

# **Sexually Transmitted Disease (STD) Morbidity Surveillance**

## **Justification Section A**

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# Sexually Transmitted Disease (STD) Morbidity Surveillance

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### Section

#### A. Justification

##### 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called "Sexually Transmitted Disease (STD) Morbidity Surveillance" for a period of three years.

#### Background

The CDC is responsible for the reporting and dissemination of nationally notifiable STD morbidity information for prevention and control purposes in collaboration with state and local health departments.

Recent changes in sexually transmitted disease (STD) epidemiology in the United States indicate that the existing passive surveillance for STDs which are included in the National Disease Surveillance System do not include all the data elements needed in order to control and prevent STDs in the U.S. Towards this end, CDC is proposing a new electronic information collection called *STD Morbidity Surveillance* which will include information on laboratory confirmation of syphilis infection and risk behaviors of persons infected with syphilis and other STDs. The STD Morbidity Surveillance data will identify population subgroups at increased risk for STDs, accommodate evidence-based intervention strategies, evaluate the impact of ongoing control efforts and generally enhance our understanding of STD transmission.

The proposed STD Morbidity surveillance activity is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

#### Privacy Impact Assessment

##### Overview of the data collection system

The surveillance case definitions used to confirm STDs is jointly developed and approved by the Council of State and Territorial Epidemiologists (CSTE) and CDC for nationally notifiable STDs. The nationally notifiable STDs include chancroid, genital *Chlamydia trachomatis* infection, gonorrhea, and all stages of

syphilis. The information content of the electronic STD morbidity case reports submitted to CDC is defined in collaboration with state and local STD programs.

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, and submits the information electronically, to the state and local public health departments. Clinical specimens obtained from case-patients are submitted to private or public diagnostic laboratories with laboratory requisition forms including information on the provider and case-patient.

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.

The data elements defining STD morbidity that are needed for the new surveillance will be submitted by state and local health departments electronically. The Division of STD Prevention at NCHHSTP will extract the information needed by accessing the STD data bases through the CDC mainframe.

#### Items of Information to be collected

Attachment 3 is a comprehensive list of STD-specific data variables that will accompany a case report in the new STD Morbidity Surveillance. Table 1 in Attachment 3 lists data elements unique to the proposed STD Morbidity surveillance. Table 2 of Attachment 3 lists data elements that are currently submitted by state, local, and territorial health agencies for the National Notifiable Disease Surveillance System and will be used by the STD Morbidity Surveillance.

The date of birth is the only Information in Identifiable Form (IIF) that is transmitted to CDC as part of the STD morbidity surveillance record and this is associated with a unique case identification number assigned by the state or local health departments. CDC cannot access any personal information regarding the case report. This is a convention used to report all notifiable diseases to CDC. No other personal identifiable information is associated with the date of birth in case records transmitted to CDC so that the identification of a person is not possible. CDC does not have the key to access any other information that would identify a person associated with the

unique case record identification assigned to the STD case report by the local or state health departments. The date of birth is used exclusively in the data cleaning procedures; to identify duplicate records with the same case identification numbers for two different case reports.

### Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age .

CDC does not have a website for STD information nor website content for children under 13 years of age.

## **2. Purpose of Use of the Information Collection**

The STD morbidity information is being collected in order to monitor morbidities and risk profiles of persons with specific trends in specific STDs at the local, state, and national level. The feedback to local and state departments improves STD prevention and control efforts. Reporting selected demographic and risk behavior data on persons infected with notifiable STDs from state and local STD prevention programs to CDC allows cross-jurisdictional, regional, and national STD trends and emerging epidemiologic patterns to be identified to guide public health response.

CDC will use the STD morbidity information to plan and implement interventions, and to guide the allocation of prevention resources. Without the STD morbidity information, the distribution of STDs by risk behavior group (e.g. men who have sex with men) across the United States will be unavailable. DSTDP will not be able to make data-based decisions regarding national prevention program planning and resource allocation without STD incidence data.

Once STD morbidity data are reported to CDC, the use and release of the data are guided by a June 1996 policy, "Data Release Guidelines of the Council of State and Territorial Epidemiologists (CSTE) for the National Public Health Surveillance System" (NPHSS). These guidelines defines the subgroups of STD morbidity data that can be released (Attachment 4). The policy for data release intends to facilitate the use of national notifiable STD morbidity data while preserving the confidentiality of the data. Without the new STD Morbidity data elements, CDC will not be able to respond to the changing epidemiology of STDs within subgroups with common risk behaviors.

Annually, CDC disseminates a comprehensive summary of the trends in STD morbidity, by etiology, as the STD surveillance report and syphilis surveillance supplement presenting (URL: <http://www.cdc.gov/std/Syphilis2006/default.htm> , <http://www.cdc.gov/std/stats/toc2006.htm> )

Epidemiologists and program consultants at CDC, review STD morbidity data at weekly, monthly, and on an 'ad hoc' basis -- to identify potential outbreaks. The STD morbidity data is also used to estimate the burden of disease, identify population subgroups at increased risk for STDs, and monitor trends in STD distribution by geographic, temporal, and risk behavior characteristics to identify opportunities for prevention and control and to evaluate ongoing control efforts.

The Syphilis Elimination Data Workgroup conducts weekly review of morbidity data to identify syphilis outbreaks and emerging disease trends that may require immediate public health action. Other users of data include, but are not limited to, congressional offices, state and local health agencies, health care providers, non-governmental organizations, academia, and other health-related groups. Their data requests are handled via ad hoc data analyses or referral to our surveillance reports or CDC Wonder (URLs, respectively: [http://www.cdc.gov/nchstp/dstd/Stats\\_Trends/Stats\\_and\\_Trends.htm](http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm) ; <http://wonder.cdc.gov/std.html> ).

In conjunction with national population-based surveys conducted by CDC's National Center for Health Statistics, e.g. National Health and Nutrition Examination Survey, CDC periodically derives population-based estimates of the burden of STDs in the United States and aid interpretation of nationally notifiable STD surveillance data.

The limits to generalization of findings from this collection are common to notifiable disease surveillance in general. Since notifiable STD surveillance requires infected individuals to seek care in order for their condition to be diagnosed by a health care provider or detected via a screening test, notifiable STDs (especially asymptomatic conditions e.g., genital *Chlamydia* infection) may be under-detected. Health care providers or clinical labs are required by local/state laws/statutes/regulations to report notifiable STDs to the public health system. However, notifiable STDs may be underreported by providers or labs. Periodically, states evaluate the completeness of STD surveillance and estimate under reporting; under detection which is affected by health-care seeking



behaviors and health care provider practices (e.g., screening and reporting practices) is more difficult to assess. When surveillance deficiencies are noted via routine monitoring, remedial efforts are initiated.

CDC disseminates STD surveillance information through the weekly MMWR, the MMWR Surveillance Summaries, the annual Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, CDC publishes an annual STD-specific surveillance summary and supplements in hard copy on CD-ROM and on the Internet ([http://www.cdc.gov/nchstp/dstd/Stats Trends/Stats and Trends.htm](http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm)).

#### Privacy Impact Assessment Information

This STD Morbidity information collection request includes sensitive information on sexual and drug-using behaviors associated with the case-patient and identified only as a case identification number. The date of birth, which is included in the case report submitted to CDC allows in the data cleaning step by distinguishing duplicate records with different case identification numbers or vice versa. The date of birth is also used to assign age of the patient. The proposed STD Morbidity data collection will have no effect on the respondent's privacy because date of birth is not associated with any other personal information that can be used to identify an individual in the STD Morbidity Surveillance.

At CDC, the STD Morbidity Data are maintained on secure servers behind the CDC firewall. Password-protected access is required and directory-specific user access rights are assigned by a CDC data steward following review of and sign-off on a data use policy that references the CSTE data release guidelines (Attachment 4). Restricted access to STD data is provided to Division of STD Prevention (DSTDP)/CDC scientists, researchers, and program managers via an intranet web-based data query application called STD Net. Epidemiologists and program consultants in the DSTDP create analytic data files from the case report line listing in order to monitor trends in STDs by demographic and geographic characteristics.

In order to gain the maximum benefit for existing STD prevention and control efforts, CDC will disseminate aggregated STD morbidity reports with local and state STD prevention programs, policy makers, academia and the general public, in the form of MMWR series of publications, including the weekly MMWR, the MMWR

Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, DSTDP publishes an annual STD-specific surveillance summary and supplements in hard copy on CD-ROM and on the Internet ([http://www.cdc.gov/nchstp/dstd/Stats\\_Trends/Stats\\_and\\_Trends.htm](http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm)).

### **3. Use of Improved Information Technology and Burden Reduction**

More than 98% of the state and local jurisdictions submit STD morbidity reports to CDC electronically via the National Electronic Telecommunications System for Surveillance. Over the next 4 years, CDC will maintain greater than 98% electronic reporting. Local data collection methods are not directed or mandated by CDC, but the majority of state STD prevention and control programs use STD\*MIS (CDC-provided freeware) or a commercial or locally-developed information system for collection of a wide range of surveillance and programmatic information - only a subset of which is reported to CDC as part of the STD case report.

### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC is the only agency that conducts national surveillance for 60 diseases through the funded assistance of state and local health departments. The new STD Morbidity Surveillance will have 53 data elements; 16 of which are collected by the National Notifiable Disease Surveillance (Attachment 3, Tables 1 & 2). National and regional distribution of STD morbidity by etiology is not available in the U.S. CDC has also verified through CSTE, state and local STD prevention programs and, the National Coalition of STD Directors, that there is no other nationwide collection of STD-specific morbidity information.

CDC has also confirmed the absence of duplicate information systems in the U.S. through literature searches and communication with other health professionals and organizations.

The Program Evaluation and Monitoring System (PEMS) of the Division of HIV/AIDS Prevention collects HIV-related information at STD clinics using their standardized case report form. However, the PEMS form collects only HIV testing and counseling information and not STD information. Any common information, e.g. self-reported risk behaviors, is collected once and used (as relevant) to meet both STD morbidity and HIV infections.

To minimize data collection efforts, in 2007, DSTDP and DHAP harmonized the risk factor information 'questions' so the risk factor information reported by state and local health departments on an MMWR STD case report form is the same as the risk factor information needed for PEMS reporting. Thus, in the STD prevention program setting, relevant data are collected only once by state and local programs and reported separately for STD morbidity surveillance, HIV counseling and testing monitoring, or both, as appropriate.

## **5. Impact on Small Business or Other Small Entities**

Several states mandate the reporting of STDs by private physicians to report STDs to their local and state health authorities. There is no additional impact on small business or other small entities.

## **6. Consequences of Collecting the Information Less Frequently**

STD control is dependent upon the rapid identification of changes in disease transmission. Weekly reporting of STD morbidity data is required for early detection of potential STD outbreaks. Timely collection of information supports continual analysis of surveillance data in order to detect unusual disease reporting patterns that may indicate an STD outbreak. There are no legal obstacles to reduce the burden.

## **7. Special Circumstances relating to the Guidelines of [5 CFR 1320.5](#)**

The STD morbidity information collection request is consistent with 5 CFR 1320.5 except for the frequency of reporting.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

Attachment 2 is a copy of the Federal Register notice which appeared on April 10, 2008, Volume 73, No. 70, pp. 19507-08. No public comments were received.

### *External consultants*

CDC periodically consults with CSTE regarding STD morbidity surveillance procedures and processes, including review of the conditions under surveillance and their case definitions and frequency and information content of morbidity case reports. The Executive Director of CSTE is Patrick McConnon (770-458-3811) and

Cort Lohff, Vermont State Epidemiologist [Vermont Department of Health, 108 Cherry Street, Burlington, VT 05402; 802-863-7240], is the lead CSTE consultant for STD surveillance and prevention. The most recent consultation with Dr. Lohff occurred in June 2007 when DSTDP consulted Dr. Lohff on the issue of a surveillance case definition for neonatal herpes and proposed making neonatal herpes a notifiable condition. The surveillance case definition was finalized, but CSTE did not support making neonatal herpes a notifiable condition.

## **9. Explanation of Any Payment or Gift to Respondents**

No payments or gifts are provided to respondents.

## **10. Assurance of Confidentiality Provided to Respondents**

The Privacy Act does not apply to this submission. All IIF categories are retained by the state, city, and territorial health departments – and are not transmitted to CDC. Each STD case record transmitted to CDC includes a state-assigned case number.

The STD Morbidity Surveillance is not considered research involving human subjects and is exempted from Regulations for the Protection of Human Subjects (45 CFR 46) (Attachment 5)

### **Privacy Impact Assessment Information**

#### **A. Data collection and processing procedures described:**

Date of birth delinked from other personal identifiers will be part of the data set. Date of birth will be used to determine with duplicate case identification numbers belong to the same or 2 different case reports. Each case report represents a single record in the STD Morbidity Surveillance and is assigned a unique case identification number by the local, state, or territorial agencies. The case record transmitted to CDC does not include personal identifiable elements. Local health jurisdictions maintain the information needed for case follow-up and other disease control interventions. Case records will be encrypted and transmitted to CDC through the Secure Data Network (a secure file transfer protocol and application requiring user authentication and authorization) as established for the reporting of notifiable diseases to CDC. CDC will never have key to the code and all follow-up will need to be coordinated through the State and Local health departments.

*B. Security of the information addressing relevant technical, physical, and administrative safeguards.*

Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

Access to STD morbidity data reported to and managed by CDC is limited even within CDC, using technical controls (user identification, passwords, and firewalls), physical controls (guards, identification badges, key cards), and administrative controls (daily file backups, data release guidelines, data user agreements).

Physician or laboratory reporting of notifiable STD conditions to local and state public health systems is mandated by local or state law or regulation. Consent of the patient is not required. State and territorial health departments report nearly 60 notifiable diseases including the 4 STDs to CDC on a voluntary basis and the data elements needed for STD Morbidity Surveillance will follow the transmission protocols established by CDC.

## **11. Justification for Sensitive Questions**

Sensitive information elements reported to CDC as part of the STD Morbidity surveillance is limited to sexual and drug-using behaviors associated with the STD case report (Attachment 3). These sensitive elements are essential to better understand the sexual practices that increase the risk of transmission or acquisition of the STDs. Sexual and drug-use behaviors also impact STD distribution and epidemiology; therefore it is necessary to collect the STD morbidity information on new STD cases. This information will help CDC formulate more efficient intervention strategies, and evaluate the impact of ongoing control efforts.

## **12. Estimates of Annualized Burden Hours and Costs**

**A.** The total annualized burden estimate for the STD Morbidity Surveillance request is 989 hours. CDC estimates that 57 respondents will spend 20 minutes each week extracting the new data elements for the STD Morbidity Surveillance from their electronic information system and transmitting the encrypted STD Morbidity Surveillance data elements electronically to CDC via CDC's Secure Data Network. These estimates are for the new data elements that constitute the STD Morbidity Surveillance described in Attachment 3.

Table 12-A: Estimate of Annualized Burden Hours

Types of Respondent	Form name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State Health Departments	Electronic STD Case report	50	52	20/60	867
Territorial Health Agencies	Electronic STD Case report	5	52	20/60	87
City and county health departments	Electronic STD Case report	2	52	20/60	35
State, city, and county health departments (Territories will not provide additional data elements)	Additional data entry and modification of data extract programs	52	1	6	306
<b>Totals</b>		<b>57 (unduplicated)</b>	--	--	<b>1295</b>

**B.** At the state and local health departments, data are entered by computer support specialists trained to use the secure data network provided by CDC. The average hourly wage for the computer specialists is \$20 which is used to estimate the annualized cost to the respondents. This amount is included in the funds provided to the state, local, and territorial health departments to support their participation in the STD

surveillance activities. The cost below is for the new STD Morbidity Surveillance.

Table 12-B: Estimate of Annualized Cost to Respondents

Types of respondents	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs**
State Health Departments	867	\$20.00	\$17,340.00
Territorial Health Agencies	87	\$20.00	\$ 1,740.00
City and county health departments	35	\$20.00	\$ 700.00
State, city, and county health departments	306	\$20.00	\$ 6,120.00
<b>Totals</b>	<b>1295</b>	<b>\$20.00</b>	<b>\$25,900.00**</b>

\* Hourly wage estimate based on Computer Support Specialist (15-1041) hourly wage available at:

[http://www.bls.gov/oes/current/oes\\_nat.htm#b15-0000](http://www.bls.gov/oes/current/oes_nat.htm#b15-0000) .

\*\* Respondents receive federal funds for comprehensive STD prevention services through CDC cooperative agreements.

### 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents other than their time.

### 14. Annualized Cost to the Federal Government

The annual cost is summarized in Exhibit A.14. Management of the STD morbidity surveillance system requires the support of data managers (IT specialists), scientific information specialists (health scientists), and computer programmers. CDC personnel listed in Table 14-A provide technical support and data management, analysis, and dissemination support for this surveillance activity.

Table 14-A: Estimate of Annualized Cost to Federal Government

Expense type	Explanation of expense	Annual Costs (\$)
Direct Costs	GS-2210-13, IT Specialist, 0.75 FTE	\$68,424
	GS-2210-13, IT Specialist, 0.75 FTE	\$68,424

Expense type	Explanation of expense	Annual Costs (\$)
	GS-2210-12, IT Specialist, 0.5 FTE	\$38,360
	GS-601-14, Health Scientist, 0.2 FTE	\$21,561
	GS-601-15, Supervisory Epidemiologist, 0.1 FTE	\$12,681
	Office supplies and equipment	\$5,000
	Printing of surveillance reports	\$25,000
Cooperative agreements	57 health jurisdictions	\$19,780.00*
Employee Benefits	25% of FTE and cooperative agreement wages	\$57,308
	<b>Total estimated annualized cost to the government</b>	<b>\$316,538</b>

\* Included as cost to respondent in Table 12.B. Salary estimates were obtained from OPM salary scale (<http://www.opm.gov/oaca/08tables/indexGS.asp> ).

## 15. Explanation for Program Changes or Adjustments

This is a new electronic data collection.

## 16. Plans for Tabulation and Publication and Project Time Schedule

The dissemination of STD surveillance information is accomplished through the *MMWR* series of publications, including the weekly *MMWR*, the *MMWR* Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Since STD Morbidity data are disseminated each week, data management and analysis occurs each week throughout the year.

Additionally, CDC publishes an annual STD-specific surveillance summary and supplements in hard copy on CD-ROM and on the Internet (<http://www.cdc.gov/nchstp/dstd/Stats Trends/Stats and Trends.htm> ). The annual STD surveillance summary is usually published in paper-copy and disseminated and posted to the internet within 11 months following the end of the calendar year (i.e., the 2005 annual STD surveillance summary was distributed in November 2006.). The new information will be presented in the Division



and Agency level surveillance reports in the form of figures and tables in the "Special Focus" sections of the report.

## Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Distribute updated national notifiable STD case report specifications (i.e., electronic record format) to respondents for comment and input.	1-3 months after OMB approval
Modify DSTDP's STD*MIS (state STD program freeware) to allow collection, analysis and reporting of new data elements	4-10 months after OMB approval
Test the modifications, revised algorithms, and quality of modified variables for analysis	11-12 months after OMB approval.
Modify DSTDP's SAS programs and STD*MIS (state STD program freeware) for data quality monitoring and epidemiologic analysis at CDC	12-13 months after OMB approval.
Test the SAS programming and creation of analytic data set at DSTDP.	13-16 months after OMB approval
Disseminate first provisional weekly electronic national notifiable STD morbidity data from respondents.	16 months after OMB approval and Ongoing weekly thereafter per <i>MMWR</i> , OMB #0920-0007
Disseminate first modified final national notifiable STD morbidity data (including new information content) in DSTDP-specific annual surveillance summaries	17-18 months after OMB approval and annually thereafter

During the remaining 18 months of this request and thereafter, STD Morbidity Surveillance will follow the *MMWR* publication schedule as described for the *MMWR* STD Surveillance in 0920-0007 and summarized below:

### Weekly reports

The weekly *MMWR* report of notifiable diseases covers the week preceding the report's publication. The beginning and ending dates of the reporting week are those established by CSTE, and correspond with the usual work week. The reporting period is constant from week to week. The report should be received electronically in Atlanta as soon as possible after the close of the reporting week, and no later than noon on the following Tuesday.

STD Morbidity Annual Surveillance Report 2008-2010

MARCH - JUNE - DSTDP will create an annual surveillance report data base after verifying the data on NETSS data bases and the STD Morbidity sub-set.

JULY- Annual STD surveillance data summary tables are distributed to State and Territorial Epidemiologists for approval of final notifiable STD case count totals for the previous year.

JULY - SEPTEMBER - DSTDP will update STD Morbidity Annual Surveillance Report analysis and graphics files to produce tables, graphs and maps.

SEPTEMBER - The STD Morbidity Annual Surveillance Report will be submitted to CDC clearance. Simultaneously, CDC will publish the table of final annual STD morbidity data ('final' data for prior year) by state in the *Morbidity and Mortality Weekly Report*.

OCTOBER - NOVEMBER - DSTDP will submit a copy of the cleared STD Morbidity Annual Surveillance Report to the Management Information and Services Branch, MASO for printing.

Annual summaries will be distributed to persons and agencies included in the CDC mailing list and list provided by the Superintendent of Documents. These summaries are for use by local, state, and federal health agencies, schools of medicine and public health, communications media, and other agencies or persons interested in notifiable disease surveillance and epidemiology in the United States.

#### **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

No paper-based data collection form supports the collection of the STD morbidity case report variables. Respondents extract relevant data from their own information systems into the record format for reporting to CDC. Therefore, there is no physical form on which to display an OMB expiration date.

#### **18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)**

There are no exceptions to the certification.