National Notifiable Diseases Surveillance System (NNDSS)

OMB Control Number 0920-0728
Expiration Date: 01/31/2019

Program Contact

Umed Ajani
Associate Director for Science
Division of Health Informatics and Surveillance
Center for Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention
1600 Clifton Rd, MS-E97
Atlanta, GA 30329
Phone: (404) 498-0258
E-mail: UAjani@cdc.gov

Submission Date: February 16, 2017

(Revised and Resubmitted on May 4, 2017)

Circumstances of Change Request for OMB 0920-0728

This is a nonmaterial/non-substantive change request for OMB No. 0920-0728, expiration date 01/31/2019, for the reporting of Nationally Notifiable Diseases. The National Notifiable Diseases Surveillance System (NNDSS) is the nation's public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that the Council of State and Territorial Epidemiologists (CSTE) has officially designated as either "nationally notifiable" or as under "national surveillance."

The NNDSS facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 57 jurisdictions: health departments in every U.S. state, New York City, Washington DC, and 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands). NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor health occurrence of notifiable conditions and to plan, conduct and prioritize prevention and control programs at the state, territorial, local and national levels.

This request is for the addition of five disease-specific data elements to the HL7 Message Mapping Guide for jurisdictions adopting or modernizing the reporting of cases of Sexually Transmitted Diseases (STD). The data elements in this change request allow the program to specify the definitions for "Ocular syphilis," "Otosyphilis," and "Late Clinical Manifestations (tertiary syphilis)" to better describe morbidity associated with cases of reported syphilis. Additionally, NNDSS seeks clearance to pilot test the addition of two data elements that would allow the program to specify sexual orientation and whether or not the person is transgender.

Program rationale for requesting the addition of sexual orientation and whether or not the individual is transgender includes recognition of a growing body of evidence indicating that sexual orientation and gender identity are important covariates for sexually transmitted diseases. For example, enhanced surveillance activities in six geographically diverse jurisdictions recently documented a sharp increase (158%) in the rate of gonorrhea cases occurring among gay, bisexual and other men who have sex with men from 2010 to 2015. Pilot testing the collection of SO/GI data through NNDSS for STD case report data is determine if CDC can more specifically describe burden of disease by these key covariates and could be used to better target interventions to reduce disease transmission.

Justification for Pilot to Collect SOGI Variable

To address the lack of data on sexual orientation and gender identity in health systems, the Department of Health and Human Services' (HHS) Healthy People 2020 included an objective to "increase the number of states, territories, and the District of Columbia that include questions that identify sexual orientation and gender identity on state level surveys or data systems" to improve "the health, safety, and well-being of lesbian, gay, bisexual, and transgender (LGBT) individuals." Increasing the number of population based data systems which collect standardized data on (or for) lesbian, gay and bisexual populations and on (or for) transgender populations and expanding the availability of sexual orientation/gender identity (SO/GI) statistics has also been a priority for other federal agencies. To offer guidance and address methodological issues related to collecting SO/GI in surveys, OMB convened an Interagency Working Group on Measuring Sexual Orientation and Gender Identity. The Working Group developed three working papers describing how SO/GI is currently measured in Federal surveys, to evaluate questionnaire measurement and to propose a research agenda. Another limitation of this work for the NNDSS is that it focuses on respondent provided survey data rather than medical records or other administrative data collections.

Although SO/GI variables for reportable STDs are currently collected in many state and local jurisdictions, these data elements currently cannot be reported to CDC through NNDSS. Specifically, "current sex" is reported to CDC for all notifiable conditions, but categorically coded as male, female and unknown; therefore, it is not possible to determine if a person is transgender or determine the direction of transgender (e.g., male-to-female) which likely impacts the STD risk. In recognition of these gaps, some jurisdictions have requested that CDC include variables to capture sexual orientation and whether or not a person is transgender in national STD surveillance.

As such, CDC is proposing to pilot test providing States and local jurisdictions with the opportunity to report sexual orientation and transgender status. This pilot test will inform CDC's further deliberations regarding the need for and format and approach to collecting SOGI information in the context of the NNDSS. These deliberations will include consideration of whether or not to revise the "current sex" variable that has appeared on NNDSS for many years. CDC is not recommending making that change at this time.

With respect to collection of a transgender variable on STD case reports we will pilot the following response categories: transgender male-to-female; transgender female-to-male; transgender

other/unspecified; cisgender/not transgender; unknown. These data collection categories were selected to allow for collection of minimal information on transgender without substantial additional burden on jurisdictions until best practices can be determined. First, the variable and value set was selected to easily map to the response values already collected by many jurisdictions on their communicable disease report forms which will maximize data harmonization and minimize mapping errors. Allowing jurisdictions to report already collected data will help determine feasibility of sending these data for national reporting. Second, collection of these data will increase data completeness and allow CDC to determine what proportion of reported STDs are attributable to transgender male-to-females and transgender female-to-males and better describe the burden of STDs in the U.S.

Analyses of these pilot data will include comparison of the proposed STD-specific variable for transgender to values reported in the sex variable to allow CDC to directly ascertain what proportion of cases with "unknown" sex is accounted for by transgendered individuals. Additional analysis using the indicated direction of transgender (male-to-female or female-to-male) for cases reported with sex indicated as male or female will allow for better understanding of how transgendered patients are coded with respect to the current sex variable that long has been on the NNDSS. These results will be considered in the context of available guidance on best practices for data collection, with the goal of balancing minimized burden on the 57 jurisdictions reporting and maximizing the utility of the information collected.

With respect to sexual orientation, the choice of variable was designed to increase data harmonization and reduce duplication of efforts. The value sets selected for the sexual orientation variable to be collected in STD case report data align, to the extent applicable for administrative data reporting, with response values used in the National Health Interview Survey (NHIS) which were developed based on extensive cognitive testing. Specifically, the categories that CDC will make available in NNDSS will be: gay or lesbian; straight, not gay or lesbian; bisexual; something else; unknown. CDC will assess the utility of categories such as "something else" for its reporting needs and the impact on the choice of categories on the quality of reporting. A short questionnaire to data providers could provide insight regarding both burden and quality issues associated with data reporting categories for both the sexual orientation and transgender variables.

The new data elements requiring the change request are in the following table:

Sexually Transmitted Diseases Data Elements

Data Element Identifier	Data Element Name	Data Element Description
410478005	Ocular Manifestations	Infection of any eye structure with *T. pallidum*, as evidenced by manifestations including posterior uveitis, panuveitis, anterior uveitis, optic neuropathy, and retinal vasculitis.
PHC1472	Otic Manifestations	Infection of the cochleovestibular system with *T. pallidum*, as evidenced by manifestations including sensorineural hearing loss, tinnitus, and vertigo.
72083004	Late Clinical Manifestations (tertiary syphilis)	Late clinical manifestations of syphilis (tertiary syphilis) may include inflammatory lesions of the cardiovascular system, skin, bone, or other tissue. Certain neurologic manifestations (e.g., general paresis and tabes dorsalis) are late clinical manifestations of syphilis.
76691-5	Transgender	Patient identified as transgender (i.e., an individual's personal sense of being male, female, or transgender).
76690-7	Sexual Orientation	Patient identified sexual orientation (i.e., an individual's physical and/or emotional attraction to another individual of the same gender, opposite gender, or both genders).

Burden

Burden of reported STDs varies by sexual orientation and gender. STDs are common among non-heterosexual populations; an estimated 60% of reported cases of primary and secondary syphilis and 20-40% of reported gonorrhea cases are among non-heterosexual populations. The proportion of reported STDs that occur among transgender populations is likely low. For example, in one jurisdiction that routinely collects and reports SO/GI data for reported cases of STDs, 0.5% of chlamydia cases, 1.0% of gonorrhea cases, and 0.6% of early syphilis cases occurred among transgender persons. Given that over 1.8 million STDs are reported to CDC annually, it is likely that there are thousands of STD cases in this population representing a significant burden of disease and a need for targeted treatment and prevention efforts.

The annualized burden hours and cost to reporting jurisdictions (states, cities, and territories) to submit these additional data elements to CDC does not change from the original estimates in the "Estimates of Annualized Burden Hours and Costs" section in A.12 of OMB No. 0920-0728. All reporting jurisdictions (except for Guam and the U.S. Virgin Islands) will send these additional data elements to

CDC electronically through NNDSS since case notifications for STDs are submitted electronically from existing surveillance databases. This change request does not apply to Guam and the U.S. Virgin Islands since they do not yet send their case notifications electronically to CDC. The addition of disease-specific data elements will add a minimal one-time burden. Many jurisdictions already collect this information through routine case reporting; for jurisdictions not currently collecting these data, these data elements remain optional and future implementation will be prospective, not requiring re-coding or re-ascertainment of any new information for previously reported cases. A one-time average burden of 15 minutes will be incurred for jurisdictions to add up to 10 data elements to their existing NNDSS mechanism. In addition, a one-time average burden of 35 minutes will be incurred for jurisdictions to modify their electronic STD case notification message to accommodate up to 10 additional data elements. For the jurisdictions that do not already collect these data, an additional one-time average burden of 35 minutes will be incurred to add up to 10 additional data elements to their jurisdiction's surveillance system. This one-time burden of up to 90 minutes is noted in the following table:

One Time Burden to Add Up To 10 Data Elements to NNDSS

Respondents	Number of Respondents	Number of Responses per Respondent	Average One-Time Burden (in hours)	Total One-Time Burden (in hours)
States	50	1	90/60	75
Territories	3	1	90/60	5
Cities	2	1	90/60	3
Total				83

Since this increase in burden is one-time, minimal, and only applicable to those jurisdictions that transmit case notifications electronically, it does not affect the annualized burden hours and costs.

A.12A. Estimates of Annualized Burden Hours

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in	Total Burden (in hours)

			hours)	
Weekly and Annual Submissions				
States	50	52	10	26000
Territories	5	52	5	1 300
Cities	2	52	10	1040
Total				28,340

A.12B. Estimates of Annualized Cost Burden

Type of Respondents	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Burden Hours**	**Hourly Wage Rate**	**Respondent Cost**
States	Weekly and Annual	50	52	10	26,000	$35.63	$926,380
Territories	Weekly and Annual	5	52	5	1,300	$35.63	$46,319
Cities	Weekly and Annual	2	52	10	1,040	$35.63	$37,055
Total							**$1,009,754**