

Attachment 3

Summary of Changes to Data Collection Methods and Data Elements

STI Surveillance Network (SSuN)

Revision Request

OMB# 0920-1072

March 4, 2026

Summary of Proposed Changes in the Approved ICR for the Enhanced STI Surveillance Network (SSuN) OMB # 0920-1072

Summary of Proposed Changes

We are requesting a revision to the information collection request (ICR) for the STI Surveillance Network (SSuN), OMB #0920-1072. Data collection revisions include non-substantive response coding modifications to 9 currently collected data elements across multiple project components and the addition of 26 new data elements to capture Doxycycline and HIV Pre-exposure Prophylaxis (PrEP)_provision among sexual health clinic patients and for patients sampled for enhanced investigations, and to better capture previous syphilis history of persons sampled for enhanced investigations. Removal of 35 data elements associated with retired data items is also being proposed. Finally, a revised set of questions is being proposed for the clinic patient survey. The previous version of this survey focused on healthcare utilization among persons presenting to sexual health clinics; the revised, shortened version focuses on awareness and use of Doxy PEP among men who have sex with men. These revisions are responsive to NCHHSTP's intention to enhance monitoring uptake of Doxycycline Post-Exposure Prophylaxis (Doxy PEP), and better monitor HIV Pre-Exposure Prophylaxis (PrEP) provision within categorical sexual health clinics.

The change in burden by adding new data elements is offset by discontinuing multiple data elements, removing investigations among a sample of syphilis cases as proposed in the last revision, and reducing the number of participating sexual health clinics from a proposed 40 to 16 (across 12 Strategy A jurisdictions) that were funded for Cycle 5 (2024-2029); see **Table 1** for listing of data elements proposed for removal. Revisions to the valid response codes for existing sentinel surveillance (Strategy A) and enhanced surveillance (Strategy B) data elements are described in Tables 2A and 3A. Proposed new data elements for both strategies are summarized in Tables 2B and 3B (below). The revised anonymous clinic patient survey questions can be found in **Attachment 8**.

The burden table (**Exhibit 12A below**) is updated to reflect these changes. **Attachment 6** is updated to reflect a change in personnel in collaborating health departments.

Sentinel Surveillance Data Elements and Methods in Clinical Sexual Health Facilities (SSuN Strategy A)

This component of SSuN collects existing data for patients presenting for care in specialty sexual health clinical facilities. Changes to core data collection activities for this component include the deletion of 8 minimally informative data elements, minor modifications to 9 data elements and the addition of 8 new data elements. Core data elements are abstracted electronically from clinic record systems and the balance of additional vs deleted data elements will not result in additional burden to respondents. The revised clinic patient survey (**Attachment 8**) will also be implemented by participating clinical facilities. We are increasing our target number of surveys to 3,000 across all 16 clinics within the 12 participating jurisdictions, which increases the burden hours required for this activity. However, the overall change in burden to Strategy A jurisdictions is revised substantially downward from the 2023 revision due to the fact that only 16 clinics were selected for participation in Cycle 5 instead of the proposed 40.

Enhanced Case-based Surveillance Data Elements and Methods (SSuN Strategy B)

This component of SSuN randomly samples reported cases of gonorrhea in collaborating health jurisdictions. An additional 18 data elements are proposed to characterize Doxy PEP uptake and use by patients diagnosed with gonorrhea infections. However, the deletion of 27 minimally informative data elements will result in a net decrease in burden to respondents. Historically, Strategy B funded jurisdictions have sampled approximately 7% of their total gonorrhea cases for enhanced interviews, with a response rate of 35-60%. In Cycle 5 funded jurisdictions there were 187,883 cases of gonorrhea reported in 2023. By sampling 7% and assuming a 50% response rate, we estimate funded jurisdictions will complete 6,500 patient interviews among persons diagnosed with gonorrhea annually.

Across both strategies of SSuN, 35 data elements are being fully retired as no longer required or analytically useful.

Update to the STI Surveillance Network Principal Investigator's Contact Information in Attachment 6.

We have updated information from funded entities reflecting changes in staff and contact information for collaborating key personnel. These changes are reflected in **Attachment 6**.

Table 1. Data Elements Being Retired (Removed)

	Data Element Name	Reason
1	F1_Reason_visit	No longer relevant/not well ascertained/not required analytically
2	F1_PrEP_Scrn	No longer relevant/not well ascertained/not required analytically
3	F1_PrEP_Elig	No longer relevant/not well ascertained/not required analytically
4	F1_MPOX_Vax_Spec	No longer relevant/not well ascertained/not required analytically
5	F1_MPOX_Vx_Mthd	No longer relevant/not well ascertained/not required analytically
6	F1_MPOX_Vx_Lot	No longer relevant/not well ascertained/not required analytically
7	F1_MPOX_Vax_dosage	No longer relevant/not well ascertained/not required analytically
8	F1_MPOX_Vx_dosUnit	No longer relevant/not well ascertained/not required analytically
9	P1_InitSx	No longer relevant/not well ascertained/not required analytically
10	P1_PrevDx	No longer relevant/not well ascertained/not required analytically
11	P1_PrevDxDte	No longer relevant/not well ascertained/not required analytically
12	P1_ConcurCTDx	No longer relevant/not well ascertained/not required analytically
13	P1_PtxRaceSource	No longer relevant/not well ascertained/not required analytically
14	P1_PtxHispSource	No longer relevant/not well ascertained/not required analytically
15	P2_ProvCHC	No longer relevant/not well ascertained/not required analytically
16	P2_ProvFQHC	No longer relevant/not well ascertained/not required analytically
17	P2_ProvClinType	No longer relevant/not well ascertained/not required analytically
18	P2_ProvPTX_Insure	No longer relevant/not well ascertained/not required analytically
19	P2_ProvPTX_PDPT	No longer relevant/not well ascertained/not required analytically
20	P2_ProvPTX_HIBC	No longer relevant/not well ascertained/not required analytically
21	P2_ProvPTX_Refer	No longer relevant/not well ascertained/not required analytically
22	P3_Ptx_EPToffer	No longer relevant/not well ascertained/not required analytically
23	P3_Ptx_EPTWho	No longer relevant/not well ascertained/not required analytically

24	P3_Ptx_EPTGet	No longer relevant/not well ascertained/not required analytically
25	P3_Ptx_EPTMedorRx	No longer relevant/not well ascertained/not required analytically
26	P3_Ptx_EPTGave	No longer relevant/not well ascertained/not required analytically
27	P3_Ptx_EPTPartTake	No longer relevant/not well ascertained/not required analytically
28	P3_PTX_Opioid	No longer relevant/not well ascertained/not required analytically
29	P3_PTX_IVDU	No longer relevant/not well ascertained/not required analytically
30	P3_IVDU_HER	No longer relevant/not well ascertained/not required analytically
31	P3_IVDU_COC	No longer relevant/not well ascertained/not required analytically
32	P3_IVDU_Meth	No longer relevant/not well ascertained/not required analytically
33	P3_IVDU_Oxy	No longer relevant/not well ascertained/not required analytically
34	P3_IVDY_Oth	No longer relevant/not well ascertained/not required analytically
35	P3_IVDY_DR_TX	No longer relevant/not well ascertained/not required analytically

Table 2A. Proposed Response Coding changes to existing Data Elements, Strategy A, Sentinel Surveillance in STD Clinical Facilities

	Existing Variable	Description	Valid Response Values Added
1	F1_Prep_Ref	Was this patient referred for PrEP services?	5= No, PrEP was outside scope of clinical visit 6= No, patient is living with HIV 7= No, patient declined PrEP referral
2	F1_PrEP_Rx	Was this patient prescribed PrEP at this visit?	1= Yes, initial or refill of PrEP prescription given 4= Yes, unknown if initial or refill
3	F1_DPEP_Rx	Was the patient prescribed doxycycline prophylaxis (DoxyPEP) at this visit?	4= Yes, unknown if initial or refill
4	F1_Mpox_Vax	Was this patient vaccinated for mpox at this visit?	1=Yes 2=No 9=Not Captured
5	F1_Mpox_Vax_Dose	If mpox vaccine was provided, what dose number was given?	3=Third or more Dose 5= Unknown Dose
6	F2_DXCODE	Diagnosis Code	MPX9= Mpox (Not Categorized) CH01= Contact to HIV
7	F4_Medication	What medication was prescribed to the patient (brand name)?	46= Gepotidacin
8	P2_PR_DrugName	What drug was patient treated with?	46= Gepotidacin
9	P3_Ptx_InsType	What kind of healthcare insurance do you have?	6= Private healthcare insurance provided by a parent, spouse, or partner 10= Ryan White

Table 2B. Proposed New Variables, Strategy A, Sentinel Surveillance in STD Clinical Facilities

	Data Element ame	Description	Valid Values
2	F1_Reas_Symp	Did the patient present to care due to symptoms and/or a new health	1= Yes 2= No

		concern?	9= Not captured
3	F1_Reas_Follow	Did the patient present to care to follow-up on a previous clinical encounter or acute problem (i.e. positive test, test of cure, treatment, etc.)?	1= Yes 2= No 9= Not captured
4	F1_Reas_Scrn	Did the patient present to care to obtain routine asymptomatic HIV and/or STI screening?	1= Yes 2= No 9= Not captured
5	F1_Reas_PrEP	Did the patient present to care seeking HIV PrEP services (initiation/reinitiation, continuation, required STI screening, etc.)?	1= Yes 2= No 9= Not captured
6	F1_Reas_SPRef	Did the patient present to care because a sex partner referred them?	1= Yes 2= No 9= Not captured
7	F1_Reas_ClinRef	Did the patient present to care because another provider, clinic, or Health Department referred them?	1= Yes 2= No 9= Not captured
8	F1_Reas_DPEP	Did the patient present to care seeking DoxyPEP services (initiation/reinitiation, continuation, required STI screening, etc.)?	1= Yes 2= No 9= Not captured
9	F1_DPEP_current	Is the patient currently on Doxycycline PEP (Doxy PEP)?	1= Yes 2= No 3= Patient not sure/unknown/refused 9= Not captured

Table 2B. Proposed New Variables, Strategy B, Case-based Enhanced Surveillance

	Data Element/Variable Name	Description	Valid Values
1	P1_PrevSyDx	Has the patient been previously diagnosed and reported with syphilis?	1= Yes 2= No 3= Registry records not searched
2	P1_PrevSyDte	Date of most recent previous syphilis diagnosis	Date field
3	P1_PrevSyStage	What was the stage of most recent syphilis diagnosis?	1=Primary Syphilis 2=Secondary Syphilis 3=Early non-primary, non-secondary syphilis 4=Early Latent Syphilis 5=Syphilis, unknown duration or late 6=Congenital Syphilis 9=Unable to determine

5	P2_Prov_Contact1-3	Method of Provider Contact	1st Method of provider investigation contact 1= Phone call 2= E-mail 3= Fax 4= Direct/electronic access to medical records 5= Site visit 7= Other 8= Not contacted
6	P2_Prov_Dispo	Provider Investigation Disposition	1= Response received or access to record granted - all information complete 2= Response received or access to record granted - some information complete 3= No response - unsuccessful in obtaining any additional information 4= Not contacted
7	P2_PtxRace_White	Patient White Race (provider investigation)	1=Yes 2=No .=Missing
8	P2_PtxRace_Black	Patient Black Race (provider investigation)	1=Yes 2=No .=Missing
9	P2_PtxRace_AIAN	Patient AIAN Race (provider investigation)	1=Yes 2=No .=Missing
10	P2_PtxRace_Asian	Patient Asian Race (provider investigation)	1=Yes 2=No .=Missing
11	P2_PtxRace_NHOPI	Patient Native Hawaiian/Other Pacific Islander Race (provider investigation)	1=Yes 2=No .=Missing
13	P2_PtxRace_Other	Patient Other Race (provider investigation)	1=Yes 2=No .=Missing
14	P2_PtxHisp	Patient Hispanic Ethnicity	1=Yes 2=No .=Missing
15	P2_PtxRace_Unk	Is all information on race and Hispanic ethnicity missing from provider investigation?	1=Yes 2=No .=Missing
17	P3_Ptx_DPEP1	When you were diagnosed with gonorrhea, did your health care provider or anyone else discuss Doxy PEP medicine to prevent you from getting STIs?	1= Yes 2= No 3= Don't Know /Don't Remember/ Not Sure 4= Refused
18	P3_Ptx_DPEP2	Have you ever taken Doxy PEP?	1= Yes 2= No 3= Don't Know /Don't Remember/ Not

			Sure 4= Refused
19	P3_Ptx_DPEP3	When was the first time you ever used Doxy PEP? Your best guess is fine	MM/YYYY
20	P3_Ptx_DPEP4	How many times have you taken Doxy PEP in the past month? Your best guess is fine.	Open text
21	P3_Ptx_DPEP5	Have you ever taken Doxy PEP that was not prescribed to you, or was offered to you by someone other than a healthcare provider?	1= Yes 2= No 3= Don't Know /Don't Remember/ Not Sure 4= Refused

Changes in Estimates of Annualized Burden Hours

We estimate a slight decrease in estimated annualized burden hours from the previously approved 7,510 to 7,237 for this ICR as part of this revision, as described in Exhibit 12.A (below), which provides the current burden table for this ICR with the requested revisions.

Exhibit 12.A Estimates of Annualized Burden Hours

Type of Respondents	Form Name (if applicable)	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Data managers at sentinel STD clinics (Table B.1.A)	Electronic Clinical Record Abstraction (ATT5)	12	6	4	288
General Public – Adults (persons diagnosed with gonorrhea)	Patient interviews for a random sample of gonorrhea cases (ATT5, ATT8)	6,500	1	10/60	1,083
Data Managers: local/state health departments (strategy A) (ATT6)	Data cleaning/ validation, HIV registry matching and data transmissions for all activity components (ATT5)	12	6	40	2,880
Data Managers: local/state health departments (strategy B) (ATT6)	Data cleaning/ validation, HIV registry matching and data transmissions for all activity components (ATT5)	11	6	40	2,640

General Public – Adults (persons presenting for care in STD Clinics)	Clinic waiting room surveys	3,000	1	5/60	250
Total		9,539			7,237