National HIV Surveillance System (NHSS)

Attachment 4f
Cluster Report Form Instructions

HIV Cluster Report Form Instructions

November 2025

Table of Contents[1]

[1] If viewing this document in PDF, you can jump to relevant sections by clicking on the sections in this Table of Contents or go to the Bookmark tool. If viewing this document in Word, you can open the View tab and then click on "Navigation Pane" which will bring up a list of all of the sections listed in the Table of Contents. You can click on that list to go to the section(s) you want to visit.

Overview

The HIV Cluster Report Forms (CRFs)[2] are designed to assist jurisdictions with documenting the epidemiology, investigation and response activities, and outcomes, for HIV clusters and communicating with CDC about cluster-related activities. For HIV cluster detection and response guidance, see: www.cdc.gov/hivcluster/guidance.

For which clusters should an Initial CRF be submitted?

- Molecular clusters meeting national priority criteria in your jurisdiction. Note that molecular clusters meet national priority criteria if defined at the 0.5% genetic distance threshold with at least 5 diagnoses in the past 12 months, or at least 3 diagnoses in the past 12 months for low-morbidity jurisdictions. Analyses to detect *priority* molecular clusters only include persons with HIV diagnosed in the most recent 3-year period.
  AND
- Other clusters of concern identified through molecular analysis or time-space analysis, or other means such as a report from a local provider or identified by disease intervention specialists (DIS).
    - A cluster of concern is defined as any cluster for which active investigation or response activities have been initiated, beyond preliminary data review, or clusters with a 'High' current level of concern.
        - Activities to initially assess reasons for an increase of HIV reports (such as reaching out to local staff to understand potential reasons for an increase or preliminary data review) do not by themselves necessitate submitting a form.
        - Partner services and linkage to services, and other routine activities like testing, would count as response activities *if they are being expanded or tailored in response the cluster/outbreak*.
        - A non-comprehensive list of investigation and response activities can be found in questions 17, 11, and 13 in the Initial, Follow-up, and Annual/Closeout Forms respectively (the list is the same in each form).
- Note that multiple jurisdictions may have cluster members in a single, shared cluster. Health departments will be expected to submit an initial (and subsequent) cluster report form on any cluster that meets reporting requirements in their jurisdiction (i.e., has enough cases to meet molecular national criteria in the jurisdiction or has response activities or has a High level of concern) even if another health department has already submitted a form on the same cluster. Depending on how a cluster grows, or expands into different geographical areas, this may result in jurisdictions submitting asynchronous reports on the cluster over time (e.g., one health department may submit a closeout cluster report form at the same time another health department submits an initial report form if the geographic focus of the cluster changes over time).

Which type of CRF should be submitted?

- Submit an Initial Form for:

[2] In this document, the term "cluster" refers to both clusters and outbreaks.

    - A newly identified cluster meeting the criteria listed in the section above ("For which clusters should an Initial CRF be submitted?").
    - After an Initial Form has been submitted, Forms (either Follow-up or Annual/Closeout) should be submitted quarterly until cluster responses are closed. See below for schedule of Follow-up and Annual/Closeout Forms.
- Submit a Follow-up Form for clusters where:
    - An Initial Form was previously submitted AND
        - Response activities, beyond routine partner services and linkage to services, are ongoing, or there is evidence of ongoing rapid HIV transmission in the network.
    - Note: no Follow-up Form is necessary if an Annual/Closeout Form is submitted in the same quarter.
- Submit the Annual version of the Annual/Closeout Form in the last quarter of the calendar year for clusters for which:
    - An Initial Form was previously submitted AND
    - Response activities, beyond routine partner services and linkage to services, are ongoing, or there is evidence of ongoing rapid HIV transmission in the network.
- Submit the Closeout version of the Annual/Closeout Form at any time for clusters in which:
    - An Initial Form was previously submitted AND
    - The level of concern is low and no response activities, beyond routine partner services and linkage to care, are being, or are planned to be, implemented. A cluster that is in 'monitoring only' status with no response activities underway should have a Closeout Form submitted. Refer to the Guidance for Health Departments Investigation and Response section, subsection on "Scaling down or ending response" for details on when response activities should be stopped.
        - Remember that even after a closeout form has been submitted, a cluster can be reopened at any time by submitting a new Follow-Up or Annual Form.

What data should be included in CRF Forms?

- Use the latest available data, including all cluster members in your jurisdiction, when submitting a CRF.
- Note that, while national priority clusters are initially defined based on analysis of HIV diagnoses within the most recent 3 years, the addition of subsequent diagnoses (molecularly linked or epidemiologically linked) to the cluster may extend the timeframe beyond a total of 3 years. Total case counts should be cumulative, rather than limited by a sliding 3- year window
- Do not include names, addresses, or any other directly identifying information on the forms.

How should CRFs be submitted?

- CRFs should be submitted electronically via REDCap.
- To request access to the Cluster Report Form REDCap project, contact your assigned Detection and Response Branch epidemiologist.

When should CRFs be submitted?

- Initial Form:
    - For molecular clusters meeting national priority criteria, submit no later than the end of the month after a cluster is detected.

        - For example, if a molecular cluster meeting national priority criteria was detected in June, the Initial Form should be submitted by the end of July.
    - For other clusters, submit the Initial Report no later than the end of the month after the cluster is prioritized for investigation and response activities beyond preliminary review.
        - For example, if a time-space alert was detected in June and prioritized for investigation and response activities (beyond preliminary review) in July, the Initial Form should be submitted by the end of August.
- Follow-up Form:
    - For any cluster that remains open, submit quarterly starting in the quarter after the Initial Form was submitted
        - For example, if a molecular cluster was detected in May and the Initial Form was submitted in June, a Follow-up Form should be submitted by the end of September.
    - Note: A Follow-up Form is not needed if an Annual or Closeout Form is submitted during that quarter.
- Annual version of Annual/Closeout Form:
    - Each December, submit an Annual form for any cluster you want to keep open for which the initial form was submitted before July 31 of the current year or in a previous year.
    - Note: clusters reported August 1 or later will not require an annual form in their first year.
- Closeout version of Annual/Closeout Form: submit by the end of the quarter in which the active response activities have concluded.

Important reminders

- **Reopening a closed cluster:** Should a jurisdiction need to reopen a cluster for which a Closeout Form was previously submitted, a Follow-up Form should be submitted to indicate response activities have resumed. There is no need to submit another Initial Form on the same cluster.
- **eHARS cluster variables:** Cluster-related variables in eHARS should be populated for all persons in clusters for which a Cluster Report Form was submitted, including those who were part of the cluster when it was first identified and others who were identified to be part of the cluster during investigation/response activities. Guidance on populating cluster-related variables in eHARS is located at HSB's SharePoint (file path: HSB SharePoint → Cluster Detection and Response → Cluster Detection and Response Guidance and Implementation → "Instructions for entering HIV clusters into eHARS"). Refer to the latest document indicated by date in the filename.
- **Cases in other jurisdictions:** Health departments are not expected to report information about cases or contacts who reside in other jurisdictions.

Instructions for completing each form are outlined below.

Initial Form

Reporter Variables

- These variables, including unique record ID, reporting jurisdiction name, low morbidity jurisdiction, person completing report, and email address will be auto-populated by REDCap. If needed, the user can change the name and email address for the person completing this form (e.g., if someone else at the health department is a better point of contact for this cluster instead of the person completing the form in REDCap).

Cluster Variables

- **Question #1 Date cluster first detected**: Insert the date the cluster was first identified through any of the methods listed in Question #5. If the cluster was first identified by CDC molecular or time-space analysis, the date of detection should be the date your jurisdiction was notified of the cluster by CDC.
- **Question #2 Date form completed**: Insert the final date the form was completed. This does not have to be the same date as the date listed in Question #1.
- **Question #3 Local Cluster ID**: A local cluster ID must be populated on this form and in eHARS.
    - Insert the local cluster ID associated with the detection method that first identified the cluster (guidance on the nomenclature for local cluster IDs is located at HSB's SharePoint (file path: HSB SharePoint → Cluster Detection and Response → Cluster Detection and Response Guidance and Implementation → "Instructions for entering HIV clusters into eHARS"). Refer to the latest document indicated by date in the filename.
    - This same cluster ID should also be entered into eHARS for all cluster members to allow merging of information from eHARS with Cluster Report Form data and meet outcome standards.
    - For molecular clusters, the required nomenclature is the two-letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and Secure HIV-TRACE cluster ID (e.g., GA_202303_10.2 for a molecular cluster meeting national priority criteria through state/local analysis).
    - For time-space clusters, the required nomenclature is the two-letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and cluster ID with the initials 'TS' (e.g., GA_YYYYMM_TS789). Jurisdictions may use any naming convention to develop the cluster ID as long as it includes the initials 'TS' and does not contain personal identifiers, a dash, or a dot.
    - For clusters identified through provider notification, partner services notification, or other means, the recommended nomenclature is the two-letter jurisdiction abbreviation followed by an underscore, followed by the year and month in which the cluster was first identified as YYYYMM_, followed by a unique identifier including the initials 'PN' for partner notification, 'PS' for partner services notification, or 'OTH' for other means (GA_202306_PN321).
    - If the cluster was detected by CDC analysis but not by local analysis at the time of submitting the Initial Form, enter the CDC cluster ID in the local cluster ID field.

- **Question #4 CDC Cluster ID:** If the cluster has a CDC molecular cluster ID, enter the ID here [YYYYQQ_####].

Detection Methods, Case Definition, and Characteristics

- **Question #5 Initial cluster detection method**: Select the method by which this cluster was initially detected. Note: Only one option can be selected. This should match the information that is reported in eHARS.
    - **Question #5a**: Describe the "other" detection method.
    - **Question #5b**: If using county as the geographic unit of analysis, list the county in which the cluster was detected and add 'County' after the name.
    - **Question #5c**: Describe the inclusion criteria for cases in the cluster such as person, place, and time. For additional guidance about how to create a cluster case definition, see the "Cluster case definition" section of the "Review and prioritization" section of CDC's HIV Cluster Detection and Response Guidance.

- **Question #6 For clusters identified through molecular analysis, does this cluster meet national priority cluster criteria in your jurisdiction?** Note that molecular clusters meet national priority criteria if defined at the 0.5% genetic distance threshold with at least 5 diagnoses in the past 12 months, or at least 3 diagnoses in the past 12 months for low-morbidity jurisdictions. Analyses to detect *priority* molecular clusters include only persons with HIV diagnosed in the most recent 3-year period. Once a priority molecular cluster is detected, molecularly linked persons can be added to the cluster during subsequent analyses if their HIV diagnosis date occurred in the most recent 3 years prior to the analysis date and their sequence is within the 0.5% genetic distance threshold of the sequence of at least one other person in the same cluster whose infection was diagnosed within the most recent 3 years. Epidemiologically linked persons can be added to the molecular cluster during subsequent analyses, regardless of their HIV diagnosis date. As the cluster grows over time, it is possible that the total timeframe of diagnoses included in the cluster after initial detection may be >3 years.

- **Question #7 At what genetic distance threshold(s) is this cluster defined?** Select the option that correctly describes the genetic distance threshold used to define the molecular cluster: '0.5%', '1.5%', '0.5% with first degree links, 1.5%', or 'other (describe)'. Refer to the guidance document 'Detecting HIV Clusters' (Filepath: HSB SharePoint → Technical Guidance →Detecting HIV Clusters 2025 v1.pdf} for considerations on what genetic distance threshold to use.
    - **Question #7a**: Describe the "other" threshold.

- **Question #8 What is the time period of HIV diagnoses used to identify this cluster?** Select the option that correctly describes the time period of HIV diagnoses included in the molecular analysis in which the cluster was detected: '3 years' (includes diagnoses in the most recent 3 years), 'all years' (includes all diagnoses, regardless of diagnosis date), or 'other'. Note: Refer to the guidance document 'Detecting HIV Clusters' (Filepath: HSB SharePoint → Technical Guidance →Detecting HIV Clusters 2025 v1.pdf) for an explanation of CDC's current approach of time periods of HIV diagnoses used in molecular analysis.
    - **Question #8a**: Describe the "other" time period used.

- **Question #9 Number of people with HIV in the cluster residing in your jurisdiction at the time of this report:** Include all people with HIV in the cluster, including molecularly linked or epidemiologically linked members, who resided in your jurisdiction at the time the form is completed. For states with separately funded cities or counties, exclude cases residing in separately funded cities or counties. For separately funded cities or counties, exclude cases residing outside of the funded jurisdiction.

- **Question #10 Number of people with HIV in the cluster residing in your jurisdiction who had completed a partner services interview at the time of this report**: Include all people with HIV in the cluster residing in your jurisdiction that had completed a partner services interview at the time of this report. This number should be smaller than or equal to the number reported in question #9.

- **Question #11 Number of named partners of cluster members not known to have HIV residing in your jurisdiction at the time of this report**: Limit this to named partners residing in your jurisdiction at the time of this report. Note: If any of the cluster members named each other, this should be excluded from the total.

- **Question #12 Number of unnamed, marginal, and anonymous partners of cluster members at the time of this report:** List the number of unnamed, marginal (i.e., some identifying information given, but not enough to locate the person), and anonymous (i.e., no identifying information given) partners. Exclude any partners known to not reside in your jurisdiction, but include any partners for whom residence is unknown.

- **Question #13 Briefly describe any notable characteristics of the cluster:** These may include characteristics that inform how you prioritize or respond to the cluster such as predominant transmission risk, age group, race/ethnicity, sex, prevalence of coinfections, history of incarceration, or housing instability, among others.

- **Question #14 Were any common venues, physical sites, or virtual sites identified?** Indicate whether any common venues, physical sites, or virtual sites were identified by persons in the cluster through investigation.
    - **Question #14a**: If you select YES, describe.

Overlapping Clusters

- **Question #15 Does this cluster overlap with a cluster identified by a different method?** If the cluster overlaps with a cluster identified by a different method (i.e., if some or all of the people in this cluster are also included in a cluster defined by a different method, select YES
    - **Question #15a**: Provide the method and date of detection as well as the cluster ID for each overlapping cluster identified by a different method. For overlapping national molecular or time-space clusters identified by CDC, populate ‘date of detection’ with the date your jurisdiction was notified of the existence of the cluster by CDC.
    - **Question #15b**: This is OPTIONAL. Provide any additional relevant information about the overlapping cluster(s). If method of identification for the overlapping cluster is “other,” describe here.

Gaps or Challenges

- **Question #16 What gaps or challenges have you encountered in responding to this cluster? Check all that apply.** This is an OPTIONAL question on the Initial Form though it is required in the Follow-up and Annual/ Closeout Forms. The list of gaps and challenges corresponds to the section headers for the response activities in question 17 as response activities are generally selected to address identified gaps and challenges. Examples of syndemic conditions include viral hepatitis, sexually transmitted infections, injection drug use, or mental health conditions. Examples of structural issues include lack of housing, access to syringe services programs, or linguistic or cultural competency of service providers. See "Additional Response Activities" in the Investigation and Response section of CDC's HIV CDR Guidance for Health Departments for more information.
    - **Question 16a**: This is an OPTIONAL question on the Initial Form though it is required in the Follow-up, and Annual/Closeout Forms. Use this space to provide any additional information about the challenges your jurisdiction has encountered to respond fully to the cluster.

Investigation or Response Activities

Question #17 What investigation or response activities, if any, have you initiated in response to the cluster? This is an OPTIONAL question in the Initial Form though it is required in the Follow-up and Annual/Closeout Forms. If you choose to answer this question, check off all the activities that have been part of your cluster response. Your response should reflect a cumulative list of all activities that have been initiated, tailored, or enhanced in response to the cluster except for reporting on activities 1-4 related to individual cluster member/partner follow-up. You may check off activities 1-4 even if they were initiated before the identification of the cluster. Note that if you are unsure of where an activity fits within a domain you can place it in the "other" category of the domain.

- For all parts of this question, "cluster members" refers to people with HIV who meet the case definition for the specific cluster. "Network or affected communities" refers to people in an HIV cluster and those with whom they have sex or share drugs, who may or may not have HIV. Some people with HIV can be in the network, even if they were not part of the initially detected cluster. People without HIV in the same sexual or drug-using network are also considered part of the larger network.

Notes on selected activities:

Activity 2: Activities taken to link cluster members to care, or to re-engage them in care, should be included in this activity even if they have taken place before the cluster was identified.
Activity 3: PrEP: HIV pre-exposure prophylaxis; PEP: HIV post-exposure prophylaxis.
Activity 5: This could include enhanced/expanded interviews or reinterviews undertaken as part of the cluster response.
Activity 7: Medical chart review refers to in-depth review of medical charts, including clinic visits, emergency department visits, or hospitalizations, that is more than the usual standard chart review conducted to complete HIV surveillance case report forms for people with new HIV

diagnosis. The goal of the chart review(s) should be to understand patterns of, and missed opportunities for, prevention and care.
Activity 14: Examples include offering testing at a homeless encampment if known cluster members live there and have injected drugs with others who live in the encampment or offering testing at a bar or club that cluster or network members are known to frequent.
Activity 15: Examples include expansion of HIV testing for all people who are admitted to the emergency departments of hospitals, expanding hours for HIV testing at public health clinics, or using mobile clinics to expand testing in areas that have limited testing resources.
Activity 19: Examples include enhancing psychosocial support to cluster members to improve adherence with antiretroviral treatment, ensuring enrollment in Ryan White HIV/AIDS Program, or providing transportation to clinic visits.
Activity 20: Examples include expanding hours for HIV care and treatment at local public health clinics or expanding the use of mobile clinics for people who have limited access to treatment and care resources.
Activity 21: Examples include expanding case management services, providing language-appropriate HIV care, or enrolling cluster members in appropriate treatment adherence programs.
Activity 23: Examples include direct provision of PrEP or PEP at public health clinics to members of the network who do not have HIV or partnering with pharmaceutical companies to obtain low-cost PrEP for network members.
Activity 24: Examples include developing dedicated clinic time for provision of PrEP for populations with a high prevalence or incidence of HIV (not just members of the network), expanding options for different PrEP medications, or providing low-cost PrEP for people with low or no insurance.
Activity 33: Activities could include providing financial incentives for maintaining viral load suppression, providing transportation services to medical appointments, providing food stamps, or expanding the role of pharmacists in the provision of PrEP or PEP.

- **Question #18 If the cluster or network includes persons outside of your jurisdiction, have you contacted the other jurisdiction(s) involved?** This is an OPTIONAL question on this form. Select YES if you have contacted the other jurisdiction(s) involved in this cluster, NO if there are persons outside of your jurisdiction but you have not contacted the other jurisdiction(s) involved If there were no cluster or network members outside of your jurisdiction involved, select “No cluster or network members outside of the jurisdiction”.
    - **Question #18a Describe any collaboration or communication with other involved jurisdiction(s):** Describe your interactions with the other jurisdictions involved (i.e., email communication, phone call, coordinating response activities, etc.).

Level of Concern

- **Question #19 What is your current level of concern for this cluster?** Consider a variety of factors that may inform your level of concern. These could include the magnitude of increase in HIV diagnoses relative to baseline, potential for ongoing transmission (e.g., injection drug use, many sex partners, low rates of viral suppression), populations at risk for poor outcomes (e.g., people experiencing homelessness, pregnancy, HIV drug resistance, presenting with advanced HIV), or understanding of the network involved in the cluster. See “Questions to consider when

developing prioritization criteria" in the Review and Prioritization section in CDC's HIV CDR Guidance for Health Departments for additional considerations.

- **Question #19a:** This question is REQUIRED if high level of concern and OPTIONAL if low/medium level of concern. Use this space to provide a brief description of why you have selected the level of concern and note the epidemiological or other characteristics that informed your decision; for example, a sudden increase in diagnoses compared to baseline numbers that were detected through time-space analysis, an increase in IDU-associated HIV infections, a high proportion of infections among persons aged <18 years, or any other indications that the underlying network is substantially larger than what has been identified.

Technical Assistance Needs

- **Question #20 Do you have any technical assistance needs related to this cluster?** Select yes if you have technical assistance needs for this cluster. Detection and Response Branch staff will do our best to connect you with relevant technical assistance resources as available.
  - **Question #20a**: Describe your technical assistance needs here. Be specific if you can. If assistance is urgently needed, reach out directly to your assigned Detection and Response Branch epidemiologist.

Additional Comments

- **Question #21: Additional comments:** This is an OPTIONAL question on this form. Use this space to provide any additional information about this cluster and your investigation and response.

Submission

When submitting the form on REDCap to CDC, please remember to select "Complete" in the status drop down menu. Forms marked Incomplete or Unverified will not be reviewed by CDC.

Follow-up Form

Reporter Variables

These variables, including unique record ID, reporting jurisdiction name, low morbidity jurisdiction, person completing report, and email address will be auto-populated by REDCap. If needed, the user can change the name and email address for the person completing this form (e.g., if someone else at the health department is a better point of contact for this cluster instead of the person completing the form in REDCap).

Cluster Variables

- **Question #1 Date form completed:** Insert the final date the report was completed.

- **Questions #2 Local Cluster ID:** A value for this question will be auto-populated based on the response you provided in the Initial Cluster Report Form. If this cluster overlaps with another cluster identified by a different method, enter this information in question 9.

- **Question #3 CDC Cluster ID (if applicable)**: If the cluster has a CDC molecular cluster ID, enter the ID here [YYYYQQ_####].

Status of Cluster Response

- **Question #4 Are investigation or response activities for this cluster currently ongoing?** Select YES or NO. If there are no ongoing or planned investigation or response activities and the level of concern is 'Low,' DO NOT fill out this form. Complete and submit the Closeout Form instead. f answer to question 4 is Yes, proceed with rest of the form.

- **Question #5 Are there any updates to report?** If the case count has increased >10% since the last report or there are updates to the cluster definition (including whether a newly detected overlapping priority cluster has been identified); response activities, including gaps or challenges identified by the cluster response; or technical assistance needs, respond YES and proceed with the rest of the form.

  If there are no updates to the abovementioned sections and the cluster case count has not increased by >10% since the last submitted form (Initial, Follow-up, or Annual) respond NO. If you respond NO, scroll down and mark the form 'Complete' and hit 'Save & Exit'. You might see auto-populated responses from previous form(s) below but you do NOT have to respond any further.

Case Definition and Cluster Characteristics

- **Question #6 Since the last time you completed a Cluster Report Form for this cluster, has the cluster case definition changed?** Cluster case definitions may change over time as more

information is gathered. Molecular cluster definitions may be broadened to include epidemiologically related cluster members. Time-space cluster definitions may change as investigations may widen or narrow the focus of the cluster response. If there has been a change in the cluster definition since the last submitted Cluster Report Form (Initial, Follow-up, or Annual), respond YES and enter the new cluster definition here.

  - **Question #6a: Describe changes to the cluster case definition**.
    Write out the new case definition being used and describe which parts of the case definition were modified and why.

- **Question #7 Since the last time you completed a Cluster Report Form for this cluster, have there been any notable changes to the characteristics of the cluster?**
  This could include changes to the epidemiology of the cluster members, including predominant transmission risk, age group, race/ethnicity, sex, prevalence of coinfections, history of incarceration, housing instability, etc. If there have been notable changes in any of the cluster characteristics, respond YES and describe the changes in Question 7a.
  - **Question #7a: Describe notable changes to the characteristics of the cluster**

- **Question #8. Number of people with HIV in the cluster residing in your jurisdiction at the time of this report.** Include all people with HIV in the cluster, including molecularly linked or epidemiologically linked members, who resided in your jurisdiction at the time this form is completed. For states with separately funded cities or counties, exclude cases residing in separately funded cities or counties. For separately funded cities or counties, exclude cases residing outside of your jurisdiction. This should be a cumulative number that represents the total number of people with HIV in the cluster.

Overlapping Clusters

- **Question #9 Since the last time you completed a Cluster Report Form for this cluster, has this cluster been newly identified as overlapping with a cluster identified by a different method?**
  If the cluster was found to overlap with a cluster identified by a different method since the last Cluster Report Form was submitted (i.e., if some people in this cluster are also included in a cluster defined by a different method), select YES. If the cluster was detected by CDC analysis but not by local analysis at the time of submitting the Initial Form and subsequently detected by local analysis at the time of submitting the Follow-up Form, select YES and enter the local cluster ID.
  - **Question #9a**: Provide the method and date of detection as well as the cluster ID for each overlapping cluster identified by a different method. For overlapping molecular or time-space clusters identified by CDC, populate “date of detection” with the date your jurisdiction was notified of the existence of the cluster by CDC.
  - **Question #9b**: This is an OPTIONAL question. Provide any additional relevant information about the overlapping cluster(s). If method of identification for the overlapping cluster is “other,” describe here.

Gaps or Challenges

- **Question #10 What gaps or challenges have you encountered in responding to this cluster? Check all that apply.** This is a required question for the Follow-up Form. The list of gaps and challenges corresponds to the section headers for the response activities in question 11, as response activities are generally selected to address gaps or challenges identified. Examples of syndemic conditions include viral hepatitis, sexually transmitted infections, injection drug use, or mental health conditions. Examples of structural issues include lack of housing, access to syringe services programs, or linguistic or cultural competency of service providers. See "Additional Response Activities" in the Investigation and Response section of CDC's HIV CDR Guidance for Health Departments for more information.

  We have checked the responses you chose in previous forms. Please do not uncheck boxes unless they were mistakenly checked in previous forms.

  - **Question 10a**: This is an OPTIONAL question for the Follow-up Form. Use this space to provide any additional information about the challenges your jurisdiction has encountered to respond fully to the cluster.

Investigation or Response Activities

Question #11 What investigation or response activities have you initiated in response to the cluster? This is a required question on the Follow-up Form. Check off all the activities that have been part of your cluster response. Your response should reflect a cumulative list of all activities that have been initiated, tailored, or enhanced in response to the cluster except for reporting on activities 1-4 related to individual cluster member/partner follow-up. You may check off activities 1-4 even if they were initiated before the identification of the cluster. Note that if you are unsure of where an activity fits within a domain you can place it in the "other" category of the domain.

You must check at least one activity for this question before submitting the form. We have checked the responses you chose in previous forms. Please do not uncheck boxes unless they were mistakenly checked in previous forms.

- For all parts of question 11, "cluster members" refers to people with HIV who meet the case definition for the specific cluster. "Network or affected communities" refers to people in an HIV cluster and those with whom they have sex or share drugs, who may or may not have HIV. Some people with HIV can be in the network, even if they were not part of the initially detected cluster. People without HIV in the same sexual or drug-using network are also considered part of the larger network.

Notes on selected activities:
Activity 2: Activities taken to link cluster members to care, or to re-engage them in care, should be included in this activity even if they have taken place before the cluster was identified.
Activity 3: PrEP: HIV pre-exposure prophylaxis; PEP: HIV post-exposure prophylaxis.
Activity 5: This could include enhanced/expanded interviews or reinterviews undertaken as part of the cluster response.
Activity 7: Medical chart review refers to in-depth review of medical charts, including clinic visits, emergency department visits, or hospitalizations, that is more than the usual standard chart review conducted to complete HIV surveillance case report forms for people with new HIV

diagnosis. The goal of the chart review(s) should be to understand patterns of, and missed opportunities for, prevention and care.
Activity 14: Examples include offering testing at a homeless encampment if known cluster members live there and have injected drugs with others who live in the encampment or offering testing at a bar or club that cluster or network members are known to frequent.
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Activity 24: Examples include developing dedicated clinic time for provision of PrEP for populations with a high prevalence or incidence of HIV (not just members of the network), expanding options for different PrEP medications, or providing low-cost PrEP for people with low or no insurance.
Activity 33: Activities could include providing financial incentives for maintaining viral load suppression, providing transportation services to medical appointments, providing food stamps, or expanding the role of pharmacists in the provision of PrEP or PEP.

Level of Concern

- **Question #12 What is your current level of concern for this cluster?** Consider a variety of factors that may inform your level of concern. These could include the magnitude of increase in HIV diagnoses relative to baseline, potential for ongoing transmission (e.g., injection drug use, many sex partners, low rates of viral suppression), populations at risk for poor outcomes (e.g., people experiencing homelessness, pregnancy, HIV drug resistance, presenting with advanced HIV), or understanding of the network involved in the cluster. See "Questions to consider when developing prioritization criteria" in the Review and Prioritization section in CDC's HIV CDR Guidance for Health Departments for additional considerations
    - **Question #12a:** This question is REQUIRED if high level of concern and OPTIONAL if low/medium level of concern. Use this space to provide a brief description of why you have selected the level of concern and note the epidemiological or other characteristics that informed your decision; for example, a sudden increase in diagnoses compared to baseline numbers that were detected through time-space analysis, an increase in IDU-associated HIV infections, a high proportion of infections among persons aged <18 years, or any other indications that the underlying network is substantially larger than what has been identified

Technical Assistance Needs

- **Question #13 Do you have any technical assistance needs related to this cluster?** Select YES if you have technical assistance needs for this cluster. Detection and Response Branch staff will do our best to connect you with relevant technical assistance resources as available.
    - **Question #13a**: Describe your technical assistance needs here. Be specific if possible. If assistance is urgently needed, reach out directly to your assigned Detection and Response Branch epidemiologist.

Additional Comments

- **Question #14 Additional comments:** This is an OPTIONAL question. Use this space to provide any additional information about this cluster and your investigation and response.

Submission

When submitting the form on REDCap to CDC, please remember to select "Complete" in the status drop down menu. Forms marked Incomplete or Unverified will not be reviewed by CDC.

Annual/Closeout Form

Reporter Variables

These variables, including unique record ID, reporting jurisdiction name, low morbidity jurisdiction, person completing report, and email address will be auto-populated by REDCap. If needed, the user can change the name and email address for the person completing this form (e.g., if someone else at the health department is a better point of contact for this cluster instead of the person completing the form in REDCap).

Cluster Variables

- **Question #1 Date form completed**: Insert the final date the form was completed.

- **Questions #2 Local Cluster ID:** A value for this question will be auto-populated based on the response you provided in the Initial Cluster Report Form. If this cluster overlaps with another cluster identified by a different method, enter this information in question 11.

- **Question #3 CDC Cluster ID (if applicable)**: If the cluster has a CDC molecular cluster ID, enter the ID here [YYYYQQ_####].

Status of Cluster Response

- **Question #4 Are investigation or response activities for this cluster currently ongoing?** If you answer YES, complete this form as an Annual Form. If you answer NO, complete this form as a Closeout Form. Refer to the section titled "Considerations on submitting a Closeout Form" in this document for details on when a cluster should be closed.
    - **Question #4a Date cluster investigation and response activities closed**: This question should only be answered if you responded NO to Question #4 above. Enter the date on which your jurisdiction determined that the active response was scaled down or ended.
    - **Question #4b Reason(s) for closeout**: This question should only be answered if you responded NO to Question #4 above. Enter the reason(s) for closing the cluster.

Case Definition and Cluster Characteristics

- **Question #5 Since the last time you completed a Cluster Report Form for this cluster, has the cluster case definition changed?** Cluster case definitions may change over time as more information is gathered. Molecular cluster definitions may be broadened to include epidemiologically related cluster members. Time-space cluster definitions may change as investigations may widen or narrow the focus of the cluster response. If there has been a change in the cluster definition since the last submitted Cluster Report Form (Initial, Follow-up, or Annual), respond YES and enter the new cluster definition below.
    - **Question #5a: Describe changes to the cluster case definition**.

Write out the new case definition being used and describe which parts of the case definition were modified and why.

- **Question #6 Since the last time you completed a Cluster Report Form for this cluster, have there been any notable changes to the characteristics of the cluster?** This could include changes to the epidemiology of the cluster members, including predominant transmission risk, age group, race/ethnicity, sex, prevalence of coinfections, history of incarceration, housing instability, etc. If there have been notable changes in any of the cluster characteristics, respond YES and describe the changes in Question 6a.
    - **Question #6a: Describe notable changes to the characteristics of the cluster**

- **Question #7 Number of people with HIV in the cluster residing in your jurisdiction at the time of this report**: Include all people with HIV in the cluster, including molecularly linked or epidemiologically linked members, who resided in your jurisdiction at this time the form is completed. For states with separately funded cities or counties, exclude cases residing in separately funded cities or counties. For separately funded cities or counties, exclude cases residing outside of your jurisdiction. This should be a cumulative number that represents the total number of people with HIV in the cluster.

- **Question #8 Number of people with HIV in the cluster residing in your jurisdiction who had completed a partner services interview at the time of this report**: Include all people with HIV in the cluster residing in your jurisdiction that had completed a partner services interview at the time of this report. This should be a cumulative number that represents the total number of cluster members with a completed partner services interview. This number should be smaller than or equal to the number reported in question 7.

- **Question #9 Number of named partners of cluster members not known to have HIV residing in your jurisdiction at the time of this report**: Limit this to named partners residing in your jurisdiction at the time of this report. Note: If any of the cluster members named each other, this should be excluded from the total. This should be a cumulative number that represents the total number of named partners of cluster members not known to have HIV.

- **Question #10 Number of unnamed, marginal, and anonymous partners of cluster members at the time of this report:** List the number of unnamed, marginal (i.e., some identifying information given, but not enough to locate the person), and anonymous (i.e., no identifying information given) partners. This is not limited to those partners residing in your jurisdiction because there may be no residence information for these individuals. This should be a cumulative number that represents the total number of unnamed, marginal, and anonymous partners of cluster members.

Overlapping Clusters

- **Question #11 Since the last time you completed a Cluster Report Form for this cluster, has this cluster been newly identified as overlapping with a cluster identified by a different method?** If the cluster was found to overlap with a cluster identified by a different method since the last Cluster Report Form was submitted (i.e., if some people in this cluster are also included in a cluster defined by a different method), select YES. If the cluster was detected by CDC analysis

but not by local analysis at the time of submitting the Initial Form and subsequently detected by local analysis at the time of submitting the Annual/Closeout Form, select YES and enter the local cluster ID.

- **Question #11a**: Provide the method and date of detection as well as the cluster ID for each overlapping cluster identified by a different method. For overlapping molecular or time-space clusters identified by CDC, populate 'date of detection' with the date your jurisdiction was notified of the existence of the cluster by CDC.
- **Question #11b**: This is an OPTIONAL question. Provide any additional relevant information about the overlapping cluster(s). If method of identification for the overlapping cluster is "other," describe here.

Gaps or Challenges

- **Question #12 What gaps or challenges have you encountered in responding to this cluster? Check all that apply.** This is a required question on the Annual/ Closeout Form. The list of the gaps and challenges corresponds to the section headers for the response activities in question 13 as response activities are generally selected to address identified gaps and challenges.). Examples of syndemic conditions include viral hepatitis, sexually transmitted infections, injection drug use, or mental health conditions. Examples of structural issues include lack of housing, access to syringe services programs, or linguistic or cultural competency of service providers. See "Additional Response Activities" in the Investigation and Response section of CDC's HIV CDR Guidance for Health Departments for more information.

  We have checked the responses you chose in previous forms. Please do not uncheck boxes unless they were mistakenly checked in previous forms.

  - **Question #12a**: Use this space to provide any additional information about the challenges your jurisdiction has encountered to respond fully to the cluster.

Investigation or Response Activities

Question #13 What investigation or response activities have you initiated in response to the cluster? This is a required question on the Annual/Closeout Form. Check off all the activities that have been part of your cluster response. Your response should reflect a cumulative list of all activities that have been initiated, tailored, or enhanced in response to the cluster except for reporting on activities 1-4 related to individual cluster member/partner follow-up. You may check off activities 1-4 even if they were initiated before the identification of the cluster. Note that if you are unsure of where an activity fits within a domain you can place it in the "other" category of the domain. Note that you should put a check to all activities started even if they have not completed and/or you are not going to submit an outcome measure.

You must check at least one activity for this question before submitting the form. We have checked the responses you chose in previous forms. Please do not uncheck boxes unless they were mistakenly checked in previous forms.

- For all parts of question 13, "cluster members" refers to people with HIV who meet the case definition for the specific cluster. "Network or affected communities" refers to

people in an HIV cluster and those with whom they have sex or share drugs, who may or may not have HIV. Some people with HIV can be in the network, even if they were not part of the initially detected cluster. People without HIV in the same sexual or drug-using network are also considered part of the larger network.

Notes on selected activities:
Activity 2: Activities taken to link cluster members to care, or to re-engage them in care, should be included in this activity even if they have taken place before the cluster was identified.
Activity 3: PrEP: HIV pre-exposure prophylaxis; PEP: HIV post-exposure prophylaxis.
Activity 5: This could include enhanced/expanded interviews or reinterviews undertaken as part of the cluster response.
Activity 7: Medical chart review refers to in-depth review of medical charts, including clinic visits, emergency department visits, or hospitalizations, that is more than the usual standard chart review conducted to complete HIV surveillance case report forms for people with new HIV diagnosis. The goal of the chart review(s) should be to understand patterns of, and missed opportunities for, prevention and care.
Activity 14: Examples include offering testing at a homeless encampment if known cluster members live there and have injected drugs with others who live in the encampment or offering testing at a bar or club that cluster or network members are known to frequent.
Activity 15: Examples include expansion of HIV testing for all people who are admitted to the emergency departments of hospitals, expanding hours for HIV testing at public health clinics, or using mobile clinics to expand testing in areas that have limited testing resources.
Activity 19: Examples include enhancing psychosocial support to cluster members to improve adherence with antiretroviral treatment, ensuring enrollment in Ryan White HIV/AIDS Program, or providing transportation to clinic visits.
Activity 20: Examples include expanding hours for HIV care and treatment at local public health clinics or expanding the use of mobile clinics for people who have limited access to treatment and care resources.
Activity 21: Examples include expanding case management services, providing language-appropriate HIV care, or enrolling cluster members in appropriate treatment adherence programs.
Activity 23: Examples include direct provision of PrEP or PEP at public health clinics to members of the network who do not have HIV or partnering with pharmaceutical companies to obtain low-cost PrEP for network members.
Activity 24: Examples include developing dedicated clinic time for provision of PrEP for populations with a high prevalence or incidence of HIV (not just members of the network), expanding options for different PrEP medications, or providing low-cost PrEP for people with low or no insurance.
Activity 33: Activities could include providing financial incentives for maintaining viral load suppression, providing transportation services to medical appointments, providing food stamps, or expanding the role of pharmacists in the provision of PrEP or PEP.

- **Question 13a Did you only check off activities in Domain 1?** If you only implemented activities in Domain 1 (Individual cluster member/partner follow-up) then check “yes” here.
- **Question 13b.** If you answered “yes” to 13a, describe why response activities were limited to individual cluster member/partner follow-up.

- **Question # 14** Pick at least three of the activities you checked off in question 13 for which you report outcomes. The three activities should come from at least two different domains unless you only implemented activities from a single domain. Note that you will be presented with an auto populated list of the activities you checked off in question 13 that you can choose from. Depending on the activity you select, you will be presented with different options of how to describe the activity and report on outcomes. You only have to report outcomes for those activities that you have selected.

For activities 1-3, provide the numerical value for the outcomes. These activities refer to both routine and enhanced/tailored individual follow up/partner services activities and the outcomes should be derived from medical records or information from the DIS investigation. You do not need to provide an explanation of how the activity was implemented or the status of the activity. The required outcomes for activities 1-3 are in table 1 below.

For all the other activities (activity numbers 4-34):

- Indicate the current status (pick one)
  - Planned
  - In Progress
  - Completed
- Describe the activity (what was or is being done; who was or is the intended audience; who carried or is carrying out the activity; how, where, and when the activity was or is being implemented)
- Describe the outcome of the activity (to date if activity is still in progress) and how it was measured or planned to be measured.
- For activities 10, 14, 15, 16, 17, 20, 24, 26, 28, 29, 30, or 32, refer to table 2 for required numerical outcomes. Put the numerical outcome for the activity in the number box. If the activity is planned or is in progress, and a numerical outcome is not available, it is acceptable to put "0" in the number box.

Table 1

Activity Number	Outcome (numeric value)
1	• Number of named partners notified • Number of named partners in your jurisdiction • Number of named partners who previously tested positive for HIV • Number of named partners who had not previously tested positive for HIV, who were tested for HIV • Of the named partners who had not previously tested positive for HIV and who were tested for HIV, number who were newly diagnosed with HIV
2	• Number of cluster members with HIV in your jurisdiction • Number of cluster members with HIV in your jurisdiction who have received medical care during the past 12 months
3	• Number of named partners in your jurisdiction who tested negative for HIV • Number of named partners in your jurisdiction who tested negative for HIV and who were referred to PrEP or PEP

Table 2

Activity No.	Required Outcome (numeric value)
10	• Number of clinical providers trained on any of the above as part of the response
14	• Number of tests performed • Number of new HIV diagnoses
15	• Number of sites where HIV testing was expanded or enhanced
16	• Number of HIV self-tests distributed
17	• Number of HIV self-tests distributed
20	• Number of sites where HIV care was expanded or enhanced
24	• Number of sites where PrEP/PEP access was expanded or enhanced
26	• Number of sites where HRPs or SSPs were expanded or added
28	• Number of people who were referred to or provided housing assistance
29	• Number of people who were referred to or provided substance use treatment services
30	• Number of people who were referred to or provided mental health services
32	• Number of naloxone kits distributed to the network or affected communities during the response

Below are hypothetical examples of activity descriptions and outcomes.

Activity 5: Qualitative methods with members of the cluster, network, or affected communities

Description of activity: "Since a large number of the cluster members who injected drugs had not reported being on PrEP at the time of their HIV diagnosis, we developed a short, seven-question questionnaire to ask cluster members, and their drug sharing partners, about their attitudes towards PrEP and their ability to obtain PrEP. During May–November 2024, the DIS contacted cluster members and their partners by phone and invited them to answer the questions."

Status: Completed

Description of outcome: "A total of 22 cluster members and their partners were invited to answer the questions and 12 agreed. Eight of the respondents, all of whom injected drugs, said that they had not heard of PrEP at the time of their HIV diagnosis; one had been on PrEP but had not been taking it regularly. The results led the health department to work with syringe services programs to more regularly provide counseling about PrEP to their clients."

Activity 7: Detailed medical chart reviews

Description of activity: "Several of the cluster members were diagnosed with AIDS at the time of their HIV diagnosis and also had a history of co-infections and multiple hospital admissions for the co-infections. We wanted to learn if there were opportunities for earlier diagnosis of their HIV infections, so in July 2024 we reviewed all of the medical charts we could access on cluster members in the two years before they had a positive HIV test."

Status: Completed

Description of outcome: "We reviewed medical charts from hospitals, emergency rooms, and clinics for 12 of 15 cluster members. Eleven had been seen in an emergency room at least once in the 2 years before their first HIV diagnosis. The most common reasons for admission included abscess/wound care (9) and liver failure due to hepatitis C (4). Most had not received HIV testing at these visits so we then worked with the local hospital to

implement opt-out HIV testing in the emergency room for people presenting with skin and soft tissue infections or with hepatitis C infection."

Activity 10: Training for clinical providers on the needs of cluster or network

Description of activity: "There are two local syringe services programs (SSPs) in the county where the outbreak was taking place. Neither program had been offering PrEP to their clients. During October 2024, the health department organized on-site training for all providers at both programs about the indications for PrEP use and how to help their clients obtain it through our state's PrEP assistance program."

Status: Completed

Description of outcome: "A total of 33 staff members who worked at either of the two SSPs attended a training. At the trainings, we answered questions about who was eligible for PrEP, especially long-acting injectable PrEP, and options for minimizing the cost of PrEP. Our PrEP coordinator said that in the month after the trainings she was able to help the SSPs connect 7 new people to PrEP."

Number of clinical providers trained: "33"

Activity 15: Expanded or enhanced HIV testing

Description of activity: "The time-space alert showed an overall increase in HIV diagnoses in the county, with many diagnosed with AIDS. We wanted to increase testing to identify HIV diagnoses earlier by expanding the hours at the main health department clinic. We added extra clinic hours on Monday evenings from 6-8 PM and also offered morning clinic hours on the second and fourth Saturdays of the month. This started in March 2024."

Status: In progress

Description of the outcome: "After widely advertising the increase in clinic hours, we saw that the average number of monthly patient visits at our clinic increased by 10% during July-November 2024 (changed from 200 to 220 average monthly visits) with the average number of HIV tests increasing by 12% as compared to the same time period in 2023 (the average number of HIV tests increased from 50 to 56)."

Number of sites where HIV testing was expanded or enhanced: "1"

Activity 19: Expanded or enhanced activities for engagement in care or viral suppression

Description of activity: "We identified a cluster of 12 high school students with HIV and syphilis who attended three different schools. The age range of cluster members was 14-17 years, and many of the cluster members started to miss school and their medical appointments once the cluster became public. In January 2024, the health department, in collaboration with a youth organization, developed a weekly peer support group for members of the cluster to address stigma, life skills, and adherence to medical care."

Status: In progress

Description of outcome: "The peer support group met every two weeks from January 2024-November 2024. The average attendance was 5 people per meeting (range 3-12). Absenteeism from school by cluster members from decreased by 14% from January-June compared to baseline (August-December 2023) and canceling of medical appointments decreased by 30%. "

Activity 24: Expanded or enhanced PrEP/PEP access

Description of activity: "We identified a large, 24-person HIV cluster of men who have sex with men in the capital city. From the DIS interviews of the cluster members we learned that

there was stigma about using PrEP and difficulty finding providers who would talk about it or prescribe it. We trained 15 DIS personnel about PrEP and how to speak to clinical providers about it. We made signs and pamphlets about PrEP that could be displayed in doctors' offices."
Status: Completed
Description of Outcome: "During April-August 2025, our DIS personnel made visits to doctor's offices in the neighborhoods where the cluster members lived and discussed PrEP with the office staff, answered questions, and asked them to display the PrEP materials and talk about it with their clients."
Number of sites where PrEP/PEP was expanded or enhanced: "8"

Activity 28: Housing services referral
Description of activity: "We had 13 people in the HIV cluster who lived in a homeless encampment. There was limited housing, and the city was planning on closing the encampment. In fall 2023, to find housing for the cluster members who lived in the encampment, we convened a task force, including a housing CBO, the city public health department, advocates for the homeless, and HUD representatives. We developed data sharing MOUs with members of the task force so that we could securely share information about cluster members with partners who could provide housing. The task force met regularly from the end of 2023 through December 2024 to provide housing vouchers for cluster members and identify additional housing providers."
Status: In progress
Description of Outcome: "With the data sharing agreement, we were able to quickly identify people who qualified for housing and their specific needs for housing (accessibility, family)."
Number of people who were referred to or provided housing assistance: "5"

- **Question #15 Describe any changes to policies or processes to support the prevention, diagnosis, and treatment of HIV in your jurisdiction implemented in response to this cluster, including any successes or innovations not reported in question 14.** Comment on ways in which cluster investigation and response activities have impacted your health department's policies and processes. Examples of topics to include here include (but are not limited to): whether any enhancements were made to regular HIV prevention and treatment processes, such as provision of case management services or expansion of PrEP resources; whether communication within the health department or interactions between local and state health departments changed; whether the cluster was used to advocate for policy changes; or whether additional resources were required to respond to this particular cluster.

- **Question #16 If the cluster or network includes persons outside of your jurisdiction, have you contacted the other jurisdiction(s) involved?** This is an OPTIONAL question. Select YES if you have contacted the other jurisdiction(s) involved in this cluster. If there were no cluster or network members outside of your jurisdiction involved, select "No cluster or network members outside of the jurisdiction".
    - **Question #16a Describe any collaboration or communication with the other involved jurisdiction(s):** Describe your interactions with the other jurisdictions involved (i.e., email communication, phone call, coordinating response activities, etc.).

Level of Concern

- **Question #17 What is your current level of concern for this cluster?** Consider a variety of factors that may inform your level of concern. These could include the magnitude of increase in HIV diagnoses relative to baseline, potential for ongoing transmission (e.g., injection drug use, many sex partners, low rates of viral suppression), populations at risk for poor outcomes (e.g., people experiencing homelessness, pregnancy, HIV drug resistance, presenting with advanced HIV), or understanding of the network involved in the cluster. See "Questions to consider when developing prioritization criteria" in the Review and Prioritization section in CDC's HIV CDR Guidance for Health Departments for additional considerations
    - **Question #17a:** This question is REQUIRED if high level of concern and OPTIONAL if low/medium level of concern. Use this space to provide a brief description of why you have selected the level of concern and note the epidemiological or other characteristics that informed your decision; for example, a sudden increase in diagnoses compared to baseline numbers that were detected through time-space analysis, an increase in IDU-associated HIV infections, a high proportion of infections among persons aged <18 years, or any indications that the underlying network is substantially larger than what has been identified.

Technical Assistance Needs

- **Question #18 Do you have any technical assistance needs related to this cluster?** Select YES if you have technical assistance needs for this cluster. Detection and Response Branch staff will do our best to connect you with relevant technical assistance resources as available.
    - **Question #18a**: Describe your technical assistance needs here. Be specific if possible. If assistance is urgently needed, reach out directly to your assigned Detection and Response Branch epidemiologist.

- **Question #19 Additional comments:** This is an OPTIONAL question. Use this space to provide any additional information about this cluster and your investigation and response.

Submission

When submitting the form on REDCap to CDC, please remember to select "Complete" in the status drop down menu. Forms marked Incomplete or Unverified will not be reviewed by CDC.