

**Congenital Syphilis (CS) Case Investigation and Report Form
0920-0128**

**Supporting Statement
Part B**

Contact Information

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

Staff at the local and territorial agencies are the respondents for this request because they transcribe a physician's case report form to the CDC CS report form by removing the personal identifiers except birth of date and submit it to CDC. The case reports provide information on infants with presumptive or confirmed CS, as defined by the surveillance case definition, and their mothers will be included in this surveillance. An individual form will be completed for each case of CS, including stillbirths linked to CS.

The 60 respondents in this surveillance system will be the STD project areas incorporated in health departments in all 50 States, New York City, Philadelphia, Baltimore, Los Angeles, San Francisco, Chicago, the District of Columbia, the U.S. Virgin Islands, the Commonwealth of Puerto Rico, and Guam.

No sample selection is involved in the surveillance/reporting process; the STD project areas will provide information on all CS cases reported to them. The data from each reporting area includes an individual case report form for each diagnosed case of CS, including stillbirths due to CS. All individual case reports are sent to CDC as soon as possible after the case is reported to the health department. CDC monitors the frequency of reported CS case and contacts project areas if noticeable increases or decreases in these levels occur. CDC uses the data from the local and territorial health agencies to improve case detection, case management, and treatment of CS nationwide (see Attachment 5 for current list of publications).

2. Procedures for the Collection of Information

Many State regulations require the reporting of syphilis and syphilitic stillbirths by private and public providers. State and local health agencies establish a process for receiving case reports from the providers as part of their local requirements for reporting nationally notifiable diseases. Physicians and other providers collect demographic, risk, and clinical (including laboratory) information from persons diagnosed with notifiable STDs during a clinical encounter or counseling session. They submit the information, either

electronically or in hardcopy form, to their local health department.

The data elements defining congenital syphilis morbidity needed for this surveillance are submitted by state and local health departments either electronically via the National Electronic Telecommunications System for Surveillance (NETSS) or on the hardcopy "Congenital Syphilis (CS) Case Investigation and Report Form" to CDC. The electronically-submitted data and hardcopy surveillance forms mailed to CDC include "date of birth" delinked from personal identifiers. All other IIF data are retained by the health departments and are not transmitted to CDC. The Division of STD Prevention at NCHHSTP extracts the information needed either directly from the hardcopy form or by accessing the STD databases located on either the CDC mainframe or computer network. Medical records or other health information of individuals associated with CS or any other STDs are unavailable at CDC.

In accordance with state and local laws and regulations and Health Insurance Portability and Accountability Act (HIPAA)'s public health notification exemption, both health care providers and laboratories are required to report demographic, risk, and clinical information data elements to the local or state public health system.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Non-response is not applicable for this clinical surveillance procedure. Data for syphilis and syphilitic stillbirths are collected by State and local health departments to meet the legal requirements for nationally notifiable diseases.

4. Test of Procedures or Methods to be Undertaken

No new clinical procedure or novel method will be involved in the surveillance/reporting process; the CS/STD project areas will provide information on all Congenital Syphilis cases reported to them. The data from each reporting area includes an individual case report form for each diagnosed case of CS, including stillbirths due to CS. All individual case reports are sent to CDC as soon as possible after the case is reported to the health department.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Members of CSTE and NCSD are consulted when changes to the CS reporting process are proposed.