

National HIV Surveillance System (NHSS)

Attachment 4b.

Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Reporting Form
Technical Guidance

Technical Guidance for HIV Surveillance Programs

Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Reporting Form

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

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Pediatric HIV Confidential Case Report Form

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Technical Guidance for HIV Surveillance Programs — Pediatric HIV Confidential Case Report Form

Instructions for Completion

Purpose of Case Report Form

The Pediatric HIV Confidential Case Report (CDC 50.42B) form (PCRf) is designed to collect information that promotes understanding of HIV infection morbidity and mortality among patients less than 13 years of age at time of diagnosis. This form reflects data that is required to be collected and some that is recommended or optional. This guidance applies to all HIV infection data collection even if state or local surveillance programs use a different form or medium for HIV case surveillance. See Appendix for further guidance.

The Case Report Form in the Context of Document-Based Surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a reported case, fill out the applicable part of the form for each data source contributing information to that HIV case.

Patients for Whom Form is Indicated

- Each child less than 13 years of age, who meets the HIV infection or stage 3 (AIDS) case definition (available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>).
- In areas with perinatal exposure HIV reporting, all children born to HIV-infected mothers.
- Includes each child whose infection status has not yet been determined, seroconverters, and those exposed but determined not to be infected with HIV; inclusion of such patients is for public health surveillance purposes only.
- Each child with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis.
- Each child with HIV infection who has been reported but for whom updated information is available such as new CD4 tests, viral load tests, or drug resistance tests (genotypic) reported from a medical provider, additional risk factor information, updated current address information, or a change in vital status.

If the data is collected electronically and can be imported, recording the information on a hardcopy form is not necessary. A federal assurance of confidentiality applies to information on children exposed perinatally with or without consequent infection.

Definition of Variable Designators

- **Required:** Variables that must be collected by all programs.
- **Recommended:** Variables that programs are strongly encouraged to collect but are not absolutely required.
- **Optional:** Variables that programs may or may not choose to collect.
- **System generated:** Variables where the value is generated by the Centers for Disease Control and Prevention (CDC)-supplied software.

Disposition of Form

- The completed form is for state or local health agency use and is not to be sent to the CDC. The Pacific Islands are the only jurisdictions that send forms to CDC for data entry and all patient identifiers must be removed before they are sent.
- Data obtained from these forms are entered into standardized computer software provided by the Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC by encrypted electronic transfer via a secure data network.

1. Patient Identification

Patient Identification (record all dates as mm/dd/yyyy)

| | | | | | | | | | |
|---|--|--------------|--------------------------|----------------|--------------|-------------------|--------------|-----------|--|
| *First Name | | *Middle Name | | *Last Name | | Last Name Soundex | | | |
| Alternate Name Type (example: Birth, Call Me) | | | *First Name | | *Middle Name | | *Last Name | | |
| Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary | | | *Current Address, Street | | | | Address Date | | |
| *Phone () | | City | | County | | State/Country | | *ZIP Code | |
| *Medical Record Number | | | | *Other ID Type | | | | *Number | |

- *Information NOT transmitted to CDC
 - Patient identifier information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form. Enter the data below for all children reported with HIV infection.
- 1.1 FIRST NAME (**Required**, applies to health department & health care providers)
 - Enter patient's first name
 - 1.2 MIDDLE NAME (**Optional**, applies to health department & health care providers)
 - Enter patient's middle name.
 - 1.3 LAST NAME (**Required**, applies to health department & health care providers)
 - Enter patient's last name.
 - 1.4 LAST NAME SOUNDEX (**System generated**)
 - After patient name is entered into CDC-supplied software, the software automatically generates this variable by using the patient's last name. After the code is generated, health department staff should fill in this field on the form.
 - This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created.
 - You can access the *eHARS Technical Reference Guide* through SharePoint: <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>
 - 1.5 ALTERNATE NAME TYPE (**Optional**, applies to health department & health care providers)
 - If available, write in the alternate name type (e.g., Alias, Birth Name)
 - 1.6 ALTERNATE FIRST NAME (**Optional**, applies to health department & health care providers)
 - Enter patient's alternate first name.
 - 1.7 ALTERNATE MIDDLE NAME (**Optional**, applies to health department & health care providers)
 - Enter patient's alternate middle name.
 - 1.8 ALTERNATE LAST NAME (**Optional**, applies to health department & health care providers)

- Enter patient's alternate last name.
- 1.9 ADDRESS TYPE (**Required**, applies to health department & health care providers)
- Select one of the address types for the patient's current address.
- 1.10 CURRENT ADDRESS, STREET (**Required**, applies to health department & health care providers)
- Enter the patient's current street address.
- 1.11 ADDRESS DATE (**Required**, applies to health department & health care providers)
- Enter the earliest date that the patient was known to be residing at the current address specified in 1.10. If the patient has resided at an address more than once (and has evidence that they resided elsewhere in between), the address date captured should be the earliest date that the patient moved to the address in the most recent instance.
 - You may enter the most recent date the patient was known to be residing at the address in the Comments section.
 - Enter date in *mm/dd/yyyy* format using '.' for unknown values (e.g., 03/./2011).
- 1.12 PHONE (**Required** if patient has a telephone, applies to health department & health care providers)
- Enter patient's primary area code and telephone number associated with the current address specified in 1.10.
- 1.13 CITY (**Required**, applies to health department & health care providers)
- Enter patient's current city.
- 1.14 COUNTY (**Required**, applies to health department & health care providers)
- Enter patient's current county.
- 1.15 STATE/COUNTRY (**Required**, applies to health department & health care providers)
- Enter patient's current state and country name.
- 1.16 ZIP CODE (**Required**, applies to health department & health care providers)
- Enter patient's current zip code.
- 1.17 MEDICAL RECORD NUMBER (**Optional**, applies to health department & health care providers)
- Enter medical record number of the patient if available.
 - This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
 - If the patient has more than one medical record number, enter the number of the primary record that has HIV infection or stage 3 (AIDS) documentation. Additional numbers can be noted in the Comments section annotating which facility is associated with which record number.
- 1.18–1.19 OTHER ID TYPE and NUMBER (**Optional**, applies to health department & health care providers)
- Enter any additional patient identifier type (such as social security number) and the number of the other identifier. For a list of ID types, please reference the *eHARS Technical Reference Guide*.

2. Health Department Use Only

Health Department Use Only (record all dates as mm/dd/yyyy)

| | | |
|---|---|--------------------|
| Date Received at Health Department ____/____/____ | eHARS Document UID | State Number |
| Reporting Health Dept—City/County | | City/County Number |
| Document Source | Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown | |
| Did this report initiate a new case investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | Report Medium <input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk | |

- 2.1 DATE RECEIVED AT HEALTH DEPARTMENT (**Recommended**, applies to health department)
 - Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 2.2 eHARS DOCUMENT UID (**System generated**)
 - Enter UID after CDC-supplied software generates this variable.
- 2.3 STATE NUMBER (**Required**, applies to health department)
 - Enter the assigned state number.
 - Each patient must have a unique state number throughout the course of HIV disease in each state/jurisdiction where they are reported. If the patient was a pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different state numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to [Appendix 4.1.4](#) for the definition of a pediatric “Seroreverter”. Jurisdictions must use the “Same as” field on the duplicate review tab in eHARS to link the two cases. Enter the appropriate state number associated with the events being reported on the case report form. For example, if providing information about the “Seroreverter”, enter the state number associated with the “Seroreverter”.
 - Assigned numbers **must not** be reused, even if the case is later deleted.
 - This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge with state datasets without duplication.
- 2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY (**Required**, applies to health department)
 - Enter name of city and county of the health department that receives the report from providers of surveillance data.
- 2.5 CITY/COUNTY NUMBER (**Optional**, applies to health department)
 - Enter the assigned city/county number.
 - Each patient must have a unique city/county number throughout the course of HIV disease assigned by the separately funded city in which they are reported. If the city/county number is the primary identifier and the patient was a pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different city/county numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to [Appendix 4.1.4](#) for the definition of a pediatric “Seroreverter”. If the city/county number is the primary identifier, the jurisdiction must use the “Same as” field on the duplicate review tab in eHARS to link the two cases. Enter the appropriate city/county number associated with the events being reported on the case report form. For example, if providing information about the “Seroreverter”, enter the city/county number associated with the “Seroreverter”.
 - Assigned numbers **must not** be reused, even if the case is later deleted.
- 2.6 DOCUMENT SOURCE (**Required**, applies to health department)
 - Enter the code for the document source that provided the information for this report (formerly report source).
 - To clearly identify multiple data sources for a given HIV case (all stages), use a separate case report form for each source.

- Refer to the *eHARS Technical Reference Guide* for a list of the allowable document source codes.
- 2.7 SURVEILLANCE METHOD (**Required**, applies to health department)
- Enter the method the case report was ascertained.
 - For definitions of active, passive, follow up, re-abstraction refer to the file *Source Data and Completeness of Reporting*.
- 2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (**Optional**, applies to health department)
- Enter whether this case report initiated a new investigation by the health department.
- 2.9 REPORT MEDIUM (**Optional**, applies to health department)
- Health department staff review medical records at provider facilities (i.e., field visits) or receive information over the telephone, by fax, US mail, or other method, to establish an HIV case and to elicit information for HIV case report forms. The health department can also receive HIV case reports from physicians, laboratories, or other individuals or institutions through electronic transfer or CD/disks. Enter the medium in which the case report was submitted.

3. Facility Providing Information

Facility Providing Information (record all dates as mm/dd/yyyy)

| | | | |
|---------------------|--|-------------------------|---|
| Facility Name | | *Phone () | |
| *Street Address | | | |
| City | County | State/Country | *ZIP Code |
| Facility Type | <i>Inpatient:</i> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ | | <i>Outpatient:</i> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Pediatric clinic <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____ |
| Date Form Completed | | *Person Completing Form | *Phone () |

- 3.1 FACILITY NAME (**Recommended**, applies to health department & health care providers)
- Enter name of the facility providing the information.
 - If data was reported from different facilities, enter name of each on separate forms.
- 3.2 PHONE (**Recommended**, applies to health department & health care providers)
- Enter facility's current area code and telephone number.
- 3.3 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
- Enter facility's street address.
- 3.4 CITY (**Recommended**, applies to health department & health care providers)
- Enter city where facility providing information is located.
- 3.5 COUNTY (**Recommended**, applies to health department & health care providers)
- Enter county where facility providing information is located.
- 3.6 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
- Enter state and country name where facility providing information is located.
- 3.7 ZIP CODE (**Recommended**, applies to health department & health care providers)
- Enter ZIP code where facility providing information is located.
- 3.8 FACILITY TYPE (**Required**, applies to health department & health care providers)
- Select the type of facility providing information.
 - Refer to the *eHARS Technical Reference Guide* for additional information regarding allowable facility types.
- 3.9 DATE FORM COMPLETED (**Required**, applies to health department & health care providers)
- Enter date in *mm/dd/yyyy* format using '.' for unknown values (e.g., 03/./2011).
- 3.10 PERSON COMPLETING FORM (**Optional**, applies to health department & health care providers)

providers)

- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

3.11 PHONE (**Recommended**, applies to health department & health care providers)

- Enter the telephone number of the person completing the form.

4. Patient Demographics

Patient Demographics (record all dates as mm/dd/yyyy)

| | | |
|--|---|--|
| Diagnostic Status at Report <input type="checkbox"/> 3-Perinatal HIV exposure <input type="checkbox"/> 4-Pediatric HIV <input type="checkbox"/> 5-Pediatric AIDS <input type="checkbox"/> 6-Pediatric seroreverter | Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown | Country of Birth <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (please specify) _____ |
| Date of Birth ____/____/____ | Alias Date of Birth ____/____/____ | |
| Vital Status <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead | Date of Death ____/____/____ | State of Death _____ |
| Date of Last Medical Evaluation ____/____/____ | Date of Initial Evaluation for HIV ____/____/____ | |
| Ethnicity <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown | Expanded Ethnicity _____ | |
| Race (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown | Expanded Race _____ | |

4.1 DIAGNOSTIC STATUS AT REPORT (**Optional**, applies to health department & health care providers)

- Use one form to capture each event regardless of the interval between diagnostic status dates, and where the same source of these data reported more than one event. Fill out suitable number of case report forms:
 - Fill out the first form completely for the first diagnosis.
 - Fill out subsequent forms partially, capturing additional or updated data absent from the first form.
- Forms referred to in the preceding bulleted item must include at least the following data: Diagnostic Status Report; Residence at Diagnosis (see [Residence at Diagnosis](#) below); and Facility of Diagnosis (see [Facility of Diagnosis](#) below).
- Status depends on child’s age, clinical profile, and laboratory findings. Refer to [Appendix 4.1.1–4.1.4](#) for further guidance.

4.1.1 PERINATAL HIV EXPOSURE

- Select “Perinatal HIV Exposure” if the patient is less than 18 months of age, was born to an HIV-infected mother, and does not meet the criteria for HIV infection or the criteria for “Not Infected with HIV.”
- Refer to [Appendix 4.1.1](#) for further guidance.

4.1.2 PEDIATRIC HIV

- Select “Pediatric HIV” if the patient meets the criteria specified in the Revised Surveillance Case Definition for HIV Infection in children < 13 years of age and does not meet the current CDC pediatric HIV infection stage 3 (AIDS) case definition.
- Refer to [Appendix 4.1.2](#) for further guidance.

4.1.3 PEDIATRIC AIDS

- Select “Pediatric AIDS” if patient meets the current HIV infection stage 3 case definition for children < 13 years of age.
- Refer to [Appendix 4.1.3](#) for further guidance.

4.1.4 PEDIATRIC SEROREVERTER

- Select “Seroreverter” if the perinatally exposed child initially has a positive HIV test but is found NOT to be HIV-infected through criteria listed in [Appendix 4.1.4](#).
- Of the four diagnostic status categories available on the case report form (CRF), “Pediatric Seroreverter” is synonymous with “Not Infected with HIV.”

4.2 SEX ASSIGNED AT BIRTH (**Required**, applies to health department & health care providers)

- Select patient’s sex assigned at birth.

- In addition to “Male” or “Female” sex at birth, CDC-supplied software includes a third choice of “Unknown.”

4.3 COUNTRY OF BIRTH (**Recommended**, applies to health department & health care providers)

- Select applicable response.
- For patients born in US minor outlying areas, specify the name of the US dependency from the following table:

| US Dependencies | |
|-----------------|----------------|
| Baker Island | Midway Islands |
| Howland Island | Navassa Island |
| Jarvis Island | Palmyra Atoll |
| Johnston Atoll | Wake Island |
| Kingman Reef | |

- For patients born in any other area outside of the US and US minor outlying areas, specify the country/US dependency name.
- 4.4 DATE OF BIRTH (**Required**, applies to health department & health care providers)
- Enter patient’s date of birth in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 4.5 ALIAS DATE OF BIRTH (**Optional**, applies to health department & health care providers)
- If available, enter the Alias date of birth in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 4.6 VITAL STATUS (**Required**, applies to health department & health care providers)
- Enter vital status at time of this report.
 - For further guidance on death ascertainment, see the file *Death Ascertainment*.
- 4.7 DATE OF DEATH (**Required** if applicable, applies to health department & health care providers)
- If patient is deceased, enter date of death in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
 - For further guidance on death ascertainment, see the file *Death Ascertainment*.
- 4.8 STATE OF DEATH (**Required**, if applicable, applies to health department & health care providers)
- If patient is deceased, enter the state name where the death occurred. If the death occurred outside of the US, enter “Foreign Country”.
- 4.9 DATE OF LAST MEDICAL EVALUATION (**Optional**, applies to health department & health care providers)
- Enter the date of the child’s last medical evaluation in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011) regardless of reason for exam. This includes emergency room visits.
- 4.10 DATE OF INITIAL EVALUATION FOR HIV INFECTION (**Optional**, applies to health department & health care providers)
- Enter the date of initial evaluation for HIV infection in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011). This is the date when HIV infection was first considered, either clinically or through laboratory evaluation.
 - For a child whose mother is known to be HIV infected at the time of birth and for whom assessment of HIV is done at birth, use the date of birth. This assessment does not necessarily include an order for an HIV test, although documentation of an HIV test is often the earliest evidence that the diagnosis was considered.

- Evidence of HIV infection in a child **must be obtained on or after the birth date**.
- 4.11 ETHNICITY (**Required**, applies to health department & health care providers)
- If search for this datum was completed and ethnicity could not be determined or if ethnicity was documented to be unknown, select “Unknown”.
 - If no search for this datum was completed, leave this field blank.
 - Regardless of the availability of data on race, collect data on ethnicity.
 - As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic/Latino, Not Hispanic/Latino) for a person be collected as separate variables.
 - A wide variety of ethnicities may be selected from values available in CDC-supplied software. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.
- 4.12 EXPANDED ETHNICITY (**Optional** if applicable, applies to health department & health care providers)
- Enter more specific ethnicity information for greater detail such as “Hispanic or Latino - Cuban” or “Hispanic or Latino - Puerto Rican”.
 - Refer to the *eHARS Technical Reference Guide* for listing of expanded ethnicity.
- 4.13 RACE (**Required**, applies to health department & health care providers)
- Select patient’s race even if information was submitted for ethnicity.
 - Select more than one race if applicable.
 - If no race information is available, select “Unknown”.
 - As of January 2003, the US Office of Management and Budget (OMB) required that systems collect multiple races for a person (OMB Policy Directive 15 updated standards); at a minimum, collect data on the following five categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.
 - Refer to the *eHARS Technical Reference Guide* for further details.
- 4.14 EXPANDED RACE (**Optional**, if applicable, applies to health department & health care providers)
- Enter more specific race information for greater detail such as “American Indian or Alaska Native.Navajo” or “White.Middle Eastern or North African”.
 - Refer to the *eHARS Technical Reference Guide* for listing of expanded race.

5. Residence at Diagnosis

Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)

| | | | | | | | | | | |
|---|---|--|--|--|--|-----------------------------------|--------------------------------|---------------------------------|----------------------------------|------------------------------------|
| Address Event Type (check all that apply to address below) | <input type="checkbox"/> Residence at HIV diagnosis | <input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis | <input type="checkbox"/> Residence at perinatal exposure | <input type="checkbox"/> Residence at pediatric seroreverter | <input type="checkbox"/> Check if SAME as current address | | | | | |
| Address Type | <input type="checkbox"/> Residential | <input type="checkbox"/> Bad address | <input type="checkbox"/> Correctional facility | <input type="checkbox"/> Foster home | <input type="checkbox"/> Homeless | <input type="checkbox"/> Military | <input type="checkbox"/> Other | <input type="checkbox"/> Postal | <input type="checkbox"/> Shelter | <input type="checkbox"/> Temporary |
| *Street Address | | | | | | | | | | |
| City | | | County | | | State/Country | | | *ZIP Code | |

- Refer to [Appendix 5.0](#) for further guidance.
 - If patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis are different, enter the address information associated with the stage 3 (AIDS) diagnosis in the Comments section.
- 5.1 ADDRESS EVENT TYPE (**Required**, applies to health department & health care providers)
- Select the address event type for the patient’s residence at diagnosis.
 - If the patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis was the same, you may check both.
- 5.2 ADDRESS TYPE (**Required**, applies to health department & health care providers)
- Select one address type for the patient’s address of residence at diagnosis.

- 5.3 STREET ADDRESS (**Required**, applies to health department & health care providers)
 - Enter street address of residence at diagnosis.
- 5.4 CITY (**Required**, applies to health department & health care providers)
 - Enter city of residence at diagnosis.
- 5.5 COUNTY (**Required**, applies to health department & health care providers)
 - Enter county of residence at diagnosis.
- 5.6 STATE/COUNTRY (**Required**, applies to health department & health care providers)
 - Enter the state and country name of residence at diagnosis.
- 5.7 ZIP CODE (**Required**, applies to health department & health care providers)
 - Enter the ZIP code of residence at diagnosis.

6. State/Local Use Only

| STATE/LOCAL USE ONLY | |
|------------------------------------|------------|
| *Provider Name (Last, First, M.I.) | *Phone () |
| Hospital/Facility | |

- The information in this section is not transmitted to CDC and is meant only for state and local health department use. State and local health departments should develop their own policies for collecting the data elements within this section. Collection of information within this section is **Optional**.

7. Facility of Diagnosis

Facility of Diagnosis (add additional facilities in Comments)

| | | | |
|--|--------|---|------------|
| Diagnosis Type (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Perinatal exposure <input type="checkbox"/> Check if <u>SAME</u> as facility providing information | | | |
| Facility Name | | | *Phone () |
| *Street Address | | | |
| City | County | State/Country | *ZIP Code |
| Facility Type <i>Inpatient:</i> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ | | <i>Outpatient:</i> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Pediatric clinic <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____ | |
| | | <i>Other Facility:</i> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ | |
| *Provider Name | | *Provider Phone () | Specialty |

- If the patient's HIV diagnosis and stage 3 (AIDS) diagnosis occurred at different facilities, enter the stage 3 (AIDS) facility information in the Comments section.
- 7.1 DIAGNOSIS TYPE (**Recommended**, applies to health department & health care providers)
 - Enter the diagnosis type that corresponds to the facility of diagnosis being reported.
 - 7.2 FACILITY NAME (**Recommended**, applies to health department & health care providers)
 - Enter name of the facility where patient was first diagnosed which corresponds with the "Diagnosis Type" reported in 7.1.
 - Refer to [Appendix 7.2](#) for further details.
 - 7.3 PHONE (**Recommended**, applies to health department & health care providers)
 - Enter area code and telephone number of the facility of diagnosis.
 - 7.4 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
 - Enter street address of the facility of diagnosis.
 - 7.5 CITY (**Recommended**, applies to health department & health care providers)
 - Enter city of the facility of diagnosis.
 - 7.6 COUNTY (**Recommended**, applies to health department & health care providers)
 - Enter county of the facility of diagnosis.
 - 7.7 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
 - Enter state and country name of the facility of diagnosis.
 - 7.8 ZIP CODE (**Recommended**, applies to health department & health care providers)

- Enter ZIP code where the facility of diagnosis is located.
- 7.9 FACILITY TYPE (**Required** applies to health department & health care providers)
- Select the type of facility of diagnosis.
 - Refer to the *eHARS Technical Reference Guide* for listing of facility types.
- 7.10 PROVIDER NAME (**Recommended**, applies to health department & health care providers)
- Enter provider’s name where the patient was first diagnosed which corresponds with the “Diagnosis Type” reported in 7.1.
- 7.11 PROVIDER PHONE (**Recommended**, applies to health department & health care providers)
- Enter area code and telephone number for provider selected in 7.10.
- 7.12 SPECIALTY (**Optional**, applies to health department & health care providers)
- Enter provider’s specialty for provider selected in 7.10.

8. Patient History

Patient History (respond to all questions) (record all dates as mm/dd/yyyy)

| | |
|---|--|
| Child’s biological mother’s HIV infection status (select one): <input type="checkbox"/> Refused HIV testing <input type="checkbox"/> Known to be uninfected after this child’s birth | |
| <input type="checkbox"/> Known HIV+ before pregnancy <input type="checkbox"/> Known HIV+ during pregnancy <input type="checkbox"/> Known HIV+ sometime before birth <input type="checkbox"/> Known HIV+ at delivery | |
| <input type="checkbox"/> Known HIV+ after child’s birth <input type="checkbox"/> HIV+, time of diagnosis unknown <input type="checkbox"/> HIV status unknown | |
| Date of mother’s first positive test to confirm infection ____/____/____ | Was the biological mother counseled about HIV testing during this pregnancy, labor, or delivery? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| After 1977 and before the earliest known diagnosis of HIV infection, this child’s biological mother had: | |
| Perinatally acquired HIV infection | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Injected nonprescription drugs | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Biological mother had HETEROSEXUAL relations with any of the following: | |
| HETEROSEXUAL contact with intravenous/injection drug user | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with bisexual male | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with transfusion recipient with documented HIV infection | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with transplant recipient with documented HIV infection | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with person with documented HIV infection, risk not specified | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Biological mother had: | |
| Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| First date received ____/____/____ Last date received ____/____/____ | |
| Received transplant of tissue/organs or artificial insemination | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Before the diagnosis of HIV infection, this child had: | |
| Injected nonprescription drugs | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Received clotting factor for hemophilia/coagulation disorder | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Specify clotting factor: _____ Date received ____/____/____ | |
| Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| First date received ____/____/____ Last date received ____/____/____ | |
| Received transplant of tissue/organs | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Sexual contact with male | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Sexual contact with female | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Other documented risk (please include detail in Comments) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |

- These data yield information about how patients may have acquired their infection.
- Respond to each risk factor, selecting “Yes” for all factors that apply; “No” for those that do not apply (only select “No” if medical record specifically states this is not a risk factor); and “Unknown” for those for which investigation failed to yield an answer. If an investigation for a particular item was not performed, then you should leave it blank. Collect data about risk factors that occurred before the earliest known diagnosis of HIV infection. For further guidance, see the file *Risk Factor Ascertainment*.
- If the biological mother is known to be HIV infected and this is the only maternal risk, then the case will initially be classified as “mother has HIV infection, risk not specified”.
- Information on the child refers to circumstances or behaviors that were thought to have

- exposed the child to HIV, not to treatments since the child became HIV infected. For example, if the child received a blood transfusion after the documentation of HIV infection, do not enter that information on the form.
- The state or local Cases of Public Health Importance (COPHI) coordinator should contact the CDC COPHI coordinator as soon as possible if any unusual transmission circumstances are suspected. For further guidance, see the file *Risk Factor Ascertainment*.
- 8.1 CHILD’S BIOLOGICAL MOTHER’S HIV INFECTION STATUS (**Required**, applies to health department & health care providers)
- If mother was diagnosed with HIV infection, select from boxes 3–8 (i.e., box “Known HIV+ before pregnancy” to box “HIV+, time of diagnosis unknown”), depending on information available to determine the timing of her diagnosis. Where date of mother’s first positive HIV confirmatory test is available, select the appropriate box by comparing the date of birth to the date of the mother’s diagnosis.
 - Refer to [Appendix 8.1](#) for further guidance.
- 8.2 DATE OF MOTHER’S FIRST POSITIVE HIV CONFIRMATORY TEST (**Optional**, applies to health department & health care providers)
- Where mother is known to be HIV infected, enter month, day, and year of the first positive HIV confirmatory test in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03../2011).
 - Refer to [Appendix 8.2](#) for further guidance.
- 8.3 WAS THE BIOLOGICAL MOTHER COUNSELED ABOUT HIV TESTING DURING THIS PREGNANCY, LABOR, OR DELIVERY? (**Optional**, applies to health department & health care providers)
- Complete this question for all mothers regardless of whether they were diagnosed with HIV infection before this pregnancy.
 - Select “Yes” if mother was counseled at any time during this pregnancy, labor, or delivery by a health care provider (private or public) about the risks of HIV in pregnancy and the risks, benefits, and meaning of HIV testing.
 - If not, select “No.”
 - If no information in the medical chart is available regarding counseling, then select “Unknown”.
- 8.4 AFTER 1977, AND BEFORE THE EARLIEST KNOWN DIAGNOSIS OF HIV INFECTION, THIS CHILD’S BIOLOGICAL MOTHER HAD:
- 8.4.1 PERINATALLY ACQUIRED HIV INFECTION (**Required**, applies to health department & health care providers)
- Select applicable response.
- 8.4.2 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response.
- 8.5 BIOLOGICAL MOTHER HAD HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:
- This section relates to ascertainment of risk among heterosexual sex partners of the biological mother of the case patient.
 - Verification of sex partner’s HIV infection status is not necessary.
- 8.5.1 INTRAVENOUS/INJECTION DRUG USER (**Required**, applies to health department & health care providers)
- Select applicable response.
- 8.5.2 BISEXUAL MALE (**Required**, applies to health department & health care providers)
- Select applicable response.

- 8.5.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- “Coagulation disorder” or “hemophilia” refers only to a disorder of a clotting factor, which is any of the circulating proteins named Factor I, Factor II, Factor III, etc., through Factor XII. These disorders include Hemophilia A and Von Willebrand’s disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
 - Refer to [Appendix 8.5.3](#) for further guidance.
 - If yes, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.5.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion in the comments section.
 - Refer to [Appendix 8.5.4](#) for further guidance.
 - If yes, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.5.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion/transplant in the Comments section.
 - If yes, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.5.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to health department & health care providers)
- Select “Yes” only if male partner is known to be HIV-positive and that partner’s risk for HIV is unknown.
- 8.5.7 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to health department & health care providers)
- ‘Blood,’ is defined as a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
 - ‘Blood components’ that can be transfused, include erythrocytes, leukocytes, platelets, and plasma.
 - If “Yes,” specify the month, day, and year of the first and last transfusion before the child’s biological mother received a diagnosis of HIV infection (stage 1,2, unknown) or stage 3 (AIDS). Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
 - Consider documenting the reason for transfusion/transplant in the Comments section.
 - If the last transfusion was after March 1985, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.5.8 FIRST DATE RECEIVED (**Required**, applies to health department & health care providers)
- Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 8.5.9 LAST DATE RECEIVED (**Required**, applies to health department & health care providers)
- Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 8.5.10 RECEIVED TRANSPLANT OF TISSUES/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to health department & health care providers)

- If this is the only risk factor present and the biological mother did not have a diagnosis of HIV infection at the time of child’s birth, the transmission mode will be initially classified as “risk not reported/identified” pending outcome of the COPHI investigation.
 - If yes, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.6 BEFORE THE DIAGNOSIS OF HIV INFECTION, THIS CHILD HAD
- Alert state/local COPHI coordinator if the child had one or more of the risk factors documented in this section.
- 8.6.1 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response.
- 8.6.2 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER (**Required**, applies to health department & health care providers)
- “Coagulation disorder” or “hemophilia” refers only to a disorder of a clotting factor; factors are any of the circulating proteins named Factor I through Factor XII. These disorders include Hemophilia A and Von Willebrand’s disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
 - This risk factor is generally documented in the history and physical section of the patient’s medical chart.
 - They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
 - If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select “No.”
 - Alert state/local COPHI coordinator if child was born after March 1998 and receipt of clotting factor is the suspected mode of HIV transmission.
- 8.6.3 SPECIFY CLOTTING FACTOR (**Required**, applies to health department & health care providers)
- If “Yes” to 8.6.2, above, then enter the specific clotting factor.
 - Enter the date the clotting factor was received in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 8.6.4 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to health department & health care providers)
- If child received a transfusion of blood cells (red cells, white cells, and platelets) or plasma, specify month, day, and year of first and last transfusion before the patient was infected with HIV or received a diagnosis of stage 3 or AIDS. Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
 - It is often helpful to document the reason for the transfusion in the Comments section.
- 8.6.5 RECEIVED TRANSPLANT OF TISSUE/ORGANS (**Required**, applies to health department & health care providers)
- The case will be initially classified as “risk not reported/identified” pending outcome of the no identified risk (NIR) investigation.
 - If yes, alert the state/local Cases of Public Health Importance (COPHI) coordinator.
- 8.6.6 SEXUAL CONTACT WITH A MALE (**Required**, applies to health department & health care providers)
- If child is known to have had sexual contact/abuse, mark the appropriate box.
 - If this is the only risk history, the case will be initially classified as “risk not

- reported/identified” pending outcome of NIR investigation.
- Alert state/local COPHI coordinator.
- 8.6.7 **SEXUAL CONTACT WITH A FEMALE (Required, applies to health department & health care providers)**
 - If the child is known to have had sexual contact/abuse, mark the appropriate box.
 - If this is the only risk history, the case will be initially classified as “risk not reported/identified” pending outcome of NIR investigation.
 - Alert state/local COPHI coordinator.
- 8.6.8 **OTHER DOCUMENTED RISK (Alert State/Local NIR Coordinator) (Required, applies to health department & health care providers)**
 - Include detail in Comments section.

9. Clinical: Opportunistic Illnesses

Clinical: Opportunistic Illnesses (record all dates as mm/dd/yyyy)

| Diagnosis | Dx Date | Diagnosis | Dx Date | Diagnosis | Dx Date |
|--|---------|---|---------|--|---------|
| Bacterial infection, multiple or recurrent (including Salmonella septicemia) | | HIV encephalopathy | | Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary | |
| Candidiasis, bronchi, trachea, or lungs | | Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis | | M. tuberculosis, pulmonary ¹ | |
| Candidiasis, esophageal | | Histoplasmosis, disseminated or extrapulmonary | | M. tuberculosis, disseminated or extrapulmonary ¹ | |
| Carcinoma, invasive cervical | | Isosporiasis, chronic intestinal (>1 mo. duration) | | Mycobacterium, of other/unidentified species, disseminated or extrapulmonary | |
| Coccidioidomycosis, disseminated or extrapulmonary | | Kaposi's sarcoma | | Pneumocystis pneumonia | |
| Cryptococcosis, extrapulmonary | | Lymphoid interstitial pneumonia and/or pulmonary lymphoid | | Pneumonia, recurrent in 12 mo. period | |
| Cryptosporidiosis, chronic intestinal (>1 mo. duration) | | Lymphoma, Burkitt's (or equivalent) | | Progressive multifocal leukoencephalopathy | |
| Cytomegalovirus disease (other than in liver, spleen, or nodes) | | Lymphoma, immunoblastic (or equivalent) | | Toxoplasmosis of brain, onset at >1 mo. of age | |
| Cytomegalovirus retinitis (with loss of vision) | | Lymphoma, primary in brain | | Wasting syndrome due to HIV | |

¹If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

9.1 CLINICAL: OPPORTUNISTIC ILLNESSES

9.1.1–9.1.27 (Optional, applies to health department & health care providers)

- Select all that apply and enter diagnosis dates. Enter date in mm/dd/yyyy format using ‘..’ for unknown values (e.g., 03/./2011).
- For additional information, refer to the most recent case definition for HIV infection (available at <http://wwwn.cdc.gov/nndss/conditions/hiv-infection/>).

9.1.28 RVCT CASE NUMBER (Optional, applies to health department & health care providers)

- If this patient has a verified case of tuberculosis (TB), health department staff enter the nine-digit alphanumeric code from the TB case report or TB data management system. Providers in the private and public sectors diagnosing tuberculosis in their stage 3 (AIDS) patients may get this number from TB surveillance staff.

10. Laboratory Data

Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)

| | | | |
|--|--|---|--|
| HIV Immunoassays (Nondifferentiating) | | | |
| TEST 1 <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 IA <input type="checkbox"/> HIV-2 WB | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | Collection Date ____/____/____ <input type="checkbox"/> Point-of-care rapid test | |
| TEST 2 <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 IA <input type="checkbox"/> HIV-2 WB | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | Collection Date ____/____/____ <input type="checkbox"/> Point-of-care rapid test | |
| HIV Immunoassays (Differentiating) | | | |
| <input type="checkbox"/> HIV-1/2 type-differentiating immunoassay (differentiates between HIV-1 Ab and HIV-2 Ab) | | Role of test in diagnostic algorithm <input type="checkbox"/> Screening/initial test <input type="checkbox"/> Confirmatory/supplemental test | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result ¹ Overall interpretation: <input type="checkbox"/> HIV-1 positive <input type="checkbox"/> HIV-2 positive <input type="checkbox"/> HIV positive, untypable <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity <input type="checkbox"/> HIV-1 indeterminate <input type="checkbox"/> HIV-2 indeterminate <input type="checkbox"/> HIV indeterminate <input type="checkbox"/> HIV negative | | | |
| Analyte results: HIV-1 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | Collection Date ____/____/____ <input type="checkbox"/> Point-of-care rapid test | |
| HIV-2 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | ¹ Always complete the overall interpretation. Complete the analyte results when available. | |
| <input type="checkbox"/> HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab) | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Ag positive <input type="checkbox"/> Ab positive <input type="checkbox"/> Both (Ag and Ab positive) <input type="checkbox"/> Negative <input type="checkbox"/> Invalid | | | |
| Collection Date ____/____/____ <input type="checkbox"/> Point-of-care rapid test | | | |
| <input type="checkbox"/> HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab) | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result ² Overall interpretation: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Index value _____ | | | |
| Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Not reportable due to high Ab level Index value _____ | | | |
| HIV-1 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index value _____ | | | |
| HIV-2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index value _____ | | | |
| Collection Date ____/____/____ <input type="checkbox"/> Point-of-care rapid test | | ² Complete the overall interpretation and the analyte results. | |
| HIV Detection Tests (Qualitative) | | | |
| TEST <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-1 culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-2 culture | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | Collection Date ____/____/____ | |
| HIV Detection Tests (Quantitative viral load) Note: Include earliest test at or after diagnosis. | | | |
| TEST 1 <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative viral load) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative viral load) | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Detectable <input type="checkbox"/> Undetectable Copies/mL _____ | | Log _____ Collection Date ____/____/____ | |
| TEST 2 <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative viral load) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative viral load) | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Result <input type="checkbox"/> Detectable <input type="checkbox"/> Undetectable Copies/mL _____ | | Log _____ Collection Date ____/____/____ | |
| Drug Resistance Tests (Genotypic) | | | |
| TEST <input type="checkbox"/> HIV-1 Genotype (Unspecified) | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Collection Date ____/____/____ | | | |
| Immunologic Tests (CD4 count and percentage) | | | |
| CD4 at or closest to diagnosis: CD4 count _____ cells/ μ L CD4 percentage _____ % Collection Date ____/____/____ | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| First CD4 result <200 cells/ μ L or <14%: CD4 count _____ cells/ μ L CD4 percentage _____ % Collection Date ____/____/____ | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Other CD4 result: CD4 count _____ cells/ μ L CD4 percentage _____ % Collection Date ____/____/____ | | | |
| Test brand name/Manufacturer _____ | | Lab name _____ | |
| Facility name _____ | | Provider name _____ | |
| Documentation of Tests | | | |
| Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | |
| If YES, provide specimen collection date of earliest positive test for this algorithm ____/____/____ | | | |
| Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, viral load, qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence. | | | |
| If laboratory tests were not documented, is patient confirmed by a physician as | | HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Date of diagnosis ____/____/____ | |
| | | Not HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Date of diagnosis ____/____/____ | |

- Throughout this section, "Collection Date" refers to the date when the specimen was

collected or drawn. Enter collection dates in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).

- Record all laboratory tests. Include all diagnostic tests, viral load tests, CD4 tests, and drug resistance tests (genotypic) where possible. Where the number of tests exceeds the number of fields available on the form, record such results in the Comments section. In eHARS, enter the additional test results on the lab data tab with the applicable test type.
- Include tests with negative or indeterminate results that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected).
- In the absence of lab tests, record HIV infection or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.

10.1 HIV IMMUNOASSAYS (NON-DIFFERENTIATING)

- Assuming active case finding, review patient’s chart and lab reports for the earliest date of documented HIV positivity. “Indeterminate” refers to Indeterminate HIV antibody test results.
- Enter the brand name of the test and/or its manufacturer, lab name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
 - Enter specimen collection date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- Check the Point-of-care rapid test box if the test is a CLIA waived point-of-care rapid test. (**Optional**, applies to health department & health care providers)

10.1.1 HIV-1 IA

- Enter result and collection date of first HIV-1 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means repeatedly reactive tests on a single sample.

10.1.2 HIV-1/2 IA

- Enter result and collection date of first HIV-1/2 combination IA test. (**Required**, applies to health department & health care providers)

10.1.3 HIV-1/2 AG/AB

- Enter result and collection date of combined p24 antigen and anti HIV1/2 antibody screening assay. (**Required**, applies to health department & health care providers)

10.1.4 HIV-1 WESTERN BLOT

- Enter the result and collection date of first HIV-1 Western blot. (**Required**, applies to health department & health care providers)
- Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations “Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections ” (*MMWR*, 1989:38:No.S-7).

10.1.5 HIV-1 IFA

- Enter the result and collection date of first HIV-1 IFA. (**Required**, applies to health department & health care providers)

10.1.6 HIV-2 IA

- Enter result and date of first HIV-2 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means repeatedly reactive tests on a single sample.

10.1.7 HIV-2 WESTERN BLOT

- Enter the result and collection date of first HIV-2 Western blot. (**Required**, applies to health department & health care providers)
- 10.2 HIV IMMUNOASSAYS (DIFFERENTIATING)
- Assuming active case finding, review patient’s chart and lab reports for the earliest date of documented HIV positivity.
 - Enter the brand name of the test and/or its manufacturer, lab name, facility name and provider name. (**Optional**, applies to health department & health care providers)
 - Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
 - Enter specimen collection date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 10.2.1 HIV-1/2 TYPE-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Type-Differentiating IA. (**Required**, applies to health department & health care providers)
 - Enter the role of the test in the diagnostic algorithm, “screening/initial” or “confirmatory/supplemental”. That is, was the test used as a screening/initial test in the recommend diagnostic algorithm or was the test used as a confirmatory/supplemental test in the recommended diagnostic algorithm.
 - Enter the overall interpretation of the test (**Required**, applies to health department & health care providers)
 - Record the result for each analyte (HIV-1Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers).
 - Check the Point-of-care rapid test box if the test is a CLIA waived point-of-care rapid test. (**Optional**, applies to health department & health care providers)
- 10.2.2 HIV-1/2 AG/AB-DIFFERENTIATING IMMUNOASSAY
- Enter result and collection date of first HIV-1/2 Ag/Ab-Differentiating IA. (**Required**, applies to health department & health care providers)
 - If the result is HIV Ab reactive or HIV Ag reactive and HIV Ab reactive, check the box for “Ab positive” or “Both (Ag and Ab reactive)”, respectively, on the ACRF. These indicate that antibodies to HIV-1 or HIV-2 were detected.
- 10.2.3 HIV-1/2 AG/AB AND TYPE-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Ag/Ab and Type-Differentiating IA. (**Required**, applies to health department & health care providers)
 - Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
 - If provided enter index value for the overall interpretation. (**Optional**, applies to health department & health care providers)
 - Record the result for each analyte (HIV-1 Ag and HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
 - Enter the index value for each analyte. (**Optional**, applies to health department & health care providers)
- 10.3 HIV DETECTION TESTS (QUALITATIVE)
- All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as the IA or Western blot establish the presence of the immune system’s response to the pathogen (i.e., HIV antibodies).

- Assuming active case finding, review patient’s chart and lab reports for the earliest date of documented HIV positivity.
 - Enter the brand name of the test and/or its manufacturer, lab name, facility name and provider name. (**Optional**, applies to health department & health care providers)
 - Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
 - Enter specimen collection date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 10.3.1 HIV-1 RNA/DNA NAAT (QUALITATIVE)
- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
- 10.3.2 HIV-1 CULTURE
- Enter result and collection date of earliest test by culture. (**Required**, applies to health department & health care providers)
- 10.3.3 HIV-2 RNA/DNA NAAT (QUALITATIVE)
- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
- 10.3.4 HIV-2 CULTURE
- Enter result and collection date of earliest test by culture. (**Required**, applies to health department & health care providers)
- 10.4 HIV DETECTION TESTS (QUANTITATIVE VIRAL LOAD)
- Enter the brand name of the test and/or its manufacturer, lab name, facility name and provider name. (**Optional**, applies to health department & health care providers)
 - Indicate if results are “Detectable” or “Undetectable”. Viral load tests with undetectable results should also be entered. (**Optional**, applies to health department & health care providers)
 - Enter results in units of viral copies per milliliter (mL) and Log. (**Required**, applies to health department & health care providers)
 - Where results are reported above the limit of quantification (LOQ), select “Detectable” then enter “greater than detection limits for this assay” and the result value in the copies/mL field.
 - Where the results reported are below the LOQ, select “Undetectable” then enter “fewer than detectable by this assay” and the result value in the copies/mL field. For example, a result of “<48 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 48 cp/mL”.
 - Enter specimen collection date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 10.4.1 HIV-1 RNA/DNA NAAT (QUANTITATIVE VIRAL LOAD)
- Enter result and collection date of earliest test. (**Required**, applies to health department & health care providers)
- 10.4.2 HIV-2 RNA/DNA NAAT (QUANTITATIVE VIRAL LOAD)
- Enter result and collection date of earliest test. (**Required**, applies to health department & health care providers)
- 10.5 DRUG RESISTANCE TESTS (GENOTYPIC)
- This section should be completed if there is evidence of a drug resistance test (genotypic), regardless of the type of drug resistance test, in the patient’s medical or other record.
 - Enter the brand name of the test and/or its manufacturer, lab name, facility name and

- provider name. (**Optional**, applies to health department & health care providers)
 - Enter the collection date of the earliest test. (**Required**, applies to health department & health care providers)
 - When entering this information in eHARS, you should use the lab data tab and choose “HIV-1 Genotype (Unspecified)” as the test type. You will not be able to enter a genotype sequence since this test type only captures evidence of a drug resistance test (genotypic). If a corresponding genotype sequence is subsequently received, you should import this information as a separate laboratory document using the test type that reflects the type of drug resistance test that was conducted (e.g., HIV-1 Genotype (PR/RT Nucleotide Sequence)).
- 10.6 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)
- Enter the brand name of the test and/or its manufacturer, lab name, facility name and provider name. (**Optional**, applies to health department & health care providers)
 - Whenever CD4 count and percentage are both available for the same specimen collection date, record both.
 - Enter specimen collection date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011). (**Required**, applies to health department & health care providers)
- 10.6.1 CD4 AT OR CLOSEST TO DIAGNOSIS
- This is the first CD4 result closest to the date of initial HIV infection diagnosis, regardless of stage of disease at diagnosis.
- 10.6.1.1 CD4 COUNT
- Record the CD4 count closest to the time when the patient was determined to be HIV infected. If this information is not available when the initial case report is completed, it may be entered later.
 - Enter result and specimen collection date of first CD4 count. (**Required**, applies to health department & health care providers)
- 10.6.1.2 CD4 PERCENTAGE
- Record the CD4 percentage closest to the time when the patient was determined to be HIV infected. If this information is not available when the initial case report is completed, it may be entered later.
 - Record result and specimen collection date of first CD4 percentage. (**Required**, applies to health department & health care providers)
- 10.6.2 FIRST CD4 RESULT < 200 cells/μL or < 14%
- This is the first CD4 result indicative of stage 3 (AIDS). The stage is based primarily on the CD4 count; the CD4 count takes precedence over the CD4 percentage, and the percentage is considered only if the count is missing.
- 10.6.2.1 CD4 COUNT
- Record results and specimen collection date of first CD4 indicative of stage 3 (i.e., < 200 cells/μL). (**Required**, applies to health department & health care providers)
- 10.6.2.2 CD4 PERCENTAGE
- Record results and specimen collection date if: (**Required**, applies to health department & health care providers)
 - The CD4 percentage was from a specimen collected on the same date as the first CD4 count indicative of stage 3 (see section 9.5.2.1 above) or
 - The first CD4 percentage indicative of stage 3 (i.e., <14%) was from a specimen collected on an earlier date than the first CD4 count indicative of stage 3 and was not accompanied by a CD4 count for the same date.

- 10.6.3 Other CD4 RESULT
 - 10.6.3.1 CD4 COUNT
 - Enter results and specimen collection date of other CD4 count. (**Required**, applies to health department & health care providers)
 - 10.6.3.2 CD4 PERCENTAGE
 - Record results and specimen collection date of other CD4 percentage. (**Required**, applies to health department & health care providers)
- 10.7 DOCUMENTATION OF TESTS
 - 10.7.1 DID DOCUMENTED LABORATORY TEST RESULTS MEET APPROVED HIV DIAGNOSTIC ALGORITHM CRITERIA? (**Required** if applicable, applies to health department & health care providers)
 - This section captures diagnoses through novel algorithms, and should only be completed if none of the following were positive for **HIV-1**: Western blot, IFA, culture, viral load, qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen test, or nucleotide sequence.
 - HIV-1 antigen analyte results from combination antigen/antibody tests in which the antigen result can be differentiated from the antibody result, such as an “HIV-1/2 Ag/Ab differentiating immunoassay” or an “HIV-1/2 Ag/Ab and type-differentiating immunoassay”, are *not* considered stand-alone p24 antigen tests. Refer to sections 10.2.2 and 10.2.3 for more information regarding these combination Ag/Ab immunoassays.
 - “Approved HIV diagnostic algorithm criteria” means any criteria that satisfy the HIV surveillance case definition, regardless of whether approved for other purposes such as laboratory-based HIV testing or point-of-care HIV screening.
 - If “Yes”, enter date of earliest positive test for this algorithm in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011). (**Required** if applicable, applies to health department & health care providers)
 - 10.7.2 IF LABORATORY TESTS WERE NOT DOCUMENTED, IS PATIENT CONFIRMED BY A PHYSICIAN AS (HIV-INFECTED or NOT HIV-INFECTED) (**Required** if applicable, applies to health department & health care providers)
 - If laboratory evidence of an HIV test is unavailable or was insufficient to meet surveillance case definition in the patient’s medical or other record and written documentation of lab evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter “Yes”; otherwise enter “No” or “Unknown.”
 - 10.7.2.1 HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)
 - IF “YES” TO 10.7.2.1, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of lab results, applies to health department & health care providers)
 - Date of diagnosis is defined as the date (at least the year) of diagnosis reported in the content of the medical record. If the diagnosis date was not reported in the note, the date when the note was written can be used as a proxy. For example, if a health care provider writes a note in a medical chart on 4/10/2010 stating the patient had positive HIV EIA and WB on 2/11/2010, this should be recorded as 2/11/2010 as the date of diagnosis by the physician.
 - 10.7.2.2 NOT HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)

- IF “YES” TO 10.7.2.2, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of lab results, applies to health department & health care providers)
- Date of diagnosis is defined as the date (at least the year) when the patient was determined to be “not HIV-infected”.

11. Birth History (for Perinatal Cases only)

Birth History (for Perinatal Cases only)

| | | | |
|---|---------------------------------------|--|----------------------------|
| Birth history available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | |
| Residence at Birth <input type="checkbox"/> Check if <u>SAME</u> as current address | | | |
| Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary | | | |
| *Street Address | | City | |
| County | State/Country | *ZIP Code | |
| Facility of Birth <input type="checkbox"/> Check if <u>SAME</u> as facility providing information | | | |
| Facility Name of Birth (if child was born at home, enter “home birth”) | | | *Phone () |
| Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ <u>Outpatient:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ | | | |
| *Street Address | | City | |
| County | State/Country | *ZIP Code | |
| Birth History | Birth Weight ___ lbs ___ oz ___ grams | Type <input type="checkbox"/> 1-Single <input type="checkbox"/> 2-Twin <input type="checkbox"/> 3-More than two <input type="checkbox"/> 9-Unknown | |
| Delivery <input type="checkbox"/> 1-Vaginal <input type="checkbox"/> 2-Elective Cesarean <input type="checkbox"/> 3-Nonelective Cesarean <input type="checkbox"/> 4-Cesarean, unknown type <input type="checkbox"/> 9-Unknown | | | |
| Birth Defects <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, specify types | | | |
| Neonatal Status <input type="checkbox"/> 1-Full-term <input type="checkbox"/> 2-Premature <input type="checkbox"/> 9-Unknown | | Neonatal Gestational Age in Weeks (99 = Unknown, 00 = None) | |
| Prenatal Care—Month of Pregnancy Prenatal Care Began (99 = Unknown, 00 = None) | | Prenatal Care—Total Number of Prenatal Care Visits (99 = Unknown, 00 = None) | |
| Did mother receive any antiretrovirals (ARVs) prior to this pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ___/___/___ Date of last use ___/___/___ | | If yes, specify all ARVs | |
| Did mother receive any ARVs during pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ___/___/___ Date of last use ___/___/___ | | If yes, specify all ARVs | |
| Did mother receive any ARVs during labor/delivery? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ___/___/___ Date of last use ___/___/___ | | If yes, specify all ARVs | |
| Maternal Information | | Maternal DOB ___/___/___ | Maternal Last Name Soundex |
| Maternal State ID Number | | Maternal Country of Birth | |
| *Other Maternal ID (specify type of ID and ID number) | | | |

11.1 BIRTH HISTORY AVAILABLE (**Optional**, applies to health department & health care providers)

- If birth history is not available, proceed to next section.

11.2 RESIDENCE AT BIRTH (**Required**, applies to health department & health care providers)

- Select one of the address types for the patient’s residence at time of birth.
- Enter the street address, city, county, state, country name, and zip code of the patient’s residence at time of birth

11.3 FACILITY OF BIRTH (**Optional**, applies to health department & health care providers)

- Check if same as facility providing information.
- Enter name, address, phone, city, county, state/country and zip code of the hospital/clinic of birth.
- Sites should uniformly record hospital names, including abbreviations.
- If this child was born at home, enter “home birth”.

11.4 BIRTH HISTORY

11.4.1 BIRTH WEIGHT (**Optional**, applies to health department & health care providers)

- Enter the birth weight in pounds and ounces, or grams.
- If recorded only in pounds and ounces, convert to grams.

11.4.2 TYPE (**Optional**, applies to health department & health care providers)

- Select applicable response. If unknown, select “9.”
- 11.4.3 DELIVERY (**Optional**, applies to health department & health care providers)
 - Elective cesarean section refers to a cesarean section that occurs before rupture of membranes and before the onset of labor.
 - Elective cesarean section has been demonstrated to reduce perinatal transmission of HIV, if performed before the onset of labor.
 - It will be important to monitor the trends in the use of elective cesarean section for the prevention of perinatal HIV.
 - Notes in the child’s records are acceptable even if no birth records are available.
- 11.4.4 BIRTH DEFECTS (**Optional**, applies to health department & health care providers)
 - If “Yes,” specify type.
 - Refer to [Appendix 11.4.4](#) for further guidance and an abbreviated list of birth defects.
- 11.4.5 NEONATAL STATUS (**Optional**, applies to health department & health care providers)
 - Select applicable response and record the child’s gestational age, if known, in the boxes provided.
 - “Full term” is defined as gestational age greater than or equal to 37 weeks.
 - “Premature” is defined as gestational age less than 37 weeks.
 - If search for gestational age was unsuccessful, then enter “99” for unknown number of weeks.
 - Post mature neonatal status (after 40 weeks) should be recorded as full term.
- 11.3.5.1 NEONATAL GESTATIONAL AGE IN WEEKS
 - Enter weeks of gestation.
- 11.4.6 PRENATAL CARE (**Optional**, applies to health department & health care providers)
 - Prenatal care is defined as any care for the pregnancy beyond pregnancy testing and before delivery, even if no regular follow-up ensued.
- 11.4.7 MONTH OF PREGNANCY PRENATAL CARE BEGAN (**Optional**, applies to health department & health care providers)
 - Record the gestational month of pregnancy (01 to 09) that the mother began her prenatal care.
 - If any fraction of a month is reported, round to the next whole month.
 - In the absence of prenatal care, enter “00.”
 - If search for this datum was unsuccessful, then enter “99” for month of first visit.
 - Refer to [Appendix 11.4.7](#) for further guidance.
- 11.4.8 TOTAL NUMBER OF PRENATAL CARE VISITS (**Optional**, applies to health department & health care providers)
 - Record the total number of times the mother went to the clinic or doctor for her prenatal care; exclude visits unrelated to prenatal care.
 - In the absence of prenatal care visits, enter “00”.
 - In the presence of prenatal care and search for this datum was unsuccessful, then enter “99” for number of prenatal visits.
 - Where data source reports a range of visits (e.g., “10–13”), enter the lowest number (e.g., “10”).
- 11.4.9 DID MOTHER RECEIVE ANTIRETROVIRALS (ARVs) PRIOR TO THIS PREGNANCY? (**Recommended**, applies to health department & health care providers)
 - ‘Pregnancy’ is defined as: The condition of having a developing embryo or fetus in the body after union of an ovum and spermatozoon. Labor and delivery occur after this interval, so they are not considered part of the ‘pregnancy’.

- Select “Yes” if information is available that states that the mother used ARVs prior to this pregnancy. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- Select “No” if mother did not use ARVs prior to this pregnancy.
- If a woman did not receive ARVs, do not assume it was because she refused. Select “Refused” only if explicit documentation in the medical record indicates that the patient was offered the drug, but the patient declined.
- Select “Unknown” after an unsuccessful search for this datum.

11.3.9.1 IF “YES,” PLEASE SPECIFY ALL

11.4.10 DID MOTHER RECEIVE ARVs DURING PREGNANCY? (**Recommended**, applies to health department & health care providers)

- Select “Yes” if information is available that states that the mother used ARVs any time during pregnancy. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- Select “No” if mother did not use ARVs during pregnancy.
- Select “Refused” only if explicit documentation in the medical record indicates that the patient was offered the drug, but the patient declined.
- Select “Unknown” if it is unknown whether the mother ever used ARVs during pregnancy.
- 11.3.10.1 IF “YES,” PLEASE SPECIFY ALL

- For a list of antiretroviral therapies currently available and link to treatment guidelines, refer to [Appendix 11.4.10](#).

11.4.11 DID MOTHER RECEIVE ARVs DURING LABOR/DELIVERY? (**Recommended**, applies to health department & health care providers)

- Select “Yes” if information is available that states that the mother used ARVs any time during labor/delivery. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- Select “No” if mother did not use ARVs during labor/delivery.
- Select “Refused” only if explicit documentation in the medical record indicates that the patient was offered the drug, but the patient declined.
- Select “Unknown” if it is unknown whether the mother ever used ARVs during labor/delivery.

11.3.11.1 IF “YES,” PLEASE SPECIFY ALL

11.5 MATERNAL INFORMATION

11.5.1 MATERNAL DATE OF BIRTH (DOB) (**Optional**, applies to health department & health care providers)

- Enter the biological mother’s date of birth in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).

11.5.2 MATERNAL LAST NAME SOUNDEX (**Optional**, applies to health department)

- Enter maternal soundex here.
- After patient name is entered into CDC-supplied software, the software automatically generates this variable by using the patient’s last name. After the code is generated, health department staff should fill in this field on the form.
- This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created. You can access the *eHARS Technical Reference Guide*

through SharePoint:

<https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>

- Refer to [Appendix 11.5.2](#) for further guidance.

- 11.5.3 MATERNAL STATE ID NUMBER (**Optional**, applies to health department)
- Enter assigned state number if the biological mother is known to be HIV infected.
 - State numbers should not be reused.

- 11.5.4 MATERNAL COUNTRY OF BIRTH (**Optional**, applies to health department & health care providers)

- Select applicable response.
- For mothers born in US minor outlying areas, specify the name of the US dependency from the following table:

| US Dependencies | |
|-----------------|----------------|
| Baker Island | Midway Islands |
| Howland Island | Navassa Island |
| Jarvis Island | Palmyra Atoll |
| Johnston Atoll | Wake Island |
| Kingman Reef | |

- For mothers born in any other area outside of the US and US minor outlying areas, specify the country name.
- If this information is not available in the child’s records, it can be left blank and updated on follow-up.

- 11.5.5 OTHER MATERNAL ID (**Optional**, applies to health department & health care providers).
- Enter any other maternal ID type (such as social security number) and the number of the other ID.

12. Treatment/Services Referrals

Treatment/Services Referrals (record all dates as mm/dd/yyyy)

| | | |
|---|-----------------------|---|
| This child ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | |
| If yes, reason for ARV use (select all that apply) | | |
| <input type="checkbox"/> HIV Tx | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| <input type="checkbox"/> PrEP | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| <input type="checkbox"/> PEP | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| <input type="checkbox"/> PMTCT | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| <input type="checkbox"/> HBV Tx | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| <input type="checkbox"/> Other (specify reason) _____ | ARV medications _____ | Date began ___/___/_____ Date of last use ___/___/_____ |
| Has this child ever taken PCP prophylaxis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | |
| Date began ___/___/_____ Date of last use ___/___/_____ | | |
| Was this child breastfed? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | |
| This child’s primary caretaker is <input type="checkbox"/> 1-Biological parent <input type="checkbox"/> 2-Other relative <input type="checkbox"/> 3-Foster/Adoptive parent, relative <input type="checkbox"/> 4-Foster/Adoptive parent, unrelated <input type="checkbox"/> 7-Social service agency <input type="checkbox"/> 8-Other (please specify in comments) <input type="checkbox"/> 9-Unknown | | |

- This section should be completed by the person initially notifying the health department of the HIV case. Where health department staff populated fields in the Treatment/Services Referrals section through chart abstraction, providers of surveillance data may defer this task to public health workers.
- This information should be updated for each child when there is a change in diagnostic status, whenever possible.

- 12.1 THIS CHILD EVER TAKEN ANY ARVS (**Required**, applies to health department & health

- care providers)
- This variable indicates whether the patient has ever taken any antiretroviral medication. “Yes” indicates there is evidence that the person has taken ARVs, including self-report.
 - If “Yes”, it is important to enter the dates when use began and, if appropriate, ended. Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
 - “No” indicates there is evidence that the patient has never taken ARVs.
 - “Unknown” should be used when the person completing the form does not know whether or not the patient has ever taken ARVs, after searching for the information or asking the patient.
 - Leave the field blank if there was no attempt to find the information.
- 12.2 IF YES, REASON FOR ARV USE (**Required**, applies to health department & health care providers)
- Select all that apply.
 - “HIV Tx” indicates that the patient used ARVs to treat HIV infection.
 - “PrEP” indicates that the patient used ARVs prior to HIV diagnosis for HIV preexposure prophylaxis (PrEP).
 - “PEP” indicates that the patient used ARVs as postexposure prophylaxis (PEP).
 - “PMTCT” indicates that the patient used ARVs to prevent HIV mother-to-child-transmission during pregnancy.
 - “HBV Tx” indicates that the patient used ARVs to treat hepatitis B virus infection.
 - “Other” indicates that the patients used ARVs for a reason other than those indicated above.
- 12.3 ARV MEDICATIONS (**Recommended**, applies to health department & health care providers)
- For each ARV use reason indicated in 12.2, list the medications taken.
 - This variable is used to verify that the medication taken was actually an antiretroviral.
 - It is not necessary to list every drug combination that may have been used; record at least one ARV. Enter “unspecified” if an ARV was taken but the name is not known.
 - Refer to [Appendix 12.3](#) for further guidance.
- 12.4 DATE BEGAN (**Required**, applies to health department & health care providers)
- For each ARV use reason indicated in 12.2, enter the earliest date that the patient took the ARVs, even if ARV use was sporadic.
 - If the first time ARVs were taken occurred after HIV diagnosis, it is very important to enter a date, even an estimated date, later than the date of HIV diagnosis.
 - Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 12.5 DATE OF LAST USE (**Required**, applies to health department & health care providers)
- For each ARV use reason indicated in 12.2, enter the most recent date of ARV use.
 - For patients currently on ARVs, record the date of the most recent prescription or known usage. If the information was collected during a patient interview, the date would be the interview date. If the information was collected as part of a medical record review, record the date of the most recent prescription or date of the most recent physician’s note.
 - Enter date in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).
- 12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS? (**Optional**, applies to health department & health care providers)
- If nothing in the medical chart indicates the use of any of these drugs or refers to the prophylactic treatment of PCP, then select “No.”
 - If “Yes,” enter the date the child was started on therapy to prevent the occurrence of PCP and the date of last use in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011).

- “Unknown” is used if treatment information in the medical chart is unclear or was unavailable.
 - Refer to [Appendix 12.6](#) for further guidance.
- 12.7 WAS THIS CHILD BREASTFED? (**Optional**, applies to health department & health care providers)
- If there is suspicion that the child’s only exposure to HIV was through breast milk, the local/state NIR coordinator should be alerted.
 - Refer to [Appendix 12.7](#) for further guidance.
- 12.8 THIS CHILD’S PRIMARY CARETAKER IS (**Optional**, applies to health department & health care providers)
- Select the person who provides the majority of care for the child.
 - Refer to [Appendix 12.8](#) for further guidance.

13. Comments (Optional, applies to health department & health care providers)

Comments

| |
|--|
| |
| |
| |
| |
| |

- This section can be used for information not requested on the form or for information requested but where there might not be room in the space provided.
- As appropriate, information collected in this section can be entered in existing fields on the PCRf of the CDC-supplied software.
- Information entered into the “Comments” tab on the PCRf of the CDC-supplied software will not be transmitted to CDC.

14. Local/Optional Fields (Optional, applies to health department)

*Local/Optional Fields

| |
|--|
| |
| |
| |
| |

- This section is for collection of data that is not on the form at the state and local level.
- This information is not sent to CDC.

Appendix. Pediatric HIV Confidential Case Report Form (CDC 50.42B)

Instructions for Completion

Purpose

- Information captured on the Pediatric HIV Confidential Case Report Form (PCRf) provides population-based data on diagnostic testing and initiation of prophylaxis and treatment, as well as HIV-related morbidity and mortality among children (*CARE Amendments [Section 2626]*) to support states with prevention activities.
- CDC’s Division of HIV/AIDS Prevention (DHAP) needs initial reports and updates to reflect the earliest dates that children meet each reporting criteria (i.e., perinatal exposure, HIV

- infection, stage 3 or AIDS, seroreverter), as well as changes in diagnostic or vital status.
- When a child who was previously reported as HIV infected has progressed to stage 3 (AIDS) or has died, state/reporting area personnel update the National HIV Surveillance System (NHSS) accordingly.
 - After programs receive initial reports of evidence of HIV exposure or infection among children, surveillance staff follow up to determine whether diagnostic status of the child changes. For example, staff updates reports of children with perinatal exposure after 6 months of age to confirm or refute HIV infection and again at 18 months of age.
 - The PCRf can accommodate updated information including immunologic markers and diagnoses of opportunistic infections.
 - CDC updated the PCRf and related software in 2000 to: evaluate the implementation and impact of the Public Health Service (PHS) recommendations on the prevention of transmission of HIV from mother to child; accommodate surveillance requirements of the Ryan White CARE Act Amendments of 1996; and accommodate the revised 2000 HIV case definition for perinatal HIV exposure, pediatric infection, and those perinatally exposed but not infected with HIV.
 - In 1995, CDC added variables on receipt of maternal ARVs during pregnancy and labor/delivery and neonatal ARV.
 - Maternal HIV counseling and testing, prenatal care, and refusal of ARV treatment were added in 1996.
 - Viral load tests, receipt of additional antiretroviral (ARV) therapy during labor/delivery for the newborn and elective cesarean were added to the pediatric reporting form in 1999.
 - These additions enable reporting areas to identify possible reasons for failures in preventing HIV transmission related to childbirth (i.e., receipt of maternal HIV testing, prenatal care, and antiretroviral treatment).
 - As states move toward pediatric HIV exposure reporting, information on receipt of prenatal, intrapartum, and neonatal ARV and receipt of other antiretroviral therapy can be collected for all children born to HIV-infected women. Timely follow-up of these children to determine infection status will aid in evaluating the impact of these recommendations most effectively.
 - For evolution of the pediatric case definition, please refer to the 1987 pediatric AIDS case definition (*MMWR* 1987;36(suppl):1–15S), the 1994 revised classification system for HIV infection in children less than 13 years of age (*MMWR* 1994;43:(No. RR-12):1–10), and the 2000 HIV case definition in the CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome (*MMWR* 1999;48(RR-13):1–31), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm>, the 2008 case definition (*MMWR* 2008; 57 (RR-10) 1-12 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm>, and the Revised Surveillance Case Definition for HIV Infection — United States, 2014 (*MMWR* 2014;63 (RR03);1-10 at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e.

Pediatric Cases of Public Health Importance (COPHI)

- Reporting area staff should continue to discuss certain priority cases directly with CDC surveillance staff. These include HIV infection in a health care setting, HIV-2 infection, HIV infection attributed to tissue or organ transplantation, suspected transmission due to sexual contact, mother-to-infant transmission due to breast feeding, transfusions after March 1985, or any other unusual transmission circumstances. This direct communication will ensure the timeliest technical support. For further guidance, see the file *Risk Factor Ascertainment*.

4. Patient Demographics

4.1 DIAGNOSTIC STATUS AT REPORT

4.1.1 PERINATAL HIV EXPOSURE

- The “Perinatal HIV Exposure” category is composed of “Presumptively Not Infected,” “Definitively Not Infected,” and “Indeterminate.”
- A child aged less than 18 months born to an HIV-infected mother will be categorized as having perinatal exposure to HIV infection if the child does not meet the criteria for HIV infection or the criteria for “not infected with HIV.”

4.1.2 PEDIATRIC HIV

- Among children <18 months old whose mothers were not infected and all children aged ≥18 months, a reportable case of HIV infection must meet at least one of the following criteria:

1.1: Persons Aged ≥18 Months and Children Aged <18 Months whose Mothers were Not Infected

1.1.1: Laboratory Evidence

Laboratory criteria require reporting of the date of the specimen collection for positive test results in multitest algorithms or stand-alone virologic tests and enough information about the tests to determine that they meet any of the following criteria:

- A multitest algorithm consisting of
 - A positive (reactive) result from an initial HIV antibody or combination antigen/antibody test, and
 - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test.

The initial HIV antibody or antigen/antibody test and the supplemental HIV test that is used to verify the result from the initial test can be of any type used as an aid to diagnose HIV infection. For surveillance purposes, supplemental tests can include some not approved by the Food and Drug Administration (FDA) for diagnosis (e.g., HIV-1 viral load test, HIV-2 Western blot/immunoblot antibody test, and HIV-2 NAT). However, the initial and supplemental tests must be "orthogonal" (i.e., have different antigenic constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Because the antigenic constituents and test principles are proprietary information that might not be publicly available for some tests, tests will be assumed to be orthogonal if they are of different types. For example:

- One test is a combination antigen/antibody test and the other an antibody-only test.
- One test is an antibody test and the other a NAT.
- One test is a rapid immunoassay (a single-use analytical device that produces results in <30 minutes) and the other a conventional immunoassay.
- One test is able to differentiate between HIV-1 and HIV-2 antibodies and the other is not.

Tests also will be assumed to be orthogonal if they are of the same type (e.g., two conventional immunoassays) but made by different manufacturers. The type of HIV antibody test that verifies the initial test might be one formerly used only as an initial test (e.g., conventional or rapid immunoassay, HIV-1/2 type-differentiating immunoassay), or it might be one traditionally used as a

supplemental test for confirmation (e.g., Western blot, immunofluorescence assay).

- A positive result of a multitest HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used only as a supplemental test (e.g., HIV Western blot, immunofluorescence assay) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known).
- A positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests:
 - Qualitative HIV NAT (DNA or RNA)
 - Quantitative HIV NAT (viral load assay)
 - HIV-1 p24 antigen test
 - HIV isolation (viral culture) or
 - HIV nucleotide sequence (genotype).

1.1.2: Clinical (Non-Laboratory) Evidence

Clinical criteria for a confirmed case (i.e., a "physician-documented" diagnosis for which the surveillance staff have not found sufficient laboratory evidence described above) are met by the combination of:

- A note in a medical record by a physician or other qualified medical-care provider that states that the patient has HIV infection, and
- One or both of the following:
 - The laboratory criteria for a case were met based on tests done after the physician's note was written (validating the note retrospectively).
 - Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained diagnosis of an opportunistic illness.

- Among children aged less than 18 months whose mothers have an unknown infection status or were known to be infected, a reportable case of HIV infection must meet at least one of the following criteria:

1.2: Children Aged <18 Months Born to Mothers Who Have an Unknown Infection Status or were Known to be Infected

1.2.1: Laboratory Evidence

A child aged <18 months is categorized for surveillance purposes as HIV infected if all of the following criteria are met:

- Positive results on at least one specimen (not including cord blood) from any of following HIV virologic tests:
 - HIV-1 NAT (DNA or RNA)
 - HIV-1 p24 antigen test, including neutralization assay for a child aged >1 month
 - HIV isolation (viral culture) or
 - HIV nucleotide sequence (genotype).
- The test date (at least the month and year) is known.
- One or both of the following:
 - Confirmation of the first positive result by another positive result on one of the above virologic tests from a specimen obtained on a different date or
 - Both of the following:
 - No subsequent negative result on an HIV antibody test, and no subsequent negative result on an HIV NAT before age 18 months.

1.2.2: Clinical Evidence

- The same criteria as for section 1.1.2 above (1.1.2 Clinical [Non-Laboratory] Evidence for Persons Aged ≥18 Months and Children Aged <18 Months whose Mothers were Not Infected) or
- All three of the following alternative criteria:
 - Evidence of perinatal exposure to HIV infection before 18 months of age:
 - A mother with documented HIV infection or
 - A confirmed positive test for HIV antibody (e.g., a positive initial antibody test confirmed by a supplemental antibody test) and a mother whose infection status is unknown or undocumented.
 - Diagnosis of a stage-3-indicative opportunistic illness.
 - No subsequent negative result on an HIV antibody test.

4.1.3 PEDIATRIC AIDS

- Children who are HIV infected and exhibit any of the following AIDS-defining clinical conditions should be reported as Stage 3 (AIDS) cases; although most of these conditions appear among adult AIDS diagnostic criteria, asterisked conditions apply only to aged <6 years, and conditions with a dagger footnote

symbol apply only to children aged ≥ 6 years and adults.

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive[†]
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) (>1 month's duration); or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary
- *Mycobacterium tuberculosis* of any site, pulmonary[†], disseminated, or extrapulmonary
- *Mycobacterium*, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jirovecii* (previously known as "*Pneumocystis carinii*") pneumonia
- Pneumonia, recurrent[†]
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain, onset at age >1 month
- Wasting syndrome due to HIV

[†] Only among adults and children aged ≥ 6 years.

* Only among children aged <6 years.

4.1.4 PEDIATRIC SEROREVERTER

- Virtually all children less than 18 months of age born to HIV-infected mothers are antibody positive at birth.
- A child aged < 18 months born to an HIV-infected mother will be categorized for surveillance purposes as “not infected with HIV” if the child does not meet the criteria for HIV infection but meets the following criteria:

3.1: Uninfected

A child aged <18 months who was born to an HIV-infected mother or had a positive HIV antibody test result is classified for surveillance purposes as not infected with HIV if the following criteria are met:

- Laboratory criteria for HIV infection are not met (see section 1.2.1)
- No diagnosis of a stage-3-defining opportunistic illness attributed to HIV infection and
- Either laboratory or clinical evidence as described below.

3.1.1: Laboratory Evidence

Definitively Uninfected

- No positive HIV NAT (RNA or DNA) and
- At least one of the following two criteria:
 - At least two negative HIV NATs from specimens obtained on different dates, both of which were at age ≥ 1 month and one of which was at age ≥ 4 months.
 - At least two negative HIV antibody tests from specimens obtained on different dates at age ≥ 6 months.

Presumptively Uninfected

- Criteria for definitively uninfected with HIV are not met
- At least one of the following four laboratory criteria are met:
 - At least two negative NATs from specimens obtained on different dates, both of which were at age ≥ 2 weeks and one of which was at age ≥ 4 weeks.
 - One negative NAT (RNA or DNA) from a specimen obtained at age ≥ 8 weeks.
 - One negative HIV antibody test from a specimen obtained at age ≥ 6 months.
 - If criteria for HIV infection had initially been met by one positive HIV NAT test then it must have been followed by at least two negative test results from specimens obtained on different dates, one of which is:
 - A NAT test from a specimen obtained at age ≥ 8 weeks, or
 - An HIV antibody test from a specimen obtained at age ≥ 6 months.
- No subsequent positive NAT

3.1.2: Clinical Evidence

A note in a medical record by a physician or other qualified medical-care provider states that the patient is not infected with HIV.

5. Residence at Diagnosis

- For reports of HIV infection or perinatal HIV exposure, enter the patient’s city, county, state/country, and ZIP code of residence at the time of the first confirmatory test for HIV infection or when HIV infection was first considered, either clinically or through laboratory

evaluation.

- Documentation of an HIV test is often the earliest evidence that HIV diagnosis was considered, however, an HIV test may not have been ordered at that time.
- If the patient's residence changes between diagnosis of perinatal HIV exposure and confirmed HIV infection, record new address.
- If laboratory slips are not available, enter the patient's residence at the date of *physician diagnosis* of HIV infection. For HIV, stage 3 (AIDS) case reports, enter patient's residence at the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.
- For further guidance about residency assignment, see the file *Date and Place of Residence*.

7. Facility of Diagnosis

7.2 FACILITY NAME

- For reports of perinatal HIV exposure, enter the name of the facility where child was first evaluated for HIV infection, either clinically or through laboratory evaluation.
- The hospital where the mother obtained prenatal care should not be used to answer this question unless it was also the facility where the child was born and HIV infection was considered as a diagnosis at the time of the child's birth or at the time of subsequent physician/clinic visits.
- For reports of confirmed HIV infection, enter the name of the facility where the child was confirmed to be HIV-infected.
- If test results were not in the medical record, enter the name of the facility where the child's HIV infection was diagnosed and documented by the health care provider. Enter facility uniformly to prevent the occurrence of multiple names for a given facility.
- For HIV, stage 3 (AIDS) case reports, enter the name of the facility where the patient was first diagnosed with stage 3 (AIDS) based on the applicable case definition.
- These fields strictly apply to facility where HIV or HIV infection stage 3 (AIDS) was diagnosed. Where chart abstraction is conducted at a facility other than the Facility of Diagnosis (Section 4), document report source.

8. Patient History

- This information is often found in the mother's chart in the discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact the child's provider about maternal/child risk factor information.
- See the file *Risk Factor Ascertainment* for further guidance on risk factor data collection. This information can be difficult to find, particularly if the patient has not been interviewed. States should have risk factor ascertainment procedures tailored to their jurisdictions.

8.1 CHILD'S BIOLOGICAL MOTHER'S HIV INFECTION STATUS

- "Refused HIV testing" should be selected if mother's refusal is documented in the medical chart.
- If the biological mother has been tested for HIV and found to be uninfected at or after the child's birth, then perinatal transmission is not the presumed mode of exposure to HIV infection.
- If mother-to-infant transmission through breast-feeding is considered to be the only mode of transmission, please alert the state or local NIR coordinator, check "Yes" in the "Other documented Risk", and provide detail in the Comments section.
- If dates are not available, please review medical charts to determine when maternal HIV diagnosis occurred in relationship to the child's birth and select:
Known HIV+ before pregnancy;

Known HIV+ during pregnancy;
Known HIV+ sometime before birth;
Known HIV+ at delivery;
Known HIV+ after child's birth; or
HIV+, time of diagnosis unknown.

- If no information is available regarding maternal HIV status, please select: HIV status unknown.

8.2 DATE OF MOTHER'S FIRST POSITIVE HIV CONFIRMATORY TEST

- Enter the date of the mother's first positive test that confirmed HIV infection in *mm/dd/yyyy* format using '..' for unknown values (e.g., 03../2011).

8.5 BIOLOGICAL MOTHER HAD HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING

8.5.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION

- Do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
- If a transfusion of only platelets, other blood cells, or plasma was received by the partner, then code "No" and see question 8.5.4 below.

8.5.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION

- Refers to someone with documented HIV infection who received a transfusion of blood cells (red cells, white cells, platelets) or plasma.

9. Clinical: Opportunistic Illnesses

9.1 CLINICAL: OPPORTUNISTIC ILLNESSES

9.1.1–9.1.27 (**Optional**, applies to health department & health care providers)

- Select all that apply and enter diagnosis dates. Enter date in *mm/dd/yyyy* format using '..' for unknown values (e.g., 03../2011).
- For additional information, refer to the most recent case definition for HIV infection (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e).

11. Birth History (For Perinatal Cases only)

11.4 BIRTH HISTORY

11.4.4 BIRTH DEFECTS

- Data collected will be used to evaluate changes in incidence or other unusual patterns of serious birth defects among children exposed to zidovudine in utero compared with those who were not exposed and with the general population.
- Approximately 3%–4% of all babies will have serious birth defects (e.g., neural tube defects, congenital heart defects, esophageal atresia, and cleft lip/palate).
- The methods and definitions used were developed by the CDC National Center on Birth Defects and Developmental Disabilities and are currently used in the Metropolitan Atlanta Congenital Defects Program, an active surveillance system for birth defects in the Atlanta metropolitan area.
- Select "Yes" if the child meets the case definition for birth defects as defined by the CDC National Center on Birth Defects and Developmental Disabilities as listed below.

Criteria for Inclusion as Reportable Birth Defect:

- The child must have a structural or genetic birth defect or other specified birth outcome that can adversely affect his or her health and development;
- The structural or genetic birth defect must be diagnosed or its signs or

- symptoms recognized within the first year of life;
- The infant must have a gestational age of at least 20 weeks or a birth weight of at least 500 grams; and
- A case must be abstracted by the child's sixth birthday.

Criteria for Exclusion:

- Defects such as normal variants or minor anomalies are considered excludable. Diagnoses that may be normal variants or minor anomalies may be included only if associated with another reportable defect.
- Imprecise diagnoses (probable, possible, compatible with, consistent with, suspected, questionable, suggestive of, etc.) should be abstracted and coded as such and follow-up conducted to ascertain true status.
- For children with possible birth defects, please review newborn and hospital records including the face sheet; history and physical; discharge summary; operative, laboratory, x-ray, cardiac catheterization, and autopsy reports; and notes and consultations by physicians, nurses, and social and psychological services.
- In addition, birth defect (i.e., congenital anomalies) information is also collected on the standard US birth certificate.
- Hospital records should be reviewed to determine if a reportable defect is present. Each reportable condition is coded separately according to the birth defect code (see below). These codes are based on ICD-9 codes but provide more specific diagnostic information.
- If reportable birth defects are diagnosed, select "Yes" and abstract all diagnoses onto the case report form.
- Include discrepant diagnoses. Also include diagnoses appearing in the chart that have not been ruled out by an expert or lab test.
- If the infant is diagnosed with a syndrome, record the name and code of the syndrome as well as the individual defects.
- If there is a question about whether a diagnosis is reportable or how to code any diagnosis, please call the CDC HIV Incidence and Case Surveillance Branch (HICSB) at (404) 639-2050.

BIRTH DEFECTS CODE

- The 6-digit defect codes are based on 3- to 5-digit ICD-9-CM or ICD-10-CM codes from a birth certificate or medical records (or ICD-9 or ICD-10 codes from death certificates). The shorter codes may be used in place of the 6-digit codes. Enter the code for the birth defect given in the birth certificate, medical record, or death certificate. If the code is not available in those places, but the birth defect is described using medical terminology, then look up the corresponding code in the ICD-9-CM-based list (downloadable from <http://www.cdc.gov/ncbddd/birthdefects/macdp.html>) if the record was from before October 1, 2014, or in the ICD-10-CM-based list (downloadable from <http://www.cdc.gov/nchs/icd/icd10cm.htm>) if the record was from October 1, 2014 or later.
- If defects exist, list all on the case report form and enter in the Comments section.

11.4.7 MONTH OF PREGNANCY PRENATAL CARE BEGAN

- Enter “09” if care began in the ninth month or later.
- If entry is reported in weeks, convert to appropriate months as follows:

| Weeks | Months | Weeks | Months |
|-------|--------|-------|--------|
| 1–4 | 1 | 23–26 | 6 |
| 5–9 | 2 | 27–30 | 7 |
| 10–13 | 3 | 31–35 | 8 |
| 14–17 | 4 | 36+ | 9 |
| 18–22 | 5 | | |

11.4.10 DID MOTHER RECEIVE ARVs DURING PREGNANCY?

- Clinicians initiating antiretroviral regimens in the HIV-1-infected pregnant patient should refer to *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States* at <https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0>.

11.5 MATERNAL INFORMATION

11.5.2 MATERNAL LAST NAME SOUNDEX

- If not already complete, enter the name and date of birth of the patient’s biological mother in the CDC-supplied software. The SOUNDEX CODE will automatically be generated based on the biological mother’s surname.
- Retrieve the soundex code from the database and enter here.

12. Treatment/Services Referrals

12.3 ARV MEDICATIONS

- Please refer to the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection* <https://aidsinfo.nih.gov/guidelines/html/2/pediatric-treatment-guidelines/0/#>.

12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS?

- Please refer to *MMWR* 1995;44(RR-4):1–11 for the 1995 Revised Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia (PCP) for Children Infected with or Perinatally Exposed to HIV. Examples of PCP prophylaxis include Trimethoprim/sulfamethoxazole (TMP/SMX, Bactrim, Septra), Pentamidine, and Dapsone.
- TMP/SMX (Bactrim, Septra) can be used to treat infections other than HIV but is usually used for a shorter period. For example, TMP/SMX is used for 2–3 weeks to treat otitis media and would NOT be recorded as “Yes” in this field.
- Include as PCP prophylaxis if it is clearly noted as such in the medical chart or given for a period of 2 weeks or longer.

12.7 WAS THIS CHILD BREASTFED?

- Avoidance of breast-feeding to prevent postpartum transmission of HIV has been recommended for HIV-infected mothers in the United States.

12.8 THIS CHILD’S PRIMARY CARETAKER IS

- “Other relative” refers to children living with an aunt, grandmother, etc. in an informal arrangement, and the relative does not receive a stipend for providing care.
- If a child lives with a relative and that relative is paid a stipend for caring for the child, “Foster/Adoptive parent, relative” should be selected.
- A child is in “foster/adoptive parent, unrelated” if living with someone other than a relative.
- “Adoptive parent, relative” refers to child who has been legally adopted by a relative. This

includes children with deceased parents whose legal custody has been transferred to a relative.

- If the adoptive parent is unrelated please select “foster/adoptive parent, unrelated.” This includes children with deceased parents whose legal custody has been transferred to a person who is unrelated to the child.
- “Social service agency” refers to children whose primary caretaker is a social service agency, which usually refers to children living in group home situations.
- For children being cared for in situations not described above, select “other” and specify in this section.

Technical Guidance for HIV Surveillance Programs — Perinatal HIV Exposure Reporting (PHER) Form

Instructions for Completion

Purpose of Perinatal HIV Exposure Reporting (PHER) Form

The *Perinatal HIV Exposure Reporting* (PHER) form is used to collect information on perinatal exposure cases. The form facilitates collection of additional standardized data on HIV-exposed children. This guidance applies to data collection even if surveillance sites use a different form or medium for HIV case surveillance. Information on children who are perinatally exposed to HIV or who have HIV stage 3 (AIDS) is protected under a federal assurance of confidentiality.

The PHER Form in the Context of Document-Based Surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a given reported case, fill out the applicable part of the form for each data source contributing to that case.

Definition of Variable Designators

- **Required:** Variables that must be collected by all programs.
- **Recommended:** Variables that programs are strongly encouraged to collect but are not absolutely required.
- **Optional:** Variables that programs may or may not choose to collect.

Disposition of Form

- The completed PHER form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC). The Pacific Islands are the only jurisdictions that send forms to CDC for data entry and all patient identifiers must be removed before they are sent.
- Data obtained from these forms are entered into standardized computer software provided by the Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC (or other compatible software), linked to maternal records, and then transferred without identifiers to CDC. Electronic transfers are encrypted via secure data network.

Chart Abstraction Guidance

Accurate data abstraction is critical. For example, the dates of receipt of prenatal care should be before the infant's date of birth. If inconsistent information is found in medical records indicate that in the Comments section on the data abstraction form. This will serve as documentation that the inconsistency was in the medical record and is not an error in abstraction, notation, or data entry. The HIV Surveillance Coordinator in each project area, or their designee, should review all data abstraction forms before the data are entered.

Qualifications of Abstractors

- Abstractors should be familiar with the components of a medical record (e.g., demographic/financial information, doctor’s progress notes, prenatal care records, labor and delivery records, nurse’s notes, operative notes, lab results, discharge summaries, problem lists, drug lists, etc.).
- Abstractors should be familiar with medical abbreviations and terminology, especially as related to HIV.
- Abstractors should be familiar with the procedures required to abstract records from various providers and facilities.
- Abstractors must be trained in security and confidentiality (S&C) requirements and sign a statement of compliance. Health departments and academic institutions should have S&C training requirements and methods in place to document completion of this training.

Records to be Abstracted

- At a minimum the following records should be reviewed. Additional records may be reviewed if available (e.g., STD records, Health Department records).

Mother

Maternal prenatal records
Maternal labor and delivery records
Maternal HIV clinic records

Infant

Pediatric birth records (hospital records)
Birth certificate
Pediatric medical records (HIV clinic, non-HIV clinic, or other medical records)
Death certificate

Abstraction of Mother’s Records

- All maternal variables refer to information on the infant’s biologic mother.
- If it is not possible to obtain a medical chart for the mother, the PHER form should still be completed to the extent possible.
- If information on the mother is available in the infant’s chart and also in the mother’s chart, use the mother’s chart as the primary record for questions related to the mother’s care.

Abstraction of Infant’s Records

- Complete this form only for live births. The definition of a live birth as defined by the World Health Organization is:
‘...the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born.’
Thus, if a birth certificate has been completed for the infant, the record should be abstracted.
- If a woman has had several pregnancies during the project period, each pregnancy should be considered a separate event and should be abstracted separately.
- If the outcome of a pregnancy is multiple births (e.g., twins, triplets), a separate eHARS and supplemental exposure reporting form should be completed for each infant, however the maternal information need only be abstracted once.

Follow-up Chart Review

Review the pediatric chart at 6 months, 12 months, and 18 months (and at 6 month intervals thereafter if the child's infection status is still undetermined). When reviewing the pediatric chart, abstract all data needed for eHARS updates (e.g., HIV diagnostic tests, CD4 counts, treatment, prophylaxis, AIDS-defining conditions, birthweight, vital status, and birth defects). A new pediatric form should be completed documenting the updates. On the additional form the demographics section for both the mother and the infant should be completed as well as those portions of the form that need to be newly completed or updated. The updated infant's HIV diagnostic tests, CD4 counts, and viral load test results should be entered directly into eHARS.

Indicating 'Unknown'

A '99' should be checked or written to indicate an unknown value for any question. Type of response is indicated on the form. Unknown should only be checked if the source records are not available.

Not Documented

Responses of 'Not documented' should only be checked if the source records are available but there is no indication in the affirmative or negative for the question being asked.

Dates

All dates on this abstraction form should be written as month/day/year (*mm/dd/yyyy*) or Month/Year (*mm/yyyy*) as indicated on the form. If all or part of a date is unknown, '..' should be entered into the appropriate space (e.g., 02/./2005). No not use '99' to indicate unknown/missing dates. Be sure that the infant's date of birth is consistent with the date of delivery and that the dates of receipt of prenatal care, CD4 and viral load testing, receipt of antiretrovirals, and other data are based on this date of birth.

Records That Are 'Not Available'

Records will be considered 'not available' after two attempts, separated in time, have been made to review the record. Before a chart is considered 'not available', attempt to locate other sites of care where the chart may be located. Record not available should only be selected if the information cannot be obtained from any record source.

Conflicting Information

The medical chart from which a specific question should be answered depends on the question itself. For example, a maternal obstetrical chart and the HIV chart may have different dates for receipt of prenatal care. We recommend using information from the obstetrical chart. Similarly, if there are different start dates for administration of ARV, use the HIV infectious disease (HIV/ID) chart unless the obstetrical chart documents a good reason to the contrary (e.g., the OB/GYN physician may have also managed the patient's antiretroviral therapy). In general, obstetrical information should be pulled from the obstetrical prenatal or postnatal chart and HIV/ID information should be pulled from the HIV/ID chart.

Form Fields

The state/city number fields for the mother and infant at the top of the PHER Form are **required**.

U.S. Department of Health
& Human Services

Perinatal HIV Exposure Reporting (PHER)

Centers for Disease Control
and Prevention

Infant's State Number _____
Infant's City Number _____

Mother's State Number _____
Mother's City Number _____

Form Approved OMB No. 0920-0573 Exp. Date 06/30/2019

- 1. Child adopted or in foster care (Recommended, if applicable, applies to health department & health care providers).**

1. If information on the mother is not available, was the child adopted, or in foster care?
 Yes No Not applicable

- Select 'Yes' only if the maternal information is not available due to child being adopted, in foster care or abandoned.
 - If the maternal information is not available for other reasons, check 'No'. Else, check 'Not applicable'.
- 2. Records abstracted (Optional, if applicable, applies to health department & health care providers).**

2. Records abstracted
(1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again)

| | |
|-----------------------------------|--|
| ___ Prenatal care records | ___ Pediatric medical records (non-HIV clinic or provider) |
| ___ Maternal HIV clinic records | ___ Birth certificate |
| ___ Labor and delivery records | ___ Death certificate |
| ___ Pediatric birth records | ___ Health department records |
| ___ Pediatric HIV medical records | ___ Other (Specify.) _____ |

- For each type of record, code whether it was: (1) abstracted; (2) attempted but record was not available; (3) not abstracted; or (4) attempted, will try again.
 - Do not simply indicate an X or √ for each record abstracted, rather, use the appropriate number code.
- 3. Week's gestation at first prenatal care visit (Required, if applicable, applies to health department & health care providers).**

3. Weeks' gestation at first prenatal care visit
___ weeks

- Enter value in weeks.
 - A prenatal care visit is the first visit where intake information is obtained. Normally a woman knows she is pregnant at the time of this first prenatal care visit. A visit to a doctor to confirm pregnancy status would not be considered the first prenatal care visit unless intake data and other services typical of the first prenatal care visit are obtained at the time of that confirmation. Such services would include intake prenatal blood tests, for example. If the woman had been seen by more than one prenatal care provider, then the date of the visit to the first prenatal care provider seen should be documented.
- 4. Screening of mother for disease during pregnancy (Recommended, if applicable, applies to health department & health care providers).**

| 4. Was the mother screened for any of the following during pregnancy? (Check test performed before birth, but closest to date of delivery or admission to labor and delivery.) | | | | | | |
|---|--------------------------|-------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Yes | Date (mm/dd/yyyy) | No | Not documented | Record not available | Unknown |
| Group B strep | <input type="checkbox"/> | ____/____/____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hepatitis B (HBsAg) | <input type="checkbox"/> | ____/____/____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Rubella | <input type="checkbox"/> | ____/____/____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Syphilis | <input type="checkbox"/> | ____/____/____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- Use test done prior to birth but closest to delivery date or at admission for labor and delivery.
- 4.1 **GROUP B STREP (GBS)** - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized into early onset (1st week of life) and late-onset (usually at 3-4 weeks of life). Colonization late in pregnant women and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
- Screening all pregnant women at 35 to 37 weeks for vaginal and rectal GBS colonization and offering intrapartum chemoprophylaxis to those identified as GBS carriers; or
 - Risk factor based strategy - prophylaxis given to women with intrapartum risk factors including gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature of 38° C or greater.
- 4.2 **HEPATITIS B** (Hepatitis B surface antigen, HBsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant women is recommended. Babies of mothers who are HbsAg (+) must have HBIG and HBV vaccine within 12 hours of birth to prevent perinatal HBV infection. Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg), or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). This test is usually done at the initial prenatal visit or at the time of labor and delivery for high risk women and women whose status is unknown.
- 4.3 **RUBELLA** - Screening is usually done at the initial prenatal visit. If ‘negative’ the mother should be immunized.
- 4.4 **SYPHILIS** - All pregnant women should receive serologic screening for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL and RPR). In addition, screening is recommended in the third trimester for those in high risk prevalence areas or for women at high risk. Nontreponemal antibody tests are used for screening purposes and presumptive diagnosis: VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test; STS serologic test for syphilis, syphilis screening test); ART (automated reagin test). The nontreponemal antibody test should be confirmed with a treponemal antibody test (e.g., FTA-ABS, MHA-TP). If a pregnant woman has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred.
(Reference: Red Book 2000- American Academy of Pediatrics).

5. Diagnosis (for the mother) during this pregnancy or at time of labor and delivery
(Recommended, if applicable, applies to health department & health care providers).

| 5. Diagnosis (for the mother) of the following conditions during this pregnancy or at the time of labor and delivery (See instructions for data abstraction for definitions.) | | | | | | |
|--|--------------------------|-------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Yes | Date (mm/dd/yyyy) | No | Not documented | Record not available | Unknown |
| Bacterial vaginosis | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>Chlamydia trachomatis</i> infection | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Genital herpes | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Gonorrhea | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Group B strep | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hepatitis B (HbsAg+) | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hepatitis C | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PID | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Syphilis | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Trichomoniasis | <input type="checkbox"/> | ___/___/_____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- For this question, “diagnosed” refers to newly diagnosed, a recurrence of, or a chronic infection with any of the following conditions. Screening for syphilis, gonorrhea, and chlamydia is typically done during prenatal care. Generally, diagnosis of an STD/STI will be documented in multiple places in the chart including progress notes, a prenatal clinic visit summary sheet (which should include summary of lab tests for various sexually transmitted diseases), lab results section, or in sexually transmitted disease summary sheets (typical in public health clinics).
- Diagnoses may be presumptive or definitive depending on symptoms and lab tests. If a diagnosis is made either presumptively or definitively, note the answer as ‘Yes’. Specific criteria for answering ‘Yes’ to this question are outlined below.
- All dates on this abstraction form should be written as month/day/year (*mm/dd/yyyy*) or Month/Year (*mm/yyyy*) as indicated on the form. If all or part of a date is unknown, ‘.’ should be entered into the appropriate space (e.g., 03/./2011). No not use ‘99’ to indicate unknown/missing dates.

5.1 BACTERIAL VAGINOSIS - Clinician diagnosis of bacterial vaginosis. Sometimes abbreviated BV.

5.2 CHLAMYDIA (*Chlamydia trachomatis*) - Record positive test for chlamydia (a positive culture, positive EIA, or detection of chlamydial antigen or nucleic acid).

- Name of lab tests - *Chlamydia* cell culture (TRIC Agent Culture); direct fluorescent antibody (DFA) tests; enzyme immunoassay (EIA) tests; nucleic hybridization (DNA probe) tests; and PCR and LCR.

5.3 GENITAL HERPES - Active (herpes genitalis) - Primary herpes (first episode of herpes) or recurrence of herpes during pregnancy or at labor and delivery.

- Name of lab tests - herpes virus culture; herpes cytology (herpetic inclusion bodies, cytology, inclusion body stain, Tzanck smear, Giemsa stain viral study); rapid diagnostic tests- direct immunofluorescent AB or EIA; HSV Ag; or polymerase chain reaction (PCR).

5.4 GONORRHEA (*Neisseria gonorrhoea*) - Record if culture positive.

- Name of lab tests - *Neisseria gonorrhoea* culture (GC Culture, Gonorrhea Culture); Thayer-Martin medium; chocolate agar; detection of nucleic acid.

- 5.5 GROUP B STREP - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized as early onset (1st week of life) and late-onset (usually at 3-4 weeks of life). Colonization late in pregnant women and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
- Screening all pregnant women at 35 to 37 weeks for vaginal & rectal GBS colonization, offering intrapartum chemoprophylaxis to those identified as GBS carriers; or
 - Risk factor based strategy in which prophylaxis is given to women with intrapartum risk factors: gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature 38° C or greater.
- 5.6 HEPATITIS B (Hepatitis B surface antigen, HbsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant women is recommended. Babies of mothers who are HbsAg (+) must have HBIG & HBV vaccine within 12 hours of birth to prevent perinatal HBV infection.
- Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg) or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). Tests are usually done at the initial prenatal visit or at the time of labor and delivery for high risk women and women whose status is unknown.
- 5.7 HEPATITIS C - Tests do not distinguish between acute, chronic, or resolved infection. Diagnosis by antibody assays involves initial screening EIA. Repeatedly positive results are confirmed by a recombinant immunoblot assay (RIBA). Highly sensitive PCR assays for detection of HCV RNA are also available.
- Name of lab test - EIA (Enzyme immunoassay) screen, confirmed by recombinant immunoblot assay (RIBA).
- 5.8 PELVIC INFLAMMATORY DISEASE (PID) - Look for documentation of a clinical diagnosis of PID. A note stating 'rule out PID' does not indicate the woman had PID.
- 5.9 SYPHILIS (*Treponema pallidum*) - All pregnant woman should receive a serologic screen for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL, RPR, STS, and ART) and preferably again at delivery. In addition, screening is recommended in the third trimester for those in high prevalence areas or those at high risk.
- Nontreponemal antibody tests are used for screening. Any reactive nontreponemal test must be confirmed by a specific treponemal test (FTA-ABS and MHA-TP) to exclude false positive results which can be caused by a viral infection (e.g., infectious mononucleosis, hepatitis, varicella and measles), lymphoma, TB, malaria, endocarditis, connective tissue disease, pregnancy, or abuse of injection drugs. If a pregnant woman has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred. A positive FTA-ABS or MHA-TP usually remains reactive for life, even after successful therapy. Also, look for evidence of treatment for syphilis - receipt of penicillin (bicillin) 2.4 million units is the standard treatment for syphilis in the mother. Check whether the child was diagnosed with or treated for congenital syphilis with penicillin for 10 days. A physician diagnosis will be clearly documented in the infant's birth chart. Also check the congenital syphilis registry to confirm congenital syphilis, with consideration for confidentiality and security of an individual's HIV or stage 3 or AIDS status.

- Name of lab tests - *Presumptive* diagnosis: nontreponemal tests (for screening purposes) VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test, serologic test for syphilis, STS, syphilis screening test, ART-automated reagin test). *Definitive* diagnosis: treponemal tests (for diagnostic purposes) Darkfield examination (Darkfield microscopy, syphilis; *Treponema Pallidum* Darkfield examination); FTA-ABS (Fluorescent Treponemal Antibody Absorbed Test, Fluorescent Treponemal Antibody Adsorption); MHA-TP (Microhemagglutination assay for Antibody to *Treponema Pallidum*; Microhemagglutination, *Treponema Pallidum*.

5.10 TRICHOMONAS (*Trichomonas vaginalis*) - Record clinician diagnosis of trichomonas. Trichomonas is diagnosed by finding trichomonas on a wet mount.

- Name of lab tests - Trichomonas preparation (Hanging Drop Mount for Trichomonas, *Trichomonas vaginalis* wet preparation; Trich Prep; wet preparation for *Trichomonas vaginalis*.

6. Mother’s reproductive history (Optional, if applicable, applies to health department & health care providers).

| | | | |
|---|---|---------------------------------------|--|
| 6. Mother’s reproductive history | | | |
| _____ No. of previous pregnancies | _____ No. of previous miscarriages or stillbirths | | |
| _____ No. of previous live births | _____ No. of previous induced abortions OR | _____ Total No. of previous abortions | |

- An obstetrical history should be documented at the first prenatal visit in the progress notes section or the prenatal care flow sheet. The obstetrical history should list the outcome of all the woman’s past pregnancies.

6.1 NUMBER OF PREVIOUS PREGNANCIES: This number should include all pregnancies, regardless of outcome (e.g., including abortions and miscarriages) up to but EXCLUDING the pregnancy that is being abstracted.

6.2 NUMBER OF PREVIOUS LIVE BIRTHS: The number of live births is the total preterm and term births (excluding abortions, miscarriages, and stillbirths). Note that parity (commonly reported in medical charts) refers to the number of viable pregnancies, that is, the number of pregnancies carried to 20 weeks. Parity excludes miscarriages and elective abortions but includes stillbirths. Parity cannot be used for this answer.

6.3 NUMBER OF PREVIOUS MISCARRIAGES: A miscarriage is an abortion which occurs naturally and may also be referred to as a ‘spontaneous abortion’ (SAB). A spontaneous abortion is a fetal death that occurs before 20 weeks (a stillbirth is a fetal death that occurs at or after 20 weeks). Record the number of miscarriages.

6.4 NUMBER OF PREVIOUS INDUCED ABORTIONS: An ‘induced’ abortion is brought on purposely and may also be known as an ‘artificial’ or ‘therapeutic’ abortion (TAB), or referred to as a ‘termination of pregnancy’ (TOP). In cases where the woman has had an abortion, the chart may abbreviate this as ‘A’ or ‘Ab’ or ‘TAB’ or ‘TOP’ followed by a number designating the number of abortions prior to this pregnancy. Record the number of induced abortions.

- *The medical record does not always differentiate spontaneous from elective abortions. In those cases the only data available is ‘total’.* Number of total abortions: *spontaneous abortion + elective abortion = total.* The total number of abortions is usually noted at intake at the time of the first prenatal care visit in the obstetrical history. If the provider documented parity as a four-digit number, the third digit (number of pregnancies ending in abortion) can be used to answer this question. Remember to record the number of previous induced abortions (above) AND the number of previous miscarriages (above) OR (if the chart does not break these two categories out) the total number of abortions, but not both.

Note on G_P_Abbreviations In the Medical Record: This information is often written in the following format: G _ P_, as in G₅ P₃ or it may be written as G₅P₃A₁. The ‘G’ (gravida) refers to the total number of pregnancies (including current pregnancy), the ‘P’ (para) to the number of live births (at least 20 weeks gestation) and the ‘A’ to the number of induced and spontaneous abortions. Information on gravida status is usually noted at intake at the time of the first prenatal care visit. Also note that ‘multigravida’ refers to a woman who has been pregnant more than once, ‘primigravida’ refers to a woman who is pregnant for the first time (by definition, has no prior pregnancies), and a ‘grand multiparous’ woman refers to a woman who has had more than 5 pregnancies.

- G = gravida, the number of pregnancies including the current pregnancy;
- P = parity, the number of pregnancies > 20 weeks gestation (excludes miscarriages and 1st trimester abortions); and
- A = Abortion, the number of abortions (both spontaneous and induced abortions).

For example, a woman who is G₅ P₃A₁ has been pregnant 5 times (including the current pregnancy), 3 of those pregnancies were carried to at least 20 weeks gestation, and she had 1 spontaneous or induced abortion.

Parity may also be documented as a four digit number. The first digit represents the number of pregnancies delivered at full-term (at least 37 weeks gestation). The second digit represents the number of pregnancies delivered pre-term (20-37 weeks). The third digit represents the number of abortions including spontaneous or therapeutic abortions; and the last digit represents the number of living children the woman currently has.

P = parity may be documented as a 4 digit number:

1st digit = term pregnancies (>37 weeks);

2nd digit = preterm pregnancies (20-37 weeks);

3rd digit = abortions (includes both spontaneous and induced abortions); and

4th digit = living children

For example, a woman’s record may read G₅ P₂₁₁₃. This woman has delivered 2 infants who were full-term, delivered one infant pre-term, had one abortion and has 3 living children. This patient is currently pregnant (total number of pregnancies=5) and she has had four previous pregnancies.

If you are using G_P_ notation to complete Q.6, remember that you will have to subtract the current pregnancy from the gravida (G) notation.

This format is not always followed exactly as described here. When possible, it will be useful to ask clinic nurses what their standard notation is.

7. Complete the chart for all siblings (Recommended, if applicable, applies to health department & health care providers).

| 7. Complete the chart for all siblings. | | | | |
|---|---------------------------------|------------------------------------|-----------------|----------------|
| Date of birth (mm/dd/yyyy) | Age (yrs: mos as of mm/yyyy) | HIV serostatus (See list below) | State Number | City Number |
| Sib 1 | ___/___/___ | :___ as of ___/___/___ | _____ | _____ |
| Sib 2 | ___/___/___ | :___ as of ___/___/___ | _____ | _____ |
| Sib 3 | ___/___/___ | :___ as of ___/___/___ | _____ | _____ |
| Sib 4 | ___/___/___ | :___ as of ___/___/___ | _____ | _____ |

HIV serostatus: **1** = Infected, **2** = Not infected, **3** = Indeterminate, **9** = Not documented, **U** = Unknown

- If possible, record the dates of birth and/or age in years and months of live born siblings.
- Indicate the current serostatus of the sibling and the STATENO and the CITYNO. This information is not always available on prenatal care charts or labor and delivery records.

8. Substance use during pregnancy (Recommended, if applicable, applies to health department & health care providers).

8. Was substance use during pregnancy noted in the medical or social work records?
 Yes No (Go to 9) Record not available (Go to 9) Unknown

8a. If yes, indicate which substances were used during pregnancy. (Check all that apply)

| | | | |
|--|--|--|--|
| <input type="checkbox"/> Alcohol | <input type="checkbox"/> Cocaine | <input type="checkbox"/> Marijuana (cannabis, THC, cannabinoids) | <input type="checkbox"/> Opiates |
| <input type="checkbox"/> Amphetamines | <input type="checkbox"/> Crack cocaine | <input type="checkbox"/> Methadone | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Barbiturates | <input type="checkbox"/> Hallucinogens | <input type="checkbox"/> Methamphetamines | <input type="checkbox"/> Specific drug(s) not documented |
| <input type="checkbox"/> Benzodiazepines | <input type="checkbox"/> Heroin | <input type="checkbox"/> Nicotine (any tobacco product) | |

8b. If substances used, were any injected?
 Yes No Not documented Unknown Specify injected substance(s). _____

- This section provides information on whether substance use occurred during the mother’s pregnancy.
- This information is typically found in the progress notes, social worker notes, lab results summary section, or in the summary sheet listing all prenatal care visits, lab results, gestational ages, and other information.

8.1 WAS SUBSTANCE USED DURING PREGNANCY?

- Indicate whether substances were used during pregnancy by selecting “Yes”, “No”, “Record not available”, or “Unknown”.
- If ‘Yes’, indicate which substances were used. The drugs listed here are in alphabetical order and may be checked if there is evidence of a toxicology screen or a notation in records not based on a toxicology screen (e.g., patient self-report).
- Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology lab results sheet.
- Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid, THC or simply marijuana.
- Methadone is a synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as ‘Yes’ to this question.
- If ‘Other’, be sure to specify the name of the drug(s) used.

8.2 IF SUBSTANCE USED, WERE ANY INJECTED?

- If ‘Yes’, write the name of the drug in the space provided.

9. Was toxicology screen done on mother? (Recommended, if applicable, applies to health department & health care providers).

9. Was a toxicology screen done on the mother (either during pregnancy or at the time of delivery)?

Yes, positive result (Check all that apply)

| | | | |
|--|--|--|--|
| <input type="checkbox"/> Alcohol | <input type="checkbox"/> Cocaine | <input type="checkbox"/> Marijuana (cannabis, THC, cannabinoids) | <input type="checkbox"/> Opiates |
| <input type="checkbox"/> Amphetamines | <input type="checkbox"/> Crack cocaine | <input type="checkbox"/> Methadone | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Barbiturates | <input type="checkbox"/> Hallucinogens | <input type="checkbox"/> Methamphetamines | <input type="checkbox"/> Specific drug(s) not documented |
| <input type="checkbox"/> Benzodiazepines | <input type="checkbox"/> Heroin | <input type="checkbox"/> Nicotine (any tobacco product) | |

Yes, negative result
 No
 Toxicology screen not documented

- Check ‘Yes, positive result’ for any drug testing positive and indicate the drug resulting in the positive test.
- Check ‘Yes, negative result’ if a screen was conducted and all drugs tested for were negative.
- Check ‘No’ if it is known that a screen was not conducted.
- Otherwise check ‘Toxicology screen not documented’ if no testing or results are documented in any records.
- The toxicology testing must have been completed during pregnancy, not before pregnancy.
- Toxicology screens are usually done using urine or serum and are usually listed as ‘positive’ if there is evidence of the drug in the urine or blood serum.
- Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology lab results sheet.
- Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid, THC or simply marijuana.
- Methadone is a totally synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as ‘Yes’ to this question.
- If ‘Other’, be sure to specify the name of the drug(s) used.
- Select the appropriate response(s) from given legal values. If screening for ‘Other’ drug was done, be sure to indicate what the drug was in the space provided.

10. Toxicology screen on infant at birth (Recommended, if applicable, applies to health department & health care providers).

10. Was a toxicology screen done on the infant at birth?

Yes, positive result (Check all that apply)

| | | | |
|--|--|--|--|
| <input type="checkbox"/> Alcohol | <input type="checkbox"/> Cocaine | <input type="checkbox"/> Marijuana (cannabis, THC, cannabinoids) | <input type="checkbox"/> Opiates |
| <input type="checkbox"/> Amphetamines | <input type="checkbox"/> Crack cocaine | <input type="checkbox"/> Methadone | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Barbiturates | <input type="checkbox"/> Hallucinogens | <input type="checkbox"/> Methamphetamines | <input type="checkbox"/> Specific drug(s) not documented |
| <input type="checkbox"/> Benzodiazepines | <input type="checkbox"/> Heroin | <input type="checkbox"/> Nicotine (any tobacco product) | |

Yes, negative result
 No
 Toxicology screen not documented

- Most toxicology screens on infants are done using urine. A positive screen at birth indicates illicit maternal drug use before delivery. This information should be noted in the infant's birth chart.
- See toxicology report interpretation in section 9 above.
- Select all drugs identified on screening, including methadone.
- If screening for 'Other' drug was done, specify the drug metabolites in the space provided.

11. Mother's HIV serostatus (Required, if applicable, applies to health department & health care providers).

11. Was the mother's HIV serostatus noted in her prenatal care medical records?

- Yes, HIV-positive Yes, HIV-negative No No prenatal care Record not available Unknown

- This information may be found in the history or progress notes, or on a lab report.
- Select "No" if there is evidence of prenatal care but no indication that an HIV test was conducted.
- If no prenatal care was received, indicate "No prenatal care".

12. Antiretroviral drugs prescribed for mother (Required, if applicable, applies to health department & health care providers).

12. Were antiretroviral drugs prescribed for the mother during this pregnancy?

- Yes (Complete table) No (Go to 12a) Not documented (Go to 13) Record not available (Go to 13) Unknown (Go to 13)

| | Drug name | Drug refused | Date drug started (mm/dd/yyyy) | Gestational age drug started (weeks; round down) | Drug stopped | | | Date stopped (if yes in preceding column) (mm/dd/yyyy) | Stop codes (See list on p. 4) |
|------|-----------|--------------------------|--------------------------------|--|--------------------------|--------------------------|--------------------------|--|-------------------------------|
| | | | | | Yes | No | ND | | |
| i. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| ii. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| iii. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| iv. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| v. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| vi. | _____ | <input type="checkbox"/> | ___/___/___ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |

(After completing table, go to 13)

12a. If no antiretroviral drug was prescribed during pregnancy, check reason.

- No prenatal care Mother known to be HIV-negative during pregnancy Not documented Unknown
 HIV serostatus of mother unknown Mother refused Other (Specify) _____

12.1 WERE ANTIRETROVIRAL DRUGS PRESCRIBED FOR THE MOTHER DURING THIS PREGNANCY?

- 'During this pregnancy' refers to the time up to, but not including, labor and delivery.
- Select 'yes' if the mother was previously taking, began taking, or restarted antiretroviral medications after interruption during the 1st trimester. See section 12.2 for instructions on coding individual drugs.
- Select 'no' if no ARV was prescribed during this pregnancy. See section 12.3 for instructions on coding why no ARV was prescribed.

12.2 IF 'YES', ANTIRETROVIRAL DRUGS PRESCRIBED FOR THE MOTHER DURING THIS PREGNANCY.

- DRUG NAME - Note all antiretrovirals either used or refused during the pregnancy. COMBIVIR is a combination of ZDV (AZT) and 3TC. If combivir is discontinued during pregnancy but either ZDV (AZT) or 3TC (lamivudine) is continued, code Combivir as

stopped and indicate that ZDV or 3TC was begun (as a single drug) and the date this change was made. If the woman received drug therapy as part of ACTG 316, receipt of NEVIRAPINE should not be indicated on the antiretroviral drug chart since it is not known whether the mother received the drug or the placebo. If the specific drugs she received or refused are unknown, complete the grid and write ‘Unknown’ in the ‘Drug Name’ column. Also, enter the receipt of ARVs during pregnancy in eHARS.

- DRUG REFUSED - If any antiretroviral drug was refused, write the name of the drug in the grid and check the column labeled ‘Drug Refused’. Do not assume that a woman who did not receive antiretroviral drugs refused the drugs; she may not have been offered ARV medications. Only code ‘refused’ if refusal is documented. This is asked to distinguish between women who were not prescribed drugs because they were not offered and those who were not prescribed drugs because they refused them.
- DATE DRUG STARTED - Enter the date the drug was started in *mm/dd/yyyy* format using ‘.’ for unknown values (i.e., 03../2011). In the case of a woman having interrupted antiretroviral medications due to pregnancy, the column ‘Date Started’ refers to the date when the mother initially started the antiretroviral drugs.
- GESTATIONAL AGE STARTED - Enter week of gestation antiretrovirals were started. Round down to the nearest completed week of gestation (e.g., if the medical chart indicates 37 4/7 weeks then round to 37 weeks). In the case of a woman having interrupted antiretroviral medications due to pregnancy, the column ‘Gestational Age Started’ refers to the gestational age when the mother initially started the antiretroviral drugs. If the week is unknown then indicate ‘99’ for Unknown.
- DRUG STOPPED - If the drug was stopped (discontinued) prior to the birth of the infant but administered sometime during the pregnancy, indicate ‘Yes’, the drug was stopped. Enter ‘ND’ if it is not documented.
- DATE STOPPED - Enter date the antiretrovirals were stopped (if completely discontinued) in *mm/dd/yyyy* format using ‘.’ for unknown values (i.e., 03../2011).
- DRUG STOP CODE - To answer this question, use the stop codes found at the end of the abstraction form. Up to two codes are allowed. If there are more than two reasons why a drug is stopped, indicate the two most important reasons. Code the reasons as they are written in the physician’s notes. Do not attempt to provide reasons if they are not clearly documented in the chart. If a woman interrupts use only temporarily, for example while she is in the first 3 months of pregnancy and then restarts, do not code as stopped.
- Enter ‘Unknown’ in the ‘Drug Name’ column if the specific drugs she received are unknown.

12.3 IF NO ARV WAS PRESCRIBED IN PREGNANCY, INDICATE REASON:

- NO PRENATAL CARE - The mother did not receive any prenatal care during her pregnancy.
- HIV STATUS OF MOTHER UNKNOWN - The physician may not have known the HIV status of mother because she refused testing or the physician did not offer testing. Sometimes the mother is not identified as being HIV positive until after delivery.
- MOTHER KNOWN TO BE HIV NEGATIVE DURING PREGNANCY - If the mother tested HIV negative during pregnancy (with no further testing to indicate HIV seroconversion), she would not receive ARV for prevention of perinatal transmission. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.
- MOTHER REFUSED - Mother refused ARV during pregnancy.
- OTHER - If ‘Other’ is indicated, be sure to specify why ARV was not prescribed.
- NOT DOCUMENTED - Indicate ‘Not Documented’ if the woman was not prescribed ARV but the reason why is not known.

13. Was mother’s HIV serostatus noted in her labor and delivery records? (Required, if applicable, applies to health department & health care providers).

13. Was mother’s HIV serostatus noted in her labor and delivery records?

Yes, HIV-positive Yes, HIV-negative No Record not available Unknown

- Select ‘Yes, HIV-Positive’ if there is explicit reference to her positive HIV status in the chart (including receipt of ARV). For the majority of women tested before or during pregnancy, the answer here is ‘Yes, Positive’. For some patients the HIV test date may not be documented at all. The chart should indicate, however, she was known to be HIV-infected during her pregnancy. In such cases, check ‘Yes, HIV-positive’.
- Select ‘Yes, HIV-negative’ if there is explicit reference to her negative HIV status in the chart. This must be evident by the presence of a negative test result.
- Select ‘No’ if:
 - The progress notes in the prenatal records state that this is a woman at risk for HIV infection but that her HIV infection status is unknown.
 - The woman may have been tested before delivery, but appears not to be known to be HIV-infected by medical staff include: being tested so late in pregnancy that results are not available before delivery, failure of physicians to inquire about HIV status, failure to be offered a test during prenatal care, and failure of patient to disclose.

14. Did mother receive antiretroviral drugs during labor and delivery? (Required, if applicable, applies to health department & health care providers).

14. Did mother receive antiretroviral drugs during labor and delivery?

Yes (Complete table) No (Go to 14a) Not documented (Go to 15) Record not available (Go to 15) Unknown (Go to 15)

| | Drug name | Drug refused | Date received (mm/dd/yyyy) | Time received (See military time) | Type of administration | | |
|------|-----------|--------------------------|----------------------------|-----------------------------------|--------------------------|--------------------------|--------------------------|
| | | | | | Oral | IV | Not documented |
| i. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ii. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iii. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iv. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| v. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| vi. | _____ | <input type="checkbox"/> | __/__/____ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

(After completing the table, go to 15)

Military time: noon = 12:00; midnight = 00:00

14a. If no antiretroviral drug was received during labor and delivery, check reason.

- Precipitous delivery/STAT Cesarean delivery
- HIV serostatus of mother unknown
- Mother tested HIV-negative during pregnancy
- Other (Specify) _____
- Prescribed but not administered
- Birth not in hospital
- Mother refused
- Not documented
- Unknown

- The labor and delivery period is also termed the intrapartum period and refers to the time from which the woman was admitted to the hospital for labor to the time of delivery.

14.1 Select appropriate response from given values of “Yes”, “No”, “Not documented”, “Record not available”, and “Unknown”.

- Select ‘Yes’ if ARVs received during the intrapartum period, and complete the table for all drugs received during labor and delivery. Enter “Unknown” in the ‘Drug Name’ column if the specific drugs received are unknown.
 - Enter the date the drug was started in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011). Write time in military hours (e.g., 9:15 a.m. is 09:15, 1:00 p.m. is 13:00). Midnight is 00:00 and noon is 12:00. To calculate military time count the number of hours and minutes past midnight or 00:00 hours. Indicate if the drug was administered orally, through IV, or not documented.
- Select “No” if no ARV was received during labor & delivery, and indicate reason from the following given legal values:
 - *Precipitous delivery/STAT C-section* - In some cases an eminent delivery of an infant may preclude prescription and/or administration of ARV.
 - *Prescribed but not administered* - There are instances where a physician has ordered the medication, but the mother never received it. Possible reasons would include not having the specific ARV in the hospital pharmacy. If the ARV was prescribed but not administered because the women delivered prior to administration, check the previous box for ‘Precipitous delivery/STAT c-section’.
 - *HIV serostatus of mother unknown* - The physician may not have known the HIV status of mother either because she refused testing or the physician did not offer testing. Sometimes the mother is not identified as being HIV positive until after delivery.
 - *Birth not in hospital* - If the birth occurred outside a hospital, in all likelihood ARV would not have been administered.
 - *Mother tested HIV negative during pregnancy* - Some women may become HIV positive during pregnancy. The mother may have tested HIV negative at some point during pregnancy and was never retested and determined to be HIV positive. In this case she may not have been prescribed ARV during labor and delivery because she was believed to be HIV negative. There must be evidence of a negative test during pregnancy or at labor and delivery in the chart; do not use patient report.
 - *Mother Refused* - Mother refused ARV at labor and delivery.
 - *Other* - If ‘Other’ is indicated, be sure to specify why ARV was not prescribed.
- Select “Not Documented” if the woman was not prescribed ARV but the reason why is not known.
- Drug Refused - If any antiretroviral drug was refused, write the name of the drug in the grid and check ‘Yes’ in the column labeled ‘Was Drug Refused’. Do not assume that a woman who did not receive antiretroviral drugs refused the drugs - they may not have been offered. Only code ‘refused’ if refusal is documented. Our goal is to sort out women who did not receive drugs because it was not offered to them, and those who did not receive it because they refused it.

15. Was mother referred for HIV care after delivery? (Recommended, if applicable, applies to health department & health care providers).

15. Was mother referred for HIV care after delivery?

Yes
 No (Go to 17)
 Not documented (Go to 17)
 Record not available (Go to 17)
 Unknown

- Indicate if the mother was referred for HIV care after delivery. An indicator for this could be a CD4 or viral load test after the mother's discharge from the hospital following delivery of the infant. This information is usually found in the mother's chart. If not, indicate 'Not documented'.

16. If yes, indicate first CD4 or first viral load result after discharge from the hospital (up to 6 months after discharge). (Required, if applicable, applies to health department & health care providers).

| 16. If yes, indicate mother's first CD4 result or first viral load result after discharge from hospital (up to 6 months after discharge). | | | | | |
|---|--|-------------------------------|-----------------------------------|--|-------------------------------|
| 16a. CD4 result | | | 16b. Viral load result | | |
| <input type="checkbox"/> Not done | <input type="checkbox"/> Not available | | <input type="checkbox"/> Not done | <input type="checkbox"/> Not available | |
| Result | Unit | Date blood drawn (mm/dd/yyyy) | Result in copies/mL | Result in logs | Date blood drawn (mm/dd/yyyy) |
| _____ | cells/ μ L | ___/___/___ | _____ | _____ | ___/___/___ |
| ___ | % | ___/___/___ | | | |

- This question is most relevant for those project areas that have laboratory reporting of CD4 counts and viral loads. If the mother receives CD4 or viral load testing this information can be used as a marker that the mother has received care after delivery.
- Indicate the first CD4 count and percentage and the first viral load result following the mother's discharge from the hospital (after delivery of the infant). This information will most likely be found in the mother's clinic chart. If there is no indication of a subsequent CD4 or viral load result, mark 'Not done'.
- See the PCRF, Section 9 above, for instructions on coding CD4 and viral load results.

17. Birth information (Required, if applicable, applies to health department & health care providers).

| 17. Birth information | | | | | |
|--|---|-------------------|----------------------|--------------------------|-------------------|
| <input type="checkbox"/> Birth not in hospital | <input type="checkbox"/> Record not available | | | | |
| | Time (See military time) | Date (mm/dd/yyyy) | | Time (See military time) | Date (mm/dd/yyyy) |
| Onset of labor | ___:___ | ___/___/___ | Rupture of membranes | ___:___ | ___/___/___ |
| Admission to labor and delivery | ___:___ | ___/___/___ | Delivery | ___:___ | ___/___/___ |

Military time: noon = 12:00; midnight = 00:00

- This information may be listed in the labor and delivery record or in a dictated/transcribed labor and delivery summary by the physician. Write time in military hours (e.g., 9:15 a.m. is 09:15, 1:00 p.m. is 13:00). Midnight is 00:00 and noon is 12:00. To calculate military time count the number of hours and minutes after midnight or 00:00 hours. Enter the date in *mm/dd/yyyy* format using '..' for unknown values (e.g., 03/./2011).
- **Onset of labor** - This should be found on the labor and delivery summary sheet. The onset of labor is defined as the time when contractions are 3-5 minutes apart. The date and time are necessary to calculate the duration of ruptured membranes, and duration of labor. In an 'elective cesarean section' there will not be onset contractions, because by definition, an elective cesarean occurs prior to onset of labor. In this case, write 'none' in the space provided.
- **Admission to Labor and Delivery** - Time of admission should be available on the face sheet (likely stamped on this sheet). If possible, record the time of admission to Labor and Delivery (L&D), rather than to hospital. A short time between admission and delivery ('precipitous delivery') may be a reason for not receiving ARVs. You should make sure that the date and time of admission to L&D is for the admission associated with delivery. The woman may have been admitted on another date and/or time for false labor or some other reason and sent home, then readmitted for delivery.
- **Rupture of membranes** - This should be found on the labor and delivery summary sheet.

The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. Rupture of membranes refers to the time when the amniotic sac is either purposely broken or ruptures on its own. When a physician/health care provider ruptures the membranes this is referred to as artificial rupture of membranes--often abbreviated as AROM. When membranes rupture on their own, spontaneously, this is referred to as spontaneous rupture of membranes (SROM). Premature rupture of membranes is referred to as PROM. In the case of cesarean section, the rupture of membranes may be almost concurrent with time of delivery.

- **Delivery** - This should be found on the labor and delivery summary sheet. The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. If the time of delivery is unknown because of a home or out-of-hospital delivery, enter ‘...’. Verify that the delivery date is the same as the date of birth noted on the first page of the abstraction form. If there is an inconsistency, verify the correct date of birth and update eHARS if necessary.

18. If Cesarean delivery, mark all the following indications that apply (Required, if applicable, applies to health department & health care providers).

| | | |
|---|---|---|
| 18. If Cesarean delivery, mark all the following indications that apply. | | |
| <input type="checkbox"/> HIV indication (high viral load) | <input type="checkbox"/> Mother's or physician's preference | <input type="checkbox"/> Other (e.g., herpes, disproportion) (Specify) _____ |
| <input type="checkbox"/> Previous Cesarean (repeat) | <input type="checkbox"/> Fetal distress | <input type="checkbox"/> Not specified |
| <input type="checkbox"/> Malpresentation (breech, transverse) | <input type="checkbox"/> Placenta abruptia or p. previa | <input type="checkbox"/> Not applicable |
| <input type="checkbox"/> Prolonged labor or failure to progress | | |

- Mode of delivery information should be noted in the delivery summary sheet, nurse’s notes, anesthesiologist’s notes, or physician’s progress notes. Often there is a standard check off list of procedures that may have been performed in the course of labor and delivery. A cesarean delivery may be noted there.
- Elective cesarean section refers to a cesarean section that occurs before rupture of membranes and before the onset of labor. If a cesarean section was planned but then performed ahead of schedule due to unexpected circumstances, it should still be coded as ‘Elective.’ Non-elective (or emergent) C-sections are usually done because the fetus has shown signs of distress during labor. Elective C-sections are planned, done for a variety of reason (e.g., previous C-section, breech position, HIV prevention) and usually occur before the onset of labor. C-sections that are done in the middle of the night are usually not elective. Review the chart for clarification if summary sheet indicates ‘elective’. Whether a C-section was elective or emergent may not be noted in the delivery summary sheet, but the dictated discharge summary will make this clear. The reason(s) for a C-section are given in the labor and delivery medical record. Notes in the child’s records are acceptable even if no birth records are available.
- If not documented, select ‘Not specified’.

19. Was the mother’s HIV serostatus noted on the child’s birth record? (Recommended, if applicable, applies to health department & health care providers).

19. Was mother’s HIV serostatus noted on the child’s birth record?

No Yes, HIV-positive Yes, HIV-negative Record not available Unknown

- Select appropriate response from given values.

20. Were antiretroviral drugs prescribed for the child? (Required, if applicable, applies to health department & health care providers).

20. Were antiretroviral drugs prescribed for the child?

Yes (Complete table) No (Go to 20a) Not documented Record not available Unknown

| | Drug name | Drug refused | Date drug started (mm/dd/yyyy) | Time started (See military time) | Drug stopped | | | | Stop date (if therapy not completed) (mm/dd/yyyy) | Stop codes (See list) |
|------|-----------|--------------------------|--------------------------------|----------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---|-----------------------|
| | | | | | Yes | No | ND | UNK | | |
| i. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| ii. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| iii. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| iv. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| v. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |
| vi. | _____ | <input type="checkbox"/> | ___/___/___ | __:__ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | ___/___/___ | _____ |

Military time: noon = 12:00; midnight = 00:00

20a. If no antiretroviral drug was prescribed, indicate reason.

HIV serostatus of mother unknown Other (Specify) _____
 Mother known to be HIV-negative during pregnancy Not documented
 Mother refused

- Select “Yes” if any ARVs were prescribed for the child, and complete the grid.
 - Enter the dates in *mm/dd/yyyy* format using ‘.’ for unknown values (e.g., 03/./2011). Write time in military hours (e.g., 9:15 a.m. is 09:15, 1:00 p.m. is 13:00). Midnight is 00:00 and noon is 12:00. To calculate military time count the number of hours and minutes after midnight or 00:00 hours.
- Enter all ARVs for the child
- If no ARV prescribed, indicate reason
 - *HIV serostatus of mother unknown* - The physician may not have known the HIV status of mother either because she refused testing or the physician did not offer testing. Sometimes the mother is not identified as being HIV positive until after delivery.
 - *Mother known to be HIV negative during pregnancy* - If the mother tested HIV negative during pregnancy (with no further testing to indicate HIV seroconversion), she would not receive ARV for prevention of perinatal transmission. There must be evidence of a negative test during pregnancy or at labor and delivery in the chart; do not use patient report.
 - *Mother Refused* - Mother refused ARV for infant during first six weeks of life.
 - *Other* - If ‘Other’ is indicated, be sure to specify why ARV was not prescribed.
 - *Not Documented* - Indicate ‘Not Documented’ if the infant was not prescribed ARV but the reason why is not known.
- Select “Unknown” if the specific drugs prescribed are unknown, complete the grid, and write “Unknown” in the “Drug name” column.