Attachment 3
Summary of Changes to Data Collection Methods and Data Elements

STD Surveillance Network (SSuN)
Revision Request

OMB# 0920-1072

May 12, 2023

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

Summary of Proposed Changes

We are requesting revision to the information collection request (ICR) for the STD Surveillance Network (SSuN), OMB #0920-1072. The revisions requested for this ICR future expansion to up to 29 additional STD clinical facilities inclusion of enhanced investigations of a sample of syphilis cases reported in up to 12 sites. Data collection revisions include non-substantive response coding modifications to currently collected data elements across multiple project components, addition of 22 new data elements to capture Mpox testing, diagnoses, and vaccination and for screening and eligibility for Pre-Exposure Prophylaxis for HIV among STD clinic patients and for patients sampled for enhanced investigations. Removal of 28 data elements associated with retired data items is also being proposed. These revisions are responsive to NCHHSTP's intention to enhance monitoring for newly emergent STDs such as Mpox, enhance existing data collection activities to support evaluation of 'End the HIV Epidemic' initiatives and to better monitor health equity measures in relation to access to STD care, symptoms, diagnoses, and treatments associated with STDs.

Agency estimate of the burden for HIV surveillance registry matching is being reduced to zero (**wkst2e**) based on collaborating Health Department automation efforts and a modest increase in Health Department data management for Strategy A and B is requested to maintain this activity (see **wkst2b** and **wkst2d**).

Change in burden by adding new data elements and activities is partially offset by discontinuing multiple data elements and no change in burden is anticipated by the addition of investigations among a sample of syphilis cases; 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 and have no additional burden associated with them. Proposed new data elements for both strategies are summarized in Tables 2B and 3B (below).

Additionally, diagnosed and reported cases of adult syphilis are proposed for addition to case-based enhanced case investigations to monitor patient demographics, HIV co-infection, treatment and repeat episodes of disease among persons diagnosed and reported with syphilis. Data elements associated with this activity are already collected as part of enhanced gonorrhea case investigations; this activity results in additional data transmitted to CDC in existing datasets.

Burden table (**Attachment 3A**) 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 STD Clinical Facilities (SSuN Strategy A)

This component of SSuN collects existing data for patients presenting for care in STD-specialty clinical facilities. Expansion to include up to 25 additional facilities (total not to exceed 40) and addition of 24 data elements are proposed to characterize Mpox vaccination history, administration and the screening for, offer of and acceptance and use of HIV pre-and post-exposure. Several new data elements designed to capture symptomatic presentation and treatment for specific STDs are also added. Response options for existing laboratory data elements are revised to include the capture of Mpox testing and diagnosis. These changes in laboratory data element response coding for data collected from STD clinics will accommodate collection of Mpox-related tests, provide additional information on the uptake and potential cluster-vaccination, should emergent clusters of Mpox be observed in the participating communities. Because these data are abstracted electronically from clinic record systems, no additional burden is anticipated.

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. Additional data elements (7) are proposed to characterize Mpox vaccination in an at-risk patient population and fully capture laboratory source for HIV-related laboratory results. Response options for existing laboratory data elements are being revised to include Mpox testing and enhanced investigations are being expanded to include a random sample of syphilis cases; these data will provide a valuable source of information to monitor characteristics of cases considering recent increases, especially in congenital syphilis. Reduction in the sample size for gonorrhea cases selected for enhanced investigations will offset any increase in burden from inclusion of a random sample of syphilis cases.

Across both strategies of SSuN, 28 data elements are being fully retired as no longer required or analytically useful.

Update to the STD 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**.

Table1. Data Elements Being Retired (Removed)

Data Element Name	Reason
P1_RecSx	No longer relevant/not well ascertained/not required analytically
P1_PrevPtx	No longer relevant/not well ascertained/not required analytically
P1_Othno	No longer relevant/not well ascertained/not required analytically
P1_Othsx	No longer relevant/not well ascertained/not required analytically
P1_Dispo	No longer relevant/not well ascertained/not required analytically
P1_Referral1	No longer relevant/not well ascertained/not required analytically
P3_PTX_HISPOrgin	No longer relevant/not well ascertained/not required analytically
P3_PTX_HISPTXT	No longer relevant/not well ascertained/not required analytically
P3_PTX_AsianOrigin	No longer relevant/not well ascertained/not required analytically
P3_PTX_PIOrigin	No longer relevant/not well ascertained/not required analytically
P3_PTXNativity	No longer relevant/not well ascertained/not required analytically
P3_PTXBirtState	No longer relevant/not well ascertained/not required analytically
P3_PTXBirtCount	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasA	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasB	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasC	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasD	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasE	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasF	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasI	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasG	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasH	No longer relevant/not well ascertained/not required analytically
P3_PTX_reasJ	No longer relevant/not well ascertained/not required analytically
P3_PTX_othReasonTex	No longer relevant/not well ascertained/not required analytically

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P3_PTX_refusreason	No longer relevant/not well ascertained/not required analytically
P3_PTX_DIS_EPT	No longer relevant/not well ascertained/not required analytically
P3_PTX_DIS_EPTnum	No longer relevant/not well ascertained/not required analytically
P3_PTX_DIS_OtherPS	No longer relevant/not well ascertained/not required analytically
F1_Sympt	No longer relevant/not well ascertained/not required analytically
F1_Contact_STD	No longer relevant/not well ascertained/not required analytically
F1_MSM_12	No longer relevant/not well ascertained/not required analytically
F1_CMT	No longer relevant/not well ascertained/not required analytically
F1_Adnexal	No longer relevant/not well ascertained/not required analytically

Table2A. Proposed Response Coding changes to existing Data Elements, Strategy A, Sentinel Surveillance in STD Clinical Facilities

Existing Variable	Description	Valid Response Values Added
F2_DXCODE	Diagnosis Code	MPX1=MPX(Suspected) MPX2=MPX(Probable) MPX3=MPX(Confirmed)
F3_Test_Type	What type of test was used? (Will be expanded, recoded)	74=Syphilis EIA test 75=T. Vaginalis Rapid Test 76=T. Vaginalis NAAT 81=T. Vaginalis Culture 84=Mpox (Orthopoxvirus), DNA, PCR
F4_Medication	What medication was prescribed to the patient (brand name)?	73=Apretude (Cabotegravir)
F4_Dosage	What was the dosage of the medication prescribed?	17=2.4 Million Units 18=7.2 Million Units

Table2B. Proposed New Variables, Strategy A, Sentinel Surveillance in STD Clinical Facilities

Data Element/Variable Name	Description	Valid Values
F1_MPOX_VaxHx	Has this patient been previously vaccinated for smallpox or mpox?	1=Yes, fully vaccinated 2=Yes, not fully vaccinated 3=No, no prior smallpox or mpox vaccination 4=Refused to provide vaccination information 9=Not captured
F1_MPOX_VaxDATE	If patient previously vaccinated for smallpox or mpox, date of most recent dose.	MM/YY ../..
F1_MPOX_Vax	Was this	1=Yes, Administered Initial Dose

		2=Yes, Administered Second Dose 3=Yes, Administered >2nd dose 4=No, no MPX vaccine administered 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_MPOX_Vax_Spec	What smallpox or mpox vaccine was administered at this visit?	*1=JYNNEOS (Imvamune or Imvanex)* *2=ACAM2000* *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed if F1_MPX_Vax= 1,2 or 3.*
F1_MPOX_Vx_Mthd	What was the method of smallpox or mpox vaccine administration at this visit?	1=Intradermal (ID) 2=Subcutaneous (SQ) 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed if F1_MPX_Vax= 1,2 or 3.*
F1_MPOX_Vx_Lot	What is the vaccine lot number of the vaccine administered at this visit?	Text *A response of 9999 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed if F1_MPX_Vax= 1,2 or 3.*
F1_MPOX_Vx_dosage	What vaccine dose was administered at this visit?	##### *A response of 9999 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed if F1_MPX_Vax= 1,2 or 3.*
F1_MPOX_Vx_dosUnit	What was the vaccine dose unit for the vaccine administered at this visit?	1=mL 2=CC 3=mG 4=μG (microgram) 9=Not Captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed if F1_MPX_Vax= 1,2 or 3*
F3_Source	Did lab record originate from eHARS match?	*Default to 0 for records NOT coming from the eHARS registry, 1 for lab data from eHARS*
F1_Prep_Scrn	Was this patient counseled and screened for PrEP eligibility?	1=Yes 2=No, Patient HIV+ 3=No, Patient Refused 4=No, Express Visit Only 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_Prep_Elig	Was this	1=Yes

	patient eligible for PrEP?	2=No, Patient Not Eligible (HIV+) 3=No, Patient Not Eligible (Other Reason) 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_Prep_Ref	Was this patient referred for PrEP services?	1=Yes, Referred to in-house PrEP specialist 2=Yes, Referred to external PrEP provider 3=No, Patient Not Eligible 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_Prep_Rx	Was this patient prescribed PrEP at this visit?	1=Yes, Initial PrEP prescription given 2=Yes, Prescription refilled 3=No, Patient not prescribed PrEP 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_dPEP_Rx	Was the patient prescribed doxycycline prophylaxis at this visit?	1=Yes 2=No 9=Not Captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value not allowed.*
F1_Contact_GC	Was the patient a contact to or exposed to gonorrhea?	1= Yes 2= No 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.*
F1_Contact_CT	Was the patient a contact to or exposed to chlamydia?	1= Yes 2= No 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.*
F1_Contact_SY	Was the patient a contact to or exposed to syphilis?	1= Yes 2= No 9= Not captured *A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.*
F1_contact_Other	Was the patient a	1= Yes, HSV 2= Yes, MPX

	contact or exposed to a STD (other than syphilis, chlamydia, or gonorrhea)?	3. Yes, multiple 4. Yes, don't know specific STD 5. No, not a contact or exposed to STD 9= Not captured A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.
F4_TxMethod	Method of administration	1=PO - oral dosing 2=IM - intramuscular 3=IV - intravenous/infusion 4=Other 5=Unknown 6=Intravaginal 7=Topical
F1_Sxitching	Did the patient report a vaginal (abnormal), rectal or penile (urethral) itching?	1= Yes 2= No 9= Not captured A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response.
F1_SXPain	Did the patient report a vaginal (abnormal), rectal or genital pain?	1= Yes 2= No 9= Not captured A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response.
F1_SXRash	Did the patient report a genital/anal rash?	1= Yes 2= No 9= Not captured A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response.
F1_Sxbleeding	Did the patient report a vaginal (abnormal), rectal or (urethral) penile bleeding?	1= Yes 2= No 9= Not captured A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for

		a "no" response.
F1_GCtx	Was patient prescribed antimicrobials for gonorrhea treatment?	1= Yes 2= No, not indicated/refused 9= Not captured
F1_CTtx	Was patient prescribed antimicrobials for chlamydia treatment?	1= Yes 2= No, not indicated/refused 9= Not captured

Table2B. Proposed New Variables, Strategy B, Case-based Enhanced Surveillance

Data Element/Variable Name	Description	Valid Values
P2_ProvPTX_PrepRx	Was patient prescribed PrEP?	1=Yes 2=No *Missing/unknown information code as null ('.').*
P2_ProvPTX_dPEPRx	Was patient prescribed doxycycline as STI prophylaxis?	1=Yes 2=No *Missing/unknown information code as null ('.').*
P3_mpox	Has a doctor or other health care provider ever told you that you had Mpox (monkeypox)?	1=Yes 2=No 3=Don't Know/Not sure/Unknown 4=Refused
P3_mpox_vax	Have you ever received a vaccine for mpox?	1=Yes 2=No (skip to XXX) 3=Don't Know/Not sure/Unknown (skip to XXX) 4=Refused (skip to xxx)
P3_mpox_vaxD	How many doses of vaccine for mpox have you received?	1=One 2=Two 3=Don't Know/Not sure/Unknown 4=Refused
P3_mpox_vaxDTE	When was your last mpox vaccine shot?	This should be character data: "MM/YYYY", *missing/REFUSED information as"../YYYY" or "../...."*
P1_L1_Source	Did lab record originate from eHARS match?	*Default to 0 for records NOT coming from the eHARS registry, 1 for lab data from eHARS*

Changes in Estimates of Annualized Burden Hours

We estimate increase in estimated annualized burden hours from the previously approved 6,303 to 7,510 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**)	40	6	4	960
General Public – Adults (persons diagnosed with gonorrhea)	Patient interviews for a random sample of gonorrhea and syphilis cases (**ATT5, ATT8**)	7,000	1	10/60	1,190
Data Managers: local/state health departments (strategy A) (**ATT6**)	Data cleaning/ validation, HIV registry matching and data transmissions for all activity components (**ATT5**)	11	6	40	2,640
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	1000	1	0.08	80
Total	....		....	....	7,510