Enhanced STD Surveillance Network (eSSuN)
OMB No. 0920-NEW

SUPPORTING STATEMENT
Part B

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

The Enhanced STD Surveillance Network (eSSuN) is a network of 10 collaborating surveillance sites in the United States serving as a platform to identify STD trends, monitor STD epidemiology and evaluate the effectiveness of public health interventions through active surveillance collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information. Enhanced SSuN activities will utilize two distinct surveillance strategies to collect information: facility-based STD surveillance and population-based STD surveillance, as outlined below.

Facility-based STD surveillance:

The respondents providing the information for eSSuN's facility-based surveillance are (1) the clinic data managers at the facilities/networks and (2) the data managers at the 10 eSSuN collaborating sentinel surveillance sites (Table B.1.A). Within these 10 collaborating sites there are a total of 131 facilities: 30 STD clinics that together report data from approximately 161,000 patient visits per year, 65 family planning and reproductive health facilities/networks that together report data from approximately 220,000 female patient visits per year and 37 other facilities/networks (school-based clinics and federally healthcare qualified centers) that report data from approximately 40,000 female patient visits per year (Table B.1.A). All patient visits to the STD clinics and all patient visits from females aged 15-44 to the family planning/reproductive health facilities/networks will be included in the project and reported to CDC by the collaborating sites. As part of routine patient care, information on demographics, limited behavioral risk factors, and details about the clinical encounter (e.g., signs and physical exam findings, diagnoses, laboratory tests and treatment) is collected by clinic staff and entered

into the patient's health record. Clinic staff will abstract data from routine electronic medical records and transmit to eSSuN project staff at the local level.

Table B.1.A

Collaborating sentinel surveillance sites	Participating Facilities			Total No. of Clinic Data Managers abstracting data	Estimated # STD patient visits/yr	Estimated # FP/RH patient visits/yr	Estimated # other patient visits/yr
	STD Clinic	Family Planning/Reproductive Health	Other (school based and federally qualified healthcare center)				
Baltimore City Health Department	Druid, Eastern	Eastern FP, Druid FP, Health teens/Young adults clinic	N/A	1	12,000	10,000	N/A
California Department of Public Health	Antelope Valley, Central, Curtis Tucker, Hollywood-Wilshire, Monrovia, North Hollywood, Pomona, Ruth Temple, Simms Mann, South Torrance, Whittier	PP Los Angeles (n = 22)	Logan Heights, FHCSD (n = 14); Community Health Alliance of Pasadena, Westside Family Health Center, Chinatown Service Center, JWCH institute (n = 5), Samuel Dixon Family Health Center (3), Women's Clinic, Fresno County EOC	3	19,000	65,000	35,000
Florida Department of Health	Miami-Dade STD Clinic	Escambia and Hillsborough Community Health	N/A	3	12,000	17,500	N/A
Massachusetts Department of Public Health	Massachusetts STD clinic	Planned Parenthood League of Massachusetts	N/A	2	5,500	20,000	N/A
Minnesota	Red Door	North Point	School-based	3	10,000	8,000	5,000

Department of Health			(n = 9)				
Multnomah County Health Department	Multnomah STD Clinic	Planned Parenthood of Columbia	NA	2	9,000	7,500	N/A
New York City Department of Health & Mental Hygiene	Central Harlem, Manhattanville, Corona, Fort Greene, Jamaica, Chelsea, Crown Heights, Morrisania,	Flatbush FP/RH Clinic, Fort Green FP/RH Clinic	N/A	1	60,000	20,000	N/A
Philadelphia Department of Public Health	Philadelphia Health Clinic # 1, Philadelphia Health Clinic # 5	Childrens Healthcare Karabots and Cobbs Creek	N/A	3	15,000	12,000	N/A
San Francisco Department of Public Health	SF City STD Clinic	COPC (Castro Mission, Maxine Hall, Silver Avenue, Southeast)	N/A	2	11,000	15,000	N/A
Washington State Department of Health	Harborview STD Clinic	Planned Parenthood of Great Northwest (n=21)	N/A	2	7,500	45,000	N/A
Totals	**30 facilities**	**65 facilities**	**37 facilities**	**22**	**161,000**	**220,000**	**40,000**

Population-based STD surveillance:

The respondents providing the information for eSSuN's population-based surveillance are (1) the the data managers at the 10 eSSuN collaborating sentinel surveillance sites (Table B.1.A), and, (2) persons identified as having gonorrhea by case report in the 10 state or municipal health departments participating in eSSuN. From the latter group, a sample of patients will be chosen for interview by random probability sampling (Table B.1.B). Within these 10 collaborating sites there is an estimated population of more than 69 million people (U.S. Census Bureau 2012, Summary File 2, 100% count). In 2013, there were there were 95,560 gonorrhea case reports from this population, representing approximately 21.6% of the national gonorrhea case reports in that year. Health departments will approach randomly-selected persons reported with gonorrhea

and request their participation for interview. These randomly-selected persons will be interviewed until the requisite annual interviews are complete.

Table B.1.B

Collaborating sentinel surveillance sites	Total # of gonorrhea case reports in 2013	# of interviews to be completed for eSSuN
1 Baltimore City Health Department	2,158	250
2 California Department of Public Health	38,166	700
3 Florida Department of Health	20,818	425
4 Massachusetts Department of Public Health	3,106	250
5 Minnesota Department of Health	3,873	250
6 Multnomah County Health Department	783	250
7 New York City Department of Health & Mental Hygiene	13,459	350
8 Philadelphia Department of Public Health	6,303	250
9 San Francisco Department of Public Health	2,525	250
10 Washington State Department of Health	4,369	250
Totals	95,560	3,225

Minimum sample size for subgroup analysis for population-based activities

For the population-based component of eSSuN, each of the 10 collaborating eSSuN sites will randomly select a sample of gonorrhea case-reports sufficient to conduct a minimum of 250 interviews per year (or up to 2.5% of total morbidity if annual cases exceed 10,000 cases) for a total of 3,225 interviews per year with persons infected with gonorrhea. Data collected on completed interviews will include basic demographics, medical history, sexual and drug use behaviors

2. Procedures for the Collection of Information

Facility-based STD surveillance:

Clinic staff at each facility or network of facilities at participating eSSuN sites will abstract and electronically transmit clinical data from (1) all patients visiting participating STD clinics and (2) female patients aged 15-44 years of age in family planning/reproductive health and other facilities to funded staff at the state and local health jurisdictions. Data are de-identified and recoded by health departments and then uploaded on a monthly basis by a trained local data manager at collaborating site to a CDC-designed and operated secure access management system (SAMS). None of the data transmitted to CDC will contain any information in identifiable form. Data will be downloaded from SAMS, stored, and maintained at CDC by a data manager in the Surveillance and Data Management Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

Data elements collected in this facility-based STD surveillance include patient demographics, limited behavioral risk factors associated with STDs, clinical history and physical exam findings, STD laboratory test and results, STD diagnoses, and treatment (see data elements attachment). These data elements were developed collaboratively and agreed upon by members of eSSuN. Participation in eSSuN does not require the collection of data elements that are not already collected at collaborating facilities. Completeness of reporting and the quality of data submitted will be monitored by CDC on a monthly basis. Site visits, regular communication with CDC, data quality checks and technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

Population-based STD surveillance:

A random sample of persons with gonorrhea reported to the health department will be identified and recruited for interview by state/local health departments. As a gonorrhea case report is received by the local health department, it will be assigned a random number (e.g. from 1 to 100)

by local officials. If the random number assigned to a particular case is below a set threshold value for the site (the threshold value might vary from one site to another, depending on how many case reports a particular site expects to receive in a year), the case will be contacted for interview. If the random number assigned to a case is above the threshold number for that site, the case will not be contacted for interview. Each site will use this randomization method to identify cases and then complete interviews with the target number of not less than 250 interviews per year.

Cases that fall within the sampling fraction will be contacted by trained interviewers working at local health departments for a telephone or in-person interview within 60 days of receipt of their case report. Interviewers will collect information on demographics, STD clinical history, and behavioral risk factors associated with STDs (see data elements attachment). The entire interview is expected to last for approximately 10 minutes. These data elements were developed collaboratively by eSSuN participating sites and CDC.

Interviewed data will be maintained in electronic format by the collaborating jurisdictions. These interviews will collect more detailed information than is generally provided by case reports received by the jurisdiction.

Locally, data will be routinely verified by trained data management personnel using a CDC-designed edit check program. On a monthly basis, data will be uploaded by trained data managers at collaborating sites to a CDC-designed and operated secure access management system (SAMS). At CDC, data will be downloaded from SAMS, stored, and maintained by a data manager in the Statistics and Data Management Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on a monthly basis. Site visits, regular

communication with CDC, data quality checks and technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

Data on race and ethnicity will be collected in compliance with the two-question format described in the 1997 Office of Management and Budget's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, also known as Statistical Policy Directive 15.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Facility-based STD surveillance:

Facility data for eSSuN are extracted from data collected as a routine part of all STD facility encounters. The challenge of non-response is not applicable for this study because the data elements will be extracted according to a pre-determined protocol for all patients who use the facility and submitted to CDC through the existing secure data network.

Population-based STD surveillance:

Trained interviewers at participating sites will contact patients via phone call or letter to complete a phone or in-person interview with the patient. Protocols for maximizing the likelihood of a successful interview with patients vary by site, but at least three attempts to contact a selected patient will be made in all sites. Locating information will be verified with diagnosing providers to assure up-to-date contact information. Patients participating in the interview will not be offered reimbursement for their participation. Participants are informed participation in the interview is voluntary and refusal to participate is at no risk or harm to them. If local regulations offer additional partner management services for patients with gonorrhea, then the patient will be referred accordingly. If not, the patient will be thanked for his or her

time. Similar interviews have been conducted in other surveillance systems, and non-response rates or patient refusals to be interviewed have been very low.

These methods are designed to result in a representative sample of patients diagnosed with gonorrhea and will significantly improve ascertainment of critically important information often missing from routine case reporting such as the race, Hispanic ethnicity, gender of sex partners of the patient, anatomic site(s) of infection, clinical care and care-seeking and HIV co-morbidity.

Stratification weights will be calculated separately for each collaborating jurisdiction based on the effective sample fraction for the participating jurisdiction. Post-stratification weights will be calculated to adjust for observed non-response at the jurisdiction level by sex, age and diagnosing provider type. Additionally, overall project weights will be calculated based on the proportion of cases each jurisdiction contributes to the project allowing for weighted analysis of these data at the individual site and overall project levels.

4. Test of Procedures or Methods to be Undertaken

Facility-based STD surveillance:

Enhanced SSuN will collect the results of multiple diagnostic tests, clinical procedures, and laboratory methods such as bacterial culture, gram stain, wet mount, nucleic acid amplification tests, pregnancy test, rapid HIV test, ELISA, Western blot. The information received for this project reports the results carried out by the collaborating facilities as part of the routine clinical care of their patients.

Population-based STD surveillance:

The eSSuN Interview data collection instrument was developed using questions from BRFSS, California and previous CDC surveillance projects. Internal testing by one of our collaborating

jurisdictions on a small number of patients validated the skip patterns using a paper version of the interview instrument. The pilot interviews performed took approximately 10 minutes to complete and no difficulties or anomalies with skip patterns were detected.

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

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