and reported to state health departments and the CDC should reflect the number of infants treated. Hundreds of infants with reactive serologic tests for syphilis (STS) are reported each year to the New Jersey Department of Health and Senior Services (NJDHSS). The majority of these infants do not meet the case definition for congenital syphilis, and most are treated although treatment guidelines indicate that treatment is not necessary.

Objective. To determine whether infants with reactive STS in New Jersey are being treated according to the AAP treatment guidelines.

Methods. Medical records of newborns with reactive STS reported to NJDHSS between July 1, 1992, and June 30, 1996, were reviewed to determine status of infection and compliance with the AAP treatment guidelines. The 1995 NJDHSS Uniform Billing and Hospital Discharge Data was used to estimate the mean cost of hospitalization per day for infants with the diagnosis of congenital syphilis.

Results. During the study period, 1669 newborns with reactive STS were reported to the NJDHSS Sexually Transmitted Disease Program. Medical record review was completed for 1480 infants (88%). Infants were classified by CDC surveillance criteria as follows: 0 confirmed cases; 515 (35%) presumptive cases; 16 (1%) syphilitic stillbirths; and 949 (64%) cases that did not meet the definition for congenital syphilis.

Of the 515 presumptive cases that survived the immediate perinatal period, 495 (95%) were treated with antibiotics and 459 (90%) were treated according to the AAP treatment guidelines. Only 27 infants (6%) were treated with a single intramuscular dose of benzathine penicillin. Thirty-four infants (7%) were not treated; instead, their physicians chose to follow them clinically and serologically. All of those treated were asymptomatic, and most were born to mothers with a history of adequate treatment before or during pregnancy, but who were without serologic follow-up.

Of the 949 infants that did not meet the case definition, 329 infants (35%) were not treated and 620 (65%) were treated with antibiotics. The 508 (82%) infants treated with antibiotics were treated with intravenous or intramuscular antibiotics for \( \geq 10 \) days; only 62 (10%) were treated with a singular intramuscular dose of benzathine penicillin.

According to NJDHSS Uniform Billing Hospital Discharge Data, 267 infants weighing \( \geq 2500 \) g were discharged with a diagnosis of congenital syphilis in 1995. The median number of hospital days for these infants was 10, and the mean cost of hospitalization per day was $1010. Sources of payment of hospital charges for most infants were public insurance and self-pay. The estimate cost for 9 excess days of hospitalization for treatment of 231 infants with reactive STS who did not meet the case definition in New Jersey in 1995 was $2100 000.

Discussion. Nearly half of the infants classified as presumptive cases were born to mothers who had been administered proper treatment for syphilis before or during pregnancy, but who failed to drop their titer fourfold after treatment. Of these infants, 99% were asymptomatic. If the recommended diagnostic testing of infants had been performed, the majority probably could have been treated with a single intramuscular injection. Most of the infants not meeting the case definition were treated for 10 days with intravenous or intramuscular antibiotics. It is unclear why the majority of infants were treated, but it is unlikely that maternal treatment history was unknown to the clinician at the time the treatment decision was made and the infant was managed as if the mother were untreated. However, it is our experience that even when documentation of maternal treatment is readily and conspicuously available in the maternal medical record, most infants are treated for 10 days. Unnecessary and
R
tates of primary and secondary syphilis among young women rose sharply in the 1980s and
peaked in 1990 with 22,276 cases reported to the Centers for Disease Control and Prevention
(CDC) that year. This increase in syphilis in women was followed by a dramatic increase in the rate of
congenital syphilis; in 1991, 4,436 cases were reported to the CDC. Syphilis and congenital syphilis
have declined in recent years but remain important public health problems. Diagnosis of congenital
syphilis has always been troublesome; infants with congenital syphilis are often asymptomatic, and
signs in symptomatic infants are frequently subtle and nonspecific. Furthermore, there are no readily
available diagnostic tests that provide a definitive diagnosis; conventional serologic testing of infants
can reflect maternal antibody. Previously, the diagnosis of congenital syphilis was based on a complex
set of clinical and laboratory criteria that required serologic testing of infants over a long period to
determine status of infection and response to treatment. Only infants with clinically apparent illness or
laboratory findings indicating congenital syphilis were classified as cases and reported to health
departments and to the CDC. In response to the complexities of diagnosis, treatment, and case-re-
porting, the CDC developed a standardized surveillance case definition in 1988 (Appendix). This
case definition includes symptomatic as well as asymptomatic infants of mothers with untreated or
inadequately treated syphilis during pregnancy. The congenital syphilis surveillance case definition is compatible with the 1994 American Academy of Pediatrics (AAP) and 1993 Sexually Transmitted Disease (STD) Treatment Guidelines; thus, the number of infants identified and reported to state health departments and to the CDC should reflect the number of infants treated. The surveillance case definition is intended to be highly sensitive and includes both asymptomatic and stillborn in-

confirmed case: an infant or child in whom Treponema pallidum is identified by dark-field microscopy, direct fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material.

Presumptive case: 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 had a reactive treponemal test for syphilis and any one of the following:
  - evidence of congenital syphilis on physical examination;
  - evidence of congenital syphilis on long-bone x-ray;
  - reactive CSF VDRL;
  - elevated CSF cell count or protein (without other cause);
- reactive test for FTA-ABS-195-IgM antibody.

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


APPENDIX.

CDC Surveillance Case Definition for Congenital Syphilis*

**APPENDIX.

CDC Surveillance Case Definition for Congenital Syphilis**


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Abbreviations. CDC, Centers for Disease Control and Prevention; AAP, American Academy of Pediatrics; STD, sexually transmitted disease; STS, serologic tests for syphilis; NJDHSS, New Jersey Department of Health and Senior Services; CSF, cerebrospinal fluid; VDRL, venereal diseases research laboratory (test).
fants so that burden of disease in the community can be estimated more reliably and interventions and resources targeted appropriately. Treatment guidelines are intentionally conservative and err on the side of overtreatment—many infants will receive treatment although they may be uninfected. However, the surveillance case definition and treatment guidelines also cite criteria to identify which infants born to seropositive mothers do not need 10 days of treatment, or treatment at all.3 In New Jersey, as in most states, reactive serologic tests for syphilis (STS) are required by law to be reported to the state health department. Review of records of infants with reactive STS revealed that the majority were hospitalized and treated with parenteral antibiotics even when treatment was not indicated by the treatment guidelines. The New Jersey Department of Health and Senior Services (NJDHSS) undertook a formal evaluation of case-reporting and treatment of infants with reactive STS to determine whether infants were being identified properly and treated according to the AAP treatment guidelines.

METHODS

New Jersey statutes require that all pregnant women receive STS during pregnancy or at the time of delivery if no test was performed during pregnancy. Infants born in areas of high syphilis incidence also routinely receive STS at the time of birth. Laboratories are required to report all reactive STS to NJDHSS. Reports of all reactive infant STS received by NJDHSS are investigated by the staff within 24 to 72 hours of the infant’s birth. Investigations include review of laboratory results, health department records to determine maternal history of infection and treatment, and infant and maternal medical records. Health care providers and mothers are interviewed when needed to verify or collect information. Based on the results of these investigations, infants are classified by the CDC surveillance case definition as a confirmed case, a presumptive case, a syphilitic stillbirth, or not a case (ie, infant did not meet the case definition for congenital syphilis)35 (Appendix).

The study population included infants with reactive syphilis serology reported to the NJDHSS STD Control Program from July 1, 1992, to June 30, 1996. Data were collected from laboratory, health department, and infant and maternal medical records and included demographics; syphilis serology and confirmatory test results; clinical signs and symptoms of congenital syphilis; the CDC case classification; type and duration of infant treatment; and maternal demographic, clinical, and treatment information. Means, medians, and proportions were calculated for infant demographic and clinical data. The Kruskal-Wallis test was used to evaluate the significance of the difference of means between groups. Infant treatment was compared with the 1994 AAP Recommended Treatment of Neonates (<4 weeks of age) with Proven or Possible Congenital Syphilis (Table 1).6 The 1995 NJDHSS Uniform Billing and Hospital Discharge Data was used to estimate the mean cost of hospitalization per day for infants with a birth weight ≥2500 g and a discharge diagnosis of congenital syphilis (International Classification of Diseases—9 code 090.0–090.9) and to determine source of payment of hospital costs. Infants with birth weight ≥2500 g were chosen to estimate hospital costs to avoid inflation of costs associated with low birth weight or sick neonates. The mean cost of hospitalization per day was multiplied by the number of excess hospital days for treatment (9 days) and then by the number of uninfected infants hospitalized and treated in 1995.

RESULTS

During the study period, 1669 newborns with reactive STS were reported to the NJDHSS STD Program. Medical record review was completed for 1480 infants (88%). Infants were classified by CDC surveillance criteria as follows: 0 confirmed cases; 515 (35%) presumptive cases; 16 (1%) syphilitic stillbirths; and 949 (64%) cases that did not meet the case definition for congenital syphilis. Median infant rapid plasma reagin titers were 1:4 (range, nonreactive: 1:1024) for presumptive cases; 1:16 (range, 1:4–1:32) for syphilitic stillbirths; and 1:2 (range, nonreactive: 1:32) for infants who did not meet the case definition (P < .01).

Presumptive Cases

Nearly half (42%) of the mothers of presumptive cases had no prenatal care; of those with at least one prenatal visit, the median number of prenatal visits was four. The majority of the mothers of infants classified as presumptive cases (343/515, 67%) had been treated for syphilis before the birth of the infant: 106 (21%) were treated before pregnancy, and 237 (46%) were treated during pregnancy. In most cases, the treatment was adequate (220/343, 64%), but the mother did not manifest a fourfold drop in titer after treatment or had missing baseline titer information (186/220, 85%). The median birth weight of these infants was 2781 g and median gestational age 37 weeks. Nearly all (96%) of these infants were asymptomatic. Long-bone radiography was either not taken or results were unknown for the 398 infants (77%). Of those who underwent long-bone radiography, 11 (9%) infants had long-bone changes consistent with congenital syphilis, and 106 (91%) had no signs of congenital syphilis. Half (236/515) of the infants had a nonreactive cerebrospinal fluid (CSF) venereal diseases research laboratory (VDRL) test result, 32 (6%) infants had a reactive CSF VDRL test.

<table>
<thead>
<tr>
<th>Clinical Status</th>
<th>Antimicrobial Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly probable or proven disease</td>
<td>Aqueous crystalline penicillin G, IV for 10–14 days</td>
</tr>
<tr>
<td>Asymptomatic, normal CSF, and x-ray</td>
<td></td>
</tr>
<tr>
<td>Maternal treatment</td>
<td></td>
</tr>
<tr>
<td>None, inadequate, undocumented, failed, or reinfected</td>
<td>Aqueous crystalline penicillin G, IV for 10–14 days</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Clinical, serologic follow-up and benzathine penicillin G, im, single dose</td>
</tr>
<tr>
<td>Adequate therapy but given &lt;1 month before delivery, or mother’s response to treatment is not demonstrated by a fourfold decrease in titer of a nonreacted serologic test</td>
<td>Clinical, serologic follow-up and benzathine penicillin G, im, single dose</td>
</tr>
</tbody>
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result, and 218 (44%) underwent no CSF VDRL testing, or the results were unknown.

Of the 515 presumptive cases, 512 survived the immediate perinatal period (3 low birth weight infants died). Of those 512 surviving infants, 478 (93%) were treated with antibiotics; 459 (90%) were treated according to the AAP treatment guidelines (Tables 1 and 2). Only 27 infants (6%) were treated with a single intramuscular dose of benzathine penicillin. Thirty-four (7%) infants were not treated; instead, their physicians chose to follow them clinically and serologically. All of these untreated infants were asymptomatic, and most were born to mothers with a history of adequate treatment before or during pregnancy, but who were without serologic follow-up.

Infants Not Meeting Case Definition

Of the 949 infants who did not meet the case definition, 329 (35%) were not treated and 620 (65%) were treated with antibiotics. Of those infants treated with antibiotics, 508 (82%) were treated with intravenous or intramuscular antibiotics for ≥10 days; only 62 (10%) were treated with a single intramuscular dose of benzathine penicillin (Table 3).

According to NJDHSS Uniform Billing Hospital Discharge Data, 267 infants weighing ≥2500 g were discharged with a diagnosis of congenital syphilis in 1995. The median number of hospital days for these infants was 10, and the mean cost of hospitalization per day was $1010. Source of payment of hospital charges for infants with a discharge diagnosis of congenital syphilis were Medicaid (66%), self-pay (20%), health maintenance organization (12%), and private major medical insurance (2%). According to NJDHSS surveillance data, 231 infants who did not meet the congenital syphilis surveillance case definition were hospitalized and treated for congenital syphilis in 1995. Using the mean cost of $1010/day, the estimated cost for 9 excess days of hospitalization for treatment of these uninfected infants was $2 100 330. The burden of this cost fell primarily on the public system and on the patient’s families themselves.

DISCUSSION

Almost all of the infants classified as presumptive cases of congenital syphilis were treated according to AAP treatment guidelines. Of greater concern is the hospitalization and treatment of infants who did not meet the case definition. Of 1669 infants with reactive serology, 949 infants did not meet the case definition for congenital syphilis, because all mothers were previously and adequately treated. However, 65% of the infants were treated and hospitalized for ≥10 days. It is unclear why the majority of infants were treated, but it is likely that maternal treatment history was unknown to the clinician at the time the treatment decision was made and the infant was managed as if the mother were untreated. Since 1992, the NJDHSS has made regular efforts to educate neonatal clinicians to contact the health department when maternal syphilis treatment and titer history are vague or unknown, but very few inquiries are made. Since 1994, NJDHSS congenital syphilis liaison field workers have visited hospitals in high-risk areas almost daily to investigate reports of infants at risk for congenital syphilis at birth. During these investigations, newborn nursery staff are provided with any existing documentation of maternal treatment. Provision of this documentation appears not to have affected treatment decisions because rates of treatment of infants who do not meet the case definition have remained ~65% since 1992. It is our experience that even when documentation of maternal treatment is readily and conspicuously available in the maternal medical record, most infants are treated for 10 days.

Furthermore, a number of infants classified as presumptive cases could have been spared 10 days of treatment. Nearly half of the infants classified as presumptive cases were born to mothers who had been administered proper treatment for syphilis before or during pregnancy but failed to drop their titer fourfold after treatment; 99% of these infants of treated mothers were asymptomatic. In many cases, there was insufficient time between treatment and birth to see a fourfold drop in titer. With appropriate diagnostic testing, the majority of these infants of adequately treated mothers probably could have been treated with a single intramuscular injection. However, few of these infants had the appropriate diagnostic testing; only 10% of these infants underwent long-bone radiography, and only 55% underwent CSF VDRL testing. Asymptomatic infants with normal CSF findings and long-bone radiographs who are born to mothers who were treated appropriately during pregnancy but who did not have serologic evidence of cure can be followed without

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<table>
<thead>
<tr>
<th>Antibiotic Therapy</th>
<th>Number (%) of Infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not treated</td>
<td>34 (7)</td>
</tr>
<tr>
<td>Treated</td>
<td>478 (93)</td>
</tr>
<tr>
<td>≥10 Days IV or IM penicillin G</td>
<td>403 (84)</td>
</tr>
<tr>
<td>&lt;10 Days IV or IM penicillin G</td>
<td>6 (1)</td>
</tr>
<tr>
<td>IV ampicillin and IV penicillin G ≥10 days</td>
<td>29 (6)</td>
</tr>
<tr>
<td>IM benzathine penicillin G, single dose</td>
<td>27 (6)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (3)</td>
</tr>
<tr>
<td>Total</td>
<td>512 (100)</td>
</tr>
</tbody>
</table>

**TABLE 3. Antibiotic Therapy of Infants With Reactive STS That Did Not Meet the Congenital Syphilis Case Definition, New Jersey, 1992-1996**

<table>
<thead>
<tr>
<th>Antibiotic Therapy</th>
<th>Number (%) of Infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not treated</td>
<td>329 (35)</td>
</tr>
<tr>
<td>Treated</td>
<td>620 (65)</td>
</tr>
<tr>
<td>≥10 Days IV or IM penicillin G</td>
<td>495 (80)</td>
</tr>
<tr>
<td>&lt;10 Days IV or IM penicillin G</td>
<td>35 (6)</td>
</tr>
<tr>
<td>IV ampicillin and IV penicillin G ≥10 days</td>
<td>13 (2)</td>
</tr>
<tr>
<td>IM benzathine penicillin G, single dose</td>
<td>62 (10)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (2)</td>
</tr>
<tr>
<td>Total</td>
<td>949 (100)</td>
</tr>
</tbody>
</table>
treatment,6–8 or if not followed, can be treated with a single dose of benzathine penicillin.6–8 New Jersey data are consistent with those from Houston, TX, where only 35% of infants at risk for congenital syphilis underwent CSF VDRL testing.10 Stoll11 noted that despite recommendations, infants have been evaluated inconsistently. It is unclear why diagnostic testing is not performed more consistently. Diagnostic testing may have been withheld intentionally because it was felt that the results would not affect treatment decisions. Some clinicians do not perform CSF tests because the lack of sensitivity and specificity make results of these tests difficult to interpret and therefore not useful in treatment decisions.3,10,11 Unnecessary and prolonged hospitalization and treatment of infants with reactive serology has significant social, medical, and economic consequences and should be prevented when possible.3,11,12 Hospitalization of uninfected infants for antimicrobial treatment separates newborns from their parents at a critical time for integration into the family unit. There are thought to be significant detrimental long-term effects on mother–infant pairs separated in the first few days and weeks after birth.13,14 Mothers separated from their infants in the postnatal period are at much higher risk of developing delayed feelings of attachment,15,16 being subsequently less affectionate with their infants,14 and feeling less competent in caring for their infants than mothers who are not separated.16 The deleterious long-term effects of separation may be more pronounced in poor, single, and substance-abusing mothers,17–19 classic correlates of syphilis infection, than in less disadvantaged mothers. Separation of the mother and infant also has negative consequences for breastfeeding; mothers separated from their infants in the first few days of life are unlikely to breastfeed or to continue breastfeeding if they have begun.20–22

Hospitalization itself represents some hazards for the infant. Infants who are hospitalized after birth, even for minor health problems, are more likely to be perceived by their parents as vulnerable23 and are at risk of developing a nosocomial infection.24 Rates of nosocomial infection are highest among infants,24–29 especially among those hospitalized in the neonatal intensive care unit.24,27,30 Intravenous lines, nursery overcrowding, and understaffing increase the risk of nosocomial infection.27,30 In the context of total health care expenditures, the economic cost of unnecessary treatment for congenital syphilis is small. Extrapolated to the nation, the cost is considerable. Significant cost savings could be realized for public health insurance programs and the infant’s family if infants were treated according to treatment guidelines.

It is unknown why clinicians treat infants with reactive serology when treatment is not indicated by the treatment guidelines. Perhaps there is difficulty in interpreting the case definition, treatment guidelines, or maternal clinical and treatment history, or perhaps there is a feeling that by treating all infants, no infant in need of treatment will be missed. In response to this problem, we have developed a set of recommendations intended to reduce overtreatment of infants with reactive syphilis serology. Clinicians should be trained regarding the interpretation of maternal and infant serology test results and indications for treatment. The recommended diagnostic work-up of infants at risk for congenital syphilis should be performed, including a thorough physical examination for signs of congenital syphilis; quantitative nontreponemal STS on infant serum, not cord blood; CSF analysis for cells, protein, and VDRL; and long-bone radiography when indicated.2 The recommended antibiotic therapy for infants should be administered after review of maternal history and the results of the infant physical examination and diagnostic tests. Clinicians should be aware that health departments possess and are required to retain information about maternal serology titer history and treatment, which can be used to make clinical decisions about the treatment of infants at risk for congenital syphilis. Clinical agencies and health departments need to develop strategies for improving the exchange of information. Health departments should be able to provide information about maternal titer history and treatment to clinical agencies within 1 working day if birth of the infant occurs on a weekday and within 2 days if birth of the infant occurs on the weekend. Clinicians should improve the exchange of information between obstetric and pediatric services, because obstetric services may have documentation of maternal syphilis serology titer and treatment history to guide infant treatment decisions. Finally, all untreated or inadequately treated mothers should be treated before being discharged from the hospital so that they are treated adequately before their next pregnancy. In New Jersey, adherence to the treatment guidelines will expedite the discharge of newborns with reactive syphilis and prevent the medical, social, and economic costs associated with inappropriate and necessary treatment.

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Treatment of Infants With Reactive Syphilis Serology, New Jersey: 1992 to 1996
Lyn Finelli, Eileen M. Crayne and Kenneth C. Spitalny
*Pediatrics* 1998;102;e27

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