

Has the program discussed this project with Dr. Chesley Richards, who is leading CDC Surveillance Initiative to coordinate state-level surveillance efforts across the agency? If so, how does this project, which involves 16 hours of burden per year on each entity, fit within that initiative?

RESPONSE: The CDC Surveillance Strategy led by Chesley Richards, guides efforts to make essential surveillance systems more adaptable to the rapidly changing technology landscape, more versatile in meeting demands for expanding knowledge about evolving threats to health, and more able to meet the demands for timely and population specific and geographically specific surveillance information. The Enhance STD Surveillance Network has not been specifically discussed with Dr. Richards because this activity does not create new data systems, software tools or health information platforms at CDC and is fully consistent with CDC's newly adopted (2014) surveillance strategy. In this project, State/City eSSuN grantees collect information using existing data management resources; grantees externally recode information from their local systems into SAS datasets and transmit these files individually using CDC's existing Secure Access Management System (SAMS). Additionally, eSSuN has been vetted with OCISO leadership and was determined not to require Security Certification & Accreditation (C&A) because no new computer systems or software platforms were being developed.

#### Detail Clarifications

• The protocol refers to Cycles 1 and 2. Did those projects have data collection associated with them? Please provide the PRA numbers. How will the data from these 10 grantees who are participating in the cycle 3 work nest within the data collected in the prior two cycles?

Response: Similar to all disease surveillance activities, analysis of broad, general trends across similar activities conducted previously is anticipated, such as proportion of cases reported by provider type, proportion of gonorrhea cases attributable to Gay, Bisexual and other men who have sex with men, or the distribution of cases by age group or gender. However, there are different grantees collaborating in the current activity and the resulting data is not directly comparable with respect to specific data elements; data from previous cycles of sentinel surveillance will not be combined for specific statistical comparisons.

Cycle I did not have a PRA number. OMB clearance was not sought for this pilot project (SSuN cycle I) because reporting sites (public health departments) instead of people were mistakenly counted as respondents. There were only 6 sites that were reporting data to CDC for the clinic portion of the project; however, more than 10 subjects were involved with the population portion of the pilot.

Cycle II had the following PRA number: OMB Control No. 0920-0842.

• Is this surveillance network designed to be a long term endeavor?

Response: Yes, surveillance is the ongoing, systematic collection of information related to health outcomes or disease. The STD Surveillance Network is designed to be a sentinel surveillance project to monitor trends over time in the incidence of gonorrhea and the characteristics and healthcare delivery patterns of persons seeking care in sentinel facilities important to STD prevention and control.

• What is the purpose of doing the interviews more than once?

Response: Patient interviews for a case included in the random sample are not conducted twice. The randomizing unit are cases reported to health departments collaborating in the network. It is possible that a specific individual can be diagnosed with gonorrhea more than once, and also possible that this new case of disease will be reported and included in the random sample. In that event, the individual associated with this reported case will be contacted for interview.

• What is the basis of the sample size for each location? Why is the sample size for the interviews 250 when the prevalence rate is less than 10,000 in that location? Are there power calculations associated with the sample sizes?

Response: 250 completed interviews per annum is the minimum acceptable performance for jurisdictions collaborating in the STD surveillance network. Most jurisdictions will contribute considerably more completed case investigations, based on their sample fraction and interview success rate. The collaborating jurisdictions all have different capacity for conducting routine follow-up of reported cases; eSSuN supplements existing resources for disease control locally. Each jurisdiction will adjust their sample fraction according to local capacity to assure that they meet minimum standards of performance for eSSuN.

The STD Surveillance Network is a sentinel disease surveillance project, not a research study; analyses are powered post hoc following examination of the data for bias and application of stratification and post stratification case weights. In the previous cycle of the STD Surveillance Network (OMB CONTROL NUMBER: 0920-0842) of 246,299 cases reported (the sample frame), 23,728 completed case investigations were obtained for an effective sample fraction of 9.6%. This sample size allowed for a margin of error of 0.6% in descriptive analyses at a confidence level of >99%.

• It isn't clear what the 250 cases are designed to be representative of – since you have some information in from the sampling frame, wouldn't it be better to use a stratified sampling approach to ensure better age, race, sex representation?

Response: The universe for sampling includes all gonorrhea cases reported in the collaborating jurisdiction. The sample frame is obtained from the health department's disease registry, the sample is representative of gonorrhea cases reported in the jurisdiction. The surveillance imperative and primary analytic intent is to describe characteristics of cases, not persons with gonorrhea. If, for instance, women or non-Hispanic Asians are under-represented in reported cases compared to their proportion in the general population, this indicates that they have a lower rate of disease – not that that the sample is biased or under-representative of these groups. Stratification or over-sampling is not necessary to obtain a sample representative of gonorrhea case reports.

• What is the purpose of conducting the personal interview component in full for three years in a row?

Response: The intent of sentinel surveillance (consistent with the primary goal of all disease surveillance) is to monitor changes in the distribution and determinants of disease. Monitoring change over time requires on-going, systematic investigation of the characteristics of the population of interest (reported gonorrhea cases).

• We understand that there are 137 clinics, but only 22 clinic data managers; however it is not clear why those data managers who are responsible for multiple facilities would have the same burden as those who only worry about a single location (and thus likely a single data system). Please demonstrate how this is taken into account in the burden table.

Response: Actually there are 132 clinics (30 STD clinics, 65 FP/RH clinics and 37 other facilities, largely made of federally qualified health centers and community health centers). Some of the facilities are single free standing clinics with their own data systems. However, other facilities are nested in a network with a single data system infrastructure. So for example, California is providing data from 12 STD clinics, 22 facilities nested within Planned Parenthood of Los Angeles and data from 28 of the 'other' facility types (family planning encounter patient data for all of California's title X facilities). The 12 STD clinics share a single data repository and hence, the data manager can develop a clinic extraction protocol to meet data transmission requirements. All the data is in one physical server location and the data manager only has to apply the data extraction protocol once, not 12 times. This is also the case for the clinics within Planned parenthood. The data from the other facility types all come from the California Family Health Council, which routinely reports to the State of California quarterly. This does not require implementation of extraction protocols and computer code. Hence, where sites the data managers were grouped according to data systems infrastructures rather than number so clinics.

· It isn't clear to us why informed consent isn't necessary for the personal interview component of this study (see stmt on page 11, which is inconsistent with statement on page 10).

Response: eSSuN is a sentinel surveillance project, not a study. All health departments in the United States routinely contact patients diagnosed with STDs such as gonorrhea to elicit information about sexual partners to control the spread of disease. They contact and interview patients under specific disease intervention authority structured in the Public Health laws and regulations of the state or jurisdiction. Informal, verbal consent is routinely obtained from patients for this public health disease control activity (referred to as "STD Partner Services"). eSSuN is specifically designed to overlay and to use this existing infrastructure for disease control by standardizing information usually collected in the process of STD Partner Services and to provide structure in terms of how collaborators prioritize cases for public health follow up and how they document information routinely collected.

· The abstract in ROCIS states: "This information will enable public health officials to understand important characteristics of persons tested, diagnosed, and treated for STDs, inform and guide state/local and national programs and policies for STD control, and identify and evaluate the effectiveness of public health interventions to reduce STD morbidity." Please describe why three years of data collection is necessary to achieve these goals. Please discuss the involvement in the study design of the state and local health departments who are the beneficiaries of these data.

Response: Public health surveillance is the ongoing and systematic collection, analysis, interpretation and dissemination of standardized data for the purpose of public health action. National STD surveillance data is needed for various reasons including assessing inequalities in disease incidence and/or prevalence, monitor STD program impact, detect emergent STD issues, and guide development of recommendations and policy. However, National case reporting data for STDs lack completeness with respect to critical patient demographics and are of narrow scope with respect to risk behavior, provider and clinical information, treatment and partner characteristics. Supplemental surveillance data from eSSuN are needed 1) to refine estimates of the burden of STDs, including incidence and prevalence among at-risk and vulnerable populations, and 2) to better monitor STD prevention program impact and STD-related care seeking behaviors. In much the same way that public health reporting for nationally notifiable STDs is continuous, collection and transmission of eSSuN data is essential to determining changes over time related to burden, behaviors characteristics, prevalence, and incidence.

The involvement of the state and local health departments for eSSuN include 1) working collaboratively with CDC and other funded project areas to standardize protocols and data elements for SSuN population and facility activities, 2) designing and implementing data management methods to support Part A activities that are efficient, sustainable, routine and automated, 3) participating in regularly scheduled conference calls, and annual face-to-face awardees meetings to develop or revise protocols, develop best practices, report progress toward meeting SSuN objectives, present preliminary data and describe status of ongoing activities, and 4) use findings and methods from their SSuN activities to improve and enhance existing core STD (or STD/HIV, if integrated) surveillance capacity in their jurisdictions.

· How will CDC characterize how they obtained its sampling frame to the individuals that it tries to recruit?

Response: All cases of gonorrhea reported in the collaborating jurisdiction are included in the de-identified datasets transmitted to CDC with a limited subset of demographics. For each case, information about whether the case was randomized into the sample is included. For each sampled case, information is included about recruitment attempts and the outcome of the enhanced case investigation. All of the information necessary to fully characterize the sampling frame, the sample, and the characteristics of investigated cases is present in the datasets provided by the sentinel surveillance sites.