ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total					2,700

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–1072; Docket No. CDC–2023–0017]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of Government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled STD Surveillance Network (SSuN). This information collection request is designed to strengthen national and local surveillance capacity for incident, new and emerging sexually transmitted diseases (STDs) by collecting relevant risk, demographic, and clinical information on patients at risk for STDs attending STD-related healthcare facilities, and providing more accurate estimates of the burden of disease, incidence of STDs, trends and impact of STDs at the population level.

DATES: CDC must receive written comments on or before May 9, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0017 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

The STD Surveillance Network (SSuN), (OMB Control No. 0920–1072, Exp. 10/31/2023)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting revision of the information collection entitled, The STD Surveillance Network (SSuN). Revisions to this submission include addition of mpox-related data elements for monitoring mpox risk, vaccination, diagnoses, and laboratory testing as part of ongoing surveillance for this emergent public health issue. Additionally, this Revision incorporates future expansion of SSuN to additional STD clinical facilities, addition of several new data elements to sentinel surveillance activities in STD clinical facilities related to Pre-Exposure Prophylaxis for HIV (PrEP), and enhanced investigations of a random sample syphilis cases reported to participating health departments. Multiple data elements associated with enhanced gonorrhea case investigations and provider reporting forms are also being retired.

The purpose of this project is to enhance national capacity for STD surveillance and better meet CDC's disease surveillance mandate by: (1) addressing gaps in epidemiologically-relevant information by providing more complete behavioral and demographic data on reported cases of notifiable STDs to enhance the ability of public health authorities to interpret trends in case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD

treatment and selected adverse health outcomes of STDs; (2) monitoring STD and HIV co-infection, screening, uptake of STD and HIV prevention interventions and health care access trends among patients seeking care for, and those diagnosed with, STDs in specialty clinical settings; and (3) providing a robust sentinel monitoring system for newly emergent and/or re-emergent health threats such as mpox.

Routine STD case surveillance activities are ongoing in all U.S. jurisdictions. Cases diagnosed in U.S. jurisdictions are voluntarily reported to CDC through the National Notifiable Diseases Surveillance System (NNDSS) and case data are collaboratively defined in cooperation with the Council of State and Territorial Epidemiologists (CSTE). However, case data received by CDC through NNDSS are increasingly missing required patient demographics and are extremely limited in scope with respect to risk behaviors, treatments prescribed, co-infection with other infections, preventive services, and sexual network characteristics. These data are needed to monitor incidence and prevalence and to inform prevention and control efforts.

Additionally, clinical information on patients seeking STD-specific care in specialty STD clinics is not available through any other national medical record abstracts or data sources. These data are critical to detecting emergent STD-related sequela or reemergence of mpox, appropriately informing local disease control activities and to inform analyses of national trends in the epidemiology of STD incidence. These data are also useful to monitor care services in essential safety-net STD clinics and evaluate local and national STD prevention and control measures. SSuN is the only surveillance infrastructure providing such comprehensive, representative information on patient and sex-partner characteristics, clinical presentation, STD screenings, uptake of HIV testing, screening for and uptake of mpox vaccine in STD clinics, curative and preventive treatment patterns, provider compliance with treatment recommendations, HIV co-infection among persons diagnosed with STDs and uptake of STD and HIV prevention interventions such as pre-exposure prophylaxis for HIV (PrEP) and/or Post-Exposure Prophylaxis (PEP) for bacterial STDs. These measures are key elements of the U.S. national strategy to End the HIV Epidemic (EHE) and support the Sexually Transmitted Infections, National Strategic Plan for the United States.

The STD Surveillance Network was established in 2005 as a network of six funded state and local public health agencies providing more comprehensive STD case-level and clinical facility information. In 2008, SSuN was expanded to 12 recipients to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. The network's activities were continued in a third funding cycle in 2013, with 10 recipients conducting core data collection activities in STD clinics and among a random sample of reported cases.

The current project, SSuN Cycle 4 (2019–2024), comprises 11 U.S. local/state health departments, including Baltimore City Health Department, California Department of Public Health, City of Columbus Public Health Department, Florida Department of Health, Indiana Department of Public Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, Utah Department of Public Health and Washington State Department of Health.

SSuN Cycle 4 continues to provide critical information addressing CDC's Division of Sexually Transmitted Disease (DSTDP) priorities as articulated in the STI National Strategic Plan, including contributing data to CDC's annual STD Surveillance Report, CDC's quarterly progress indicators and contributing to the body of literature related to STDs. Trend data across multiple cycles of SSuN are frequently used to inform policy discussions on prevention and treatment recommendations for common bacterial STDs. Of particular importance, SSuN provides data on use of pre- and post-exposure prophylaxis to prevent STDs and HIV infection (PEP and PrEP). SSuN also provides documentation of critical changes in clinical services provided by specialty STD clinics, and on the proportion of cases treated with appropriate antimicrobial regimens, an essential indicator of compliance with CDC treatment recommendations to combat the emergence of antimicrobial resistance (AMR). More recently, SSuN data have also been invaluable in assessing COVID–19 and mpox impacts on reported case incidence and patient access and care-seeking patterns and provides a reliable monitoring infrastructure for mpox re-emergence. STD clinics were the front-line provider of choice for persons suspecting mpox infection or seeking preventive services such as mpox vaccination.

Data collection components of SSuN are grouped into two primary strategies, reflecting different sentinel and enhanced population-based surveillance methods and activities. Strategy A includes sentinel surveillance in STD clinics to monitor patient care, screening and diagnostic practices, HIV co-infection, treatment and STD-related HIV prevention services delivered to patients. In collaboration with participating local/state health departments and their clinical partners, SSuN implements consensus protocols to collect demographic, clinical and risk behavior data on patients presenting for care in selected specialty STD clinics. Records for patients presenting for care are also matched to the jurisdiction's HIV surveillance registry, providing data on HIV co-infection not currently available from any other multi-jurisdictional source. Data for these activities are abstracted from existing electronic medical records at participating STD clinics, leveraging information that is already collected in the provision of routine STD clinical care. All records are fully de-identified by collaborating facilities or health departments and transmitted to CDC through secure file transport mechanisms six times annually. The estimated time for the clinic data managers to abstract/recode data is four hours every two months. The current revision anticipates expansion of this activity from the current 15 clinics to up to 40 STD clinics beginning in 2024 with a resulting burden of 960 hours (40 × 4 hours × 6 times/year).

The second core data collection activity, Strategy B, currently includes: (1) abstraction recoding and reporting of all gonorrhea and syphilis cases reported in the collaborating jurisdiction; (2) enhanced investigations on a random sample of all persons diagnosed with gonorrhea or syphilis; and (3) health department abstraction and registry matching for a complete census of reported gonorrhea and syphilis cases. For the first activity, a random sample of all gonorrhea cases diagnosed and reported to health departments within the participating jurisdictions are selected for enhanced investigations. Beginning in 2024, these investigations will be expanded to include a random sample of reported syphilis cases, include abstracting clinical data from diagnosing providers, matching cases with existing health department disease registries and brief patient demographic and behavioral interviews (10 minutes per response). The population of interest includes all persons diagnosed and reported with

gonorrhea and syphilis; existing case records are matched to other health department disease registries to determine co-infections and to document laboratory and treatment information known by the health department through routine case investigations and local laboratory reporting. In the proposed revision, syphilis cases will also be selected for enhanced provider and patient investigations utilizing the same consensus protocols used for enhanced gonorrhea case investigations. Considering recent increases in syphilis cases in the U.S., especially congenital syphilis, these data are critical to informing local and national syphilis prevention and control activities. SSuN recipients implement protocols providing uniformly coded data on demographic characteristics, behavioral risk factors, clinical care, laboratory data and health care seeking behaviors that are combined into a national dataset following data quality assurance at CDC.

In 2021, there were 211,791 cases of gonorrhea diagnosed and reported across the 11 current recipients of SSuN. Approximately 7.4%, or 15,715 cases were randomly sampled for enhanced investigation; full enhanced investigations were completed for 6,186 (39.4%). During the COVID–19 public health emergency, a slightly larger proportion of cases were lost to follow-up than in prior years due to local staffing shortages, issues with timely laboratory and case reporting, and higher than average patient refusals. No additional burden is anticipated from the future inclusion of early syphilis cases in Strategy B because of the decrease in gonorrhea case investigations.

Data managers at each of the local/state health departments or clinical facilities receiving funding are responsible for transmitting validated datasets for these activities to CDC every other month. This reflects 5,280 burden hours for Strategy A and B data management (11 respondents × 12 data transmissions × 40 hours per data transmission).

The total estimated annual burden hours for SSuN are 7,407. Respondents from local/state health departments and/or clinical facilities receive Federal funds to participate in this project. There are no costs to patients or respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
Data managers at STD clinics (Strategy A).	Electronic Clinical Record Abstraction.	40	6	4	960
General Public, Adults (sample of persons diagnosed and reported with gonorrhea and/or syphilis).	Patient interviews for a random sample of gonorrhea and syphilis cases.	7,000	1	10/60	1,167
Data Managers: 11 local/state health departments.	Data cleaning/validation, HIV-registry matching, data transmission.	11	12	40	5,280
Total					7,407

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22ET]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Traveler-based Genomic Surveillance'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 6, 2022, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Traveler-based Genomic Surveillance—New—National Center for