Attachment 3

Summary of Changes to Data Collection Methods and Data Elements

Enhanced STD Surveillance Network (SSuN)

Revision Request

OMB# 0920-1072

March 2020

**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 (eSSuN), OMB #0920-1072. The revisions requested for this ICR include non-substantive response coding modifications to currently collected data elements across multiple project components as well as substantive revisions to data elements and methods with removal of 115 data elements associated with a retired activity, addition of 94 new data elements to capture HIV registry matching of STD clinic patients, gonorrhea patient symptoms, patient nativity, STD-related HIV prevention activities, monitor opioid use, antimicrobial treatment, more fully characterize patient-reported and clinician-observed signs and symptoms of STDs, and to assess patient healthcare seeking behaviors through a brief, self-administered survey in STD clinics. These revisions are responsive to NCHHSTP leadership intention to enhance existing data collection activities to support the ‘End the HIV Epidemic’ initiatives and to better monitor symptoms and treatments associated with STDs.

Change in burden by adding HIV registry matching and patient survey activities is partially offset by discontinuing follow-up investigations among syphilis cases reporting ocular, otic or neurologic symptoms. This activity is being discontinued because the data previously collected have been sufficient to answer the emergent surveillance questions; therefore all 115 data elements associated with this activity are being removed. Several other data elements from patient interviews and from STD clinical records are also being removed as no longer needed; 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 surveillance datasets to monitor 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 routine case reporting and are structured identically to the approved data elements currently collected for gonorrhea cases; this activity results in additional records transmitted to CDC in existing datasets rather than collection of any new data at the state/city health department level.

Burden table (**Attachment 3A**) is updated to reflect discontinuation of ocular, otic and neuro syphilis activity, addition of new HIV registry matching activities, addition of reported syphilis case data to enhanced surveillance component (using existing, generalized data elements), and to reflect a change in collaborating health departments (**Attachment 6**).

**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. Additional data elements are proposed to characterize the offer, acceptance and use of HIV pre-and post-exposure prophylaxis as well as to better characterize patient reported and clinician-observed signs and symptoms of STDs. Additionally, participating clinics will submit patient data to the collaborating health departments for matching to the jurisdiction’s HIV surveillance registry. Response options for existing laboratory data elements are revised to include the capture of HIV-related test results. These changes in laboratory data element response coding for data collected from STD clinics will accommodate collection of HIV-related tests and testing algorithms, provide additional information on the availability and use of STD-related, high-impact HIV prevention activities and provide additional information on patient-reported signs and symptoms of STDs. The addition of a brief, anonymous, self-administered patient survey (Attachment 8) will allow for aggregate assessment of patient demographics and behaviors not otherwise available in routine medical records.

**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 and added newly funded jurisdiction for the upcoming 5-year cooperative agreement. These changes are reflected in **Attachment 6**.

***Table1. Data Elements Being Retired (Removed)***

|  |  |  |
| --- | --- | --- |
| **Data Element Name** | **Description** | **Response Coding** |
| NS1\_SITE | *Which participating site submitted this patient’s data* | *2-character code* |
| NS1\_PATIENTID | *Unique patient identifier assigned by SSuN site* | *Alphanumeric format* |
| NS1\_VISDATE | *Date of syphilis screening interview* | *MM/DD/YYYY* |
| NS1\_DX\_MM | *Month of syphilis diagnosis date* | *MM* |
| NS1\_DX\_DD | *Day of syphilis diagnosis date* | *DD* |
| NS1\_DX\_YYYY | *Year of syphilis diagnosis date* | *YYYY* |
| NS1\_PATIENTCONSENT | *Did the patient agree to be screened for neuro/ocular symptoms?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_PARTNERSERVICES | *Was this patient prioritized for a partner services interview based on health department protocol?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_GENDER | *What is your current gender identity?* | *1 = Male, 2 = Female, 3 = Transgender F to M, 4 = Transgender M to F, 5 = Transgender unspecified, 6 = Other, 9 = Unknown* |
| NS1\_SEX | *What sex were you assigned at birth?* | *1 = Male, 2 = Female, 9 = Unknown* |
| NS1\_AGE | *How old are you?* | *# (age in years), 999 = Unknown* |
| NS1\_HISP | *Are you of Hispanic ethnicity?* | *1= Yes, 2 = No, 9 = Unknown* |
| NS1\_AIAN | *Are you American Indian or an Alaskan Native?* | *1= Yes, 2 = No* |
| NS1\_ASIAN | *Are you Asian?* | *1= Yes, 2 = No* |
| NS1\_PIH | *Are you Pacific Islander or Hawaiian?* | *1= Yes, 2 = No* |
| NS1\_BLACK | *Are you Black?* | *1= Yes, 2 = No* |
| NS1\_WHITE | *Are you White?* | *1= Yes, 2 = No* |
| NS1\_OTHERRACE | *Do you identify as an Other race not included in the list above?* | *1= Yes, 2 = No* |
| NS1\_OTHERRACE\_TEXT | *If NS1\_OTHERRACE = 1 include text description.* | *Text* |
| NS1\_RACEUNKN\_REFUSED | *Is patient race unknown or did patient refuse to report their race?* | *1= Yes, 2 = No* |
| NS1\_SEXUALITY | *Do you consider yourself gay/homosexual, straight/heterosexual, or bisexual?* | *1 = Gay/Homosexual, 2 = Straight/Heterosexual, 3 = Bisexual, 4 = Other, 9 = Unknown* |
| NS1\_MALESP | *Have you ever had sex with a male?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_MALESPTIMEPERIOD | *How recently have you had sex with a male? In the past (select most recent time period):* | *1 = 3 months, 2 = 6 months, 3 = 9 months, 4 = 12 months, 5=> 12 months, 9 = Unknown* |
| NS1\_MENSEX | *How many male partners have you had sex with in the past 3 months?* | *#, 999 = Unknown* |
| NS1\_FEMALESP | *Have you ever had sex with a female?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_FEMALESPTIMEPERIOD | *How recently have you had sex with a female? In the past (select most recent time period):* | *1 = 3 months, 2 = 6 months, 3 = 9 months, 4 = 12 months, 5=> 12 months, 9 = Unknown* |
| NS1\_FEMSEX | *How many female partners have you had sex with in the past 3 months?* | *#, 999 = Unknown* |
| NS1\_NEUROOCULARDX | *Has a doctor or other medical person recently told you that you had neurosyphilis, or syphilis affecting your brain, eyes, or ears?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_DXLOC | *If yes (NS1\_NEUROOCULARDX = 1), where was this diagnosis made?* | *1 = STD Clinic, 2 = HIV Care Facility, 3 = Eye clinic, 4 = Emergency room, 5 = Primary Care Clinic, 6 = Other (please describe), 9 = Unknown* |
| NS1\_DXLOCOTHER\_TEXT | *If NS1\_DXLOC = 6 include text description* | *Text* |
| NS1\_HEARINGCHANGE | *Have you experienced a change in hearing in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_HEARINGLOSS | *Have you experienced hearing loss in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_TINNITUS | *Have you experienced ringing or buzzing in your ears (tinnitus) in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_HEADACHES | *Have you experienced headaches in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_ALTMENSTAT | *Have you experienced an altered mental status in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_STROKE | *Have you experienced stroke-like symptoms in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_OTHERNEUROSYMP | *Have you experienced other neurological symptoms in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_OTHERNEUROSYMP\_TEXT | *If NS1\_OTHERNEUROSYMP = 1 then include text description* | *Text* |
| NS1\_EYEPAIN | *Have you experienced eye pain in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_BLURRYVISION | *Have you experienced blurry vision in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_REDEYE | *Have you experienced red eye in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_VISIONCHANGES | *Have you experienced vision changes in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_FLASHLIGHTS | *Have you experienced any flashing lights in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_FLOATERS | *Have you experienced any floaters in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_VISIONLOSS | *Have you experienced vision loss in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_OTHEROCULARSYMP | *Have you experienced any other ocular symptoms in the past 60 days?* | *1 = Yes, 2 = No* |
| NS1\_OTHEROCULARSYMP\_TEXT | *If NS1\_OTHEROCULARSYMP = 1 include text description* | *Text* |
| NS1\_LUMBPUNC | *As part of your care for syphilis, did you receive a spinal tap or lumbar puncture?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_LUMBPUNC\_MM | *If you received a spinal tap or lumbar puncture (NS1\_LUMBPUNC = 1), what was the month of the date?* | *MM* |
| NS1\_LUMBPUNC\_DD | *If you received a spinal tap or lumbar puncture (NS1\_LUMBPUNC = 1), what was the day of the date?* | *DD* |
| NS1\_LUMBPUNC\_YYYY | *If you received a spinal tap or lumbar puncture (NS1\_LUMBPUNC = 1), what was the year of the date?* | *YYYY* |
| NS1\_SYPHSTAGE | *What stage of syphilis was this patient diagnosed with?* | *1 = Primary, 2 = Secondary, 3 = Early Latent, 4=Late latent, 9 = Unknown* |
| NS1\_SYPHRPRTITER | *What was the patient’s highest RPR titer recorded?* | *1 = 1:1, 2 = 1:2, 3 = 1:4, 4 = 1:8, 5 = 1:16, 6 = 1:32, 7 = 1:64, 8 = 1:128, 9 = 1:256, 10 = 1:512, 11 = 1:1024, 12 = > 1:1024, 99 = Unknown* |
| NS1\_SYPHTPPA | *What was the patient’s serologic TPPA result?* | *1 = Reactive, 2 = Nonreactive, 3 = Not done, 4 = Unsatisfactory* |
| NS1\_SYPHEIA | *What was the patient’s serologic EIA result?* | *1 = Reactive, 2 = Non-reactive, 3 = Not done* |
| NS1\_SYPHFTA\_ABS | *Serologic FTA-ABS result* | *1 = Reactive, 2 = Non-reactive, 3 = Not done* |
| NS1\_BENZPENC\_A | *Was the patient prescribed Benzathine penicillin G, 2.4 million units IM single dose?* | *1 = Yes, 2 = No* |
| NS1\_BENZPENC\_B | *Was the patient prescribed Benzathine penicillin G, 2,4 million units in 3 doses at 1 week intervals (max total 7.2 million units)* | *1 = Yes, 2 = No* |
| NS1\_BENZPENC\_C | *Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, single dose (max total 2.4 million units)* | *1 = Yes, 2 = No* |
| NS1\_BENZPENC\_D | *Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, 3 doses, 1 week intervals (max total 7.2 million units)* | *1 = Yes, 2 = No* |
| NS1\_AQCRYSTPENG\_A | *Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as 3-4 million units IV every 4 hrs, for 10-14 days?* | *1 = Yes, 2 = No* |
| NS1\_AQCRYSTPENG\_B | *Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as continuous infusion, for 10-14 days?* | *1 = Yes, 2 = No* |
| NS1\_DOXYCYC\_A | *Was the patient prescribed Doxycycline, 100 mg 2x/day for 14 days?* | *1 = Yes, 2 = No* |
| NS1\_DOXYCYC\_B | *Was the patient prescribed Doxycycline, 100 mg 2x/day for 28 days?* | *1 = Yes, 2 = No* |
| NS1\_TETRACYC\_A | *Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 14 days?* | *1 = Yes, 2 = No* |
| NS1\_TETRACYC\_B | *Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 28 days?* | *1 = Yes, 2 = No* |
| NS1\_PROCPENPROB | *Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily, PLUS probenecid (500 mg, 4 times a day, both for 10-14 days?* | *1 = Yes, 2 = No* |
| NS1\_PROCPEN | *Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily for 10-14 days without probenecid?* | *1 = Yes, 2 = No* |
| NS1\_CEFTRIAX\_A | *Was the patient prescribed Ceftriaxone 250 mg IM in a single dose?* | *1 = Yes, 2 = No* |
| NS1\_CEFTRIAX\_B | *Was the patient prescribed Ceftriaxone 1 g IM in a single dose?* | *1 = Yes, 2 = No* |
| NS1\_OTHERTX | *Was the patient prescribed any other treatment?* | *1 = Yes, 2 = No* |
| NS1\_SYPHTX\_TEXT | *If NS1\_OTHERTX = 1 (“Yes”) include text description* | *Text* |
| NS1\_HIVTESTEVER | *Was this patient ever tested for HIV prior to this event?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_HIVTESTEVER\_MM | *What was the month of the date of the most recent HIV test prior to this event?* | *MM* |
| NS1\_HIVTESTEVER\_DD | *What was the day of the date of the most recent HIV test prior to this event?* | *DD* |
| NS1\_HIVTESTEVER\_YYYY | *What was the year of the date of the most recent HIV test prior to this event?* | *YYYY* |
| NS1\_PREVHIVRES | *What was the result of this prior HIV test?* | *1 = Reactive, 2 = Nonreactive, 3 = Indeterminate, 9 = Unknown* |
| NS1\_HIVSTAT | *What is final HIV test result at this event?* | *1 = Previous HIV positive, not retested, 2 = Tested and verified HIV positive at this event, 3 = Tested and verified HIV negative at this event, 4 = Indeterminate, 5= Not tested at this event, 9 = Unknown* |
| NS1\_HIVART | *If patient is HIV positive, are they currently taking antiretrovirals?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS1\_HIVVLTEST\_MM | *When was the patient’s most recent HIV viral load test?* | *MM* |
| NS1\_HIVVLTEST\_DD | *When was the patient’s most recent HIV viral load test?* | *DD* |
| NS1\_HIVVLTEST\_YYYY | *When was the patient’s most recent HIV viral load test?* | *YYYY* |
| NS1\_HIVVLRESULT | *What was the result of the most recent HIV viral load test?* | *1 = undetectable, 2 = <500 copies/ml, 3 = 500-10,000 copies/ml, 4 = > 10,000 copies/ml, 9 = Unknown* |
| NS2\_SITE | *Which participating site submitted this patient’s data* | *FL = Florida, MC = Multnomah County, NY = New York City, PH = Philadelphia, WA = Washington State* |
| NS2\_PATIENTID | *Unique patient identifier assigned by SSuN site* | *Alphanumeric format* |
| NS2\_VISDATE | *Date of syphilis screening interview* | *MM/DD/YYYY* |
| NS2\_DX\_MM | *Month of date of syphilis diagnosis* | *MM* |
| NS2\_DX\_DD | *Day of date of syphilis diagnosis* | *DD* |
| NS2\_DX\_YYYY | *Year of date of syphilis diagnosis* | *YYYY* |
| NS2\_CONTACT | *Were you able to contact the patient for a 3-month follow-up?* | *1=Yes, 2=No* |
| NS2\_TXCOMPLETE | *Did you complete your prescribed syphilis treatment?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS2\_CHANGEHEARINGRESOLV | *Has your change in hearing resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_HEARINGLOSSRESOLV | *Has your hearing loss resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_TINNITUSRESOLV | *Has the buzzing or ringing in your ears (tinnitus) resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_HEADACHESRESOLV | *Have your headaches resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_ALTMENTALRESOLV | *Has your altered mental status resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_EYEPAINRESOLV | *Has your eye pain resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_REDEYERESOLV | *Has your red eye resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_BLURRYVISIONRESOLV | *Has your blurry vision resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_VISIONCHANGESRESOLV | *Have your vision changes resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_VISIONLOSSRESOLV | *Has your vision loss resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_FLOATERSRESOLV | *Have your floaters resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_FLASHLIGHTSRESOLV | *Have the flashing lights resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_OTHERRESOLV\_1 | *Were there any other symptoms not listed that have since resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_OTHERRESOLV\_1\_TEXT | *If NS2\_OTHERRESOLV\_1 ≠ 1 include text description* | *Text* |
| NS2\_OTHERRESOLV\_2 | *Were there any other symptoms not listed that have since resolved?* | *1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened* |
| NS2\_OTHERRESOLV\_2\_TEXT | *If NS2\_OTHERRESOLV\_2 ≠ 1 include text description* | *Text* |
| NS2\_SYMPADD | *Did you develop any additional symptoms after treatment?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS2\_SYMPADDHEARINGCHANGE | *Did you experience a change in hearing following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDHEARINGLOSS | *Did you experience a loss in hearing following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDHEADACHES | *Did you experience headaches following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDSTROKE | *Did you experience any stroke-like symptoms following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDALMENSTAT | *Did you experience an altered mental status following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDTINNITUS | *Did you experience a ringing or buzzing in ears (tinnitus) following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDEYEPAIN | *Did you experience any eye pain following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDREDEYE | *Did you experience any red eye following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDBLURRYVISION | *Did you experience any blurry vision following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDVISIONCHANGES | *Did you experience any vision changes following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDFLOATERS | *Did you experience any floaters following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDVISIONLOSS | *Did you experience any vision loss following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDFLASHINGLIGHTS | *Did you experience any flashing lights following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDOTHER | *Did you experience any other symptoms following treatment?* | *1 = Yes, 2 = No* |
| NS2\_SYMPADDOTHER\_TEXT | *If NS2\_SYMPADDOTHER = 1 (“Yes”) include text description* | *Text* |
| NS3\_SITE | *Which participating site submitted this patient’s data* | *FL = Florida, MC = Multnomah County, NY = New York City, PH = Philadelphia, WA = Washington State* |
| NS3\_PATIENTID | *Unique patient identifier assigned by SSuN site* | *Alphanumeric format* |
| NS3\_VISDATE | *Date of syphilis screening interview* | *MM/DD/YYYY* |
| NS3\_DX\_MM | *Month of date of syphilis diagnosis* | *MM* |
| NS3\_DX\_DD | *Day of date of syphilis diagnosis* | *DD* |
| NS3\_DX\_YYYY | *Year of date of syphilis diagnosis* | *YYYY* |
| NS3\_ROUTINE | *Do you routinely screen your patients with syphilis for symptoms of ocular, otic, or neurosyphilis?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS3\_ROUTINEFORM | *If patients with syphilis are routinely screened for ocular, otic, or neurosyphilis do you have a form that you use for screening?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS3\_NEURODX | *Did this patient receive a clinical diagnosis of neurosyphilis?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS3\_OCULARDX | *Did this patient receive a clinical diagnosis of ocular syphilis?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS3\_HEARINGCHANGE | *Did the patient present with a change in hearing?* | *1 = Yes, 2 = No* |
| NS3\_HEARINGLOSS | *Did the patient present with hearing loss?* | *1 = Yes, 2 = No* |
| NS3\_HEADACHES | *Did the patient present with headaches?* | *1 = Yes, 2 = No* |
| NS3\_STROKE | *Did the patient present with stroke-like symptoms?* | *1 = Yes, 2 = No* |
| NS3\_ALTMENSTAT | *Did the patient present with an altered mental status?* | *1 = Yes, 2 = No* |
| NS3\_TINNITUS | *Did the patient present with buzzing or ringing in ears (tinnitus)?* | *1 = Yes, 2 = No* |
| NS3\_OTHERNEUROSYMP | *Did the patient present with other symptoms consistent with neurosyphilis?* | *1 = Yes, 2 = No* |
| NS3\_OTHERNEUROSYMP\_TEXT | *If NS3\_OTHERNEUROSYMP = 1 (“Yes”) include text description* | *Text* |
| NS3\_EYEPAIN | *Did the patient present with eye pain?* | *1 = Yes, 2 = No* |
| NS3\_REDEYE | *Did the patient present with red eye?* | *1 = Yes, 2 = No* |
| NS3\_VISIONLOSS | *Did the patient present with vision loss?* | *1 = Yes, 2 = No* |
| NS3\_VISIONCHANGES | *Did the patient present with vision changes?* | *1 = Yes, 2 = No* |
| NS3\_FLASHINGLIGHTS | *Did the patient present with symptoms of flashing lights?* | *1 = Yes, 2 = No* |
| NS3\_BLURRYVISION | *Did the patient present with blurry vision?* | *1 = Yes, 2 = No* |
| NS3\_FLOATERS | *Did the patient present with symptoms of floaters?* | *1 = Yes, 2 = No* |
| NS3\_OTHEROCULARSYMP | *Did the patient present with any other symptoms consistent with ocular syphilis?* | *1 = Yes, 2 = No* |
| NS3\_OTHEROCULARSYMP\_TEXT | *If NS3\_OTHEROCULARSYMP = 1 (“Yes”) include text description* | *Text* |
| NS3\_OPTHALEXAM | *Did the patient have an ophthalmologic exam?* | *1 = Yes, 2 = No, 9 = Unknown* |
| NS3\_OPTHALEXAMUVEITIS | *Was uveitis one of the ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OPTHALEXAMSCLERITIS | *Was Scleritis/keratitis one of the ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OPTHALEXAMRETINITIS | *Was Retinitis/Chorioretinitis one of the ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OPTHALEXAMNEURITIS | *Was Optic Neuritis one of the ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OPTHALEXAMRETDETACH | *Was Retinal Detachment one of the ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OTHEROPTHALEXAM | *Were there any other ophthalmologic exam findings?* | *1 = Yes, 2 = No* |
| NS3\_OTHEROPTHALEXAM\_TEXT | *If NS3\_OTHEROPTHALEXAM = 1 (“Yes”) include text description* | *Text* |
| NS3\_LUMBPUNC | *Was a spinal tap or lumbar puncture performed?* | *4 = Yes, 2 = No, 9 = Unknown* |
| NS3\_LUMBPUNC\_MM | *If a spinal tap or lumbar puncture was done, during which month was this performed?* | *MM* |
| NS3\_LUMBPUNC\_DD | *If a spinal tap or lumbar puncture was done, on which day was this performed?* | *DD* |
| NS3\_LUMBPUNC\_YYYY | *If a spinal tap or lumbar puncture was done, during which year was this performed?* | *YYYY* |
| NS3\_LUMBPUNCROUTINE | *Was the lumbar puncture performed because it is a routine procedure at this facility?* | *1 = Yes, 2 = No* |
| NS3\_LUMBPUNCSYMPTOMS | *Was the lumbar puncture performed based on patient symptoms?* | *1 = Yes, 2 = No* |
| NS3\_LUMBPUNCHIVSTAT | *Was the lumbar puncture performed based on the patient’s HIV status?* | *1 = Yes, 2 = No* |
| NS3\_LUMBPUNCUNKNOWN | *Was the lumbar puncture performed for an unknown reason?* | *1 = Yes, 2 = No* |
| NS3\_OTHERLUMBPUNC | *Was there another reason the lumbar puncture was performed?* | *1 = Yes, 2 = No* |
| NS3\_OTHERLUMBPUNC\_TEXT | *If NS3\_OTHERLUMBPUNC = 1 (“Yes”) include text description* | *Text* |
| NS3\_CSFVDRL | *CSF VDRL result* | *1 = Reactive, 2 = Non-reactive, 3 = Not done* |
| NS3\_CSFFTA\_ABS | *CSF FTA-ABS result* | *1 = Reactive, 2 = Non-reactive, 3 = Not done* |
| NS3\_CSFWBC | *WBC total* | *# (WBC/mm3)* |
| NS3\_CSFTOTPROTEIN | *CSF total protein* | *# (mg/100 ml)* |
| NS3\_CSFGLUCOSE | *CSF glucose* | *# (mg/100 ml)* |
| NS3\_BENZPENG\_A | *Was the patient prescribed Benzathine penicillin G, 2.4 million units IM single dose?* | *1 = Yes, 2 = No* |
| NS3\_BENZPENG\_B | *Was the patient prescribed Benzathine penicillin G, 2,4 million units in 3 doses at 1 week intervals (max total 7.2 million units)* | *2 = Yes, 2 = No* |
| NS3\_BENZPENG\_C | *Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, single dose (max total 2.4 million units)* | *3 = Yes, 2 = No* |
| NS3\_BENZPENG\_D | *Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, 3 doses, 1 weel intervals (max total 7.2 million units)* | *4 = Yes, 2 = No* |
| NS3\_AQCRYSTPENG\_A | *Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as 3-4 million units IV every 4 hrs, for 10-14 days?* | *1 = Yes, 2 = No* |
| NS3\_AQCRYSTPENG\_B | *Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as continuous infusion, for 10-14 days?* | *1 = Yes, 2 = No* |
| NS3\_DOXYCYC\_A | *Was the patient prescribed Doxycycline, 100 mg 2x/day for 14 days?* | *1 = Yes, 2 = No* |
| NS3\_DOXYCYC\_B | *Was the patient prescribed Doxycycline, 100 mg 2x/day for 28 days?* | *1 = Yes, 2 = No* |
| NS3\_TETRACYC\_A | *Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 14 days?* | *2 = Yes, 2 = No* |
| NS3\_TETRACYC\_B | *Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 28 days?* | *3 = Yes, 2 = No* |
| NS3\_PROCPENPROB | *Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily, PLUS probenecid (500 mg, 4 times a day, borh for 10-14 days?* | *1 = Yes, 2 = No* |
| NS3\_PROCPEN | *Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily for 10-14 days without probenecid?* | *1 = Yes, 2 = No* |
| NS3\_CEFTRIAX\_A | *Was the patient prescribed Ceftriaxone 250 mg IM in a single dose?* | *1 = Yes, 2 = No* |
| NS3\_CEFTRIAX\_B | *Was the patient prescribed Ceftriaxone 1 g IM in a single dose?* | *1 = Yes, 2 = No* |
| NS3\_OTHERTX | *Was the patient prescribed any other treatment?* | *1 = Yes, 2 = No* |
| NS3\_SYPHTX\_TEXT | *If NS3\_OTHERTX = 1 (“Yes”) include text description* | *Text* |
|  |  |  |
| P3\_PTX\_GEOMRSP | *(72) Thinking back to the last person you had sex with, about how far away does that person live from you. If you don’t know for sure, it’s OK to make your best guess.* | |  | | --- | | 0=Partner lives with me | | 1=less than 5 minutes | | 2=5 to 15 minutes | | 3=15 to 30 minutes | | 4=30 minutes to 1 hour | | 5=> 1 hour | | 6=They live in another state | | 7=They live in another country | | 8=Don't know / Not sure | | 9=Refused | |
| F1\_Sympt | Does the patient have STI symptoms? | |  | | --- | | 1= Yes | | 2= No | | 9= Not captured | |
| F1\_prep\_offer | Was the patient offered PrEP at the STD clinic? | |  | | --- | | 1= Yes | | 2= No | | 9= Not captured | |
| F1\_pep\_offer | Was the patient offered PEP at the STD clinic? | |  | | --- | | 1= Yes | | 2= No | | 9= Not captured | |
| F1\_EPT | Is the patient eligible for expedited partner therapy? | |  | | --- | | 1= Yes | | 2= No | | 3= Not indicated  9= Not captured | |
| F1\_Partner\_txACCPT | Did the patient accept expedited partner therapy? | |  | | --- | | 1= Yes | | 2= No | | 9= Not captured | |

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

|  |  |  |
| --- | --- | --- |
| **Data Element/Variable Name** | **Description** | **Valid Values** |
| F1\_SiteID | Unique site code | BA=Baltimore (Cycle II, Cycle III, Cycle IV)  CB=Columbus (Cycle IV)  CA=California (Cycle II, Cycle III, Cycle IV)  FL=Florida (Cycle III & Cycle IV)  IN=Indiana (Cycle IV)  MC=Multnomah County (Cycle III &Cycle IV)  NY=New York City (Cycle II, Cycle III, Cycle IV)  PH=Philadelphia (Cycle II, Cycle III, Cycle IV)  SF=San Francisco (Cycle II, Cycle III, Cycle IV)  WA= Washington (Cycle II, Cycle III, Cycle IV)  UT=UTAH (Cycle IV)  LA=Louisana (Cycle II)  VA=Virginia (Cycle II)  AL=Alabama (Cycle II)  CO=Colorado (Cycle II)  CH=Chicago (Cycle II)  MA=Massachusetts (Cycle III)  MN=Minnesota (Cycle III) |
| F3\_Test\_Type | Type of laboratory test performed | 1= Culture  2= Nucleic acid amplification test (NAAT)  3= Non-amplified nucleic acid test/DNA probe  4= Gram stain  10= HIV Nucleic acid test (NAT)  11= rapid HIV-1 or HIV-1/2 antibody (Ab) test  12= HIV-1 Immunoassay (IA)  13= HIV-1/2 IA  14= HIV-1/2 Ag/Ab IA  15= HIV-1 WB  16= HIV-1 IFA  17= HIV-1/HIV-2 differentiation IA  18= pooled RNA  19=HIV Viral Load (ultra quantitative)  20=HIV Viral Load (quantitative)  21=CD4+ assay  22=HIV-1 IA (EIA or Other)  23=HIV-1/2 IA (EIA or Other)  24=HIV-2 IA (EIA or Other)  25=HIV-1/2 Ag/Ab  26=HIV-1/2 Type-Differentiating Immunoassay  27=HIV-1 Western Blot  28=HIV-2 Western Blot  29=HIV-1 IFA  30=HIV-1 Culture  31=HIV-2 Culture  32=HIV-1 p24 Antigen  33=HIV-1 RNA/DNA NAAT (Qualitative)  34=HIV-2 RNA/DNA NAAT (Qualitative)  35=HIV-1 RNA/DNA NAAT (Quantitative viral load)  36=HIV-2 RNA/DNA NAAT (Quantitative viral load)  37=CD4 T-lymphocytes  38=CD4 Percent  39=HIV-1 Genotype (PR Nucleotide Sequence)  40=HIV-1 Genotype (RT Nucleotide Sequence)  41=HIV-1 Genotype (PR/RT Nucleotide Sequence)  42=HIV-1 Genotype (IN Nucleotide Sequence)  43=HIV-1 Genotype (PR/RT/IN Nucleotide Sequence)  44=STARHS (BED)  45=STARHS (Vironostika-LS)  46=STARHS ( BIO-RAD AVIDITY)  47=STARHS (Other)  48=STARHS (Unknown)  49=Rapid (Retired)  50=HIV-1/2 Ag/Ab-Distinguishing Immunoassay  51=HIV-1 Genotype (EN Nucleotide Sequence)  52=HIV-1 Genotype (FI Nucleotide Sequence)  53=HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay  54=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 p24 Antigen Analyte  55=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 Antibody Analyte  56=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-2 Antibody Analyte  57=HIV-1/2 Type-Differentiating Immunoassay (Supplemental)  58=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-1 Antibody Analyte  59=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-2 Antibody Analyte  60=HIV-1 Genotype (Unspecified)  61=WB/IFA-Legacy  62=RIPA-Legacy  63=Latex Ag-Legacy  64=Peptide-Legacy  65=Rapid-Legacy  66=Iga-Legacy  67=IVAP-Legacy  68=Other HIV Antibody-Other-Legacy  69=Other HIV Antibody-Unspecified-Legacy  70=Viral Load-Other-Legacy  71=Viral Load-Unspecified-Legacy  72=HIV Detection/Antigen/Viral Load-Other-Legacy  73=HIV Detection/Antigen/Viral Load-Unspecified-Legacy  74= Pregnancy  88= Other  99=Not captured |
| F3\_Condtested | What condition was the patient tested for? | 1 = Syphilis  2 = Gonorrhea  3 = Chlamydia  4 = Chancroid  5 = Trichomoniasis  6 = HIV/AIDS  7 = Bacterial vaginosis  8 = Herpes  9 = Mycoplasm genitalium  20 = Pregnancy |
| F4\_Medication | What medication was prescribed to the patient (brand name)? | |  | | --- | | 10= Amoxicillin (Amoxil, Polymox, Trimox, Wymox) | | 11= Ampicillin (Omnipen, Polycillin, Polycillin-N, Principen, Totacillin) | | 20= Azithromycin (Zithromax) | | 21= Erythromycin base | | 22= Clindamycin (Cleocin) | | 23= Gentamicin (Garamycin, G-Mycin, Jenamicin) | | 30= Cefixime (Suprax) | | 31= Ceftizoxime (Cefizox) | | 32= Cefotaxime (Claforan) | | 33= Cefoxitin (Mefoxin) | | 34= Cefpodoxime (Vantin) | | 35= Ceftibuten (Cedax) | | 36= Cefdinir (omnicef) | | 37= Ceftriaxone (Rocephin) | | 38= Cefuroxime (Ceftin, Kefurox, Zinacef, Zinnat) | | 40= Ciprofloxacin (Cipro, Cipro XR, Ciprobay, Ciproxin) | | 41= Levofloxacin (Cravit, Levaquin) | | 42= Moxifloxacin (Avelox, Vigamox) | | 43= Ofloxacin (Floxin, Oxaldin, Tarivid)  44= Gemifloxacin (Factive)  50= Doxycycline (Doryx, Vibramycin)  60= Metronidazole (Flagyl, Helidac, Metizol, Metric 21, Neo-Metric, Noritate, Novonidazol)  61= Tinidazole (Tindamax)  70= Truvada (Tenofovir/emtricitabine)  88= Other | |

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

|  |  |  |
| --- | --- | --- |
| **Variable name** | **Description** | **Valid Values** |
| F1\_SEXOR3TG | Has the patient had sex with a transgender man or woman? | |  | | --- | | 1= Yes | | 2= No | | 9= Not captured | |
| F1\_HregMatch | Was HIV registry match done for this patient? | 1=Yes  2=No |
| F1\_HregMatchStat | Did this patient match a registry entry in eHARS? | |  | | --- | | 1=Matching Record Found | | 2=No Matching Record | | 3=Match Not Performed | |
| F1\_HregID | Unique record number from HIV registry (such as stateno from eHARS). | Alphanumeric character value ($15) |
| F1\_EXPMOD | Exposure mode from HIV registry. | |  | | --- | | 1=Male who had sex with another male (MSM) | | 2=Injected illicit or non-prescription drugs (IDU) | | 3=Had sex with someone with either 1 or 2 (above) | | 4=Had Sex with Someone of the Opposite Sex but May Not Have Known whether HIV Infection was Diagnosed in that Person, or Any of the Risk factors of Sex Partners Described in Items 3 or 5 | | 5=Had Sex with Someone of the Opposite Sex in whom HIV Infection was Diagnosed after Having | | Any Risk Factor for HIV Infection in Items 6 (Receipt of Clotting Factor for Coagulation Disorder), | | 7 (Receipt of Blood Transfusion), or 8 (Receipt of Transplant or Artificial Insemination) | | 6=Received Clotting Factor Injection for Hemophilia or Another Coagulation Disorder | | 7=Received Transfusion of Blood or Blood Components (e.g., Platelets) | | 8=Received a Transplant of Tissue or Organ or Artificial Insemination | | 9=Worked in a Health-Care or Clinical Laboratory Setting with Possible Exposure to Human Blood or Other Body Fluids | | 10=Had Other Exposure to Human Blood or Body Fluids | | 11=No Risk Reported | |
| F1\_Pelvic\_exam | Was a pelvic exam performed? | 1= Yes  2= No  9= Not captured |
| F1\_prep\_offer | Was the patient offered PrEP at the STD clinic? | 1= Yes  2= No  3= No, but a referral to outside clinic was given |
| F1\_PEP\_offer | Was the patient offered PEP at the STD clinic? | 1= Yes  2= No  3= No, but a referral to outside clinic was given |
| F1\_prep\_referral | Was the patient referred for PrEP at the STD clinic? | 1= Yes  2= No |
| F1\_condom | Does the patient report receptive anal sex without a condom with a male in the last 3 months? | 1= Yes  2= No  3= Unsure/ doesn’t know  9= Not captured |
| F1\_HIVTest | Has the patient ever been tested for HIV? (excluding HIV testing on today’s visit)? | 1= Yes  2= No  3= Patient does not know/ not sure  9= Not captured |
| F1\_SXAbdomen | Did the patient report abdominal pain? | 1= Yes  2= No  9= Not captured |
| F3\_QuantRes | Quantitative result from laboratory test | A-Z, 0-9,-,\_, blank |
| F3\_QuantUnits | Units for quantitative results | |  | | --- | | 1=Copies/mL | | 2=Log Copies/mL | | 3=Cells/Cubic mm  4=CD4%  5=Titer Ratio  6=Cycles/Time (rtPCR)  9=Unk | |
| F4\_TxDate | Date treatment prescribed/dispensed | MMDDYYYY |
| F5\_PrEP\_Rx | Does the facility prescribe PrEP? | 1= Yes  2= No, facility does not prescribe PrEP |
| F5\_PrEP | Does the facility have written policies governing referral or management of PrEP? | 1= Yes  2= No |
| F5\_PEP\_Rx | Does the facility prescribe PEP? | 1= Yes  2= No, facility does not prescribe PEP |
| F5\_PrEP\_Manage | Does the facility actively manage patients on PrEP? | 1= Yes  2= No, facility does not refer to or manage PrEP |
| FS1\_FirstVis | Is this your first time to this clinic? | 1=Yes  2=No |
| FS1\_Welcome | Do you feel that this clinic provides a welcoming and respectful environment? | |  | | --- | | 1=Yes | | 2=No | | 3=Not Sure | |
| FS1\_Reas1 | Health problem or symptoms | 1=Yes  2=No |
| FS1\_Reas2 | No health problems or symptoms, but came to get STD screening/check-up | 1=Yes  2=No |
| FS1\_Reas3 | Told to get checked by partner | 1=Yes  2=No |
| FS1\_Reas4 | Referred by health department/disease intervention specialist (DIS) | 1=Yes  2=No |
| FS1\_Reas5 | Follow-up visit | 1=Yes  2=No |
| FS1\_Reas6 | Came to get STD test results | 1=Yes  2=No |
| FS1\_Reas7 | Came to get HIV test | 1=Yes  2=No |
| FS1\_Reas8 | Came to get medication that I can take every day to prevent getting HIV infection before I am exposed to the virus (PrEP) | 1=Yes  2=No |
| FS1\_Reas9 | Came to get medication that I can take right away because I think I was exposed to HIV in the past few days (PEP) | 1=Yes  2=No |
| FS1\_Reas10 | Came to get contraception | 1=Yes  2=No |
| FS1\_Reas11 | Some other reason | 1=Yes  2=No |
| FS1\_Reas12\_TXT | Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| FS1\_ReasThisClin | What is the main reason you chose this clinic for care (choose only one)? | |  | | --- | | 1=Could walk in or get same day appointment | | 2=Cost | | 3=Privacy concern | | 4=Expert care | | 5=Embarrassed to go to usual doctor | | 6=Some other reason | |
| FS1\_ReasThisClin\_TXT | Please specify other reason \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| FS1\_WhereElse | Where would you have gone today if this STD clinic did not exist (choose only one)? | |  | | --- | | 1=I would have waited to see how I felt and then decided what to do | | 2=Community health center | | 3=Public clinic/ health department clinic | | 4=Family planning clinic | | 5=Private doctor’s office | | 6=Urgent care clinic/walk in clinic | | 7=Hospital emergency room (ER) | | 8=Hospital outpatient department | | 9=School-based clinic | | 10=Some other place | |
| FS1\_WhereElse\_TXT | Please specify other place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| FS1\_UsualPlace | Is there a place that you USUALLY go to when you are sick or need advice about your health? | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_MostOftenGo | If YES, what kind of place do you go to most often (choose only one)? | |  | | --- | | 2=Public clinic/health department clinic | | 3=Family planning clinic | | 4=Private doctor’s office | | 5=Urgent care clinic/walk in clinic | | 6=Hospital emergency room (ER) | | 7=Hospital outpatient department | | 8=School-based clinic | | 9=Some other place | |
| FS1\_MostOftenGo\_TXT | Please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| FS1\_PrevCare | Is there a place you USUALLY go to when you need routine care or preventive care such as a physical exam or check-up? | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_PrevCareGo | If YES, what kind of place do you go to most often (choose only one) | |  | | --- | | 1=Community health center | | 2=Public clinic/health department clinic | | 3=Family planning clinic | | 4=Private doctor’s office | | 5=Urgent care clinic/walk in clinic | | 6=Hospital emergency room (ER) | | 7=Hospital outpatient department | | 8=School-based clinic | | 9=Some other place | |
| FS1\_PrevCareGo\_TXT | Please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| FS1\_Insurance | Do you have health insurance (choose only one)? | |  | | --- | | 1=Yes, parents’ insurance plan | | 2=Yes, government (Medicaid, Medicare, etc.) | | 3=Yes, private insurance (through employer) | | 4=Yes, private insurance (purchased by yourself/healthcare.gov exchange) | | 5=No coverage of any type  GO TO QUESTION # 13 | | 6=Don’t know  GO TO QUESTION # 13 | |
| FS1\_UseIns | If YES, would you be willing to use your health insurance for today’s visit? | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns1 | I do not want my insurance company to know | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns2 | Insurance company might send records home | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns3 | I do not want my parents/spouse/significant other to know | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns4 | Usual doctor might send records home | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns5 | I cannot afford to pay the co-pay or deductible | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns6 | My insurance will not cover this visit | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns7 | Some other reason | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_NOTUseIns\_TXT | Please specify |  |
| FS1\_BirthSex | What sex were you assigned at birth on your original birth certificate? | |  | | --- | | 1=Male | | 2=Female | | 3=Refused | | 4=Don't know | |
| FS1\_GendID | How do you currently describe yourself? | |  | | --- | | 1=Male | | 2=Female | | 3=Trans, Male to Female | | 4=Trans, Female to Male | | 5=Gender Queer/Non-Binary | | 6=Other | |
| FS1\_Age | How old are you? Age in years\_\_\_\_\_\_ |  |
| FS1\_HispEth | Do you consider yourself Hispanic/Latino/a? | |  | | --- | | 1=Yes, Hispanic | | 2=No, Not Hispanic | | 8=Unknown/Can't guess | | 9=Refused | |
| FS1\_RaceWhite | White | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceBlack | Black | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceAIAN | AI/AN | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceAsian | ASIAN | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceNHOPI | NH/OPI | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceOther | Other race | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceUnk | Unknown/Can't guess | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_RaceRef | Refused Race | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_SexOrient | Which of the following best represents how you think of yourself? | |  | | --- | | 1=Heterosexual/Straight | | 2=Gay/Lesbian/Homosexual | | 3=Bisexual | | 4=Other | | 5=I don't know | | 9=Refused | |
| FS1\_Employ1 | Full-time employment | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Employ2 | Part-time employment | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Employ3 | Unemployed | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Employ4 | Disabled | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Employ5 | Student | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Employ6 | Other | |  | | --- | | 1=Yes | | 2=No | |
| FS1\_Educate | What is your highest level of school you have completed or the highest degree you have received | |  | | --- | | 1=Middle school | | 2=Some high school | | 3=High school diploma | | 4=GED or equivalent | | 5=Some college | | 6=College degree or higher | |
| LGV1\_SecimenID | Specimen ID - locally assigned, unique specimen tracking  ID for LGV prevalence activity |  |

*Table3A. Proposed Response Coding changes to existing Data Elements, Strategy B, Case-based Enhanced Surveillance*

|  |  |  |
| --- | --- | --- |
| **Data Element/Variable Name** | **Description** | **Valid Values** |
| P1\_SiteID | SSuN Site ID | BA=Baltimore (Cycle II, Cycle III, Cycle IV)  CB=Columbus (Cycle IV)  CA=California (Cycle II, Cycle III, Cycle IV)  FL=Florida (Cycle III & Cycle IV)  IN=Indiana (Cycle IV)  MC=Multnomah County (Cycle III &Cycle IV)  NY=New York City (Cycle II, Cycle III, Cycle IV)  PH=Philadelphia (Cycle II, Cycle III, Cycle IV)  SF=San Francisco (Cycle II, Cycle III, Cycle IV)  WA= Washington (Cycle II, Cycle III, Cycle IV)  UT=UTAH (Cycle IV)  LA=Louisana (Cycle II)  VA=Virginia (Cycle II)  AL=Alabama (Cycle II)  CO=Colorado (Cycle II)  CH=Chicago (Cycle II)  MA=Massachusetts (Cycle III)  MN=Minnesota (Cycle III) |
| P3\_PTX\_sex | What gender or sex do you consider yourself to be? | 1= CIS Male  2=CIS Female  3=Male-to-Female TG  4=Female-to-Male TG  5=TG Unspecified  6=Queer, Gender Non-binary  8=Refused |
| P1\_L1\_TestType | As test technology advances, it is important to obtain the type of test performed | 1= Culture  2= Nucleic acid amplification test (NAAT)  3= Non-amplified nucleic acid test/DNA probe  4= Gram stain  10= HIV Nucleic acid test (NAT)  11= rapid HIV-1 or HIV-1/2 antibody (Ab) test  12= HIV-1 Immunoassay (IA)  13= HIV-1/2 IA  14= HIV-1/2 Ag/Ab IA  15= HIV-1 WB  16= HIV-1 IFA  17= HIV-1/HIV-2 differentiation IA  18= pooled RNA  19=HIV Viral Load (ultra quantitative)  20=HIV Viral Load (quantitative)  21=CD4+ assay  22=HIV-1 IA (EIA or Other)  23=HIV-1/2 IA (EIA or Other)  24=HIV-2 IA (EIA or Other)  25=HIV-1/2 Ag/Ab  26=HIV-1/2 Type-Differentiating Immunoassay  27=HIV-1 Western Blot  28=HIV-2 Western Blot  29=HIV-1 IFA  30=HIV-1 Culture  31=HIV-2 Culture  32=HIV-1 p24 Antigen  33=HIV-1 RNA/DNA NAAT (Qualitative)  34=HIV-2 RNA/DNA NAAT (Qualitative)  35=HIV-1 RNA/DNA NAAT (Quantitative viral load)  36=HIV-2 RNA/DNA NAAT (Quantitative viral load)  37=CD4 T-lymphocytes  38=CD4 Percent  39=HIV-1 Genotype (PR Nucleotide Sequence)  40=HIV-1 Genotype (RT Nucleotide Sequence)  41=HIV-1 Genotype (PR/RT Nucleotide Sequence)  42=HIV-1 Genotype (IN Nucleotide Sequence)  43=HIV-1 Genotype (PR/RT/IN Nucleotide Sequence)  44=STARHS (BED)  45=STARHS (Vironostika-LS)  46=STARHS ( BIO-RAD AVIDITY)  47=STARHS (Other)  48=STARHS (Unknown)  49=Rapid (Retired)  50=HIV-1/2 Ag/Ab-Distinguishing Immunoassay  51=HIV-1 Genotype (EN Nucleotide Sequence)  52=HIV-1 Genotype (FI Nucleotide Sequence)  53=HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay  54=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 p24 Antigen Analyte  55=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 Antibody Analyte  56=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-2 Antibody Analyte  57=HIV-1/2 Type-Differentiating Immunoassay (Supplemental)  58=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-1 Antibody Analyte  59=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-2 Antibody Analyte  60=HIV-1 Genotype (Unspecified)  61=WB/IFA-Legacy  62=RIPA-Legacy  63=Latex Ag-Legacy  64=Peptide-Legacy  65=Rapid-Legacy  66=Iga-Legacy  67=IVAP-Legacy  68=Other HIV Antibody-Other-Legacy  69=Other HIV Antibody-Unspecified-Legacy  70=Viral Load-Other-Legacy  71=Viral Load-Unspecified-Legacy  72=HIV Detection/Antigen/Viral Load-Other-Legacy  73=HIV Detection/Antigen/Viral Load-Unspecified-Legacy  74= Pregnancy  88= Other  99=Not captured |

***Table3B. Proposed New Variables, Strategy B, Case-based Enhanced Surveillance***

|  |  |  |
| --- | --- | --- |
| **Data Element/Variable Name** | **Description** | **Valid Values** |
| P1\_L1\_QuantUnits | Units for quantitative results: | 1=Copies/mL  2=Log Copies/mL  3=Cells/Cubic mm  4=CD4%  5=Titer Ratio  6=Cycles/Time (rtPCR) |
| P3\_PTX\_TGSP | During the past 12 months, have you had sex with a transgender man or transgender woman? | 1=Yes  2=No  3=Don't Know /Don't Remember/ Not Sure  4=Refused |
| P3\_PTX\_EPTPARTTAKE | Do you *think* at least one of your sex partners took this medication? | 1=Yes, I think at least one of my partner(s) took this medicine  2=No, I do not think any of my partner(s) took these medicines  9=Refused |
| P3\_PTXBirtCount | Birth Country | Text |
| P3\_PTXBirtState | Birth State | Text |
| P3\_PTXNativity | Where were you born? | 1=In the US  2=Outside the US |
| P3\_PTX\_PIOrigin | (21) patient reported NHOPI origin | 1=Native Hawaiian  2=Guamanian/Chamorro/Fijian/Chuukese/Carolinian  3=Samoan/Tokelauan/Tongan/Yapese  4=Niuean/Palauan/Pohnpeian  5=Kosraean/Marshallesse  6=Other Pacific Island  9=Refused |
| P3\_PTX\_AsianOrigin | Asian Origin | 1=Asian Indian (India)  2 =Japanese  3=Chinese/Taiwanese  4=Korean  5=Filipona/o  6=Southeast Asian (Vietnamese, Thai, Cambodian, Burmese)  7=Indonesian  8=West Asians (Middle East)  9=Other/Unk Asian  10=Refused |
| P3\_PTX\_AIAN\_TXT | Tribal Affiliation | Text |
| P3\_PTX\_HISPTXT | Other Hispanic Origin | Text |
| P3\_PTX\_HISPOrgin | Do you consider yourself to be…? | 1=Mexican, Mexican Am., Chicano/a, Latino/a  2=Puerto Rican  3=Cuban  4=Central American (Guatemalan, Honduran, Nicaraguan, El Salvadoran)  5=Other Hispanic Origin  6=Unknown  9=Refused |
| P2\_PR\_Duration\_Number | Days duration or frequency of doses | Number of days |
| P2\_PR\_Number | Number of doses/day | 0=Single dose, STAT;  Numeric value for all other |
| P2\_PR\_Method | Method of administration | 01=PO - oral dosing  02=IM - intramuscular  03=IV - intravenous/infusion |
| P2\_PR\_Dose\_Units | Dosage units | 01-Miligrams (mg)  02-Grams (g)  03-Units  04-Units/Kilogram  05-Million Units  06-Million Units/Kilogram  07-Milliliters (ml) |
| P2\_PR\_Dosage | Dosage - numeric | Number |
| P2\_PR\_OthMedTXT | Other medication if value of 88 selected for P2\_PR\_DrugName | Text |
| P2\_PR\_DrugName | What drug was patient treated with? | 01=Penicillin G (benzathine, aqueous procaine, or aqueous crystalline)  02=Probenacid  10= Amoxicillin (Amoxil, Polymox, Trimox, Wymox)  11= Ampicillin (Omnipen, Polycillin, Polycillin-N, Principen, Totacillin)  20= Azithromycin (Zithromax)  21= Erythromycin base  22= Clindamycin (Cleocin)  23= Gentamicin (Garamycin, G-Mycin, Jenamicin)  30= Cefixime (Suprax)  31= Ceftizoxime (Cefizox)  32= Cefotaxime (Claforan)  33= Cefoxitin (Mefoxin)  34= Cefpodoxime (Vantin)  35= Ceftibuten (Cedax)  36= Cefdinir (omnicef)  37= Ceftriaxone (Rocephin)  38= Cefuroxime (Ceftin, Kefurox, Zinacef, Zinnat)  40= Ciprofloxacin (Cipro, Cipro XR, Ciprobay, Ciproxin)  41= Levofloxacin (Cravit, Levaquin)  42= Moxifloxacin (Avelox, Vigamox)  43= Ofloxacin (Floxin, Oxaldin, Tarivid)  44= Gemifloxacin (Factive)  50= Doxycycline (Doryx, Vibramycin)  60= Metronidazole (Flagyl, Helidac, Metizol, Metric 21, Neo-Metric, Noritate, Novonidazol)  61= Tinidazole (Tindamax)  70= Truvada (Tenofovir/emtricitabine)  88= Other (provide text in P2\_PR\_OthMedTXT) |
| P1\_PtxGendID | Gender Identity of the patient as indicated on initial health department report. | 1=Male-to-Female Transgender  2=Female-to-Male Transgender  3=Transgender, not specified  4=CIS Gender (Male or Female, NOT transgendered)  9=Gender Identity not documented |
| P1\_ConcurCTDx | Was this patient diagnosed with CT at the same time as their current GC diagnoses? | 1=Yes, tested and found to be CT positive  2=No, tested and found to be CT negative  3=No, patient not tested for CT/No CT information available |

**Changes in Estimates of Annualized Burden Hours**

We estimate increase in estimated annualized burden hours from the previously approved 3,479 to 6,303 for this ICR as part of this change request, 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**) | 11 | 6 | 4 | 264 |
| General Public – Adults (persons diagnosed with gonorrhea) | Patient interviews for a random sample of gonorrhea cases (**ATT5, ATT8**) | 7,380 | 1 | 10/60 | 1,230 |
| General Public – Adults (STD Clinic Patients) | STD Clinic survey (**ATT5, ATT8**) | 3,850 | 1 | 5/60 | 321 |
| Data Managers: 11 local/state health departments(**ATT6**) | HIV registry matching (**ATT5**) | 11 | 6 | 20 | 1,320 |
| Data Managers: 11 local/state health departments(**ATT6**) | Data cleaning/ validation, HIV registry matching and data transmission  (**ATT5**) | 11 | 12 | 24 | 3,168 |
|  |  |  |  |  |  |
| Total | ............ |  | .............. | ............. | 6,303 |