Attachment 4(b)

National HIV Surveillance System (NHSS)

OMB # 0920-0573

Pediatric HIV Confidential Case Report Form Technical Guidance Including Perinatal HIV Exposure Reporting (PHER)

29 October 2012

Technical Guidance for HIV Surveillance Programs

Pediatric HIV Confidential Case Report Form

HIV Incidence and Case Surveillance Branch Atlanta, Georgia

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

Instructions for Completion

Purpose of case report form

The Pediatric HIV Confidential Case Report (CDC 50.42B) form 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 optional. This guidance applies to this data collection even if surveillance sites use a different form or medium for HIV case surveillance. See <u>Appendix</u> for further details.

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 given reported case, fill out the applicable part of the form for each data source contributing to that case.

Patients for whom form is indicated

- Each child with confirmed HIV infection and those who meets the pediatric AIDS case definition.
- In areas with confidential perinatal exposure HIV reporting, all children born to HIV-infected mothers.
 - Includes children whose infection status has not yet been determined, seroreverters, and those exposed but determined not to be infected with HIV; inclusion of such patients is for public health surveillance purposes only.
 - A federal assurance of confidentiality applies to information on children exposed perinatally with or without consequent infection.
 - Each person with HIV infection who has been reported but for which updated information is available such as new CD4 or viral load tests reported from a medical provider, additional risk factor information, or updated current address information.
 - If the data is collected electronically and can be imported, recording the information on a form is not necessary.

Definition of variable designators

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

Disposition of form

- The completed form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC) with patient identifiers. The Pacific Islands are the only sites that send forms to CDC for data entry and all patient identifiers should be removed before they are sent.
- Data obtained from these forms are entered into compatible or 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 electronically by encrypted electronic transfer via secure data network.

• Patient Identification

Patient Identification			
*Patient Name *First Name	*Middle Name	*Last Name	Last Name Soundex
*Alternate Name Type (ex Birth, Call Me)	*First Name	*Middle Name	*Last Name
Address Type Residential Bad Addre Foster Home Homeless Postal Sh	ess Correctional Facility *Curre elter Temporary *Curre	nt Street Address	*Phone ()
City Co	unty	State/Country	*ZIP Code
*Medical Record Number	*Other ID	Туре:	Number:

*Information NOT transmitted to CDC

Patient identifier information is for state/local health department use only and is not transmitted to CDC. Enter the data below for all persons being reported with HIV.

- 1.1 PATIENT NAME (**Required**, applies to Health Dept & Health Care Providers)
 - Enter patient's first name, middle name, and last name.
- 1.2 LAST NAME SOUNDEX (**Required**, applies to Health Dept & Health Care Providers)
 - After patient name is entered into CDC-supplied software, the software generates this variable by using the patient's last name. After the code is automatically generated, health department staff should fill 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.

1.3 ALTERNATE NAME TYPE (Optional)

- If available, write in the alternate name type (such as Birth, Call Me) and patient's alternative first name, middle name, and last name.
- 1.4 ADDRESS TYPE (**Required**, applies to Health Dept & Health Care Providers)
 - Select one of the address types (residential, bad address, correctional facility, foster home, homeless, postal, shelter, or temporary) for the patient's current address.
- 1.5 CURRENT STREET ADDRESS (**Required**, applies to Health Dept & Health Care Providers)
 - Enter the patient's current street address.
- 1.6 PHONE (**Required** if patient has a telephone, applies to Health Dept & Health Care Providers)
 - Enter patient's current home area code and telephone number.
- 1.7 CITY (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter patient's current city
- 1.8 COUNTY (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter patient's current county
- 1.9 STATE/COUNTRY (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter patient's current state/country

1.10 ZIP CODE COUNTY (each element **Required**, applies to Health Dept & Health Care Providers)

• Enter patient's current zip code

1.11 MEDICAL RECORD NUMBER

- Enter medical record number of the patient if available.
- Refer to <u>Appendix 1.11</u> for further guidance.

1.12–1.13 OTHER ID TYPE AND NUMBER

• Enter any additional patient's ID type (such as social security number) and the number of the other ID. For a list of ID type's, please reference the eHARS Technical Reference Guide.

Health Department Use Only

Health Department Use Only

Date Received at Health Department //	eHARS Document UID S		State Number
Reporting Health Dept - City / County		City/County Number	
Document Source	Surveillance Method Active Passive Follow up Reabstraction Unknown		
Did this report initiate a new case investigation?	Report Medium	□ 1-Field Visit □ 2-Mailed □ 3-F □ 5-Electronic Transfer	Faxed 4-Phone 6-CD/Disk

DATE RECEIVED AT HEALTH DEPARTMENT (Optional)

• Enter date in *mmddyyyy* format.

2.2 eHARS DOCUMENT UID

- Enter UID after CDC-supplied software generates this variable.
- 2.3 STATE NUMBER (**Required**)
 - Enter the assigned state patient number.
 - Each patient should have a unique state number throughout the course of HIV disease in each state/jurisdiction where they are reported.
 - Assigned numbers **should 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 the state datasets without duplication.

2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY

• Enter name of city and county of the health department that receives the report from providers of surveillance data.

2.5 CITY/COUNTY NUMBER

- Enter the assigned city/county patient number.
- Each patient should have a unique city/county number throughout the course of HIV disease assigned by the separately funded city in which they are reported.
- Assigned numbers **should not** be reused, even if the case is later deleted.
- 2.6 DOCUMENT SOURCE (**Required**, applies to Health Dept)
 - 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.
 - If coding proves difficult, write in document source for later coding.

• Refer to <u>Appendix 2.6</u> for code information.

2.7 SURVEILLANCE METHOD (Required)

- Enter the method the case report was ascertained- active, passive, follow up, reabstraction or unknown.
- For definitions of active, passive, follow up, re-abstraction refer to Volume 1 of the Technical Guidance for HIV Surveillance Programs —Access to Source Data, Case Finding and Completeness of Reporting.

2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (Optional)

• Enter whether this case report initiated a new investigation by the health department- yes, no or unknown.

2.9 REPORT MEDIUM (**Optional**)

• Health department staff review medical records at provider sites or receive information over the telephone, by fax, e-mail, US mail, etc. 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. Choose one of the following options: Field visit, mail, fax, phone, electronic transfer or CD/Disk.

Facility Providing Information

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

Facility N	lame			*Phone ()
*Street A	ddress			
City		County	State/Country	Zip Code
Facility Type	Inpatient: □ Hospital □ Other, specify	<u>Outpatient</u> : □ Private Physician's Office □ Pediatric HIV Clinic □ Other, specify _	Pediatric Clinic <u>Ot</u>	<u>her Facility</u> : □ Emergency Room □ Laboratory Unknown □ Other, specify
Date For	m Completed/	/ *Person Completing Fo	rm	*Phone ()

- 3.1 FACILITY NAME (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter name of the facility providing the information.
 - If HIV, stage 1-2 or 3(AIDS) were reported from different facilities, enter name of each on separate forms, specifying which occurred at which facility.
- 3.2 PHONE (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter facility's current area code and telephone number.
- 3.3 STREET ADDRESS (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter facility's street address.
- 3.4 CITY (**Optional** applies to Health Dept & Health Care Providers)
 - Enter city where facility providing information is located.
- 3.5 COUNTY (**Optional** applies to Health Dept & Health Care Providers)
 - Enter county where facility providing information is located.
- 3.6 STATE/COUNTRY (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter state, country name where facility providing information is located.

- 3.7 ZIP CODE (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter ZIP code where facility providing information is located.
- 3.8 FACILITY TYPE (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response corresponding to the type of facility providing information
 - Refer to <u>Appendix 7.9</u> for further details.
- 3.9 DATE FORM COMPLETED (**Required**, applies to Health Dept & Health Care Providers)
 - Enter date in *mmddyyyy* format.
- 3.10 PERSON COMPLETING FORM (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.
- 3.11 PHONE (**Optional**, applies to Health Dept & 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	Sex assig □ Male □	gned at Birth ∃ Female □ Unknown	Country of Birth	US Other/ US Dependency (please specify)		
Date of Birth///			Alias Date of Birth	//_		
Vital Status 1-Alive 2-Dead	Date of Death//			State of Death		
Date of Last Medical Evaluation / / Date of Initial Evaluation				for HIV/	/	
Ethnicity 🗆 Hispanic/Latino 🗆 Not Hispanic	Ethnicity Hispanic/Latino Not Hispanic/Latino Unknown			*ExpandedEth	nicity	
Race □ American Indian. (check all that apply) □ Native Hawaiian	Race American Indian/Alaska Native Asian Black/African American Check all that apply) Native Hawaiian/Pacific Islander White Unknown 					

- 4.1 DIAGNOSTIC STATUS AT REPORT (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Irrespective of the interval between diagnostic status dates, and even where the same source of these data reported more than one event, use one form to capture each 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 at preceding bulleted item must include at least the following data: DIAGNOSTIC STATUS AT REPORT; RESIDENCE AT DIAGNOSIS (see <u>Residence at</u> <u>Diagnosis</u>, below); and Facility of Diagnosis (see <u>Facility of Diagnosis</u>, below).
 - Status depends on child's age, clinical profile, and laboratory findings. Refer to <u>Appendix 4.1.1</u>–<u>4.1.4</u> for further details.

4.1.1 PERINATAL HIV EXPOSURE

- Select "Perinatal HIV Exposure" if the patient is aged less than 18 months, 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 <u>Appendix 4.1.1</u> for elaboration.
- 4.1.2 PEDIATRIC HIV
 - Select "PEDIATRIC HIV" if the patient meets criteria specified in the Revised Surveillance

Case Definition for HIV Infection and does not meet the current CDC pediatric AIDS case definition.

- Refer to <u>Appendix 4.1.2</u> for elaboration.
- 4.1.3 PEDIATRIC AIDS
 - Select "Pediatric AIDS" if patient meets the current AIDS case definition for children < 13 years of age.
 - Refer to <u>Appendix 4.1.3</u> for elaboration.
- 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 <u>Appendix 4.1.4</u>.
 - With respect to 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 Dept & Health Care Providers)
 - Select patient's sex assigned at birth.
 - Refer to <u>Appendix 4.2</u> for further details.
- 4.3 COUNTRY OF BIRTH (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response from boxes provided.
 - Refer to <u>Appendix 4.3</u> for legal values when dependency or country is to be specified.
- 4.4 DATE OF BIRTH (Required, applies to Health Dept & Health Care Providers)
 - Enter patient's month, day, and year of birth.
 - Enter date in *mmddyyyy* format.
- 4.5 ALIAS DATE OF BIRTH (**Optional**, applies to Health Dept & Health Care Providers)
 - If available, write in the Alias date of birth.
 - Enter date in *mmddyyyy* format.
- 4.6 VITAL STATUS (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - For further guidance on death ascertainment, see CDC's <u>Technical Guidance for HIV Surveillance</u> <u>Programs, Volume I: Policies and Procedures, Death Ascertainment</u>.
- 4.7 DATE OF DEATH (Required if applicable, applies to Health Dept & Health Care Providers)
 - If patient is deceased, enter date of death.
 - Enter date in *mmddyyyy* format.
 - For further guidance on death ascertainment, see CDC's <u>Technical Guidance for HIV Surveillance</u> <u>Programs, Volume I: Policies and Procedures, Death Ascertainment</u>.
- 4.8 STATE OF DEATH (**Optional** if applicable, applies to Health Dept & Health Care Providers)
 - If patient is deceased, enter the state/territory where death occurred.
- 4.9 DATE OF LAST MEDICAL EVALUATION (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter the month, day and year of the child's last medical evaluation, regardless of reason for exam. This includes emergency room visits.
 - Enter date in *mmddyyyy* format.
- 4.10 DATE OF INITIAL EVALUATION FOR HIV INFECTION (**Optional**, applies to Health Dept & Health Care Providers)

- Enter the date of initial evaluation for HIV infection. 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.
- Enter date in *mmddyyyy* format.
- Refer to <u>Appendix 4.10</u> for further details.

4.11 ETHNICITY (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If no ethnicity information is available, select "Unknown".
- Do not choose unknown unless search for this datum was unsuccessful.
- Refer to <u>Appendix 4.11</u> for further details.

4.12 EXPANDED ETHNICITY (**Optional** if applicable, applies to Health Dept & 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 Dept & 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".
- Refer to <u>Appendix 4.13</u> for further details.

4.14 EXPANDED RACE (**Optional** if applicable, applies to Health Dept & 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 Africa.Egyptian".
- Refer to the eHARS Technical Reference Guide for listing of expanded race.

5 Residence at Diagnosis

Residence at Diagnosis (add additional addresses in Comments)

ĺ	Address Type (Check all that apply to address below)	Residence at HIV diagnosis	Residence at AIDS diagnosis	 Residence at Perinatal Exposure 	Residence at Pediatric Seroreverter	Check if <u>SAME as</u> <u>Current Address</u>
Γ	* Street Address					
ſ	City	County		State/Country		*ZIP Code

- 5.1 ADDRESS TYPE (**Required**, applies to Health Dept & Health Care Providers)
 - Select one of the address types (residence at HIV diagnosis, residence at AIDS diagnosis, residence at perinatal exposure, residence at pediatric seroreverter, check if same as current address) for the patient's residence at diagnosis being reported on the case report form
- 5.2 STREET ADDRESS (**Required**, applies to Health Dept & Health Care Providers)
 - Enter residence's street address at diagnosis or HIV status
- 5.3 CITY (**Required**, applies to Health Dept & Health Care Providers)
 - Enter city of patient's residence at diagnosis or HIV status.
- 5.4 COUNTY (**Required**, applies to Health Dept & Health Care Providers)

- Enter county of patient's residence at diagnosis or HIV status.
- 5.5 STATE/COUNTRY (**Required**, applies to Health Dept & Health Care Providers)
 - Enter the state/country of patient's residence at diagnosis or HIV status.
- 5.6 ZIP CODE (**Required**, applies to Health Dept & Health Care Providers)
 - Enter the ZIP code of patient's residence at diagnosis or HIV status.

6 State/Local Use Only

Diagnosing physician or healthcare provider identifier information is supplied in this section.

– Patient identifier information is not transmitted to CDC! –			
	Medical Record		
Phone No: ()	No		
Person Completing Form:			
	Patient identifier information is no Phone No: () Person Completing Form:		

6.1 PHYSICIAN'S NAME (Optional)

- Enter name of physician who diagnosed patient (last, first, M.I.).
- Enter name of physician medically managing patient.
- Refer to <u>Appendix 6.1</u> for further guidance.

6.2 PHONE NO. (Optional)

- Enter phone number of physician named at 6.1, above.
- If no physician is named, enter phone number of the facility of diagnosis.

6.3 MEDICAL RECORD NO.

- Enter medical record number of the patient if available that is being used by the physician or healthcare provider who diagnosed the patient (if different).
- Refer to <u>Appendix 1.10</u> for further guidance.

6.4 HOSPITAL/FACILITY (Optional)

- Enter the name of the facility where the report originated.
- If this report is generated from a laboratory report of HIV infection, the laboratory slip should contain the name of the facility where the specimen was collected.
- 6.5 PERSON COMPLETING FORM (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

7 Facility of Diagnosis

Facility of Diagnosis (add additional facilities in Comments)

Diagnosi	is Type □ HIV □ AID	S 🗆 Perinatal Expo	osure (check all that apply to	a facility below) □ Check if <u>SA</u>	ME as Fa	acility Providing Information
Facility N	lame				*Pho	ne ()
*Street A	ddress					
City		County		State/Country		Zip Code
Facility Type	<u>Inpatient</u> : □ Hospital □ Other, specify	<u>Out</u> □ P	<u>patient</u> : □ Private Physician's (ediatric HIV Clinic □ Other, sp	Office ☐ Pediatric Clinic ecify	Other F	acility: □ Emergency Room □ Laboratory wn □ Other, specify
*Provider	r Name		*Provider Phone ()		*Spec	sialty

7.1 DIAGNOSIS TYPE

- Enter the diagnosis type that the patient first received (HIV, AIDS, perinatal exposure, check if same as facility providing information).
- 7.2 FACILITY NAME (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter name of the facility where patient was first diagnosed with diagnosis or exposure type being reported.
 - If HIV, stage 1-2, unknown and stage 3 (AIDS) diagnoses occurred at different facilities, enter name of each on separate forms, specifying which diagnosis occurred at which facility.
 - Refer to <u>Appendix 7.2</u> for further details.
- 7.3 PHONE (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter facility's current area code and telephone number.
- 7.4 STREET ADDRESS (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter facility's street address.
- 7.5 CITY (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter city where facility of diagnosis is located.
- 7.6 COUNTY (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter county where facility of diagnosis is located.
- 7.7 STATE/COUNTRY (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter state, country name where facility of diagnosis is located.
- 7.8 ZIP CODE (**Optional**, applies to Health Dept & Health Care Providers)
 - Enter ZIP code where facility of diagnosis is located.
- 7.9 FACILITY TYPE (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response corresponding to the type of facility where patient received diagnosis of HIV.
 - Refer to <u>Appendix 7.9</u> for further details.
- 7.10 PROVIDER NAME (**Optional**)
 - Enter provider's name where patient first received a diagnosis of HIV, stage 1-2 or stage 3 (AIDS).
- 7.11 PROVIDER PHONE (Optional)
 - Enter provider's current area code and telephone number.
- 7.12 SPECIALTY

• Enter provider's specialty.

8 Patient History

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

Child's biological mother's HIV infection sta 3-Known HIV+ before pregnancy 4-Kno 7-Known HIV+ after child's birth 8-HIV	atus (select one): 1-Refused H own HIV+ during pregnancy 4 time of diagnosis unknown	IIV testing 2-Known to be uninfected after this 5-Known HIV+ sometime before birth 6-Known	s child's birth n HIV+ at delivery
Date of mother's first positive HIV confirmatory test:		Was the biological mother counseled abo labor, or delivery? Yes No Unkn	ut HIV testing during this pregnancy, wwn
After 1977 and before the earliest know	n diagnosis of HIV infection, th	is child's biological mother had:	
Perinatally acquired HIV Infection			🗆 Yes 🗆 No 💷 Unknown
Injected non-prescription drugs			□ Yes □ No □ Unknown
Biological Mother had HETEROSEXUA	L relations with any of the follo	owing:	
HETEROSEXUAL contact with intraveno	us/injection drug user		🗆 Yes 🗖 No 🗆 Unknown
HETEROSEXUAL contact with bisexual r	male		🗆 Yes 🗆 No 🗈 Unknown
HETEROSEXUAL contact with person with	ith hemophilia / coagulation disor	der with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with transfusion	on recipient with documented HIV	/ infection	🗆 Yes 🗆 No 🗆 Unknown
HETEROSEXUAL contact with transplan	t recipient with documented HIV i	infection	🗆 Yes 🗆 No 🗆 Unknown
HETEROSEXUAL contact with person wi	ith documented HIV Infection, risl	k not specified	🗆 Yes 🗆 No 🗆 Unknown
Received transfusion of blood/blood compo	onents (other than clotting factor)	(document reason in Comments section)	
First date received//	Last date received	/	Yes No Unknown
Received transplant of tissue/organs or art	ificial insemination		🗆 Yes 🗖 No 🗆 Unknown
Before the diagnosis of HIV infection, this	child had:		
Injected non-prescription drugs			🗆 Yes 🗈 No 🗆 Unknown
Received clotting factor for hemophilia/ coagulation disorder	Specify clotting factor: Date received (mm/ dd/yyyy):		🗆 Yes 🗆 No 🗆 Unknown
Received transfusion of blood/blood compo	onents (other than clotting factor)	(document reason in Comments section)	
First date received//	Last date received		□ Yes □ No □ Unknown
Received transplant of tissue/organs			🗆 Yes 🗆 No 💷 Unknown
Sexual contact with male			🗆 Yes 🗆 No 🗆 Unknown
Sexual contact with female			□Yes □ No □ Unknown
Other Documented Risk (please include de	□ Yes □ No □ Unknown		

Maternal perinatal exposure is the predominant risk factor for pediatric HIV cases.

- Respond to each risk factor, selecting "Yes" for all factors that apply, "No" for those that do not apply, and "Unknown" for those for which investigation failed to yield an answer. See <u>Appendix</u> <u>Section V</u> for more general guidance or further information about how to ascertain risk factor information.
- Collect data about the risk factors that occurred before the first positive HIV test or AIDS diagnosis. See <u>Technical Guidance for HIV Surveillance Programs, Volume 1: Policies</u> <u>and Procedures, Risk Factor Ascertainment, Risk Factor Ascertainment Procedures, Epidemiologic Follow-Up</u>. Risk factor information on the mother refers to behaviors that started before the child's birth.
- 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 information on Cases of Public Health Importance, refer to this passwordprotected site: <u>http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf</u>. Consult your local HIV Surveillance Coordinator for access. COPHI is also covered in <u>Technical Guidance for HIV</u> <u>Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Cases</u> <u>of Public Health Importance</u>.

- 8.1 CHILD'S BIOLOGICAL MOTHER'S HIV INFECTION STATUS (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Refer to <u>Appendix 8.1</u> for further details.
 - If mother was diagnosed with HIV infection, select from boxes 3–8, depending on information available to determine the timing of her diagnosis. Where date of mother's first positive HIV confirmatory test is available, establish which box to select by comparing to the date of birth and then selecting the appropriate box.
 - Refer to <u>Appendix 8.1</u> for further details.
- 8.2 DATE OF MOTHER'S FIRST POSITIVE HIV CONFIRMATORY TEST (**Optional**, applies to Health Dept & Health Care Providers)
 - Where mother is known to be HIV infected, enter month, day, and year of the first positive HIV confirmatory test.
 - If year is present and search for month was unsuccessful, then enter "..." for the unknown month followed by the documented year.
 - Refer to <u>Appendix 8.3</u> for further details.
- 8.3 WAS THE BIOLOGICAL MOTHER COUNSELED ABOUT HIV TESTING DURING THIS PREGNANCY, LABOR, OR DELIVERY? (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Select "Yes" if mother was counseled at anytime 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.
 - Refer to <u>Appendix 8.3</u> for further details.
- 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 Dept & Health Care Providers)
 - Select applicable response.
 - 8.4.2 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - 8.4.3 BIOLOGICAL MOTHER HAD HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:
 - This section, addressed at 8.5.3–8.5.3.6, 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.
 - 8.4.3.1 INTRAVENOUS/INJECTION DRUG USER (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.

- 8.4.3.2 BISEXUAL MALE (**Required**, applies to Health Dept & Health Care Providers)
 - Applies only to female case patients.
 - Select applicable response.
- 8.4.3.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to Health Dept & 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 <u>Appendix 8.4.3.3</u> for further details.
 - Alert state/local COPHI coordinator.
- 8.4.3.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Consider documenting the reason for transfusion in the comments section.
 - Refer to <u>Appendix 8.4.3.4</u> for further details.
 - Alert state/local COPHI coordinator.
- 8.4.3.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Consider recording documentation available about the transplant in the comments section.
 - Alert state/local COPHI coordinator.
- 8.4.3.6 PERSON WITH AIDS OR DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to Health Dept & Health Care Providers)
 - Select "Yes" only if male partner is known to be HIV positive and that partner's risk for HIV is unknown.
- 8.4.4 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (each element **Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - 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 or AIDS.
 - If the last transfusion was after March 1985, then alert state/local COPHI coordinator.

8.4.5 RECEIVED TRANSPLANT OF TISSUES/ORGANS OR ARTIFICIAL INSEMINATION (each element **Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- 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; then alert state/local COPHI coordinator.
- If the biological mother is known to be HIV infected and this is the only maternal risk, then the case patient will initially be classified as "mother has HIV infection, risk not specified."

8.5 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.
- 8.5.1 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
- 8.5.2 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER (**Required**, applies to Health Dept & 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).
 - Select applicable response.
 - If "Yes" specify.
 - Alert state/local COPHI coordinator if child was born after March 1998 and receipt of clotting factor is the suspected mode of HIV transmission.
 - Refer to <u>Appendix 8.5.2</u> for further details.
 - 8.6.1.1 SPECIFY CLOTTING FACTOR (**Required**, applies to Health Dept & Health Care Providers)
 - If "Yes" to 8.6.1, above, then enter the specific clotting factor.
- 8.5.3 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to Health Dept & 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 AIDS.
 - It is often helpful to document the reason for the transfusion in the Comments section.
- 8.5.4 RECEIVED TRANSPLANT OF TISSUE/ORGANS (**Required**, applies to Health Dept & Health Care Providers)
 - The case will be initially classified as "risk not reported/identified"pending outcome of the no identified risk (NIR) investigation.
 - Alert the state/local COPHI coordinator.
- 8.5.5 SEXUAL CONTACT WITH A MALE (**Required**, applies to Health Dept & 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.
- 8.5.6 SEXUAL CONTACT WITH A FEMALE (**Required**, applies to Health Dept & 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.
- 8.5.7 OTHER DOCUMENTED RISK (Alert State/Local NIR Coordinator) (**Required**, applies to Health Dept & Health Care Providers)

• Select this response only if directed to do so by the state/local NIR coordinator.

9 Laboratory Data

Laboratory Data (record additional tests in Comments section) (record all dates as mm/dd/yyyy)		
HIV Antibody Tests (Non-type-differentiating) [HIV-1 vs. HIV-2]		
TEST 1: 0 HIV-1 EIA 0 HIV-1/2 EIA 0 HIV-1/2 Ag/Ab 0 HIV-1 WB 0 HIV-1 IFA 0 HIV-2 EIA 0 HIV-2 WB 0 Other: Specify Test		
RESULT: Positive/Reactive Negative/Nonreactive Indeterminate RAPID TEST (check if rapid): Collection Date:	1	1
Manufacturer:		
TEST 2: HIV-1 EIA HIV-1/2 EIA HIV-1/2 Ag/Ab HIV-1 WB HIV-1 IFA HIV-2 EIA HIV-2 WB Other: Specify Test:		
RESULT: Positive/Reactive Nonreactive Indeterminate RAPID TEST (check if rapid): Collection Date:		
Manufacturer:		
TEST 3: HIV-1 EIA HIV-1/2 EIA HIV-1/2 Ag/Ab HIV-1 WB HIV-1 IFA HIV-2 EIA HIV-2 WB Other: Specify Test		
RESULT: Positive/Reactive Negative/Nonreactive Indeterminate RAPID TEST (check if rapid): Collection Date:		
Manufacturer:	_	
HIV Antibody Tests (Type-differentiating) [HIV-1 vs. HIV-2]		
TEST: □ HIV-1/2 Differentiating (e.g., Multispot)		
RESULT: DIV-2 Doth (undifferentiated) Neither (negative) Collection Date: ////		
HIV Detection Tests (Qualitative)		
TEST 1: DHIV-1 RNA/DNA NAAT (Qual) DHIV-1 P24 Antigen HIV-1 Culture HIV-2 RNA/DNA NAAT (Qual) HIV-2 Culture		
RESULT: Positive/Reactive Negative/Nonreactive Indeterminate Collection Date: / /		
TEST 2: DHV-1 RNA/DNA NAAT (Qual) DHV-1 P24 Antigen DHV-1 Culture DHV-2 RNA/DNA NAAT (Qual) HIV-2 Culture		
RESULT: Positive/Reactive Nonreactive Indeterminate Collection Date: ////		
HIV Detection Tests (Quantitative viral load) Note: Include earliest test after diagnosis		
TEST 1: □ HIV-1 RNA/DNA NAAT (Quantitative viral load)		
RESULT: Detectable Dundetectable Copies/mL: Log: Collection Date:		
TEST 2: DHIV-1 RNA/DNA NAAT (Quantitative viral load)		
RESULT: Detectable Dundetectable Copies/mL: Log: Collection Date:	1	1
Immunologic Tests (CD4 count and percentage)	_	
CD4 at or closest to current diagnostic status: CD4 count; cells/µL CD4 percentage: % Collection Date:	1	1
First CD4 result <200 cells/µL or <14%: CD4 count: cells/µL CD4 percentage:% Collection Date:%	1	/
Other CD4 result: CD4 count: cells/µL_CD4 percentage:% Collection Date:%	1	1
Documentation of Tests		
Complete only if none of the following was positive: HIV-1 Western blot, IFA, culture, p24 Ag test, viral load, or qualitative NAAT [RNA or DNA]:		
Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? Yes Ves Ves Unknown		
If YES, provide date of earliest positive test for this algorithm (specimen collection date if known):/ //		
If laboratory tests were not documented, HIV-Infected Yes No Unknown Date of documentation:/	1	
is patient confirmed by a physician as: Not HIV-Infected Yes No Unknown Date of documentation: / / / / / / / / / / / / / / / / / / /	/	

- "COLLECTION DATE" refers to the date when the specimen was collected or drawn.
- Enter dates in *mmddyyyy* format.
- If search for either or both of these data was unsuccessful, then enter "..." for unknown day, month or year of "COLLECTION DATE."
- Record all laboratory tests.
- Include all diagnostic, viral detection, and CD4 tests where possible. Where number of tests exceeds the number of fields available on the form, record such results in the Comments section.
- In the absence of lab tests, record HIV, stage 1-2 or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.
- If the following brief instructions for recording HIV-related tests are insufficient, see the <u>Technical Guidance for HIV Surveillance Programs, Volume I: Policies and Procedures,</u> <u>Electronic Reporting, HIV and HIV-associated Laboratory Tests.</u>
- 9.1 HIV ANTIBODY TESTS (NON_TYPE 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 results and collection dates for first positive HIV antibody tests.
- The possible results are: Positive/Reactive, Negative/Nonreactive, or Indeterminate
- Check the Rapid Test box if the test is rapid.
- Enter date in *mmddyyyy* format. Enter the name of assay manufacturer
- 9.1.1 HIV-1 EIA (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter result and collection date of first HIV-1 EIA.
 - "Positive EIA" means repeatedly reactive tests on a single sample.
 - Enter date in *mmddyyyy* format.
- 9.1.2 HIV-1/2 COMBINATION EIA (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter result and collection date of first HIV-1/2 combination EIA test.
 - If tests indicate HIV-1 or HIV-2 results separately, please specify the results as given in the laboratory report.
 - Enter date in *mmddyyyy* format.
- 9.1.3 HIV-1/2AgAb
 - Enter results and collection date of combined p24 antigen and anti HIV1/2 antibody screening assay.
 - Enter date in *mmddyyyy* format.
- 9.1.4 HIV-1 WESTERN BLOT (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter the result and collection date of first HIV-1 Western blot.
 - Enter date in *mmddyyyy* format.
- 9.1.5 HIV-1 IFA (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter the result and collection date of first HIV-1 IFA.
 - Enter date in *mmddyyyy* format.
- 9.1.6 HIV-2 EIA (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter result and date of first HIV-2 EIA.
 - "Positive EIA" means repeatedly reactive tests on a single sample.
 - Enter date in *mmddyyyy* format.
- 9.1.7 HIV-2 WESTERN BLOT (each element **Required**, applies to Health Dept & Health Care Providers)
 - Enter the result and collection date of first HIV-2 Western blot. Enter date in *mmddyyyy* format.
 - If HIV-1 tests other than those at 9.1.1–9.1.5 were employed, specify the type of test performed.
 - Enter the result and collection date.
 - Enter date in *mmddyyyy* format.

9.2 HIV ANTIBODY TESTS (TYPE DIFFERENTIATING)

- Assuming active case finding, review patient's chart and lab reports for the earliest date of documented HIV positivity.
- Enter results and collection dates for first positive HIV antibody tests. The possible results are: HIV-1, HIV-2, Both (undifferentiated), or Neither (negative).
- Enter date in *mmddyyyy* format.
- 9.3 HIV DETECTION TESTS (QUALITATIVE) (**Required**, applies to Health Dept & Health Care Providers)
- These are all qualitative tests. All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as the EIA or Western blot establish the presence of our immune systems' response to the pathogen—HIV antibodies.
- Select applicable response corresponding to earliest positive detection test.
- The possible results are: Positive/Reactive, Negative/Nonreactive, or Indeterminate.
- 9.3.1 HIV-1 RNA/DNA NAAT (QUAL)
- 9.3.2 HIV-1 P24 ANTIGEN (Required, applies to Health Dept & Health Care Providers)
 - Antigens are the virus's own proteins; such tests are specific for these proteins.
 - Enter result and collection date of earliest antigen test.
 - Enter date in *mmddyyyy* format.
- 9.3.3 HIV-1 CULTURE (**Required**, applies to Health Dept & Health Care Providers)
 - Enter result and collection date of earliest test by culture.
 - Enter date in *mmddyyyy* format.
- 9.3.4 HIV-2 RNA/DNA NAAT (QUAL)
- 9.3.5 HIV-2 CULTURE (**Required**, applies to Health Dept & Health Care Providers)
 - Enter result and collection date of earliest test by culture.
 - Enter date in *mmddyyyy* format.

9.4 HIV DETECTION TESTS (QUANTITATIVE VIRAL LOAD)

- 9.4.1 HIV-1 RNA/DNA NAAT (QUANTITATIVE VL)
 - The possible results are: Detectable or Undetectable
 - Enter results in units of copies per milliliter (mL) and Log. Enter the month, day, and year test was collected. Viral load tests with undetectable results should also be entered here.
 - COPIES/ML (each element **Required**, applies to Health Dept & Health Care Providers) Enter result in units of viral copies per milliliter. Where detectable results are reported with log data only, enter "greater than detection limits for this assay" under the copies/mL field. Because undetectable results are typically reported as below the detection limits of the assay rather than by a specific quantitative value, enter "fewer than detectable by this assay" under the copies/mL field
- 9.5 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)

- Whenever CD4 count and percentage are both available, record both. Enter specimen collection date to the reported CD4 test result
- 9.5.1 CD4 AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS
 - 9.5.1.1 CD4 COUNT (**Required**, applies to Health Dept & Health Care Providers)
 - For HIV reports, record the CD4 count closest to the time 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. For HIV, stage 3 (AIDS) reports, record the CD4 count with date at or closest to the date of AIDS diagnosis. This AIDS diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 count < 200 cells/µL.
 - 9.5.1.2 CD4 PERCENTAGE (**Required**, applies to Health Dept & Health Care Providers)
 - For HIV reports, record the CD4 percentage with date at or closest to the date of HIV diagnosis. For stage 3 (AIDS) reports, record the CD4 percentage at or closest to the time that an AIDS-defining clinical condition was first diagnosed. This AIDS diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 percent <14%.
- 9.5.2 FIRST CD4 RESULT < 200 cells/ μ L or < 14%
 - 9.5.2.1 CD4 COUNT (**Required** if available, applies to Health Dept & Health Care Providers)
 - Enter results and specimen collection date of first CD4 < 200 cells/ μ L.
 - Enter date in *mmddyyyy* format.
 - 9.5.2.2 CD4 PERCENTAGE (**Required** if available, applies to Health Dept & Health Care Providers)
 - Record results and specimen collection date of first CD4 <14%.
 - Enter date in *mmddyyyy* format.
- 9.5.3 Other CD4 RESULT
 - 9.5.3.1 CD4 COUNT (**Required** if available, applies to Health Dept & Health Care Providers)
 - Enter results and specimen collection date of other CD4 count.
 - Enter date in *mmddyyyy* format.
 - 9.5.3.2 CD4 PERCENTAGE (**Required** if available, applies to Health Dept & Health Care Providers)
 - Record results and specimen collection date of other CD4 percentage.
 - Enter date in *mmddyyyy* format.

9.6 DOCUMENTATION OF TESTS

- 9.6.1 DATE OF EARLIEST POSITIVE TEST FOR MEETING THE HIV DIAGNOSTIC ALGORITHM CRITERIA
 - This section captures diagnoses through novel algorithms, and should only be completed if none of the following were positive: HIV-1 Western blot; p24 Ag test; or qualitative NAAT (RNA or DNA) or a detectable viral load

- Select applicable response.
- If "Yes", enter date of earliest positive test for this algorithm in *mmddyyyy* format.
- Not to be used for <18 months of age
- 9.7 IF LABORATORY TESTS WERE NOT DOCUMENTED, IS HIV DIAGNOSIS CONFIRMED BY A PHYSICIAN? (**Required** if applicable, applies to Health Dept & Health Care Providers)
 - Select applicable response. If laboratory evidence of an HIV test is unavailable 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."
 - 9.7.1 IF "YES" (TO 9.6) PROVIDE DATE OF DOCUMENTATION BY PHYSICIAN (**Required** in the absence of lab results, applies to Health Dept & Health Care Providers)
 - If antibody tests are not available in chart, enter date that physician diagnosed or first knew about patient's HIV infection. Record the date on which physician accepts and notes patient's diagnosis of HIV infection. Do not record earlier date stated by the patient.

10 Clinical

Clinical (record all dates as mm/dd/yyyy)

· · · · · · · · · · · · · · · · · · ·		5.4		
		Date	Date	
Bacterial infection, multiple or recurrent (including Salmonella septicemia)			Kaposi's sarcoma	
Candidiasis, bronchi, trachea, or lungs			Lymphoma, Burkitt's (or equivalent)	
Candidiasis, esophageal	i, esophageal Lymphoma, immunoblastic (or equivalent)			
Coccidioidomycosis, disseminated or extrapulmonary			Lymphoma, primary in brain	
Cryptococcosis, extrapulmonary			Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)	vridiosis, chronic intestinal (>1 mo. duration) M. tuberculosis, disseminated or extrapulmonary [†]			
Cytomegalovirus disease (other than in liver, spleen, or nodes)			Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Cytomegalovirus retinitis (with loss of vision)			Pneumocystis pneumonia	
HIV encephalopathy			Progressive multifocal leukoencephalopathy	
Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis			Toxoplasmosis of brain, onset at >1 mo. of age	
Histoplasmosis, disseminated or extrapulmonary			Wasting syndrome due to HIV	
Isosporiasis, chronic intestinal (>1 mo. duration)				
Has this child been diagnosed with pulmonary tuberculosis?	ial diagno /n	sis: 🗆 Definitive 🗆 Presur	pptive Date: 11f TB selected above, indicate RVCT Case Number:	

10.1 CLINICAL

10.1.1–10.1.24 (**Optional**, applies to Health Dept & Health Care Providers)

- Select all that apply and enter diagnosis dates (*mmddyyyy*).
- Enter ".." for unknown month.
- Refer to <u>Appendix 10.1</u> for further details.

10.2 HAS THIS CHILD BEEN DIAGNOSED WITH PULMONARY TUBERCULOSIS?

- Select applicable response.
- If "Yes," provide the month, day and year of diagnosis.
- 10.2.1 IF "YES," INITIAL DIAGNOSIS AND

- Select applicable response and enter month, day and year of diagnosis.
- If search for this datum was unsuccessful, enter ".." for month of initial diagnosis followed by the documented year.

10.2.2 RVCT CASE NUMBER.

• 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 AIDS patients may get this number from TB surveillance staff.

10 Birth History

Birth History Available Yes No Unknown	Residence at Bir	rth	Check if	SAME as Current Address
* Street Address		City		
County	State/Country		*Zip Code	
Hospital of Birth	-		-	
Check if <u>SAME as Facility Providing Information</u>				
Facility Name		*Phone ()	Zip Code
Street Address		City	County	State/Country
Birth History			-	
Birth Weight Type	e 🗆 1-Single 🗖 2-Tv 🗆 3->2 🗖 9-Unkno	win Delivery	1-Vaginal □ 2-Elective 0 4-Cesarean, unknown ty	Cesarean 🗆 3-Non-Elective Cesarea
Birth Defects	If yes, please sp	ecify:		
Veonatal Status 1-Full-term 2-Premature Unknown	Neonata	al Gestational Age in	Weeks:(9	9–Unknown)
Gestational Month Prenatal Care began (00-None	99-Unknown)	Prenatal Care - To care visits:	otal number of prenatal	(00-None, 99-Unknowr
id mother receive any Anti retrovirale - V h		16 1		
ARVs) prior to this pregnancy:	No 🗆 Refused	specify all:		
ARVs) prior to this pregnancy: Unknown Did mother receive any ARVs Yes D No during pregnancy: Unknown	n Refused	If yes, please specify all: If yes, please Specify all:		
Did mother receive any ARVs Unknown Did mother receive any ARVs Yes Did mother receive any ARVs Yes during pregnancy: Unknown Did mother receive any ARVs Yes Did mother receive any ARVs Unknown Did mother receive any ARVs Yes Did mother receive any ARVs Yes Unknown Yes Did mother receive any ARVs Yes Unknown Yes	lo □ Refused n > □ Refused >s □ No nknown	If yes, please specify all: If yes, please Specify all: If yes, please specify all:		
(ARVs) prior to this pregnancy: Unknown Did mother receive any ARVs Yes during pregnancy: Unknown Did mother receive any ARVs Yes Juring labor/delivery? Unknown Idternal Information Yes	io Refused Refused Refused No No	If yes, please specify all: If yes, please Specify all: If yes, please specify all:		
(ARVs) prior to this pregnancy: Unknown Did mother receive any ARVs Yes Juring pregnancy: Unknown Did mother receive any ARVs Yes Juring pregnancy: Unknown Did mother receive any ARVs Yes Juring labor/delivery? Unknown Maternal Information Maternal Sounde	NO Refused	If yes, please specify all: If yes, please Specify all: If yes, please specify all: Maternal Stateno	Maternal Count	ry of Birth

11.1 BIRTH HISTORY AVAILABLE (**Optional**, applies to Health Dept & Health Care Providers)

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

11.2 RESIDENCE AT BIRTH (**Optional**, applies to Health Dept & Health Care Providers)

- Select check if same as current address if applicable.
- Use mother's residence at time of infant's birth.
- Enter street address, city, county, state/country, and zip code of the residence at birth.

11.3 HOSPITAL OF BIRTH (**Optional**, applies to Health Dept & Health Care Providers)

- Select check if same as facility processing information if applicable.
- 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 Dept & Health Care Providers)
 - Enter the birth weight in pounds or grams as requested on the form.
 - If recorded in pounds and ounces, convert to grams.
 - 11.4.2 TYPE (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response. If unknown, select "9."
 - 11.4.3 DELIVERY (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response. If unknown, select "9."
 - Notes in the child's records are acceptable even if no birth records are available.
 - Refer to <u>Appendix 11.4.3</u> for further details.
 - 11.4.4 BIRTH DEFECTS (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - If "Yes," specify type.
 - Refer to <u>Appendix 11.4.4</u> for further details and an abbreviated list of birth defects
- 11.5 NEONATAL STATUS (**Optional**, applies to Health Dept & 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 "..." for unknown number of weeks.
 - Post mature neonatal status (after 40 weeks) should be recorded as full term.
 - 11.5.1 NEONATAL GESTATIONAL AGE IN WEEKS
 - Enter weeks of gestation.
- 11.6 PRENATAL CARE (**Optional**, applies to Health Dept & 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.
 - 11.6.1 GESTATIONAL MONTH PRENATAL CARE BEGAN (**Optional**, applies to Health Dept & 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."
 - Refer to <u>Appendix 11.6.1</u> for further details.
 - If search for this datum was unsuccessful, then enter ".." for month of first visit.
 - 11.6.2 TOTAL NUMBER OF PRENATAL CARE VISITS (**Optional**, applies to Health

Dept & 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 ".." for number of prenatal visits.
- Where data source reports a range of visits (e.g., "10–13"), enter the lowest number (e.g., "10").
- 11.7 DID MOTHER RECEIVE ANTIRETROVIRALS (ARVS) PRIOR TO THIS PREGNANCY? (**Optional**, applies to Health Dept & 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.'
 - 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.

11.7.1 IF "YES," PLEASE SPECIFY ALL

- 11.8 DID MOTHER RECEIVE ARVs DURING PREGNANCY? (**Optional**, applies to Health Dept & Health Care Providers)
 - If a woman did not receive ARVs, do not assume it was because she refused it.
 - Select "Refused" only if specific documentation in the record clearly states that she was offered the drug but she declined.
 - In the absence of evidence of the patient having taken the drug, select "No."
 - "Unknown" should be used only if the pregnancy records are not available.

11.8.1 IF "YES," PLEASE SPECIFY ALL

- 11.9 DID MOTHER RECEIVE ARVs DURING LABOR/DELIVERY? (**Optional**, applies to Health Dept & Health Care Providers)
 - Select "Yes" if information is available that states that the mother used ARVs anytime before this pregnancy.
 - Select "No" if mother never used this antiretroviral.
 - Select "Unknown" if it is unknown whether the mother ever used ARVs during labor/delivery.

11.9.1 IF "YES," PLEASE SPECIFY ALL

• For a list of antiretroviral therapies currently available and link to treatment guidelines, refer to <u>Appendix 11.10</u>.

11.10 MATERNAL INFORMATION

11.10.1 MATERNAL DATE OF BIRTH (DOB) (Optional, applies to Health Dept)

• Enter the biological mother's month, day, and year of birth.

11.10.2 MATERNAL SOUNDEX (Optional, applies to Health Dept)

- Enter maternal soundex here.
- Refer to <u>Appendix 11.10.2</u> for further details.

11.10.3 MATERNAL STATENO. (**Optional**, applies to Health Dept)

- Enter assigned state patient number if the biological mother is known to be HIV infected.
- State patient numbers should not be reused.

11.10.4 MATERNAL COUNTRY OF BIRTH (**Optional**, applies to Health Dept)

- Mark the box corresponding to the biological mother's country of birth.
- If this information is not available in the child's records, it can be left blank and updated on follow-up.
- Refer to <u>Appendix 11.10.4</u> for further details.

11.10.5 OTHER MATERNAL ID-LIST TYPE

• Enter any other maternal's ID type (such as social security number) and the number of the other ID.

11 Services Referrals

This child received or is receiving:				
Neonatal ARVs for HIV prevention:	🗆 Yes 🗆 No 🗆 Unknown	Date:		
If Yes, please specify: 1)	2)	3)	4)	5)
Anti-retroviral therapy for HIV treatment: O Yes	🗆 No 🗆 Unknown	Date:	11	
PCP Prophylaxis: Yes No Unknown Date	://	Was this	child breastfed?	Yes 🗆 No 🗖 Unknown
This child's primary 1- Biological Parent 2- Other Relative 3- Foster/Adoptive parent, relative 4- Foster/Adoptive parent, unrelated				
caretaker is: 7- Social Service Agency				

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 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 RECEIVED OR IS RECEIVING

- 12.1.1 NEONATAL ANTIRETROVIRALS FOR HIV PREVENTION (**Optional**, applies to Health Dept & Health Care Providers)
 - Record whether child received any neonatal (first 6 weeks of life) ARVs to prevent perinatal HIV infection.
 - Refer to <u>Appendix 12.1.1</u> for further details.
 - If "Yes," record the day, month, and year the child was started on other antiretrovirals as prophylaxis during the first 6 weeks of life.
 - If the year and month are present but search for day was unsuccessful, then enter ".." for the day followed by the documented year and month.
 - 12.1.1.1 IF "YES," PLEASE SPECIFY (**Optional**, applies to Health Dept & Health Care Providers)

- If "Yes," write in the type of medication received.
- Refer to <u>Appendix 12.1.1.1</u> for examples.
- 12.1.2 ANTI-RETROVIRAL THERAPY FOR HIV TREATMENT (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - If "Yes," record month, day and year the child started on any antiretroviral therapy for treatment of confirmed HIV infection.
 - Refer to <u>Appendix 12.1.3</u> for further details.
- 12.1.3 PCP PROPHYLAXIS (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - If "Yes," enter the month, day, and year the child was started on therapy to prevent the occurrence of PCP.
 - If the year and month are present without a designated day, ".." should be entered for the day followed by the documented year and month.
 - Refer to <u>Appendix 12.1.3</u> for further details.
 - 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."
 - "Unknown" is used if treatment information in the medical chart is unclear or was unavailable.
- 12.2 WAS THIS CHILD BREASTFED? (**Optional**, applies to Health Dept & Health Care Providers)
 - Select applicable response.
 - Refer to <u>Appendix 12.2</u> for further details.
 - If there is suspicion that the child's only exposure to HIV was through breast milk, the local/state NIR coordinator should be alerted.
- 12.3 THIS CHILD'S PRIMARY CARETAKER IS (**Optional**, applies to Health Dept & Health Care Providers)
 - Select the response corresponding to the persons who give the majority of care for the child.
 - For children living with two biological parents or just one, "Biological parent(s)" should be selected.
 - Refer to <u>Appendix 12.3</u> for further details.

12 Comments and Local/Optional Fields

*Comments

*Local / Optional Fields	

13.1 COMMENTS (Optional)

This section can be used for information not requested on the form. For example, surveillance staff may document investigative progress toward ascertainment of risk factor information.

- If city or facility of treatment in another state is known, record these data on as many case report forms (CRFs) as there are facilities. Each facility represents a separate information source.
- 13.2 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 (CDC 50.42B)

Instructions for Completion

Purpose

- Information captured on the form 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 their prevention activities.
- CDC's Division of HIV/AIDS Prevention (DHAP) needs reports and updates to reflect the earliest dates that children meet each reporting criteria (i.e., perinatal exposure, HIV infection, AIDS, seroreverter), as well as changes in diagnostic or vital status.
- When a child who was previously reported as HIV infected has progressed to

AIDS or has died, state/reporting area personnel update the database 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 update 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 form can accommodate updated information including immunologic markers and diagnoses of opportunistic infections.
- CDC updated the HIV reporting form 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 or to 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 <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm</u>, and the 2008 case definition (MMWR 2008; 57 (RR-10) 1-12 at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm?s cid=rr5710a1 e

Pediatric Cases of Public Health Importance (COPHI)

• **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 unusual transmission circumstances. This direct communication will ensure the timeliest technical support. COPHI is covered in <u>Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Cases of Public Health Importance (COPHI).</u>

1.0 PATIENT IDENTIFICATION

1.11 MEDICAL RECORD NUMBER

- 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 or AIDS documentation. Additional numbers can be noted in the Comments section, clearly annotating which facility is associated with which record number.

2.0 HEALTH DEPARTMENT USE ONLY

2.6 DOCUMENT SOURCE

- If "Other database," "Other Clinic," "Other," or "Out of state" is selected, specify source in Section X, Comments.
- Two-level codes for report source are shown below. The first level of source code is required, and the second level is recommended.

Document Source Codes for HIV Reporting

First level source <Source 1> Second (more detailed) level source <Source 2>

First level source <source 1=""/>	Second (more detailed) level source <source 2=""/>
A01. = Inpatient	A01.01 = IP/Acute care facility
	A01.01.02 = IP/ACF/OBGYN records
	A01.01.03 = IP/ACF/Pediatric records
	A01.01.04 = IP/ACF/Birth records
	A01.02 = IP/VA
	A01.03 = IP/Military hospital
	A01.03.02 = IP/Military/OBGYN records
	A01.03.03 = IP/Military/Pediatric records
	A01.04 = IP/Long-term care facility
	A01.04.03 = IP/LTCF/Drug TX program
	A01.05 = IP/Hospice
A02. = Outpatient	A02.01 = OP/HMO
	A02.02 = OP/VA
	A02.03 = OP/Private physician
	A02.04 = OP/Adult HIV Clinic
	A02.05 = OP/Infect. Dis. Clinic
	A02.06 = OP/County HD clinic
	A02.07 = OP/Maternal HIV clinic
	A02.08 = OP/Prenatal clinic or records
	A02.09 = OP/Pediatric HIV clinic
	A02.10 = OP/OBGYN clinic (not HIV related)
	A02.11 = OP/Pediatric clinic
	A02.12 = OP/TB clinic
	A02.14 = OP/IHS clinic
	A02.15 = OP/Early intervention nurse
	A02.16 = OP/Visiting nurse service
	A02.17 = OP/Hemophilia TX clinic
	A02.18 = OP/Hospice
	A02.19 = OP/Drug TX center
	A02.20 = OP/Rehab center
	A02.25 = OP/Other clinic
A03. = Emergency room	A03 = Emergency room

First level source <source 1=""/>	Second (more detailed) level source <source 2=""/>		
A04. = Screening, diagnosis,	A04.01 = Scr, Dx, Ref/Blood bank		
and referral agencies	A04.02 = Scr, Dx, Ref/Drug TX program		
	A04.03 = Scr, Dx, Ref/Family planning clinic		
	A04.04 = Scr, Dx, Ref/HIV case management agency		
	A04.05 = Scr, Dx, Ref/HIV counseling & testing site		
	A04.06 = Scr, Dx, Ref/Immigration report		
	A04.07 = Scr, Dx, Ref/Insurance report		
	A04.08 = Scr, Dx, Ref/Job Corps		
	A04.09 = Scr, Dx, Ref/Military		
	A04.10 = Scr, Dx, Ref/Partner referral & counseling service		
	A04.11 = Scr, Dx, Ref/STD clinic		
A05. = Laboratory	A05.01 = Lab/hosp.		
	A05.02 = Lab/state		
	A05.03 = Lab/private		

First level source <source 1=""/>	Second (more detailed) level source <source 2=""/>
A06. = Other databases	A06.01 = Other DB/ADAP
	A06.02 = Other DB/ASD
	A06.03 = Other DB/Birth certificate
	A06.04 = Other DB/Birth defects registry
	A06.05 = Other DB/Cancer registry
	A06.06 = Other DB/Database from coroner
	A06.07 = Other DB/Death certificate review
	A06.08 = Other DB/EHRAP database
	A06.09 = Other DB/EPS database
	A06.10 = Other DB/HARS database
	A06.11 = Other DB/Health department records
	A06.12 = Other DB/Hepatitis registry
	A06.13 = Other DB/Hosp billing summary or discharge data
	A06.14 = Other DB/HRSA HIV Care database
	A06.15 = Other DB/Immunization registry
	A06.16 = Other DB/Medicaid records
	A06.17 = Other DB/NDI
	A06.18 = Other DB/Out-of-state report
	A06.19 = Other DB/Prison, jail, or other correctional facility database
	A06.20 = Other DB/PSD
	A06.21 = Other DB/State disease registry
	A06.22 = Other DB/SHAS
	A06.23 = Other DB/SHDC database
	A06.24 = Other DB/STD registry
	A06.25 = Other DB/TB registry
	A06.50 = Other DB/Other database or report
A07. = Other facility records	A07.01 = Oth facility records/Prison, jail, or other correctional facility
	A07.02 = Oth facility records/Coroner, not associated with IP facility
A10 = Other source	A10 = Other source
	(specify)
Unknown	

4.0 PATIENT DEMOGRAPHICS

4.1 DIAGNOSTIC STATUS AT REPORT

• See 4.1.1–4.1.4, below.

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 CONFIRMED HIV INFECTION (NOT AIDS)

• Among children aged greater than or equal to 18 months and less than 13 years, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory Criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay), followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test) **OR**
- Positive result or report of a detectable quantity on any of the following HIV virologic (nonantibody) tests:
 - HIV nucleic acid (DNA or RNA) detection (e.g., DNA polymerase chain reaction [PCR] or plasma HIV-1 RNA)
 - HIV p24 antigen test, including neutralization assay
 - HIV isolation (viral culture)

OR

Clinical or Other Criteria (if the above laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician **OR**
- Conditions that meet criteria included in the case definition for AIDS

• Among children aged less than 18 months, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory Criteria

Definitive

- Positive results on two separate specimens (excluding cord blood) using one or more of the following HIV virologic (nonantibody) tests:
 - HIV nucleic acid (DNA or RNA) detection
 - HIV p24 antigen test, including neutralization assay, in a child greater than or equal to 1 month of age
 - HIV isolation (viral culture)

OR

Presumptive

- A child who does not meet the criteria for definitive HIV infection but who has:
 - Positive results on only one specimen (excluding cord blood) using the above HIV virologic tests and no subsequent negative HIV virologic or negative HIV antibody test

OR

Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician *OR*
- Conditions that meet criteria included in the 1987 pediatric surveillance case definition for AIDS (<u>http://www.cdc.gov/mmwr/pdf/other/mmsu3601.pdf</u>)— see next page for detailed listing.
 - In the absence of laboratory evidence of HIV infection in the child, that child meets the HIV case definition if diagnosed with conditions that meet the criteria in the 1987 pediatric case definition for AIDS if born to a mother known to be infected at the time of birth.
 - The current HIV case definition for children less than 13 years of age, and persons of all ages, is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm.

- 4.1.3 AIDS
 - The current pediatric AIDS case definition is available at <u>http://www.cdc.gov/mmwr/pdf/other/mmsu3601.pdf</u>. The current HIV case definition is located at : http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm?s_cid=rr5710a1_e The 1994 revised classification system for HIV infection in children less than 13 years of age is available at <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/00032890.htm</u>.
 - Children who are HIV infected and exhibit any of the following AIDS-defining clinical conditions should be reported as presumptive AIDS cases; although most of these conditions appear among adult AIDS diagnostic criteria, asterisked conditions apply only to pediatric cases.
 - For children with an AIDS-defining condition that requires laboratory evidence of HIV infection, a single positive HIV-detection test (i.e., HIV culture, HIV PCR, or HIV p24 antigen) is sufficient for a reportable AIDS diagnosis if the diagnosis is confirmed by a clinician.
- Candidiasis, esophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) (>1 month's duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi's sarcoma
- Lymphoid interstitial pneumonia*
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Multiple recurrent bacterial infections*
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis pneumonia
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain

• Wasting syndrome due to HIV

4.1.4 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:

Laboratory Criteria

Definitive

- At least two negative HIV antibody tests from separate specimens obtained at ≥6 months of age
- At least two negative HIV virologic tests* from separate specimens, both of which were performed at ≥ 1 month of age and one of which was performed at ≥ 4 months of age

AND

• No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

OR

Presumptive

- A child who does not meet the above criteria for definitive "not infected" status but who has:
 - One negative EIA HIV antibody test performed at ≥6 months of age and NO positive HIV virologic tests, if performed *OR*
 - One negative HIV virologic test* performed at ≥4 months of age and NO positive HIV virologic tests, if performed *OR*
 - One positive HIV virologic test with at least two subsequent negative virologic tests*, at least one of which is at ≥4 months of age; or negative HIV antibody test results, at least one of which is at ≥6 months of age

AND

• No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition).

OR

Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)

• Determined by a physician to be "not infected," and a physician has noted the results of the preceding HIV diagnostic tests in the medical record

AND

- NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)
- *HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice to exclude infection in children aged <18 months. Although HIV culture can be used for this purpose, it is more complex and expensive to perform and is less well standardized than nucleic acid detection tests. The use of p24 antigen testing to exclude infection in children aged <18 months is not recommended because of its lack of sensitivity.

4.2 SEX ASSIGNED AT BIRTH

- In addition to "Male" or "Female" sex at birth, CDC-supplied software includes a third choice of "Unk." Although "CURRENT_SEX" is not a variable appearing on the case report form, the person completing the form may record current sex in Section XI or in the form's margin next to Section III—particularly if current sex differs from sex at birth.
- Selections and legal values for "CURRENT_SEX" from eHARS Lookup Codes are as follows:

CURRENT_SEX = F = Female Person's current sex CURRENT_SEX = I = Intersexed Person's current sex CURRENT_SEX = M = Male Person's current sex

- Additionally, the current form does not include fields for patient gender, but eHARS optionally does. A variety of genders may be recorded either in the margin of the case report form at Section III or in the Comments section. Note that "CURRENT_GENDER" adds behavioral, biological, and iatrogenic selections to those of "current sex."
- Selections and legal values for "CURRENT GENDER" from eHARS Lookup Codes are as follows:

CURRENT_GENDER = CD = Cross Dresser Person's current gender CURRENT_GENDER = DQ = Drag Queen Person's current gender CURRENT_GENDER = F = Female Person's current gender CURRENT_GENDER = FM = Female to Male Person's current gender CURRENT_GENDER = I = Intersexed Person's current gender CURRENT_GENDER = M = Male Person's current gender CURRENT_GENDER = MF = Male to Female Person's current gender CURRENT_GENDER = SM = She Male Person's current gender

4.3 COUNTRY OF BIRTH

- Select first from boxes provided:
 - United States
 - Other/US dependency, specify
- For patients born in US dependencies, specify from the following table:

US dependencies			
American Samoa	Pacific Trust Terr.		
Guam	Palau		
Johnston Atoll	Puerto Rico		
Mariana Islands	Ryukyu Islands		
Marshall Islands	Swan Islands		
Micronesia	US Virgin Islands		
Midway Islands	Wake Island		
Navassa Island			

4.5 VITAL STATUS

- For further guidance on death ascertainment, see <u>Technical Guidance for HIV/AIDS</u> <u>Surveillance Programs, Volume I: Policies and Procedures, Death Ascertainment</u>.
- 4.10 DATE OF INITIAL EVALUATION FOR HIV INFECTION
 - Enter the date of initial evaluation for HIV infection.
 - Evidence of HIV infection in a child **must be obtained on or after the birth date**.
- 4.11 ETHNICITY
 - Regardless of the presence of race or absence of any information, collect data on ethnicity.
 - As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic, non-Hispanic) for a person be collected as separate variables.
 - A wide variety of ethnicities may be selected from legal values available in CDC-supplied software. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

4.13 RACE

- 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 categories:
 - American Indian or Alaska Native
 - Asian
 - Black or African American
 - Native Hawaiian or Other Pacific Islander
 - White
- A wide variety of race categories may be selected from legal values available in CDCsupplied software. These races and codes are documented in the eHARS Technical Reference Guide.

5.0 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 AIDS case reports, enter the patient's residence at the date of the first AIDS-defining clinical condition or the date of the first immunologic marker that reaches AIDS-defining thresholds.

RESIDENCE, HOMELESS

- For homeless patients, enter the address that most accurately describes where they stay including a shelter address if applicable.
- People without a usual residence should be reported by the jurisdiction where they were staying at the time of diagnosis.

For further guidance about residency assignment, see <u>Technical Guidance for HIV/AIDS Surveillance</u> <u>Programs, Volume I: Policies and Procedures, Case Residency, Case Residency Assignment</u>.

6.0 STATE/LOCAL USE ONLY

- 6.1 PHYSICIAN'S NAME
 - If the test was provided as part of a visit to a health department, an STD clinic, an HIV counseling and testing site, or other facility where no single individual is responsible for medical management of the patient, leave this space blank and complete the "Facility of Diagnosis" section appropriately.

7.0 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.
- If a facility name is not documented but a physician's name is listed, enter "Private Physician" or a numeric code for each physician; enter the name of the physician under Physician Identifier Information (Section VI).
- For reports of AIDS, enter the name of the facility where the patient's AIDS- defining clinical condition was first diagnosed.
- If a physician name is listed without facility name, enter physician name.
- These fields strictly apply to facility where HIV or AIDS was diagnosed. Where chart abstraction is accomplished at a facility other than the Facility of Diagnosis (Section IV), document report source; refer to <u>2.6</u> for further details.

7.9 FACILITY TYPE

- Select "Physician, HMO" where diagnosis was made at a private, outpatient care site not associated with a hospital.
- Examples of "Other" include HIV counseling and testing sites, STD clinics, drug treatment facilities, family planning clinics, prenatal/obstetrics clinics, tuberculosis clinics, and correctional facilities. Select "Other" for any public outpatient setting.

8.0 PATIENT HISTORY

- Surveillance staff have found such information within mother's chart at discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact child's provider about maternal/child risk factor information.
- Definition of 'Risk factors': The collective term for the individual routes of exposure/transmission on which data are routinely collected for surveillance of HIV cases. "Yes," "No," or "Unknown" must be selected.

• See <u>Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and</u> <u>Procedures, Risk Factor Ascertainment</u> for further guidance on risk factor data collection. States should have risk factor ascertainment procedures tailored to their jurisdictions as well.

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, however, mother-to-infant transmission through breast-feeding is considered as the only mode of transmission, please alert the state or local NIR coordinator and enter in the field labeled "other" in the patient/maternal history section.

(MOTHER) DIAGNOSED WITH HIV INFECTION/AIDS

- 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:
 - 3 before this child's pregnancy;
 - 4 during this child's pregnancy
 - 5 at time of delivery (i.e., when admitted for labor/delivery and before discharge from the birth hospital or within 7 days of birth;
 - 6 before child's birth, exact period unknown;
 - 7 after the child's birth (i.e., anytime after discharge from birth hospital or after 7 days of birth); or
 - 8 HIV-infected, unknown when diagnosed.
- If no information is available regarding maternal HIV status, please select:9 HIV status unknown.

8.2 DATE OF MOTHER'S FIRST POSITIVE HIV CONFIRMATORY TEST

The following is adapted from an excerpt of the adult/adolescent HIV surveillance case definition, accessible at <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm</u>:

Necessary for HIV infection (not AIDS)

- Documentation of +EIA plus +WB/IFA with date or
- Detectable viral load with date *or*
- Positive p24 antigen test with date *or*
- Positive viral culture with date *or*
- Physician documentation of HIV with date

8.3 MOTHER WAS COUNSELED ABOUT HIV TESTING DURING THIS PREGNANCY, LABOR, OR DELIVERY?

- Complete this question for all mothers regardless of whether they were diagnosed with HIV infection before this pregnancy.
- If not, then select "No."
- If no information in the medical chart is available regarding counseling, then select "Unk."

8.4.3.3 HETEROSEXUAL RELATIONS WITH PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION

• 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 the correct answer to this question is "No"; and the question below about transfusion recipient should be answered "Yes" if the partner was also known to be HIV infected.
- Refer to Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information.

8.4.3.4 HETEROSEXUAL RELATIONS WITH TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION

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

8.5.2 RECEIVED CLOTTING FACTOR FOR COAGULATION DISORDER

- 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, then the correct answer to this question is "No"; and the question below about blood transfusion should be answered "Yes." If "Yes," please specify disorder.
- If child was born after March 1985 and receipt of clotting factor is the suspected mode of HIV transmission, alert the state/local NIR coordinator.

9.0 LABORATORY DATA

- 9.1.3 HIV-1 Western blot
 - Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations "Human Immunodeficiency Virus Type 1 Infections" (*MMWR*, 1989:38:No.S-7).

10.0 CLINICAL

- 10.1 AIDS INDICATOR DISEASES
 - Enter the dates of initial diagnosis of each indicator disease.
 - If at all possible, it is important to include both month and year for future trend analysis.
 - In rare circumstances, both month and year may not be available. However, if after further searches the investigator finds that the only documentation of the diagnosis date is the year, without a designated month, "..." should be entered for the unknown month followed by the documented year.
 - Choosing an arbitrary month is not recommended.
 - Definitive diagnoses are based on specific laboratory evidence such as histology or culture.
 - Methods for the presumptive diagnosis of diseases indicative of AIDS listed in the case definition supplement are simply suggested guidelines, not requirements. If a method does not meet the requirements for definitive diagnosis, it meets the requirements for presumptive diagnosis for those conditions that may be diagnosed presumptively. Accept any method that the clinician considers diagnostic.

11.0 BIRTH HISTORY AVAILABLE (FOR PERINATAL CASES ONLY)

11.4.3 DELIVERY

- 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.

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 (i.e., neural tube defects, congenital heart defects, esophageal atresia, cleft lip/palate, etc.).
- 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 and used in the Metropolitan Atlanta Congenital Defects Program and 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.
- 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 psychologic 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. For reference, you may request the full copy of the Metropolitan Atlanta Congenital Defects Program Procedure Manual from HICSB at (404) 639-2050.

BIRTH DEFECTS CODE

The 6-digit defect code is based on 3- or 5-digit ICD-9 codes. The ICD-9 code, which may be available in the child's medical record, can be used in place of the 6-digit code. If defects exist, list all on the case report form and enter in the Comments section. Call CDC's DHAP Help Desk by phone at (877) 659-7725 for assistance with coding.

System	Condition	6-digit Codes	3-digit Codes
Central Nervous System	Spina Bifida (meningocele)	741.000– 741.990	A04
	Anencephaly	740.000– 740.100	A01
	Encephalocele	742.000– 742.090	A13
Cardiovascular	Atrial septal defects	745.510– 745.590	D06
	Ventricular septal defects	745.400– 745.490	D05
	Pulmonary valve anomalies	746.000– 746.090	D12
	Coarctation of the aorta	747.100– 747.190	D26
	Aortic valve anomalies	746.300– 746.490	D14
	Transposition of the Great	745.100-	D02

• The following is an abbreviated reference list for birth defect coding:

	Arteries	745.190	
	Tetralogy of Fallot	745.200– 742.210	D03
	Hypoplastic left heart syndrome	746.700	D18
Orofacial	Cleft palate without cleft lip	749.000– 749.090	F01
	Cleft lip with and without cleft palate	749.100– 749.290	F02
Musculoskeletal	Clubfoot	754.730	J05
	Reduction defect of upper limb	755.200– 755.290	K01
	Reduction defect of lower limb	755.300– 755.390	K02
Chromosomal	Down syndrome	758.000– 758.098	R01
	Trisomy 13 (Patau Syndrome)	758.100– 758.198	R02
	Trisomy 18 (Edwards Syndrome)	758.200– 758.298	R03
	22q11.2 deletion	758.370	R04
Eye	Cataract	743.320– 743.326	B04
	Anophthalmos and microphthalmus	743.000– 743.100	B01
Genitourinary	Hypospadius	752.600– 752.607	G02
	Anomalies of renal pelvis and ureter	753.200– 753.290	H06
	Ambiguous genitalia	752.700– 752.790	G04
Abdominal Wall	Gastrochisis	756.710	N04
Anomalies	Omphalocele	756.700	N02
Diaphragmatic Anomalies	Diaphragmatic hernia	756.600– 756.616	N01

Note: To add a birth defect that is not in this abbreviated list, please refer to the codes from the *Metropolitan Atlanta Congenital Defects Program Procedure Manual*.

11.6.1 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		

11.10 DID MOTHER RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING PREGNANCY?

• A single drug formulation often has multiple names; trade names are in bold. Drug names include the following, which serves only as a guide. This guide is current as of May 2011: <u>http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDS</u> <u>Activities/ucm118915.htm</u>

Antiretroviral drugs used in the treatment of HIV infection

Drugs Used in the Treatment of HIV Infection Multi-class Combination Products

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
<u>Atripla¹</u>	efavirenz, emtricitabine and tenofovir disoproxil fumarate	Bristol-Myers Squibb and Gilead Sciences	12-July-06	2.5 months

Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
<u>Combivir</u> ²	lamivudine and zidovudine	GlaxoSmithKline	27-Sep-97	3.9 months
Emtriva ³	emtricitabine, FTC	Gilead Sciences	02-Jul-03	10 months
Epivir ⁴	lamivudine, 3TC	GlaxoSmithKline	17-Nov-95	4.4 months
Epzicom ⁵	abacavir and lamivudine	GlaxoSmithKline	02-Aug-04	10 months
Hivid ⁶	zalcitabine, dideoxycytidine, ddC (no longer marketed)	Hoffmann-La Roche	19-Jun-92	7.6 months

Retrovir ⁷	zidovudine, azidothymidine, AZT, ZDV	GlaxoSmithKline	19-Mar-87	3.5 months		
Trizivir ⁸	abacavir, zidovudine, and lamivudine	GlaxoSmithKline	14-Nov-00	10.9 months		
<u>Truvada</u> 9	tenofovir disoproxil fumarate and emtricitabine	Gilead Sciences, Inc.	02-Aug-04	5 months		
Videx EC ¹⁰	enteric coated didanosine, ddI EC	Bristol Myers-Squibb	31-Oct-00	9 months		
Videx ¹¹	didanosine, dideoxyinosine, ddI	Bristol Myers-Squibb	9-Oct-91	6 months		
Viread ¹²	tenofovir disoproxil fumarate, TDF	Gilead	26-Oct-01	5.9 months		
Zerit ¹³	stavudine, d4T	Bristol Myers-Squibb	24-Jun-94	5.9 months		
Ziagen ¹⁴	abacavir sulfate, ABC	GlaxoSmithKline	17-Dec-98	5.8 months		
Nonnucleosid	Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)					

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
Edurant	rilpivirine	Tibotec Therapeutics	20-May-11	10 months
Intelence ¹⁵	etravirine	Tibotec Therapeutics	18-Jan-08	6 months
Rescriptor ¹⁶	delavirdine, DLV	Pfizer	4-Apr-97	8.7 months
Sustiva ¹⁷	efavirenz, EFV	Bristol Myers-Squibb	17-Sep-98	3.2 months
Viramune ¹⁸ (Immediate Release)	nevirapine, NVP	Boehringer Ingelheim	21-Jun-96	3.9 months
Viramune XR ¹⁹ (Extended Release)	nevirapine, NVP	Boehringer Ingelheim	25-Mar-11	9.9 months

Protease Inhibitors (PIs)

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
Agenerase ²⁰	amprenavir, APV	GlaxoSmithKline	15-Apr-99	6 months
<u>Aptivus</u> ²¹	tipranavir, TPV	Boehringer Ingelheim	22-Jun-05	6 months

Crixivan ²²	indinavir, IDV,	Merck	13-Mar-96	1.4 months
Fortovase ²³	saquinavir (no longer marketed)	Hoffmann-La Roche	7-Nov-97	5.9 months
Invirase ²⁴	saquinavir mesylate, SQV	Hoffmann-La Roche	6-Dec-95	3.2 months
Kaletra ²⁵	lopinavir and ritonavir, LPV/RTV	Abbott Laboratories	15-Sep-00	3.5 months
Lexiva ²⁶	Fosamprenavir Calcium, FOS-APV	GlaxoSmithKline	20-Oct-03	10 months
Norvir ²⁷	ritonavir, RTV	Abbott Laboratories	1-Mar-96	2.3 months
Prezista ²⁸	darunavir	Tibotec, Inc.	23-Jun-06	6 months
Reyataz ²⁹	atazanavir sulfate, ATV	Bristol-Myers Squibb	20-Jun-03	6 months
Viracept ³⁰	nelfinavir mesylate, NFV	Agouron Pharmaceuticals	14-Mar-97	2.6 months

Fusion Inhibitors

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
Fuzeon ³¹	enfuvirtide, T-20	Hoffmann-La Roche & Trimeris	13-Mar-03	6 months

Entry Inhibitors - CCR5 co-receptor antagonist

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
Selzentry ³²	maraviroc	Pfizer	06-August-07	8 months

HIV integrase strand transfer inhibitors

Brand Name	Generic Name	Manufacturer Name	Approval Date	Time to Approval
Isentress ³³	raltegravir	Merck & Co., Inc.	12Oct-07	6 months

Generic drugs used in the Treatment of HIV Infection³⁴

Drugs Used in the Treatment of Pediatric HIV Infection³⁵

Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan (PEPFAR)

• 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 http://www.aidsinfo.nih.gov/guidelines/.

11.12.2 MATERNAL SOUNDEX

- If name of the patient's biological mother has not been entered in the database, enter name and date of birth in the CDC-supplied software.
- The biological mother's surname will be converted to a SOUNDEX CODE when entered into the CDC-supplied software.
- If name of the biological mother has been entered in your database and a "stateno" exists, retrieve the soundex code from the database and enter here.
- Consult with your state/local health department in jurisdictions with alternatives to name-based reporting.

11.12.4 MATERNAL COUNTRY OF BIRTH

- Select first from boxes provided:
 - United States
 - US dependency, specify
 - Other, specify
 - Unknown
- For patients born in US dependencies, specify from the following table:

US dependencies				
American Samoa	Pacific Trust Terr.			
Guam	Palau			
Johnston Atoll	Puerto Rico			
Mariana Islands	Ryukyu Islands			
Marshall Islands	Swan Islands			
Micronesia	US Virgin Islands			
Midway Islands	Wake Island			
Navassa Island				

12.0 SERVICES REFERRAL

12.1.1 NEONATAL ARVs FOR HIV PREVENTION

- The neonatal component of the ACTG protocol 076 consisting of 6 weeks of neonatal prophylactic ARV therapy should begin within 24 hours of birth. Therefore, to monitor implementation and impact, we collect the day, month, and year the child was first started on ARV for prophylaxis.
 - If "Yes," record the day, month, and year the child was started on ARVs as prophylaxis during the first 6 weeks of life.
 - If search for day was unsuccessful and year and month are present, then enter "..." for the unknown day followed by the documented year and month.
 - Examples include Didanosine (ddI, dideoxyinosine, Videx), Dideoxycytidine (ddC, HIVID, Zalcitabine), Lamivudine (3TC, Epivir), Stavudine (d4t, Zerit),

- 12.1.2 ANTI-RETROVIRAL THERAPY FOR HIV TREATMENT
 - Please refer to the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection http://aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=8

12.1.3 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.

12.2 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.

12.3 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 dead 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 dead 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

Purpose of Pediatric HIV Exposure Reporting form

The *Pediatric HIV Exposure Reporting* form is to collect information on Pediatric Exposure Reporting. The form facilitates collection of additional standardized data on HIV-exposed children related to prevention of perinatal transmission beyond those in collected and stored in state eHARS systems. This guidance applies data collection even if surveillance sites use a different form or medium for HIV case surveillance. See <u>Appendix</u> for further details. Information on children who are perinatally exposed to HIV or who have HIV or AIDS is protected under a federal assurance of confidentiality.

The exposure reporting 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.

Disposition of form

- The completed form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC) with patient identifiers.
- Data obtained from these forms are entered into compatible or standardized computer software provided by the Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, linked to maternal records and then transferred without identifiers to CDC electronically by encrypted electronic transfer via secure data network.

Chart abstraction guidance

Think critically about the data you are abstracting. The information should make sense overall. For example, the dates of receipt of prenatal care, CD4 and viral load testing, receipt of antiretrovirals should make sense based on the infant's date of birth. If you find inconsistent information in the medical records indicate that information in the comments section on the data abstraction form. This will let us know that the inconsistency was in the medical record and is not an error with the abstraction, notation, or data entry of the information. 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 must be familiar with the various components of the medical record (demographic/financial information, doctor's progress or S.O.A.P. notes, prenatal care records, labor & delivery records, nurse's notes, operative notes, lab results section, discharge summaries, problem lists, drug lists, etc.)
- Abstractors need to be familiar with medical abbreviations and terminology, especially as related to HIV.
- Abstractors need to be familiar with the procedures required to abstract records from the various providers/facilities.
- Abstractors must be trained in confidentiality and security procedures and sign a statement to that effect. Most health departments and academic institutions have such training in existence and methods in place to document completion of this training.

Records to be Abstracted

At a minimum the following records should be reviewed. There may be particular instances where other records are also reviewed (i.e., STD records, Health Department Records)

Mother	Infant
Maternal prenatal records	Pediatric birth records (hospital records)

Maternal labor and delivery records Maternal HIV clinic records Birth certificate

Pediatric medical records (HIV clinic, non HIV clinic, 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 any chart at all on the mother, the Enhanced Surveillance Form should still be filled out and Questions 1, 2, and 3 should be completed as much as possible.
- If information on the mother is available in the infant's chart but also in the mother's chart, use the mother's chart as the 'gold standard' for questions related to the mother's care.

Abstraction of Infant's Record

Complete this form only for <u>live births</u>. It is not feasible for surveillance to collect data for all pregnancies (which would include fetal loss). 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, <u>irrespective of the duration of the pregnancy</u>, 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 <u>several pregnancies during the project</u> period, each pregnancy should be considered a separate event and should be <u>abstracted separately</u>.
- If the outcome of a pregnancy is <u>multiple births (e.g. twins)</u>, a separate eHARS and supplemental exposure reporting form should be used for each infant, but the maternal information only needs to be abstracted on one form.

Follow-up Chart Review

You will be reviewing 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, be sure to abstract all data needed for eHARS updates (e.g., HIV diagnostic tests, CD4 counts, treatment, prophylaxis, AIDS-defining conditions, birthweight, vital status, birth defects, etc). You will need to complete a new EPS form documenting the updates. On the additional EPS form you should complete the demographics section for both the mother and the infant and then only 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 in if you wish 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.

Record Not Available

Record not available should only be selected if the information cannot be obtained from any record source and the primary record as indicated in the hierarchy at the beginning of each section is not available.

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. <u>If all or part of a date is unknown</u>, '<u>'</u>(blank) should be entered into the appropriate space (e.g., 02/../2005). No not use '99" to indicate unknown/missing dates. <u>Be sure the dates indicated on the form make sense</u>. For example, be sure that the infant's date of birth is consistent with the date of delivery indicated and that the dates of receipt of prenatal care, CD4 and viral load testing, receipt of antiretrovirals, etc make sense based on this date of birth.

Records That Are 'Not Available'

Records will be considered 'not available' after two separate 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.

Conflicting Information

The chart which could be considered the gold standard for a specific question depends on the question itself. An example of a situation which may arise is as follows: the maternal obstetrical chart and the HIV chart may have different dates for receipt of prenatal care. We recommend that you use the information from the obstetrical chart. Similarly, if there are different start dates for administration of ARV, use the HIV infectious disease (HIV/ID) chart as the gold standard 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). Therefore, 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.

Error Correction

When correcting errors on the abstraction form, draw a single line through the error and write the correct information next to or above it. Please do not attempt to write the correct information over top of the original line, making it hard to decipher which is the correct information. It is also best not to use 'white out'. Confidential information written anywhere in the form margins can usually be covered by black ink selecter.

Required Fields

Infant state number is required on the abstraction form for linkage to eHARS data and as a quality control tool to avoid duplicative record entry.

Text boxes

Enter comments, specifics, or additional information (missing values can be left blank or entered using two periods [..]).

INFORMATION COMPLETE FOR ANALYSIS: (Y/N)

A 'Yes' response indicates that the data included on the data abstraction form is ready to be included in the analysis dataset. Whether or not the data is ready is a decision which should be made by the Perinatal Coordinator, Surveillance Coordinator, or another designee, not the data entry specialist. The following guidelines will be helpful in deciding if the data is ready for analysis:

- An attempt has been made to abstract all available records. If minimal information is available and there are no further resources for obtaining information, the form may be judged as 'complete for analysis' even though information on the mother and infant is incomplete.
- Information through the birth history should have been obtained.
- Completeness should be judged based on what information is abstracted that is most helpful to the state in performing any particular analysis.
- Note: Expected follow-up, such as documented HIV serostatus, will come later.

1. If information on the mother is not available, was the child adopted, or in foster care?

1. If information on the mother is not available, was the child adopted, or in foster care?

Yes No Not applicable

- Select appropriate response from legal values "Yes", "No", or "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

2. Records abstracted (1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—record not available, 3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—records (2 = Attempted—records (3 = Not abstracted, 4 = Attempted—will try again) (1 = Abstracted, 2 = Attempted—records (2 = Attempted - Velocitic records (3 = Attempted - Velocitic records (4 = Attempted - Velocitic records (5 = Attempted - Velocitic records (5 = Attempted - Velocitic records (6 = Attempted - Velocitic records (6 = Attempted - Velocitic records (7 = Attempted - Velocitic records (8 = Attempted - Velocitic records (9 = Attempted - Velocitic records (9 = Attempted - Veloci

• For each type of record, <u>code</u> whether it was - abstracted (1), attempted but record was not available (2), not abstracted (3), or attempted, will try again (4). Do not simply indicate an X for each record abstracted

3. Weeks' gestation at first prenatal care visit

3. Weeks' gestation at first prenatal care visit

- ___ weeks
- Enter value in weeks, by calculating difference between estimated date of conception and date of first prenatal care visit.
- 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. Was the mother screened for any of the following during pregnancy?

4. Was the mother screened for any of the following during pregnancy?

(Check test performed bef	ore birth, bu	t closest to date of delivery or	admission to lab	or and delivery.)		
	Yes	Date (mm/dd/yyyy)	No	Not documented	Record not availab	le Unknown
Group B strep						
Hepatitis B (HBsAg)		//				
Rubella		//				
Syphilis						

(Reference: Red Book 2000- American Academy of Pediatrics) Use test done prior to birth but closest to delivery date or at admission for labor and delivery.

- 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 & rectal GBS colonization, offering intrapartum chemoprophylaxis to those identified as GBS carriers <u>OR</u>
 - risk factor based strategy prophylaxis given to women with intrapartum risk factors: gestation < 37 weeks, \geq 18 hours since rupture of membrane, temperature 38° C or greater.
- 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). This test is usually done at the initial prenatal visit or at the time of labor & delivery for high risk women and women whose status is unknown.

- Rubella Screening usually done at the initial prenatal visit. If 'negative' the mother should be immunized.
- 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. For more information about syphilis see Q.5.

5. Diagnosis (for the mother) of the following conditions during this pregnancy or at the time of labor and delivery

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 to	r definitions.)					
	Yes	Date of diagnosis (mm/dd/yyyy)	No	Not documented	Record not available	Unknown
Bacterial vaginosis						
Chlamydia trachomatis infection						
Genital herpes						
Gonorrhea						
Group B strep		/				
Hepatitis B (HbsAg+)						
Hepatitis C						
PID						
Syphilis		/				
Trichomoniasis		//				

5.0 For this question, "diagnosed" refers to newly diagnosed, had a recurrence of, or had chronic infection with any of the following conditions. Screening for syphilis, gonorrhea, and chlamydia is done during prenatal care. Generally a diagnosis of an STD will show up in a number of places in the chart including progress notes, 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 of public health clinics). Diagnoses may be presumptive or definitive depending on various signs, 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:

- 5.1 Bacterial vaginosis Clinician diagnosis of bacterial vaginosis. Sometimes abbreviated BV.
- 5.2 Chlamydia (*Chlamydia trachomatis*) Record positive test for chlamydia (either 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, PCR and LCR.
- Genital Herpes Active (herpes genitalis) Record as a 'Yes' if the woman has <u>primary herpes</u> (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).

- Gonorrhea (*Neisseria gonorrhea*) Record if culture positive.
 - Name of lab tests *Neisseria gonorrhea* culture (GC Culture, Gonorrhea Culture); Thayer-Martin medium; chocolate agar; detection of nucleic acid.
- Group B Strep 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 & rectal GBS colonization, offering intrapartum chemoprophylaxis to those identified as GBS carriers <u>OR</u>
 - Risk factor based strategy in which prophylaxis is given to women with intrapartum risk factors: gestation < 37 weeks, ≥ 18 hours since rupture of membrane, temperature 38° C or greater.
- 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). Usually done at the initial prenatal visit or at the time of labor & delivery for high risk women and women whose status is unknown.
- 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).
- 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.
- Syphilis (*Treponema pallidum*) All pregnant woman should receive serologic screened 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 risk 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 remain 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/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 to *Treponema Pallidum*; Microhemagglutination, *Treponema Pallidum*.
- 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

6. Mother's reproductive history

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6.0 To specify 'Not Documented' enter 'ND'. 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 of the woman's past pregnancies.

- **Number of previous pregnancies:** This number should include all pregnancies, regardless of outcome (including abortions, miscarriages, etc) <u>up to but</u> <u>EXCLUDING the pregnancy that is being abstracted</u>.
- **Number of previous live births:** Note that <u>parity</u> 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. <u>Parity cannot be used for this answer</u>. The number of live births should be the total of preterm and term births (<u>excluding</u> abortions, miscarriages, and stillbirths).
- **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.

- 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: Record the number of previous induced abortions (above) AND the number of previous miscarriages (above) <u>OR</u> (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.
 - \circ 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)
 - \circ A = Abortion, the number of abortions (both spontaneous and induced abortions)

For example, a woman who is $G_5 P_3 A_1$ 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

 1^{st} digit = term pregnancies (>37 weeks)

 2^{nd} digit = preterm pregnancies (20-37 weeks)

- 3^{rd} digit = abortions (includes both spontaneous and induced abortions)
- 4^{th} digit = living children

For example, a woman's record may read $G_5 P_{2113}$. 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.

7. Complete the chart for all siblings.

	Date of birth (mm/dd/yyyy)	Age (yrs: mos as of mm/yyyy)	HIV serostatus (See list.)	State No.	City No.
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 of live born siblings. This information is not always available on prenatal care charts or labor and delivery records. This question is included because of limitations in the current eHARS software (v3.3) which allow only for the linking of one child with the mother's eHARS case report.

8. Substance use during pregnancy noted

8. Was substance use during pre	gnancy noted in the	medical or social work records?	
Yes No (Go to 10.)	Record not availab	ble (Go to 9.) 🔲 Unknown	
8a. If yes, indicate which su	bstances were used o	during pregnancy. (Check all that apply.)	
Alcohol	Cocaine	Marijuana (cannabis, THC, cannabinoids)	Opiates
Amphetamines	Crack cocaine	Methadone	Other (Specify.)
Barbiturates	Hallucinogens	Methamphetamines	
Benzodiazepines	Heroin	Nicotine (any tobacco product)	Specific drug(s) not documented
8b. If substances used, were	any injected?		
🛛 Yes 🔲 No 🔲	Not documented	Unknown Specify injected substance(s).	

• This section on substance abuse provides information on whether substance abuse occurred during the mother's pregnancy. This information can be found in the progress notes, social worker notes, and in the lab results summary section, or in the summary sheet listing all

prenatal care visits, lab results, gestational ages, etc.

- Select appropriate response(s) from legal values, "Yes", "No", "Record not available", or unknown.
 - The drugs listed here are in alphabetical order. 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.
 - If any drugs are used, populate the field at Q. 8b from given legal values. If any drug(s) used were injected, select 'Yes' and write the name of the drug in the space provided.
- 9. Was a toxicology screen done on the mother (either during pregnancy or at the time of delivery)? 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. Marijuana may be listed on the toxicology results as cannabis, as a cannabinoid, THC or simply marijuana. Heroin is a semisynthetic narcotic and opiate and should be listed as heroin or opiate on the toxicology lab results sheet.
 9. Was a toxicology screen done on the mother (either during pregnancy or at the time of delivery)?

Yes, positive result (Cher	ck all that apply.)		
Alcohol	Cocaine	Marijuana (cannabis, THC, cannabinoids)	Opiates
Amphetamines	Crack cocaine	Methadone	Other (Specify.)
Barbiturates	Hallucinogens	Methamphetamines	
Benzodiazepines	Heroin	Nicotine (any tobacco product)	Specific drug(s) not documented
Yes, negative result	🕽 No 📮 Toxicology s	creen not documented	

- 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. Was a toxicology screen done on the infant at birth?** 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 clearly noted in the infant's birth chart.

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

Yes, positive result (Chee	k all that apply.)		
Alcohol	Cocaine	Marijuana (cannabis, THC, cannabinoids)	Opiates
Amphetamines	Crack cocaine	Methadone	Other (Specify.)
Barbiturates	Hallucinogens	Methamphetamines	
Benzodiazepines	Heroin	Nicotine (any tobacco product)	Specific drug(s) not documented

- Yes, negative result No Toxicology screen not documented
- Select all drugs identified on screening, including methadone. If screening for 'Other' drug was done, specify the drug metabolites in the space provided.

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

1. Was the mother's HIV serostatus noted in her prenatal care medical records?							
Yes, HIV-positive	Yes, HIV-negative	No 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 'Yes, HIV-Positive' if there is indication of a positive Western Blot, a positive ELISA, a positive PCR for HIV, a positive HIV culture, or an HIV viral load result > 0. Or, medication records may indicate the mother is receiving ARV.
- Select 'Yes, HIV-Negative' if there is indication of a negative test during pregnancy or at labor and delivery.

12. Antiretroviral drugs prescribed for the mother during this pregnancy?

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

□ Yes (Complete table.) □ No (Go to 12a.) **D** Not documented (Go to 13.)

		Record not av	vailable (Go t	o 13.) 🗖 Unknown					
	Drug name (See list on p. 8.)	Other (specify)	Drug refused	Date drug started (mm/dd/yyyy)	Gestational age drug started (weeks; round down)	Drug stopped Yes No ND	Date stopped (if yes in preceding column) (mm/dd/yyyy)	Stop codes (See list on p. 8.)	
i				//			//		
ii				//			//		
ii				//			//		
v				//			//		
/				//			//		
/i				//			//		
	12a. I	f no antiretro	viral drug w	as prescribed durin	g pregnancy, check	reason.			
No prenatal care Mother known to be HIV-negative during pregnancy Not documented Unknown									
		HIV serostatu	s of mother unl	known 🔲 Mother refu	sed 🔲 Othe	er (Specify.)			

- '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. Select 'no' if no ARV was prescribed in pregnancy.
 - IF NO ARV WAS PRESCRIBED IN PREGNANCY, INDICATE REASON: 0
 - 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 Ο 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.

- o 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.
- Enter 'Unknown' in the 'Drug Name' column if the specific drugs she received are unknown.
- Antiretroviral Drug List: There is a reference list of antiretroviral drugs included at the end of the data abstraction form. In this list, the drugs are organized by drug category, NNRTI, NRTI, Protease Inhibitors, and Other, and within each category the drugs are listed in alphabetical order. As new drugs become available the drug list in the database will be updated. Call the Enhanced Perinatal Surveillance Coordinator at CDC to report drugs that are not included in the list.
 - Drug Name Using the antiretroviral drug list, 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 <u>ACTG 316</u>, receipt of <u>NEVIRAPINE</u> 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, be sure to 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 '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 were not prescribed drugs and those who were not prescribed drugs because they refused it.
 - Date Drug Started Enter 'XX' for unknown values (i.e., 03/XX/2005). In the case of a woman having interrupted antiretroviral medications due to pregnancy, the column 'Date Started' refers to the date when the mother <u>initially started</u> the antiretroviral drugs.
 - Gestational Age Started Enter week of gestation antiretrovirals were started. Round down to the nearest completed week of gestation, i.e., if medical chart indicates 37 4/7 weeks, 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.
 - Date Stopped Enter date (MM/DD/YYYY) the antiretrovirals were stopped if completely discontinued. If date is not documented then indicate 'ND'.
 - Drug Stop Code To answer this question, use the 'S' codes found at the end of the abstraction form. Please see Appendix 2, p. 5 Up to two codes are allowed as reasons why a drug may be stopped. 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, <u>do not</u> code as stopped.

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

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

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

- 13. Select appropriate response from given legal values.
 - 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 will indicate, however, she was known to be HIV-infected during her pregnancy – in such cases, check 'Yes, 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.
 - 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?

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

Yes (Complete table.)	🖵 No (Ge	o to 14a.)	Not documented (Go to 15.)	Record not availab	ole (Go t	io 15.) 🗖 (Jnknown
Drug Name (See list.)	Other (specify)	Drug refused	Date received (mm/dd/yyyy)	Time received (See military time.)	Oral	Type of admi IV	nistration Not documented
i		_ 🛛	//	:			
ii		_ 🛛	//	:			
iii			//	:			
iv		_ 🛛	//	:			
v		_ 🛛	//	:			
vi		_ 🛛	//	:			

14.0 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.

• Select suitable response from given legal values, "Yes", "No", and "Not documented", "Record not available", and "Unknown".

- Select 'Yes' if ARVs received during the intrapartum period, and complete the grid for all drugs received during labor and delivery. Enter "Unknown" in the 'Drug Name' column if the specific drugs received are unknown, complete the grid and write 'Unknown".
- If the specific drugs she received or refused are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column. Also, be sure to enter receipt of ARVs at labor and delivery in EHARS.
- Select "No" if no ARV 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 csection'.
 - HIV status 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.
- <u>Antiretroviral Drug List:</u> A reference list of antiretroviral drugs appears at the end of the data abstraction form (Please see Appendix 2, page 5). In this list, the drugs are organized by drug category, NNRTI, NRTI, Protease Inhibitors, and Other, and within each category the drugs are listed in alphabetical order. As new drugs become available the drug list in the database will be updated. Contact the CDC subject matter expert for Perinatal Surveillance to report drugs not included in the list; this SME may be reached through your jurisdiction's HIV Surveillance Coordinator or by calling the HIV Incidence and Case Surveillance Branch's main number (404) 639-2050.

15.0 If the mother receives CD4 or viral load testing (Q. 16a and 16b) this information can be used as a marker that the mother received care after delivery. This question refers to the time 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 result or first viral load after discharge from hospital (up to 6 months after discharge).

16. If yes, indicate first CD4 result or first viral load after discharge from hospital (up to 6 months after discharge).

16a. CD4 result	Not done	Not available	16b. Viral load 🛛 🔲 Not d	lone 🕒 Not ava	ilable
Result	Unit	Date blood drawn (mm/dd/yyyy)	Result in copies/mL	Result in logs	Date blood drawn (mm/dd/yyyy)
	cells/µL				//
	%	!!			

16.0This 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 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 result, mark 'Not Done'.
- If there is no indication of a subsequent viral load result, mark 'Not Done'.

17. Birth information



17.0 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 p.m. is 21:15--It is easy to calculate by adding 12 to each hour after 12 noon (1:00 p.m. is 13:00, etc...). Midnight is 00:00. Minutes after midnight are coded as 00:01 etc... (i.e., fifteen minutes after midnight is 00:15).

- **Onset of labor -** This should be easily found on the labor and delivery summary sheet. The onset of labor is defined as the time when contractions are 3-5 minutes apart. Note the date as well as the time --both are necessary to calculate the duration of ruptured membranes, and duration of labor. In an '<u>elective cesarean</u> <u>section</u>', there will not be onset contractions, because by definition, an elective cesarean occurs prior to onset of labor. In this case, write '<u>none</u>' in the space provided.
- Admission to L/D Time of admission should be available on the face sheet

(likely stamped on this sheet). If possible, record the time of admission to <u>Labor</u> and <u>Delivery</u> (L&D), rather than to hospital. A short time between admission and delivery ('precipitous delivery') may be a reason for not receiving ARVs. <u>You</u> <u>should make sure that the date and time of admission to L&D is for the admission</u> <u>associated with delivery</u>. 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 easily found on the labor and delivery summary sheet. Note the date as well as the time -- both 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 <u>AROM</u>. When membranes rupture on their own, spontaneously, this is referred to as spontaneous rupture of membranes, or <u>SROM</u>; or <u>PROM</u> which refers to premature rupture of membranes. In the case of cesarean section, the rupture of membranes may be almost concurrent with time of delivery.
 - Delivery This should be easily found on the labor and delivery summary sheet.
 Note the date as well as the time -- both 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, you will have to verify the correct date of birth and update eHARS if necessary.

18. If Cesarean delivery, select all the following indications that apply. 18. If Cesarean delivery, mark all the following indications that apply.

- HIV indication (high viral load)
 Previous Cesarean (repeat)
 Malpresentation (breech, transverse)
 Prolonged labor or failure to progress
 Mother's or physician's preference
 Retal distress
 Petal distress
 Placenta abruptia or p. previa
 Other (eg, herpes, disproportion)
 Specify
 Not specified
 Not applicable
 - Select the appropriate response from given legal values.
 - If not documented, select 'Not specified'.
 - 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. Whether cesarean was the mode of delivery may usually be noted there.
 - Elective cesarean section refers to a cesarean section that occurs <u>before</u> rupture of membranes and <u>before</u> the onset of labor. However, if a Cesarean Section was planned but then performed ahead of schedule due to unexpected circumstances, it will still be coded as 'Elective.' Nonelective (or emergent) C-sections are usually done because the fetus has shown signs of distress during labor, whereas elective C-sections are planned, because of previous C-section, breech position, HIV prevention, etc. and usually occur before the onset of labor. C-sections that are done in the middle of the night are usually not elective--review 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, <u>but the dictated discharge summary will make this</u> <u>clear</u>. 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.

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

19. Was mother's HIV serostatus noted on the child's birth record? lacksquare No

Yes, HIV-positive Yes, HIV-negative Record not available Unknown

• Select appropriate response from given legal values.

20. Antiretroviral drugs prescribed for the child during the first 6 weeks of life.

20. Were antiretroviral drugs prescribed for the child during the first 6 weeks of life?

	Yes (Complete table.)		No (Go to 20a .)	Not docume	ented 🔲 Record no	I 🔲 Record not available 🔲 Unknown			
	Drug name (See list on p. 8.)	Other (specify)	DrugDate drug startedTime startedARTStrefused(mm/dd/yyyy)(See militaryCompleted?(if therapytime.)Yes No ND UNK(mn	Date drug started (mm/dd/yyyy)	Time started (See military	ART Completed?	Stop date (if therapy not completed)	Stop codes	
				(mm/dd/yyyy)	(See list on p. 8.)				
i				_//	:		//		
ii			_ 0	_//	:		//		
iii			- 0	_//	:		//		
iv				_//	:		//		
v				_//	:		//		
vi		·	- 0	_//	:		//		

- The <u>first six weeks of life</u> are referred to as the <u>neonatal period</u>. Do not include here any antiretroviral medications received after the first six weeks of life.
- Select appropriate response from given legal values, "Yes", "No", "Not documented", "Record not available", or "Unknown".
 - Select "Yes" if ARV were prescribed, and complete the grid.
 - Select "Unknown" if the specific drugs prescribed are unknown, complete the grid, and write "Unknown" in the "Drug name" column.

• If no ARV prescribed during first 6 weeks, indicate reason

- HIV status 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.

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