

**STD Surveillance Network**

**Supporting Statement  
Part B**

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## **B. Statistical Methods**

### **1. Respondent Universe and Sampling Methods**

The STD Surveillance Network (SSuN) is a network of 12 collaborating surveillance sites around the United States with the capacity to conduct clinic-based and population-based STD surveillance activities such as monitoring the prevalence of STDs, HIV, viral hepatitis, and associated risk behaviors. SSuN activities will fall into two broad respondent universes: clinic-based STD surveillance and population-based STD surveillance, as outlined below.

#### *Clinic-based STD surveillance:*

The respondents providing the information for SSuN's clinic-based surveillance are the 12 SSuN collaborating sentinel surveillance sites (Table B.1.A). Within these 12 collaborating sites there are currently 42 STD clinics that together report data from approximately 337,000 patient visits per year (Table B.1.A). All patient visits to these clinics will be included in the study and reported to CDC by the collaborating sites. As part of routine patient care, information on demographics, behavioral risk factors, and medical history will be collected by clinic staff and entered into patient charts. Project staff will abstract data from routine electronic and hard-copy STD clinic medical records and enter them into the project's electronic database.

Table B.1.A

Collaborating sentinel surveillance sites	Participating Clinics	Estimated # patient visits/yr
1 Alabama Department of Health	Jefferson County	16,000
2 Baltimore City Health Department	Druid, Eastern	30,000
3 Chicago Department of Health	Englewood, Howard Brown, Lakeview, Roseland, South Austin, West Town	30,000
4 Colorado Department of Public Health and Environment	Denver	15,000
5 Connecticut Department of Public Health	Hartford, New Haven	4,000
6 County of Los Angeles Department of Public Health/California State Department of Public Health	Antelope Valley, Central, Curtis Tucker, Hollywood-Wilshire, Monrovia, North Hollywood, Pomona, Ruth Temple, Simms Mann, South Torrance, Whittier	48,000
7 Louisiana Office of Public Health	Delgado Personal Health Center	10,000
8 New York City Department of Public Health and Mental Hygiene	Bushwick, Central Harlem, Chelsea, Corona, East Harlem, Fort Greene, Jamaica, Morrisania, Richmond, Riverside	115,000
9 Philadelphia Department of Public Health	Health Clinic # 1, Health Clinic # 5	26,000
10 San Francisco Department of Public Health	San Francisco City Clinic	22,000
11 Virginia Department of Public Health	Richmond City, Henrico, Chesterfield	10,000
12 Washington State Department of Health	Seattle-King County	11,000
Totals	42 clinics	337,000

*Population-based STD surveillance:*

The respondents providing the information for SSuN's population-based STD surveillance activity are persons identified as having gonorrhea by case report to the 12 state or municipal health

departments participating in SSuN (Table B.1.B). Within these 12 collaborating sites there are currently 115 counties with an estimated population of more than 61 million people. In 2007 there were there were 72,642 gonorrhea case reports from this population, representing approximately 20% 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 240 yearly interviews are complete.

**Table B.1.B**

Collaborating sentinel surveillance sites	Associated counties	Total # of gonorrhea case reports in 2007	# of interviews to be completed for SSuN
1 Alabama Department of Health	Jefferson	2,859	240
2 Baltimore City Health Department	Baltimore City	3,027	240
3 Chicago Department of Health	Cook	9,388	240
4 Colorado Department of Public Health and Environment	Adams, Arapahoe, Denver	1,997	240
5 Connecticut Department of Public Health	Hartford, New Haven	1,573	240
6 County of Los Angeles Department of Public Health/California State Department of Public Health (not including San Francisco)	All 61 health jurisdictions in CA (not including SF)	29,287	240
7 Louisiana Office of Public Health	Orleans	1,529	240
8 New York City Department of Public Health and Mental Hygiene	Bronx, Kings, New York, Queens, Richmond	10,308	240

9 Philadelphia Department of Public Health	Philadelphia	5,246	240
10 San Francisco Department of Public Health	San Francisco	2,007	240
11 Virginia Department of Public Health	Chesterfield, Henrico, Richmond	1,768	240
12 Washington State Department of Health	all 39 counties in WA	3,653	240
Totals	115 counties	72,642	2,880

Minimum sample size for subgroup analysis for population-based activities

For the population-based portion of SSuN, each of the 12 collaborating SSuN sites will conduct a minimum of 240 interviews per year for a total of 2,880 interviews per year with persons infected with gonorrhea. The interviews will be conducted with persons who are randomly selected out of the total number of gonorrhea case-reports received by each site.

During the interviews, information on demographics, behavioral risk factors, and medical history will be collected. Project staff will abstract pertinent information from paper or electronic forms and enter it into the project's electronic database. Data collected from clinics and personal interviews may be able to identify groups of people in the study population who are co-infected with gonorrhea and HIV. Because infection with gonorrhea can be considered a marker for ongoing unprotected sexual activity, persons infected with HIV and undertaking unprotected sexual activity are considered higher risk for

infecting others with both gonorrhea and HIV and should be prioritized for receiving education from public health officials to prevent further high-risk behaviors. Currently, there are no systems in place that easily identify groups of people with co-infections of gonorrhea and HIV. SSuN offers a system by which such co-infections can be identified so that public health prioritizations can be made.

- To improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs and to improve the health of populations disproportionately affected by HIV/AIDS, STDs, and other related diseases and conditions, an understanding of the basic epidemiology of GC and HIV co-infection is fundamental. This includes determining the prevalence of GC-HIV co-infection by gender. An analysis will be carried out with an assumed HIV prevalence of 0.2% in women and 8.8% in men. Using Fisher's exact test with 95% power and a two-sided significance level of 0.05, it will be necessary to interview 136 women and 136 men for a total of 272 interviews per year (Table B.1.C); it is expected that SSuN will collect 2,880 interviews per year.

Table B.1.C

Subgroup	Estimated population of subgroup (% of total SSuN pop)	Assumed HIV prevalence (%) in subgroup	Minimum sample size needed in one year for each subgroup	Expected # of interviews in one year for each subgroup
Women with gonorrhea	36,321 (50)	0.2	136	1,440
Men with gonorrhea	36,321 (50)	8.8	136	1,440
Totals	72,642 (100)	--	272	2,880

- SSuN will perform analyses with further stratification of various demographic factors such as sexual orientation, sex, age, or race. Every two years, population analysis will be further stratified to derive estimates of the prevalence of gonorrhea/HIV co-infection in men who have sex with men, in heterosexual men, and in women. To make this determination with an assumed HIV prevalence of 28% and 95% confidence interval (CI) half-width of 5.6% in men who have sex with men, an assumed HIV prevalence of 0.5% and 95% CI half-width of 0.3% in heterosexual men, and an assumed HIV prevalence of 0.2% and 95% CI half-width of 0.16% in women, it will be necessary to interview 242 men who have sex with men, 1,960 heterosexual men, and 2,767 women over the three year period (Table B.1.D) for a total of 4,969 interviews over a two-year period; it is expected that SSuN will collect 5,760 interviews (2,880 per year over 2 years) over that time period.

Table B.1.D

Subgroup	Estimated population (% of total SSuN pop)	Assumed HIV prevalence(%) in subgroup	95% half width (%)	Minimum sample size needed over two years for each subgroup	Expected # of interviews over two years for each subgroup
Men Who have Sex with Men with gonorrhea	10,896 (15)	28	5.6	242	864
Heterosexual Men with gonorrhea	25,425 (35)	0.5	0.3	1,960	2,016
Women with gonorrhea	36,321 (50)	0.2	0.16	2,767	2,880
Totals	72,642 (100)	--	--	4,969	5,760



## **2. Procedures for the Collection of Information**

### *Clinic-based STD surveillance:*

Project staff in participating SSuN sites will abstract data from all patients visiting participating STD clinics. Depending on local capacities, patient information may be stored on paper records or in an electronic format. These data will be entered into the project's electronic database. STD clinic data to be transmitted to CDC for SSuN will be periodically edited by trained personnel using a CDC-designed edit check program. Data will be uploaded on a quarterly basis by trained data managers at collaborating sites to a CDC-designed and -operated secure data network (SDN). None of the data transmitted to CDC will contain any information in identifiable form. Data will be downloaded from the SDN, stored, and maintained at CDC by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention.

Data elements collected in this clinic-based STD surveillance include patient demographics, behavioral risk factors associated with STDs, STD clinical history and findings, STD laboratory test results, and STD diagnoses (see data elements attachment). These data elements were developed collaboratively and agreed upon by members of SSuN. Participation in SSuN does not require the

collection of data elements that are not already collected at collaborating STD clinics. Completeness of reporting and the quality of data submitted will be monitored by CDC on at least a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity 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 interviewed by local health departments and included in SSuN population-based STD surveillance. These persons will be a subset of all persons diagnosed with gonorrhea and reported to a health department in any of the 115 counties associated with a collaborating site.

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 complete interviews with the target number of 240 interviews per year. There will not be a screening prior to interviews. CDC will have no information in identifiable form for any of the cases and will not participate in any way in the contact of cases for interview.

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). These data elements were developed collaboratively by SSuN participating sites and CDC. Depending on resources available at each site, information collected in interviews will be recorded locally on paper records or in electronic format.

Project staff will then abstract the pertinent data from paper or electronic forms and enter them into the project's electronic database. These interviews will collect more detailed information than is available in the interviews normally conducted by the departments of health, and it will collect data in a way that is standardized across the participating sites.

Locally, data will be periodically edited by trained personnel using a CDC-designed edit check program. On a quarterly basis, data will be uploaded by trained data managers at collaborating sites to a CDC-designed and -operated secure data network (SDN) on a quarterly basis. At CDC, data will be downloaded from the SDN, stored, and maintained by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity for evaluation and troubleshooting of these processes.

Protocols for maximizing the likelihood of a successful interview with patients vary by site. For example, in some sites letters will be sent to patients to alert them that the health department will be contacting them by phone. In some project areas, letters are sent to physicians to alert them that their patients may be contacted by a representative of the health department for an interview.

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**

#### *Clinic-based STD surveillance:*

STD clinic data for SSuN are extracted from data collected as a routine part of all STD clinic encounters. Site visits and regular communication between CDC will provide opportunities for evaluation and troubleshooting to improve completeness of any data element not routinely being collected or documented. 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 clinic 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. Historical data from these sites suggest that about 90% of patients who are reached by phone or in-person agree to participate in SSuN interviews. Site visits and regular communication between CDC will provide opportunities for

evaluation and troubleshooting to improve interview success rates.

#### **4. Test of Procedures or Methods to be Undertaken**

SSuN will monitor the results of multiple diagnostic tests, clinical procedures, and laboratory methods such as bacterial culture, gram stain, wet mount, nucleic acid amplification tests, treponemal antibody tests, rapid HIV test, ELISA, Western blot, RPR, VDRL, and Treponema pallidum particle agglutination assay (TP-PA). These tests are carried out by the participating clinics as part of the routine clinical care of their patients and will not be performed expressly for SSuN; none of the tests are considered experimental.

##### *Clinic-based STD surveillance:*

The clinic-based portion of SSuN has procedures for collecting data on demographics, history of STD and other reproductive diseases, treatments received, behavioral risk factors associated with STDs, treatment of partners, symptoms, provider diagnosis, testing results, and exam findings were designed based on provider surveys and surveillance strategies currently employed by health care providers in collaborating sites.

*Population-based STD surveillance:*

The population-based portion of SSuN has procedures for collecting data on demographics, history of STD and other reproductive diseases, treatments received, and behavioral risk factors associated with STDs were designed based on provider surveys and surveillance strategies currently employed by health care providers in collaborating sites.

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

SSuN received statistical support from the following sources:

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Grantees, who are employees of the following state or local health departments:

- 1 Alabama Department of Public Health
- 2 Baltimore City Health Department
- 3 Chicago Department of Public Health
- 4 Colorado Department of Public Health and Environment
- 5 Connecticut Department of Public Health
- 6 City of Los Angeles Department of Public Health
- 7 Louisiana Department of Health and Hospitals
- 8 New York City Department of Health and Mental Hygiene
- 9 Philadelphia Department of Public Health
- 10 San Francisco Department of Public Health
- 11 Virginia Department of Health
- 12 Washington State Department of Health