Attachment 3

Summary of Changes to Data Collection Variables

Enhanced STD Surveillance Network (SSuN)

OMB# 0920-1072

This document identifies the revisions made to the ICR since the last OMB approval.

1. Removal of Family planning clinics (n = 108) from the facility-based surveillance activity:
    a. Our experience in the 2 years of data collection has shown us that the ability to extract data elements from these type of facilities was limited. In some cases, local/state health departments had not had previous working relationships with these healthcare facilities, resulting in challenges with collection and transmission of various data elements. In addition, these facilities have much lower STD morbidity than categorical STD clinics. For these reasons we saw the addition of these healthcare facilities less useful for determining STD-related screening coverage, STD diagnoses and treatment, and adverse outcomes of STDs in the patient populations that they serve.
2. STD clinic data elements, **Attachment 5**, F1 prefix variables: Emerging priorities in STD/HIV prevention, EPT, and opioid use. The following changes (10 items/data elements added, 2 data elements deleted, 3 modified) were necessary to ensure enhanced SSuN collects the most relevant STD/HIV-associated behavioral and clinical data:
    a. Measuring use of Pre-Exposure Prophylaxis (PrEP)
        1. 4 questions (F1_HIV_partner, F1_IVDU, F1_PrEP, F1_PrEP_referral,) were added for determination of PrEP eligibility and/or whether patients are currently on PrEP
    b. Opioid epidemic
        i. 1 question (F1_Opioid) were added to measure addiction to opioids
    c. Expedited partner therapy
        i. 1 question (F1_EPT) was added to better understand eligibility as documented in the clinical medical record to assess this STD prevention tool
    d. HIV care
        i. 1 question (F1_HIVcare) was added to better understand currently HIV positive patients attending STD clinics and how many of them are in care
    e. Behavioral assessment
        i. 3 questions (F1_MSM_12, F1_TRANSEX, F1_condom) were added to better assess behavioral risk in terms of their sexual partners whether patients had sex with persons Ten data elements were added and 2 data elements were removed to the STD clinic component for a net of 8 new data elements. Because these data elements are collected through routine clinical care and extracted from an existing database there should be minimal burden to add these elements to the sequel (or equivalent) scripts used to pull the data.
    f. Improvement of existing variables
        i. 1 question (F1_visit_type) assessing the visit type was modified to include the response option of a PrEP visit, to better categorize and quantify these services offered at STD clinics
        ii. 1 question (F1_sexor3) assessing sexual partners was modified to be more consistent with what is captured on electronic medical records and better categorize behavioral risk

    g. Deletion of lower priority items- Every variable was reviewed for quality and content value. Items measuring repetitive or low priority contents were removed

i. 1 question (f1_contraception) was deleted that assess whether female patients were on contraception. Given that family planning clinics were removed this information is not well ascertained in STD clinics
ii. 1 question (f1_HIV_test) was removed that assessed whether the patient had ever been tested for HIV. This question is of low yield given that most the patients attending STD clinics have been tested for HIV.

3. Population enhanced gonorrhea activity, **Attachment 5**, P3 prefix variables. Emerging priorities in STD/HIV prevention, EPT and opioid use. The following changes (addition of 11 questions) to ensure enhanced SSuN collects the most relevant STD/HIV-associated behavioral and clinical data.
    a. Addition of patient nativity question (#23.1 in Attachment 3). This question added to the patient interview at the request of CDC's National Center for HIV, Viral Hepatitis, STDs and Tuberculosis Prevention workgroup on health equity.
    b. Addition of 3 questions eliciting specific symptoms of gonorrhea (#28.1, 28.2, 28.3). Specific genital symptoms will allow for valid estimation of proportion of cases identified through general STD screening versus those tested diagnostically based on clinically relevant symptoms.
    c. Addition of 4 questions to elicit PrEP provision, acceptance, access and current use (#58.1,58.2,58.3 and 58.4). This will allow us to assess current PrEP use by patients as well as monitor provider prescribing practices.
    d. Addition of 3 questions to assess prescription opioid and injection drug use (#64.1, 64.3 and 64.3). Populations with higher opioid use may overlap those with STD risk and these questions will allow monitoring of how this changes over time.
4. The addition of a population-based STD surveillance on a patients diagnosed with early syphilis who report neurologic and/or ocular manifestations. Reported rates of syphilis have been increasing in the US since 2001 with an estimated 19.0% increase in the rate of primary and secondary syphilis in 2015 compared with 2014. Concomitantly the proportion of early syphilis cases reporting neurologic and/or ocular manifestations has also been increasing with clusters of ocular syphilis cases being reported in certain jurisdictions. At present, there are significant gaps in the surveillance of early syphilis cases with neurologic and/or ocular manifestations and there is a need to engage in systematic surveillance to estimate the proportion of cases with neurologic and/ocular manifestations and to monitor whether there has in fact been a rise in the proportion of syphilis cases with neurologic and/or ocular symptoms over time.
5. Estimated annualized burden hours changed from 2854 to 3479 primarily because 1) addition of the neuro ocular activity which added a total of 153 burden hours, 2) the additional 2267 patients will be sampled (a total of 5492 patients, from previously approved 3225 patients), and diagnosing healthcare provider information that will be extracted from health department records for the gonorrhea surveillance activity.