Attachment H. *Supplemental Surveillance Activity 3*: Enhanced Perinatal Surveillance (EPS) Data Collection Form, Form Instructions, and Procedural Guidance.

Status: new
Description: New form included.

Infant State No: _____

Enhanced HIV/AIDS Surveillance to Maximally Reduce Perinatal HIV Transmission

New **Updated**

OMB No. 0920-XXXX Exp. Date XX/XX/XXXX

Initials of person completing the form (print legibly)_____

INFORMATION COMPLETE FOR ANALYSIS Yes No

Date form completed [e.g., abstraction concluded] __ __/__ __/__ __ __ __ (mm/dd/yyyy)

Date form received by main facility: __ __/__ __/__ __ __ __(mm/dd/yyyy)

Date case was reported: __ __/__ __/__ __ __ __(mm/dd/yyyy)

How was the infant first identified?

Routine case reporting - Pediatric report
Routine case reporting - Maternal report
Birth registry match
Active case finding for Enhanced Perinatal Surveillance
Laboratory Reporting
Other than routine surveillance activities, specify _____

If maternal information is not available, was the child adopted, in foster care, or abandoned.

Yes No Not Applicable

1. Records abstracted: (REQUIRED FIELD)
(**1**=Abstracted, **2**=Attempted, but record not available, **3**=Not abstracted, **4**=Attempted, will try again)

___ Prenatal care records
___ Maternal HIV clinic records
___ Labor and delivery records
___ Pediatric birth records
___ Pediatric HIV medical records
___ Pediatric medical records (non HIV clinic/provider)
___ Birth certificate
___ Death certificate
___ Health department records
___ Other, specify _____

BASIC DEMOGRAPHICS

2. Infant

Reporting state _____(**REQUIRED FIELD**)
State No. _____ (**REQUIRED FIELD**)
City No. _____
Soundex _____
Date of Birth __ __/__ __/__ __ __ __ (**HARS**) (**REQUIRED**)
Date of Death __ __/__ __/__ __ __ __ (**HARS**)
Sex at Birth ____ (**HARS**)

3. Mother

Reporting state _____
State No. _____
City No. _____
Soundex _____
Date of Birth __ __/__ __/__ __ __ __ (**HARS**)
Date of Death __ __/__ __/__ __ __ __ (**M-HARS**)

4. Mother's Country of Birth _____(**HARS**)

4a. If Country is unknown, but Continent of birth is known, specify _____

5. Mother's Hispanic Ethnicity (**M-HARS-modified**) Yes No Unknown

6. Mother's Race *(Mark all that apply)* (**M-HARS-modified**)

American Indian/Alaska Native
Asian
Black/African American
Hawaiian/Pacific Islander
White
Other Race, specify _____
Unknown

7. Marital Status (at time of delivery)

Single
Married
Separated
Divorced
Widowed
Unknown

8. Mother's HIV risk factor *(Mark all that apply)* (**HARS**)

Injection drug user (IDU)
Person with hemophilia
Heterosexual contact with IDU
Heterosexual contact with bisexual male
Heterosexual contact with person with hemophilia
Heterosexual contact with transfusion recipient with documented HIV
Heterosexual contact with transplant recipient with documented HIV
Heterosexual contact with male with HIV/AIDS with unknown risk
Transfusion recipient
Transplant recipient (tissue/organ or artificial insemination)
Perinatal Exposure (e.g. mother was perinatally infected)
Unknown/Other documented risk (discuss with NRR Coordinator within your State)
If Other, specify _____

PRENATAL CARE

9. Did mother receive any prenatal care for this pregnancy?

Yes No ***(Go to Q15)*** Not Documented ***(Go to Q15)***

10. Date of first prenatal care visit: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

11. Month of pregnancy prenatal care began: _____ (mos) (99=unk) (**HARS**)

OR _____ (in weeks, if month is not noted in chart)

12. Date of last prenatal care visit prior to delivery: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

13. Number of prenatal care visits: (e.g., visits specifically for prenatal care) _____ (99=unk) (**HARS**)

14. In what type of facility was prenatal care primarily delivered? *(Mark only one)*

OB/GYN clinic
Adult HIV specialty clinic
HMO clinic (for prenatal care)
Private care (OB/GYN, midwife)
Correctional facility
ACTG site
Other, specify _____
Not Documented

15. Was the mother screened for any of the following during pregnancy?
(Use test done prior to birth but closest to delivery date or at admission for labor & delivery)

	Yes	Date (mm/dd/yyyy)	No	Not Documented	Record Not Available
Group B Strep		__ __/__ __/__ __ __ __			
Hepatitis B (HBsAg)		__ __/__ __/__ __ __ __			
Rubella		__ __/__ __/__ __ __ __			
Syphilis		__ __/__ __/__ __ __ __			

16. Mother's diagnosis of the following conditions during this pregnancy or at the time of labor and delivery. See "Instructions for Data Abstraction" for definitions.

	Yes	Date of Diagnosis (mm/dd/yyyy)	No	Not Doc	RNA
Bacterial vaginosis		__ __/__ __/__ __ __ __			
Chlamydia		__ __/__ __/__ __ __ __			
Genital Herpes		__ __/__ __/__ __ __ __			
Gonorrhea		__ __/__ __/__ __ __ __			
Group B Strep		__ __/__ __/__ __ __ __			
Hepatitis B (HbsAg+)		__ __/__ __/__ __ __ __			
Hepatitis C		__ __/__ __/__ __ __ __			
Pelvic Inflammatory Disease (PID)		__ __/__ __/__ __ __ __			
Syphilis		__ __/__ __/__ __ __ __			
Trichomonas		__ __/__ __/__ __ __ __			

17. Mother's reproductive history:

____ Number of previous pregnancies
____ Number of previous live births
____ Number of previous miscarriages/stillbirths
____ Number of previous induced abortions
or [____ Total number of previous abortions]

18. Complete the chart below for all siblings:

	DOB (mm/dd/yyyy)	**Age yrs:mos as of mm/yy**	**HIV Status***	**State no.**	**City no.**
Sib 1	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____
Sib 2	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____
Sib 3	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____
Sib 4	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____
Sib 5	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____
Sib 6	__ __/__ __/__ __	___:___ as of ___/___	____	_____	_____

***HIV Status:**
[1] Infected
[2] Uninfected
[3] Indeter-minate
[9] Not Documented

SUBSTANCE USE

19. Was substance use during pregnancy noted in the medical or social work records?

Yes No ***(Go to Q23)*** Record Not Available ***(Go to Q23)***

19a. If yes, indicate which substances were used during pregnancy: (Mark all that apply)

Alcohol	Hallucinogens	Methamphetamines
Amphetamines	Heroin	Nicotine / Tobacco
Barbiturates	Marijuana (cannabis,	Opiates
Benzodiazepines	THC, cannabinoids)	Other, specify _____
Cocaine	Methadone	Not Documented which drug(s)
Crack Cocaine		

19b. If any substances used, were any of the drugs injected?

Yes No Not Documented

Specify which substance(s) were injected: _____

20. Was a toxicology screen done on the mother during pregnancy or at delivery?

Yes, positive, please specify (Check all that apply):

Alcohol	Hallucinogens	Methamphetamines
Amphetamines	Heroin	Nicotine / Tobacco
Barbiturates	Marijuana (cannabis,	Opiates
Benzodiazepines	THC, cannabinoids)	Other, specify _____
Cocaine	Methadone	Not Documented which drug(s)

Yes, negative

No

Not Documented

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

Yes, positive, please specify (Check all that apply):

Alcohol	Hallucinogens	Methamphetamines
Amphetamines	Heroin	Nicotine / Tobacco
Barbiturates	Marijuana (cannabis,	Opiates
Benzodiazepines	THC, cannabinoids)	Other, specify _____
Cocaine	Methadone	Not Documented which drug(s)

Yes, negative

No

Not Documented

22. If indication of substance use, was the mother referred for treatment during or after this pregnancy?

Yes No Not Documented

MATERNAL TESTING/CLINICAL INFORMATION

23. The mother was diagnosed as being HIV positive: (HARS)

(Mother refused HIV testing)
Before this pregnancy
During this pregnancy
At time of delivery
Before child's birth, exact period unknown
After the child's birth
HIV-infected, unk when diagnosed

24. Date of mother's first positive confirmatory test (earliest known test): __ __/__ __/__ __ __ __ (**HARS**)
(Confirmatory test is Western Blot or IFA) (mm/dd/yyyy)

25. Mother's HIV screening during pregnancy.

Results§ (see below)	**Test *** (see below)	**Date** (mm/dd/yyyy)
25a. First Screening		
_____	_____	__ __/__ __/__ __ __ __
25b. Second Screening *(if negative or refused first screening)*		
_____	_____	__ __/__ __/__ __ __ __
25c. Third Screening *(if negative or refused second screening)*		
_____	_____	__ __/__ __/__ __ __ __

§ Results
Positive
Negative
Indeterminate
Results not found
Not tested
Not tested, known to be infected
Refused
Unknown

***Tests**
Rapid
EIA
Not Documented

26. Mother's HIV screening at time of labor and delivery.

Results§ (see below)	**Test *** (see below)	**Date Results at L&D** (mm/dd/yyyy)	**Time† Results at L&D** (see below)
26a. First Screening			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __
26b. Second Screening *(if applicable)*			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __
26c. Confirmatory Test			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __

§ Results
Positive
Negative
Indeterminate
Results not found
Not tested
Not tested, known to be infected
Refused
Unknown

***Tests**
Rapid
Expedited EIA
EIA
Not Documented

† Military time
noon = 12:00
4:30pm = 16:30
midnight = 00:00
12:30am = 00:30

27. Were CD4 counts obtained during pregnancy?

Yes No ***(Go to Q28)*** Not Documented ***(Go to Q28)*** Record Not Available ***(Go to Q28)***

27a. If yes, list below (If more than three in record, **prioritize** those CD4 counts closest to delivery. If CD4 counts were not conducted during pregnancy, CD4 counts within 6 months before pregnancy would be useful to record.)

Example: CD4 count 174, 12% would be coded as:		
174	Count	08/12/2000
12	Percent	08/12/2000

CD4 Result	**Units**	**Date blood drawn** (mm/dd/yyyy)
__ __ __ __	**Count**	__ __/__ __/__ __ __ __
__ __ __ __%	Percent	__ __/__ __/__ __ __ __
__ __ __ __	**Count**	__ __/__ __/__ __ __ __
__ __ __ __%	Percent	__ __/__ __/__ __ __ __
__ __ __ __	**Count**	__ __/__ __/__ __ __ __
__ __ __ __%	Percent	__ __/__ __/__ __ __ __

28. Did mother have viral quantification tests performed (i.e., viral load) during pregnancy?

Yes No ***(Go to Q29)*** Not Documented ***(Go to Q29)*** Record Not Available ***(Go to Q29)***

28a. If yes, list all results below (If more than three in record, **prioritize** those viral load tests closest to delivery. If viral load tests were not conducted during pregnancy, viral loads within 6 months before pregnancy would be useful to record.)

Result in copies/mL #	**Result in logs**	**Date blood drawn** (mm/dd/yyyy)
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __

29. What was mother's most advanced HIV classification during pregnancy:

HIV, not AIDS AIDS, CD4 criteria only AIDS, indicator condition HIV negative Not Doc RNA

30. Was mother's HIV status noted in her prenatal care medical records?

Yes, Positive Yes, Negative No No prenatal care Record Not Available

ANTIRETROVIRAL THERAPY

31. Was mother prescribed any antiretroviral medication during this pregnancy? (**HARS**)

Yes ***(Complete Table)*** No ***(Go to Q31A)*** Not Documented ***(Go to Q32)*** RNA ***(Go to Q32)***

Drug Name (Use drug list)	**Was Drug Refused**	**Date Drug Started** (mm/dd/yy)	**Gestational Age Started** (weeks, round down)	**Drug Stopped** Yes No ND	**Date Stopped** (mm/dd/yy)	**Drug Stop Codes**
i. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
ii. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
iii. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
iv. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
v. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
vi. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____
vii. _____	Yes	__ __/__ __/__ __	____		If yes, __ __/__ __/__ __	____

(After completing table, Go to Q32)

31a. If no ARV was prescribed during pregnancy, indicate reason:

No prenatal care
HIV status of mother unknown
Mother known to be HIV negative during pregnancy
Mother refused
Other reason, specify _____
Not Documented

32. Was mother's HIV status noted in her labor/delivery medical records?

Yes, Positive Yes, Negative No Record Not Available

33. Did mother receive antiretroviral medication during labor and delivery? (**HARS**)

Yes ***(Complete Table)*** No ***(Go to Q33A)*** Not Documented ***(Go to Q34)*** RNA ***(Go to Q34)***

Drug Name (Use drug list)	**Was Drug Refused**	**Date Received** (mm/dd/yy)	**Time† Received** (see below)	**Type of Administration** Oral IV Rcvd, route not doc
i. _____	Yes	__ __/__ __/__ __	__ __:__ __	
ii. _____	Yes	__ __/__ __/__ __	__ __:__ __	
iii. _____	Yes	__ __/__ __/__ __	__ __:__ __	
iv. _____	Yes	__ __/__ __/__ __	__ __:__ __	
v. _____	Yes	__ __/__ __/__ __	__ __:__ __	
vi. _____	Yes	__ __/__ __/__ __	__ __:__ __	
vii. _____	Yes	__ __/__ __/__ __	__ __:__ __	

(After completing table, Go to question 34)

† **military time**: noon = 12:00 midnight = 00:00

33a. If no ARV was received during labor & delivery, indicate reason:

Precipitous delivery/STAT c-section	Mother tested HIV negative during pregnancy
Prescribed but not administered	Mother refused
HIV status of mother unknown	Other reason, specify_____
Birth outside of hospital	Not Documented

34. Was mother referred for HIV care after delivery?

Yes No ***(Go to Q36)*** Not Documented ***(Go to Q36)*** Record Not Available ***(Go to Q36)***

35. If yes, indicate first viral load and/or CD4 after discharge from hospital up to 6 months:

35a. CD4:

	CD4 Result	Units	Date blood drawn (mm/dd/yyyy)
Not Done			
Not Available	__ __ __ __	**Count**	__ __/__ __/__ __ __ __
	__ __ __ __%	Percent	__ __/__ __/__ __ __ __

35b. Viral Load:

	Result in copies/mL #	Result in logs	Date blood drawn (mm/dd/yyyy)
Not Done			
Not Available	_____	_____	__ __/__ __/__ __ __ __

BIRTH HISTORY

36. Type of birth: (HARS)

Single Twin Triplet or greater Record Not Available

37. Birth information:

		Time*	Date (mm/dd/yyyy)
Birth Outside Hospital	Onset of labor	__ __:__ __	__ __/__ __/__ __ __ __
Record Not Available	Admission to L/D	__ __:__ __	__ __/__ __/__ __ __ __
	Rupture of Membranes	__ __:__ __	__ __/__ __/__ __ __ __
	Delivery	__ __:__ __	__ __/__ __/__ __ __ __

*__military time__: noon=12:00 midnight=00:00

38. Gestational age at time of delivery: _____ (weeks - round down to nearest whole wk) **(HARS)**

39. Mode of Delivery: (HARS)

Vaginal ***(Go to Q40)***
Elective C-section
Non-elective C-section
C-section, unknown type
Record Not Available ***(Go to Q41)***

39a. If C-section delivery, mark all the following indications for C-section that apply:

HIV indication (high viral load)
Previous C-section(repeat)
Malpresentation (breech, transverse lie)
Prolonged labor / failure to progress
Personal / Physician's Preference
Fetal distress
Placenta abruptia / previa
Other (Herpes, disproportion, etc)
specify _____
Not specified

40. Instrumentation used:

None
Forceps
Vacuum
Forceps and vacuum
Not specified

41. Child's birth weight (lbs/oz or grams): _____ lbs. _____ oz **or** _____ grams **(HARS)**

42. Was mother's HIV status noted on the exposed child's birth record?

Yes, Positive Yes, Negative No Record Not Available

PEDIATRIC HISTORY

43. Was child prescribed any antiretroviral medication during the first six weeks of life? (HARS)

Yes ***(Complete Table)*** No ***(Go to Q43A)*** Not Documented ***(Go to Q44)*** RNA ***(Go to Q44)***

Drug Name (Use drug list)	**Was Drug Refused**	**Date Drug Started** (mm/dd/yy)	**Time† Started** (see below)	**Regimen Completed** Yes No ND	**Stop Date** (mm/dd/yy)	**Drug Stop Codes**
i. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
ii. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
iii. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
iv. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
v. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
vi. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____
vii. _____	Yes	__ __/__ __/__ __	__ __:__ __		If no, __ __/__ __/__ __	____

† **military time**: noon = 12:00 midnight = 00:00

43a. If no ARV was prescribed during the first six weeks of life, indicate reason:

HIV status of mother unknown
Mother known to be HIV negative during pregnancy
Mother refused
Other reason, specify _____
Not Documented

44. Infant's HIV antibody testing.

	Results[§] (see below)	**Test** * (see below)	**Date Blood Drawn** (mm/dd/yyyy)
i.	_____	_____	__ __/__ __/__ __ __ __
ii.	_____	_____	__ __/__ __/__ __ __ __
iii.	_____	_____	__ __/__ __/__ __ __ __

§ Results
Positive
Negative
Indeterminate
Results not found
Not tested
Refused
Unknown

***Tests**
Rapid
Expedited EIA
EIA
Not Documented

45. Results of DNA/RNA screening:

	Results[§] (see below)	**Test** DNA	RNA	**Date Blood Drawn** (mm/dd/yyyy)
i.	_____			__ __/__ __/__ __ __ __
ii.	_____			__ __/__ __/__ __ __ __
iii.	_____			__ __/__ __/__ __ __ __
iv.	_____			__ __/__ __/__ __ __ __
v.	_____			__ __/__ __/__ __ __ __

§ Results
Positive
Negative
Indeterminate
Results not found
Not tested
Refused
Unknown

46. What is the child's current HIV status? (HARS-modified)

AIDS
Confirmed HIV infected (not AIDS)
HIV negative
Indeterminate as of __ __/__ __/__ __ __ __ (mm/dd/yyyy)

47. If child's HIV status is indeterminate, indicate why: (HARS-modified)

Moved from state | Lost to Follow-up | Child less than 18 months of age
Provider out of state | Died before status determined | Not Documented

48. Was PCP prophylaxis prescribed in the first year of life? (HARS)

Yes, date started __ __/__ __/__ __ __ __ | No | Not Documented | Record Not Available

49.Was child breastfed? (HARS)

Yes, duration ___ days ___ weeks ___not doc | No | Not Documented | Record Not Available

50. Were any birth defects noted in the first year of life? (HARS)

Yes No ***(Go to Q51)*** Record Not Available ***(Go to Q51)***

50a. If yes, specify type(s): _____

Code: _____._____ Code: _____._____ Code: _____._____

51. If child deceased, from death certificate, list (Please print legibly):

(Include ICD9 codes only if code appears on death certificate)

	ICD9
Immediate cause of death _____	_____
Underlying cause of death _____	_____
Underlying cause of death _____	_____
Underlying cause of death _____	_____
Contributing cause of death _____	_____

NOTE: If the child has died and you are completing this portion of the abstraction form, please verify that a date of death has been entered for the infant on page 1, Basic Demographics, Question 2.

Please include any comments or clinical information you feel is relevant to the overall understanding of this child's HIV-exposure or infection status. Include where the information came from and the relevant date.

_____

_____

_____

_____

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_____

Antiretroviral Drugs and Stop Codes

Antiretroviral Drug List **NNRTI** Delavirdine (Rescriptor) Efavirenz (Sustiva) Nevirapine (Viramune, NVP)	**NRTI** Abacavir (Ziagen, ABC) Combivir (AZT & 3TC) Didanosine (ddI, Videx) Lamivudine (3TC, Epivir) Stavudine (d4T, Zerit) Trizivir (AZT & 3TC & Abacavir) Viread (Tenofovir) Zalcitabine (ddC, Hivid) Zidovudine (AZT, Retrovir)	**PROTEASE INHIBITORS** Amprenavir (Agenerase) Indinavir (Crixivan) Kaletra (Lopinavir, Ritonavir) Nelfinavir (Viracept) Ritonavir (Norvir) Saquinavir (Fortavase, Invirase) Tipranavir (Aptivus)	**OTHER** Adefovir dipivoxil (bis-POM, PMEA, Preveon) Atripla (Efavirenz & Tenofovir & Emtricitabine) **If an antiretroviral drug not on this list, call CDC**

Stop Codes: [2 codes allowed-if more, pick the most important]

S1 = Adverse events (toxicity, lack of tolerance)
S2 = (Blank for EPS)
S3 = Drug resistance detected
S4 = Poor adherence
S5 = Inadequate effectiveness
S6 = Strategic treatment interruption (planned drug holiday)
S7 = Drug interactions
S8 = Patient choice
S9 = Pregnancy
S10 = Child determined to be HIV-uninfected
S11 = Improving effectiveness
S12 = Improving convenience
S13 = Reason not indicated, unknown
S14 = Mother couldn't afford medications
Sxx = Other reason

Enhanced HIV/AIDS Surveillance to Maximally Reduce Perinatal HIV Transmission
Instructions for Completing the Data Abstraction Form

General Comments

The purpose of this document is to provide guidance for filling out the data abstraction form, to define medical terms, and to suggest the best places in the medical records to find specific pieces of information.

Information on children who are perinatally-HIV exposed or who have HIV/AIDS are collected under a federal assurance of confidentiality. Information on HIV-exposed children must be collected on **both** the HARS case report form **and** on the Enhanced Perinatal Surveillance Supplemental Data Abstraction Form (referred to as the Enhanced Surveillance Form or EPS Form). All information that is collected using the enhanced surveillance abstraction form should be promptly included/updated in the HARS software. HARS is the gold standard for this project. Where data differs between the enhanced surveillance data abstraction form and HARS, the HARS data will be used. Next to each question on the data abstraction form that is included on the pediatric case report form and/or in the HARS software, we have indicated '(HARS)'. The HIV/AIDS pediatric case reporting form and software were updated in 1995, then in 1996 with the Ryan White CARE Act, and again in 2000 to allow for evaluation of the implementation and impact of the Public Health Service recommendations on the prevention of perinatal HIV transmission, to accommodate surveillance requirements of the Ryan White CARE Act Amendment signed into law on May 20, 1996, and to accommodate the revised 2000 HIV case definition for perinatal HIV exposure, pediatric infection, and those perinatally exposed but not infected with HIV. The Enhanced Perinatal Surveillance Data Abstraction Form collects additional standardized data related to prevention of perinatal transmission beyond those in the HARS system. These data taken together will assist in monitoring the implementation of the new pediatric case definition and impact of the PHS recommendations (counseling and voluntary testing of pregnant women and use of Zidovudine (ZDV) to prevent perinatal transmission) on pediatric HIV/AIDS trends, responding to selected requirements of the Ryan White Care Act, and evaluating of perinatal prevention efforts.

Be sure to 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, etc should make sense based on the infant's date of birth. Use of the EPS Date Worksheet, found at the end of this document, is helpful in assessing consistency of dates. 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 was not an error having to do with the abstraction, notation or data entry of the information.

The Enhanced Perinatal Surveillance Coordinator in each project area, or their designee, should review all data abstraction forms before the data is 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)

Mother	Infant
Maternal prenatal records	Pediatric birth records (hospital records)
Maternal labor and delivery records	Birth certificate
Maternal HIV clinic records	Pediatric medical records (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 live births. 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 WHO is:

  > '...the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born.'

  In other words, if a birth certificate has been completed for the infant, the record should be abstracted.

- If a woman has had several pregnancies during the project period, each pregnancy should be considered a separate event and should be abstracted separately.
- If the outcome of a pregnancy is multiple births (e.g. twins), a separate HARS and supplemental EPS 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 HARS updates (e.g., HIV diagnostic tests, CD4 counts, treatment, prophylaxis, AIDS-defining conditions, 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 (**Q.43 – Q.51**). The updated infant's HIV diagnostic tests, CD4 counts, and viral load test results should be entered directly into HARS.

Indicating 'Unknown'
A '99' or 'U' 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.

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 marked 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. If all or part of a date is unknown, 'XX' should be entered into the appropriate space (e.g., 02/XX/2005). Be sure the dates indicated on the form make sense. 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.

If Conflicting Information is Found
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 ZDV, 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 'magic' marker.

Required Fields
There are three fields which are required on the abstraction form: Infant reporting state, Infant state number and Infant date of birth. These fields are necessary for linkage to HARS data and as a quality control tool to ensure duplicate records are not entered into the database.

NEW FORM/UPDATED FORM: Indicate by marking the appropriate box if the data abstraction form is a new case abstraction or update of information for a previously abstracted case.

INITIALS OF ABSTRACTOR: Abstractors should legibly print their initials. If more than one person abstracts records for a single data form, the initials of all abstractors should be noted. These initials allow for follow-up with the abstractor for clarification and resolution of questions that may come up.

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 EPS 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.

DATE FORM COMPLETED: This should be the date that the data abstraction form is completed (e.g. all medical records have been abstracted or two attempts have been made to abstract) and record abstraction is concluded. Updates to the abstraction form and to HARS are always possible at any time.

DATE FORM RECEIVED BY MAIN FACILITY: This should be the date that the data abstraction form is received by the main facility or health department. If a site has external partners completing data abstractions, the date of receipt by the main facility (EPS Coordinator) should be included.

DATE CASE WAS REPORTED: This should be the date the case was initially reported or identified as an exposure to the health department, whether through routine case reporting or birth registry match. The date of report should be linked to the method in which the infant was first identified.

HOW INFANT FIRST IDENTIFIED: Please check the first method through which the infant was identified (e.g. an infant might have been identified through the maternal HARS record, and later been identified through the registry match. This should be coded as 'maternal report'). 'Maternal report' means that an infant was identified because the mother's case report indicated that she was pregnant at the time of diagnosis or that she delivered a live-born infant after 1977. Additionally, a child's birth information may be included on the mother's case report or there may be a notation in the comment section of the form that indicates an HIV-exposed child was born. 'Pediatric report' means an HIV-exposed child was first identified through the child's case report.

IF MATERNAL INFORMATION IS NOT AVAILABLE, WAS THE CHILD ADOPTED, IN FOSTER CARE, OR ABANODONED: Only complete check 'Yes' 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'.

RECORDS ABSTRACTED: For each type of record, code 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.

I. Basic Demographics

Questions 2-8

REPORTING STATE (mother and infant): The infant's reporting state is a required field**.**

STATE NO./CITY NO.(mother and infant): The infant's stateno is a required field. A HARS record will be entered for each mother and infant investigated as part of Enhanced Perinatal Surveillance if permissible under state reporting laws. The HARS State No. (and possibly City No.) generated for each case should be entered here. For sites without HIV exposure reporting, a project ID number should be created. A unique number should be assigned for each person, regardless of diagnostic status at first report or changing status throughout the course of disease. These numbers will be used to communicate with project areas regarding specific case reports and to link HARS records with the enhanced perinatal data collected. **State patient numbers should never be reused.**

SOUNDEX (mother and infant): Enter the soundex code for the mother and the infant unless legally prohibited from doing so. The soundex code can be generated from the patient's last name using the HARS software.

DATE OF BIRTH (mother and infant): The infant's date of birth is a required field. If all or part of the mother's date of birth is unknown, 'XX' should be coded in appropriate field (e.g. 02/XX/56).

DATE OF DEATH (mother and infant): If the mother and/or infant have died, enter their date of death. If the infant dies after the initial report is submitted, date of death must be updated in HARS.

SEX AT BIRTH (infant): M=Male, F=Female

Q. 4 **COUNTRY OF BIRTH:** Write out the country of the mother's birth. The data management system will code when the country is entered into the system.

Q. 4a If the mother's country of birth is unknown, but her **continent of birth** is known, enter the continent name in the space provided. The Continents are: Africa, Asia, North America, South America, Europe, and Antarctica. (Australia is the seventh continent, but this will be captured under country of birth so there is no need to indicate this as a continent of birth.)

Q. 5 **HISPANIC ETHNICITY (mother):** Indicate whether or not the mother is of Hispanic ethnicity (Yes, No, Unknown).

Q. 6 **RACE (mother):** More than one race can be selected. The five minimum race categories are American Indian/Alaska Native, Asian, Black/African American, Hawaiian/Pacific Islander, White, and Other.

The minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting are defined as follows:

- **American Indian or Alaska Native.** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
- **Hispanic or Latino.** A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
- **Native Hawaiian or Other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Q. 7 **MARITAL STATUS:** Check only one. This refers to the mother's marital status at the time of delivery. If there is documentation that the mother was in a common law marriage during pregnancy, it is reasonable to consider her married. This will be a site decision.

Q. 8 **MOTHER'S HIV RISK:** If a risk is found for a mother whose HARS record does not contain any risk information, update HARS with the appropriate risk. If additional, or more specific, risk information is found, update the HARS record but do not delete a risk already in the record (i.e. do not delete an existing IDU risk if heterosexual risk is found through your medical record reviews, add the heterosexual risk to HARS.) If an unusual transmission circumstance is suspected, notify the State NIR Coordinator immediately.

*After 1977, this child's biologic mother: (Mark **all** categories that apply)*

Intravenous drug user (IDU, injected nonprescription drugs)
Person with hemophilia

'Coagulation disorder' or 'hemophilia' refers only to a disorder of a clotting factor, which are any of the circulating proteins named 'Factor I', 'Factor II', 'Factor III', etc., through

'Factor XII'. These disorders include Hemophilia A and Von Willebrands disease (Factor VIII disorders) and Hemophilia B (a 'Factor IX' 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 risk would be 'transfusion'. See comments for 'transfusion' below.

Heterosexual contact with

Intravenous drug user

Bisexual male

Person with hemophilia/coagulation disorder

See comments for 'coagulation disorder' above.

Transfusion recipient with documented HIV infection

This refers to someone whose partner has documented HIV infection and whose HIV risk was receipt of a transfusion of blood cells (red cells, white cells, platelets) or plasma.

Transplant recipient with documented HIV infection

This refers to someone whose partner has documented HIV infection and whose HIV risk was receipt of a transplanted organ or tissue.

Male with AIDS or documented HIV infection, risk not specified

This category should be checked if the heterosexual partner is known to be HIV positive, and only if his specific risk for HIV is unknown.

Transfusion Recipient (other than clotting factor)

Refers to the recipient of a transfusion of blood cells (red cells, white cells, platelets) or plasma.

Perinatal Exposure

Refers to the mother's status. The mother herself was infected with HIV perinatally.

Unknown/Other documented risk

Discuss with NRR Coordinator within your state if the mother's risk factor is unknown. If 'Unknown', leave specify blank. If 'Other', then specify the documented risk.

II. Prenatal Care

Questions 9-18

Hierarchy of records for response gold standard: If conflicting information is found for any of the prenatal care questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Prenatal Care
2. Labor and Delivery
3. Pediatric Birth
4. Birth Certificate
5. Pediatric non-HIV
6. Pediatric HIV
7. Health Department

Q. 9 **DID MOTHER RECEIVE ANY PRENATAL CARE FOR THIS PREGNANCY:** A prenatal care visit is defined as a visit to a health care provider (including a physician, nurse practitioner, midwife, nurse, or physician's assistant) specifically for obstetrical/gynecological services prior to delivery of the baby. A visit by a prenatal care provider to the woman's home would be considered a prenatal care visit if it is done in the context of providing prenatal care to the woman. Sometimes the number of prenatal care visits is summarized on one sheet within the prenatal chart which lists the prenatal lab(s) and ultrasounds done at each visit, including the lab results. At time of delivery this information is tallied and a total number of prenatal care visits will be noted on the labor and delivery intake sheet. If the prenatal care record contains a prenatal care flow chart, there is usually a list of the dates of visits. Also, most birth certificates now list the number of prenatal care visits as well. (Note: the birth certificate is a notoriously poor source of data

regarding prenatal care. Only use this information if no other prenatal care information is available from medical records.) If you find conflicting numbers of visits between the medical records and the birth certificate, use the number of visits found in the medical records.

The following do not constitute a prenatal care visit: a visit to the lab to have blood tests only; a visit for the sole purpose of picking up prenatal vitamins or other medication refills; a visit solely for an illness or other medical problem not related to pregnancy; an emergency room visit; a visit to an infectious disease practitioner for care of the woman's HIV disease, a visit solely with the WIC counselor, nutritionist, social worker, pharmacist, business office personnel, office receptionist, ultrasonographer, EKG technician, HIV counselor (unless there is also a consultation with a health care provider); a visit to the home of the woman by someone who is not a prenatal care provider.

If no prenatal care is received or it is unknown if prenatal care was received, skip to **Q.15**.

Q. 10 **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, etc. If the woman had been seen by more than one prenatal care provider, then we would like the date of the visit to the first prenatal care provider seen. If this date is unknown, put 'XX/XX/XXXX'. If part of the date is unknown, 'XX' should be coded in appropriate field (i.e., 02/XX/2005).

Q. 11 **MONTH OF PREGNANCY PRENATAL CARE BEGAN:** Record the month of pregnancy (01 to 09) that the woman began prenatal care. Do not leave this question blank. Enter '09' if care began in the ninth month or later. If month is not noted in the chart but the gestational age in weeks when prenatal care began is available, record the weeks. Mark '99' if unknown what month the first visit occurred.

Q. 12 **DATE OF LAST PRENATAL CARE VISIT PRIOR TO DELIVERY:** This is the last visit for prenatal care **prior to** delivery of the baby. For definition of a prenatal care visit, see **Q. 9** above.

Q. 13 **NUMBER OF PRENATAL CARE VISITS:** See comments for **Q. 9**. If the number of visits is unknown enter '99'. If there is a range of visits reported, i.e., 10-13, enter the lower number of visits.

Q. 14 **IN WHAT TYPE OF FACILITY WAS PRENATAL CARE PRIMARILY DELIVERED**: If multiple sources of care were used, indicate the primary source of care (i.e., where the majority of visits occurred). If 'Other' is checked, be sure to specify what the facility is, using generally agreed upon terms. Do not use local terms, acronyms, or abbreviations.

- **OB/GYN clinic** - A clinic that provides obstetrical and gynecologic related, pregnancy, and preventive care to women.
- **Adult HIV specialty clinic** - A clinic associated with an inpatient facility, for the treatment of HIV/AIDS in adults.
- **HMO clinic** - A free-standing clinic run by a Health Maintenance Organization that is connected to an inpatient facility run by the same organization.
- **Private physician's office (OB/GYN, midwife)** - An office where a physician, midwife or nurse practitioner provides obstetric and gynecologic related, pregnancy, and preventive care to women.
- **Correctional facility** - A facility that provides diagnosis and/or treatment of disease in a prison, jail, or other correctional facility, clinic or infirmary.
- **ACTG site** - The AIDS Clinical Trials Group (ACTG) is an organization that was formed to conduct AIDS research that is funded by the federal government. Many universities and teaching hospitals across the country have an ACTG site associated with them.
- **Other** - A known facility that is not able to be categorized into one of the categories above.

- **Not Documented** - The type of facility is not documented in any of the source records. If the physician's name is documented but facility type is not listed, you may be able to obtain the information from the abstracting facility's personnel.

Q. 15 WAS THE MOTHER SCREENED FOR ANY OF THE FOLLOWING DURING PREGNANCY: (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. Documentation of the screening should be in the chart regardless of the diagnosis. If there is no indication that a test was conducted, mark 'Not Documented.' Responses of 'Not Documented' and 'Record Not Available' refer to both the prenatal and labor/delivery records.

- **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 OR
  - risk factor based strategy - prophylaxis 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). 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. 16.**

Q. 16 DURING THIS PREGNANCY OR AT THE TIME OF LABOR AND DELIVERY WAS THE MOTHER DIAGNOSED WITH ANY OF THE FOLLOWING CONDITIONS: For this question, "diagnosed" refers to newly diagnosed, had a recurrence of, or had chronic infection with any of the following conditions. The diagnosis of one of the conditions listed below prior to the pregnancy should not be included unless there is a recurrence of or chronic infection during the pregnancy. 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). It is not necessary to have a lab sheet to record a diagnosis on the EPS abstraction form. Diagnoses may be presumptive or definitive depending on various signs, symptoms and lab tests. If there is no indication that a test was conducted, mark 'Not Documented.' Responses of 'Not Documented' and 'Record Not Available' refer to both the prenatal and labor/delivery records. 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:

- **Bacterial vaginosis -** Clinician diagnosis of bacterial vaginosis. Sometimes abbreviated BV.
- **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 primary herpes (first episode of herpes) or recurrence of herpes during pregnancy or at labor and delivery.
  Name of lab tests - herpes virus culture; herpes cytology (herpetic inclusion bodies, cytology, inclusion body stain, Tzanck smear, Giemsa stain viral study); rapid diagnostic tests- direct immunofluorescent AB or EIA; HSV Ag; or polymerase chain reaction (PCR).
- **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 OR
  - risk factor based strategy in which prophylaxis is given to women with intrapartum risk factors: gestation < 37 weeks, ≥ 18 hours since rupture of membrane, 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 Adsorption); MHA-TP (Microhemagglutination assay for 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*.)

Q. 17 **MOTHER'S REPRODUCTIVE HISTORY:** To specify 'Not Documented' use '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) up to but EXCLUDING the pregnancy that is being abstracted.
- **Number of previous live births:** Note that parity refers to the number of viable pregnancies, that is, the number of pregnancies carried to 20 weeks. Parity excludes miscarriages and elective abortions but includes stillbirths. Parity cannot be used for this answer. The number of live births should be the total of preterm and term births (excluding 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) **OR** (if the chart does not break these two categories out) the total number of abortions, but not both.

***Note on G_P_ Abbreviations In the Medical Record:** This information is often written in the following format: G _ P_, as in G_5 P_3 or it may be written as $G_5P_3A_1$. The 'G' (gravida) refers to the total number of pregnancies (including current pregnancy), the 'P' (para) to the number of live births (at least 20 weeks gestation) and the 'A' to the number of induced and spontaneous

abortions. Information on gravida status is usually noted at intake at the time of the first prenatal care visit. Also note that 'multigravida' refers to a woman who has been pregnant more than once, 'primigravida' refers to a woman who is pregnant for the first time (by definition, has no prior pregnancies), and a 'grand multiparous' woman refers to a woman who has had more than 5 pregnancies.

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

For example, a woman who is G_5 P_3A_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

- 1st digit = term pregnancies (>37 weeks)
- 2nd digit = preterm pregnancies (20-37 weeks)
- 3rd digit = abortions (includes both spontaneous and induced abortions)
- 4th 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.17, 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.

Q. 18 **COMPLETE THE CHART BELOW FOR ALL SIBLINGS:** 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 HARS software which allow only for the linking of one child with the mother's HARS case report. Make a note of there being siblings in the abstractor's notes section of the abstraction form if complete information is not provided in the medical records.

III. Substance Use

Questions 19-22

Hierarchy of records for response gold standard (Q. 19, 20 & 22): If conflicting information is found for any of these questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Prenatal Care
2. Maternal HIV Clinic
3. Labor and Delivery
4. Pediatric Birth

5. Pediatric non-HIV
6. Pediatric HIV
7. Health Department

Hierarchy of records for response gold standard (Q. 21): If conflicting information is found for this question, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Pediatric Birth
2. Pediatric non-HIV
3. Pediatric HIV
4. Health Department

Q. 19 WAS SUBSTANCE USE DURING PREGNANCY NOTED IN THE MEDICAL OR SOCIAL WORK RECORDS: 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.

Q. 19a IF YES, INDICATE WHICH SUBSTANCES WERE USED DURING THE PREGNANCY: 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 indicate the name of the drug(s) used. If any drugs are used, be sure to complete **Q. 19b**.

Q. 19b IF ANY SUBSTANCES USED, WERE ANY OF THE DRUGS INJECTED: If any drug(s) used were injected, mark 'Yes' and write the name of the drug in the space provided.

Q. 20 WAS A TOXICOLOGY SCREEN DONE ON THE MOTHER DURING PREGNANCY OR AT 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. If screening for 'Other' drug was done, be sure to indicate what the drug was in the space provided.

Q. 21 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. Please specify all drugs identified on screening, including methadone. If screening for 'Other' drug was done, be sure to indicate what the drug was in the space provided.

Q. 22 WAS MOTHER REFERRED FOR SUBSTANCE ABUSE TREATMENT DURING OR AFTER THIS PREGNANCY: This question asks about whether the mother was referred for substance abuse treatment both during and after this pregnancy. This information is usually found in the prenatal care records or in the hospital medical records in the physician, nurses, or social workers notes.

IV. Mother's HIV Testing

Questions 23-30

Hierarchy of records for response gold standard: If conflicting information is found for any of the mother's HIV testing questions, refer to this list to determine which response to include unless abstractor

is positive of the correct response.

1. Maternal HIV Clinic
2. Prenatal Care
3. Labor and Delivery
4. Pediatric Birth
5. Pediatric non-HIV
6. Pediatric HIV
7. Health Department

Q. 23 **THE MOTHER WAS DIAGNOSED AS BEING HIV POSITIVE:** This question is asking for the same information as on HARS even though the wording is different (HARS asks about the timing of mother's HIV diagnosis). Although we can determine this by comparing date of test and date of infant's birth, this field is included both to make analysis easier and to serve as a check.

- **Mother refused testing:** only code 'refused' if refusal is documented in the maternal or infant's chart.
- **Before this pregnancy:** includes early pregnancy if subject was tested before pregnancy was diagnosed. If exact timing of test is unknown, but it is clear that the mother was diagnosed prior to this pregnancy, mark 'Before this pregnancy.'
- **During this pregnancy:** any time after pregnancy was diagnosed.
- **At time of delivery:** if tested when she was admitted for labor and delivery and ≤ 5 days after delivery.
- **Before child's birth:** the mother was known to be HIV positive before child's birth but the exact timing of the positive test is unknown.
- **After child's birth:** if first test is conducted 6 or more days after the child's birth (see Delivery/postpartum category above).
- **HIV-infected, unknown when diagnosed:** the mother was known to be HIV infected but the timing of her diagnosis is unknown.

This question seeks to document the HIV status of the mother and, if HIV infected, the timing of her HIV diagnosis relative to this child's birth. 'Refused HIV testing' should be checked if the mother's refusal is documented in the chart. If the biologic mother has been tested for HIV and found to be uninfected at or after the child's birth then perinatal transmission is not the presumed mode of exposure to HIV infection. If mother-to-infant transmission through breastfeeding is considered as the only mode of transmission, note that on the front page of the Enhanced Surveillance Form and alert the state or local NIR Coordinator and CDC.

Q. 24 **DATE OF MOTHER'S FIRST POSITIVE CONFIRMATORY TEST:** (*Western Blot or IFA*) This should be the day the blood was drawn (rather than the day the patient was counseled). If all or part of date is unknown, 'XX' should be coded in appropriate field. If there is a physician diagnosis that states, 'HIV+ for 4 years', for example, then code month and day as 'XX', and subtract 4 from the year of the note in the chart to determine year of testing. If the mother was known to be infected, but there is no indication of when she was tested in the medical record, enter the first known test date. The site's HIV/AIDS surveillance data should have the earliest confidential test date if reportable. If the mother has only been tested once and it occurred during this pregnancy, the same date should be used for this question as in **Q.25a**. Likewise, if the mother has only been tested once and it was at time of labor and delivery, the date should be recorded in **Q.26a**.

Q. 25 **MOTHER'S HIV SCREENING DURING PREGNANCY TABLE:** Women who have already been tested and reported may be retested in pregnancy.

- **Results** - Enter the results of the rapid or EIA test (Positive; Negative; Indeterminate; Results not found; Not tested; Not tested, known to be infected; Refused; Unknown). Lab documents may state that the results were reactive or non-reactive. In these instances record the results as positive and negative, respectively. If there is an indication in the chart that the test was ordered and done, but no results can be found in the chart indicate that by putting 'Results not found' in the space provided. Record as 'Unknown' if there is not indication of HIV testing or results in any of the records abstracted.

- **Test** - Enter the type of test performed (Rapid, EIA, Not documented). If the record just states 'HIV Screen,' enter 'Not Documented.'
- **Date** - Note the date the blood was drawn.

Q.25b SECOND SCREENING: If the mother had a negative or indeterminate result for the first screening or refused testing the first time it was offered, provide a response for the second screening.

Q.25c THIRD SCREENING: If the mother had a negative or indeterminate result for the first and second screening or refused testing the first and second time it was offered, provide a response for the third screening.

Q. 26 MOTHER'S HIV SCREENING AT TIME OF LABOR AND DELIVERY TABLE:
An **expedited HIV** test is a standard EIA test performed with rapid turnaround time.

- **Results** - Enter the results of rapid, expedited EIA, or EIA test (Positive; Negative; Indeterminate; Results not found; Not tested; Not tested, known to be infected; Refused; Unknown). Lab documents may state that the results were reactive or non-reactive. In these instances record the results as positive and negative, respectively. If there is an indication in the chart that the test was ordered and done, but no results can be found in the chart, indicate that by putting 'Results not found' in the space provided.
- **Test** - Enter the type of test performed (Rapid, Expedited EIA, EIA, Not documented). If the record just states 'HIV Screen,' enter 'Not Documented.'
- **Date and time results received at labor and deliver** - Note the date and time the laboratory results were received at labor and delivery. This information is important to knowing if the test results were received in time to initiate antiretroviral medication. This date and time can also be compared to the date and time of initiation of neonatal antiretroviral medications to determine timeliness for prevention of HIV infection. **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).**

Q.26b SECOND SCREENING: If the mother had a rapid test, refused testing, or results not found, negative or indeterminate for her first screening at labor and delivery, provide a response for the second screening only if it was not a confirmatory test. **If second screening was a confirmatory test, skip to Q.26c.**

Q.26c CONFIRMATORY TEST: If the mother had a rapid test, refused testing, or results not found, negative or indeterminate for the first and/or second screening, provide a response for the confirmatory test. Response is not needed if the mother's first screening was a confirmatory test.

Q. 27 WERE CD4 COUNTS OBTAINED DURING PREGNANCY: CD4 counts should be noted in number of cells/mL. CD4% is the part of the absolute lymphocyte count that is CD4 cells and equals CD4/(CD4+CD8). In AIDS, the CD4 (T4) cells are severely reduced, and the CD4/CD8 or T4/T8 ratio is <1. Note the date of the CD4 tests.

If the mother received CD4 testing during pregnancy, be sure to indicate 'Yes' and complete the chart provided in **Q. 27a**. Also include any tests performed at the hospital prior to delivery.

Q. 27a IF YES, LIST BELOW: The purpose of this question is to have an idea of the stage of HIV disease of the mother at the time of pregnancy. If no CD4 counts or percentages are available during pregnancy, CD4 counts and percentages within 6 months before pregnancy would be useful to record. If more than three are recorded in the records, prioritize those CD4 counts and percentages closest to delivery. Additional CD4 counts can be recorded in the comments section at the end of the form. Note: Fields for entry of CD4 **count** alternate with those for CD4 **percent**. Round all results to the nearest whole number.

- **Date Blood Drawn:** This is the date the blood was drawn.

Q. 28 DID MOTHER HAVE VIRAL QUANTIFICATION TESTS PERFORMED DURING PREGNANCY: Viral load testing has become the standard of care for monitoring response to therapy in HIV-infected patients. For more information on guidelines for reporting of viral load lab test results see: Centers for Disease Control and Prevention. Guidelines for laboratory test result reporting of human immunodeficiency virus type 1 ribonucleic acid determination: recommendations from a CDC working group. MMWR 2001;50(No. RR-20). These guidelines are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5020a1.htm.

If the mother received viral load testing during pregnancy, be sure to indicate 'Yes' and complete the chart provided in **Q. 28a**. Also include any tests performed at the hospital prior to delivery.

Q. 28a IF YES, LIST BELOW: Remember to enter the viral load test results into HARS. If no viral loads are available during pregnancy, viral loads within 6 months before pregnancy would be useful to record. If more than three are recorded in the records, prioritize those viral loads closest to delivery.

- **Results in copies/mL or Results in logs:** Viral load results must be reported as either copies/mL **or** log 10**.** Results for copies/mL must be reported according to the reportable range. The range for each type of test is included in the reference table below. If results are below the lower limit of detection, report it as '**below lld**' (lower limit of detection); if results are above the upper limit of detection, report it as '**above uld**' (upper limit of detection).
- **Date Blood Drawn:** This is the date the blood was drawn.

The following reference table will help you complete the chart in **Q. 28a**.

Company	Assay Type	Reportable Range (copies/mL) #
Roche	RT-PCR	S*: 400 - 750,000
		US*: 50 - 75,000
Bayer	bDNA	75 - 500,000
bioMerieux	NASBA	50 - 1,000,000
Primagen	NASBA	500 - 50,000,000

*S = standard, US = ultrasensitive

Q. 29 WHAT WAS MOTHER'S MOST ADVANCED HIV CLASSIFICATION DURING PREGNANCY: Indicate the highest level in the HIV/AIDS case definition hierarchy: (in descending order) 1) AIDS with an indicator condition (OI), 2) AIDS based on CD4 criteria only (i.e., CD4 cells <200 or CD4% ≤14%), 3) HIV (not AIDS), 4) Not Documented, or 5) Record not available. For example, an opportunistic infection in the ninth month would supersede a CD4 <200 at any point. For women who were diagnosed after their child's birth, mark 'Not documented'. If the mother tested negative during the pregnancy and there is no evidence of HIV infection, her HIV status during pregnancy should be indicated as HIV negative. HARS does not reassign the infection status as HIV after the individual has met the AIDS case definition. Since we are interested in the mother's stage of disease during pregnancy, classification should be based on what is in the medical records. If there is a difference among the records, choose the most advanced stage of disease. If during record abstraction for this project, you find information (i.e., lab data or OI information) that would change the mother's classification from that currently in HARS, indicate the new classification here and be sure to update HARS. Physician documentation can be used to indicate the HIV classification during pregnancy. This question should be consistent with the information in **Q. 28a**

above.

Q. 30 WAS MOTHER'S HIV STATUS NOTED IN HER PRENATAL CARE MEDICAL RECORDS: Mark 'Yes, 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'.

Mark 'Yes, 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.

If the progress notes in the prenatal records state that this is a woman at risk for HIV infection but that her HIV infection status is unknown, the answer to this question would be 'No'.

Situations where a 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. In these instances, the response would be 'No'.

For women who have not received any prenatal care, mark 'No prenatal care'.

V. Antiretroviral Agents in Pregnancy

Questions 31-35

Hierarchy of records for response gold standard (Q. 31 and 31a): If conflicting information is found for any of the antiretroviral agents in pregnancy questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Maternal HIV Clinic
2. Prenatal Care
3. Labor and Delivery
4. Pediatric Birth
5. Pediatric non-HIV
6. Pediatric HIV
7. Health Department

Hierarchy of records for response gold standard (Q. 33 and 33a): If conflicting information is found for any of the antiretroviral agents at labor and delivery questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Labor and Delivery
2. Pediatric Birth
3. Maternal HIV Clinic
4. Pediatric non-HIV
5. Pediatric HIV
6. Health Department

Hierarchy of records for response gold standard (Q. 34 – 35b): If conflicting information is found for any of the maternal HIV care after delivery questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Maternal HIV Clinic
2. Health Department

Q. 31 WAS MOTHER PRESCRIBED ANY ANTIRETROVIRAL MEDICATION DURING THIS PREGNANCY: 'During this pregnancy' refers to the time up to, but not including, labor and delivery. If the mother was previously taking, began taking or restarted antiretroviral medications after interruption during the 1st trimester, answer this question as 'Yes'. If the specific drugs she received are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column.

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 ACTG 316, receipt of NEVIRAPINE should not be indicated on the antiretroviral drug chart since it is not known whether the mother received the drug or the placebo. If the specific drugs she received or refused are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column. Also, be sure to enter the receipt of ZDV or other ARV during pregnancy in HARS.
- **Was 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 initially started 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 'U' for Unknown. Do not calculate gestational age if it is not in the medical records.
- **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. If the drug was stopped during the pregnancy but restarted after the birth of the child, 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. 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, do not code as stopped.**

Q. 31a IF NO ARV WAS PRESCRIBED IN PREGNANCY, INDICATE REASON:

- **No prenatal care** - The mother did not receive any prenatal care during her pregnancy.
- **HIV status of mother unknown** - The physician may not have known the HIV status of mother because she refused testing or the physician did not offer testing. Sometimes the mother is not identified as being HIV positive until after delivery.
- **Mother known to be HIV negative during pregnancy** - If the mother tested HIV

negative during pregnancy (with no further testing to indicate HIV seroconversion), she would not receive ARV for prevention of perinatal transmission. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.

- **Mother Refused** - Mother refused ARV during pregnancy.
- **Other** - If 'Other' is indicated, be sure to specify why ARV was not prescribed.
- **Not Documented** - Indicate 'Not Documented' if the woman was not prescribed ARV but the reason why is not known.

Q. 32 WAS MOTHER'S HIV STATUS NOTED IN HER LABOR/DELIVERY MEDICAL RECORDS: This information may be found in the history or progress notes, or on a lab report.

Mark 'Yes, 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 AZT.

Mark 'Yes, Negative' if there is indication of a negative test during pregnancy or at labor and delivery.

Q. 33 DID MOTHER RECEIVE ANTIRETROVIRALS DURING LABOR AND DELIVERY: 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. If, 'Yes', complete the grid for all drugs received during labor and delivery. If the specific drugs she received are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column.

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 not included in the list.

- **Drug Name** - Using the antiretroviral drug list, note all antiretroviral medications either used or refused during labor and delivery. 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 ZDV or other ARV at labor and delivery in HARS.
- **Was 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.
- **Date Received/Time Received** - Enter the date and time the antiretroviral medications were begun. If a woman received multiple doses of an antiretroviral, only indicate the first date and time of administration. Enter 'XX' for unknown values (i.e., 03/XX/2005 or XX:XX)). **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).**
- **Type if Administration** - The medication record, nurses notes, physician's progress notes, and copies of physician's orders should document the administration of antiretroviral medications if they were given. The physician's orders will generally have the nurse's initials next to the orders as indicating that they carried out the order. Zidovudine (AZT, ZDV) would usually be administered intravenously (IV). Some hospitals may not have an adequate stock of IV on hand and may give it orally rather than do nothing. 'PO' is the standard medical abbreviation for orally. If it is noted in the chart that the drug was given, but the route was not documented, check 'Rcvd, route not documented'.

Q. 33a IF NO ARV WAS RECEIVED DURING LABOR & DELIVERY, INDICATE REASON:

- **Precipitous delivery/STAT c-section** - In some cases an eminent delivery of an infant may preclude prescription and/or administration of ARV.
- **Prescribed but not administered** - There are instances where a physician has ordered the medication, but the mother never received it. Possible reasons would include not having the specific ARV in the hospital pharmacy. If the ARV was prescribed but not administered because the women delivered prior to administration, check the previous box for 'Precipitous delivery/STAT c-section'.
- **HIV 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 outside of 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.
- **Not Documented** - Indicate 'Not Documented' if the woman was not prescribed ARV but the reason why is not known.

Q. 34 WAS MOTHER REFERRED FOR HIV CARE AFTER DELIVERY: If the mother receives CD4 or viral load testing (**Q. 35a and 35b**) this information can be used as a marker that the mother received care after delivery (up to 6 months). 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'.

Q. 35 INDICATE FIRST VIRAL LOAD AND/OR CD4 AFTER DISCHARGE FROM THE HOSPITAL: This question is most relevant for those project areas that have laboratory reporting of CD4 counts and viral loads. If the mother receives CD4 or viral load testing this information can be used as a marker that the mother has received care after delivery.

Q. 35a INDICATE FIRST CD4 RESULT AFTER DISCHARGE: 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. For more information on collection of CD4 counts and percent, see **Q. 27a.** If there is no indication of a subsequent CD4 result, mark 'Not Done'. If the women was referred to care or the abstractor has evidence that she was in care, but there is no subsequent information regarding CD4 results, mark 'Not Available'.

Q. 35b INDICATE FIRST VIRAL LOAD AFTER DISCHARGE: For more information about viral load testing and how to complete the chart see **Q. 28a.** If there is no indication of a subsequent viral load result, mark 'Not Done'. If the women was referred to care or the abstractor has evidence that she was in care, but there is no subsequent information regarding viral load results, mark 'Not Available'.

VI. Birth History

Questions 36-42

Hierarchy of records for response gold standard: If conflicting information is found for any of the birth history questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Labor and Delivery
2. Pediatric Birth
3. Birth Certificate
4. Pediatric non-HIV
5. Pediatric HIV
6. Health Department

Almost all of the information in this section is routinely available on the labor and delivery summary record, a standard part of the chart (the form itself may vary from hospital to hospital but contains much of the same information).

Q. 36 TYPE OF BIRTH: Multiple births are entered into HARS as separate records. If there were multiple births (e.g. twins), each infant should have a separate Enhanced Surveillance Form completed and have a unique Stateno number in HARS.

Note: If the birth is a multiple birth (twins, triplets) you will need to complete a separate data abstraction form for each infant. (The mother's information does not need to be completed on the second form except for noting all variables in the Basic Demographics section.) Be sure abstraction forms for multiple births are submitted for data entry and stored together.

Q. 37 BIRTH INFORMATION: 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).**

- **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 Labor and Delivery (L&D), rather than to hospital. A short time between admission and delivery ('precipitous delivery') may be a reason for not receiving IV ZDV. You should make sure that the date and time of admission to L&D is for the admission associated with delivery. The woman may have been admitted on another date and/or time for false labor or some other reason and sent home, then readmitted for delivery.
- **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 'elective cesarean section', there will not be onset contractions, because by definition, an elective cesarean occurs prior to onset of labor. In this case, write '**none**' in the space provided.
- **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 AROM. When membranes rupture on their own, spontaneously, this is referred to as spontaneous rupture of membranes, or SROM; or PROM 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 **'XX:XX**'. 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 HARS if necessary.

Q. 38 **GESTATIONAL AGE AT TIME OF DELIVERY:** This age should be recorded in weeks. Round the number down to the nearest whole digit (i.e., 38 6/7 would be 38 weeks).

Q. 39 **MODE OF DELIVERY:** This 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. The mode of delivery is usually noted there. If the delivery was C-section, complete **Q. 39a**.

Q. 39a **IF C-SECTION DELIVERY:** Elective cesarean section refers to a cesarean section that occurs before rupture of membranes and before 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.' Non-elective (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, but the dictated discharge summary will make this clear. The reason(s) for a C-section are given in the labor and delivery medical record. 'HIV Indication' should only be marked if it is clear that this is the reason for conducting a C-section. DO NOT mark this option just because the mother is HIV positive. Notes in the child's records are acceptable even if no birth records are available. Check the appropriate response. If not documented, check 'Not specified'.

Q. 40 **INSTRUMENTATION USED:**

- **None** - if there was not indication that an instrument was used. If the delivery is noted as Normal Spontaneous Vaginal Delivery (NSVD), mark 'None'. Also mark 'None' if there is information regarding the delivery method, and there is no evidence that any instruments were used.
- **Forceps** - forceps are applied to the head of the infant to assist in delivering the infant.
- **Vacuum** - a vacuum is applied to the head of the infant to assist in delivering the infant.
- **Forceps and vacuum**- combination of the two methods
- **Not specified** - if the type of delivery is not available, note 'Not specified'.

Q. 41 **CHILD'S BIRTH WEIGHT:** This is usually listed on the delivery summary sheet. It will often already be listed in grams but sometimes will only be in pounds. Record weight in lbs/oz or grams (One kilogram is 1000 grams). The EPS software converts pounds/ounces to grams.

Q. 42 **WAS MOTHER'S HIV STATUS NOTED ON THE EXPOSED CHILD'S BIRTH RECORD:** Indicate if mother's HIV status was noted in the birth record.

VII. Pediatric History

Questions 43-51

Hierarchy of records for response gold standard (Q.43 – 45): If conflicting information is found for any of the pediatric ARV and testing history questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Pediatric Birth
2. Pediatric HIV
3. Pediatric non-HIV
4. Health Department

Hierarchy of records for response gold standard (Q.46 – 48): If conflicting information is found for any of the pediatric infections status and PCP questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Pediatric HIV
2. Pediatric non-HIV
3. Health Department

Hierarchy of records for response gold standard (Q.49): If conflicting information is found for any of the breastfeeding question, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Pediatric non-HIV
2. Pediatric HIV
3. Pediatric Birth
4. Health Department

Hierarchy of records for response gold standard (Q.50 and 50a): If conflicting information is found for any of the birth defects questions, refer to this list to determine which response to include unless abstractor is positive of the correct response.

1. Pediatric non-HIV
2. Pediatric HIV
3. Pediatric Birth
4. Birth Certificate
5. Health Department

If abstraction is conducted prior to the specified time interval (i.e., 6 weeks for antiretroviral therapy, 1 year for PCP), then leave the questions blank and complete at follow-up.

Pediatric Laboratory Data (for HARS): Be sure to complete the standard pediatric HIV/AIDS case report form under section VII including all HIV diagnostic tests (type, results and date of test). Begin with the earliest test. Also collect additional CD4 results and enter CD4 data into HARS, specifically including the first, most recent, and closest to current diagnostic status. Collect all available viral load data and enter into HARS. Include the type of test, viral copies per mL, and date of test. Results of number of viral copies per milliliter of plasma and date of test can be collected for each of the three commercially available assays: 1) branched DNA (bDNA) 2) nucleic acid sequence-based amplification (NASBA) 3) quantitative RNA PCR. There is also an 'other viral load assay' option in HARS for any new viral load tests developed and licensed in the future.

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 HARS updates (e.g., new HIV diagnostic tests, CD4 counts, treatment, prophylaxis, AIDS-defining conditions, 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 (**Q.43 - Q.51**) or updated. The updated infant's CD4 counts and viral load test results should be entered directly into HARS.

Q. 43 WAS CHILD PRESCRIBED ANY ANTIRETROVIRALS FOR PERINATAL HIV PREVENTION

DURING THE FIRST SIX WEEKS OF LIFE: The first six weeks of life are referred to as the neonatal period. Do not include here any antiretroviral medications received after the first six weeks of life. If the answer to this question is 'Yes', complete the grid. If the specific drugs the child was prescribed are unknown, complete the grid and write 'Unknown" in the 'Drug Used' column.

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 the drugs not included in the list.

- **Drug Name** - Using the antiretroviral drug list, note all antiretrovirals either used or refused during the first six weeks of life. If the specific drugs the child was prescribed or the mother refused are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column. Also, be sure to complete the date neonatal ZDV or other ARV started in HARS.
- **Was 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 mother refused medications for a child if the child did not receive antiretroviral drugs -- they may not have been offered. Only code 'refused' if refusal is documented. Our goal is to sort out children who did not receive drugs because it was not offered to them, and those who did not receive it because mothers refused it.
- **Date Drug Started and Time Started** - The PHS recommendations state that the neonatal component of the ACTG protocol 076 consisting of 6 weeks of neonatal prophylactic ZDV therapy should begin within 8-12 hours of birth. Therefore, to monitor implementation and impact, we collect the date and time of day the child was first started on antiretrovirals for prophylaxis. If the child was prescribed an antiretroviral drug, record the date and time of day the child was started on the drug used as prophylaxis during the first 6 weeks of life. List all prescriptions, including single dose. Enter 'XX' for unknown values (i.e., 03/XX/2005 or XX:XX).
- **Regimen Completed** - If the child completed the prescribed regimen of antiretroviral drugs, check 'Yes', if not, check 'No'. If the regimen was not completed, enter the Stop Date and the Drug Stop Code. Zidovudine is generally prescribed for 6 weeks. Indicate 'Not Documented' when pediatric records and information about completion are unavailable.
- **Stop Date** - If the drug was stopped (discontinued) prior to completion of regimen, indicate 'Yes', the drug was stopped.
- **Drug Stop Code** - To answer this question, use the 'S' codes found at the end of the data abstraction form. 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.

Q. 43a IF NO ARV WAS PRESCRIBED IN FIRST SIX WEEKS OF LIFE, 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.

Q. 44 INFANT'S HIV ANTIBODY TESTING TABLE:

Rapid tests are tests done at the bedside or locally rather than being sent out, which ensures rapid 'turnaround' of results. ELISA and Western Blot are not rapid tests. An **expedited HIV** test is a standard EIA test performed with rapid turnaround time.

- **Results** - Enter the results of rapid, expedited EIA, or EIA testing (Positive; Negative; Indeterminate; Results not found; Not tested; Refused; Unknown). If there is an indication in the chart that the test was ordered and done, but no results can be found in the chart, indicate that by putting 'Results not found' in the space provided.
- **Test** - Enter the type of test performed (Rapid, Expedited EIA, EIA, Not Documented).
- **Date blood drawn** - Note the date the blood was drawn.

Q. 45 RESULTS OF DNA/RNA SCREENING TABLE:

- **Results** - Enter the results of DNA or RNA testing (Positive; Negative; Indeterminate; Results not found; Not tested; Refused; Unknown). Record as 'Negative' if the results are below the limit of detection. If there is an indication in the chart that the test was ordered and done, but no results can be found in the chart, indicate that by putting 'Results not found' in the space provided.
- **Test** - Enter the type of test performed (DNA, RNA). The most commonly used DNA PCR test is Amplicor/COBAS HIV-1 DNA test. The most commonly used RNA PCR test is Procliex RNA test.
- **Date blood drawn** - Note the date the blood was drawn.

Q. 46 WHAT IS THE CHILD'S CURRENT HIV STATUS: This question is especially important for those project sites that are not currently sending CDC a HARS record on all HIV-exposed children. See MMWR 1999;48(No.RR-13):29-31 for the pediatric case definitions of HIV infection and AIDS**.** This publication is available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm. If the pediatric provider is unknown and there is no possibility of obtaining this information, the child should be listed as indeterminate as of the date record abstraction was conducted and check lost to follow-up.

Q. 47 IF CHILD'S HIV STATUS IS INDETERMINATE, INDICATE WHY: This question is included on the pediatric HARS software (although it is not found on the pediatric case report form). It is found immediately after the question about diagnostic status of the child (variable name is 'followup'). The codes used for this question are the similar to those found in HARS. If information is only available through the child's day of birth, abstractors should consider this child lost to follow-up.

Q. 48 WAS PCP PROPHYLAXIS RECEIVED IN THE FIRST YEAR OF LIFE: Examples of drugs used for 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 of time. For example, TMP/SMX is usually used for 10 days 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 chart or given for a period of 2 weeks or longer. If there is nothing in the chart that indicates the use of any of these drugs or that refers to the prophylactic treatment of PCP, then check 'No'. 'Not Documented' is used if treatment information in the chart is unclear or not documented.

This question refers only to the child's first year of life. If the child received or is receiving PCP prophylaxis, enter the month, day and year the child was started on therapy to prevent the occurrence of Pneumocystis carinii pneumonia (PCP). If the year and month are present without a designated day, 'XX' should be entered for the day followed by the documented year and month. Information about PCP prophylaxis is also contained in HARS but refers to PCP prophylaxis started at any age not just within the 1st year of life.

Please refer to appendix K2 in the surveillance guidelines [MMWR 1995;44(RR-4):1-11] for the revised guidelines for prophylaxis against PCP for children.

Q. 49 WAS CHILD BREASTFED (HARS): If child was breastfed at any time, check 'Yes' and complete the duration in days or weeks. If duration is not known, check 'Not Documented.' This information will usually be found in the nurse's notes in the delivery chart, in the daily summary notes, or in the pediatric chart of routine visits. If the child was fed the mother's expressed breast milk, this question should be answered 'Yes'. Avoidance of breastfeeding to prevent postpartum transmission of HIV has been recommended for HIV-infected mothers in the U.S. If there is suspicion that the child's only exposure to HIV was through breast milk, note that on the front page of the Enhanced Surveillance Form and alert the state or local NIR Coordinator and CDC.

Q. 50 WERE ANY BIRTH DEFECTS NOTED IN THE FIRST YEAR OF LIFE: The goal of collecting birth defect information on children born to HIV-infected mothers is to systematically assess, on a population basis, any potential short term adverse outcomes of zidovudine or other antiretroviral exposure in utero. 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 to those who were not exposed and to that of 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 to code these defects have been developed by the CDC Division of Birth Defects and Developmental Disabilities, National Center for Environment Health and are currently used in the Metropolitan Atlanta Congenital Defects Program, an active surveillance system for birth defects in the Atlanta metropolitan area.

The Division of Birth Defects and Developmental Disabilities, NCEH, CDC, developed specific 6-digit codes based on the 1979 British Pediatric Association Classification of Diseases and the World Health Organization's 1979 International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). Five fields of codes can be entered in HARS. These 6-digit codes are explained and are indexed in *Appendix A*. The 6 digit code is based on a 3 or 5 digit ICD-9 code. The ICD-9 code, which may be available in the child's medical record, can be used on the HARS form and software in place of the 6-digit code. If defects exist, list them all on the HARS case report form and enter into the comment section of HARS. Call the Enhanced Perinatal Surveillance Coordinator for assistance with coding.

To look for possible birth defects, review newborn and hospital records including the face sheet, history and physical, discharge summary, operative, laboratory, x-ray, cardiac catheterization, autopsy reports, physicians', nurses', social, and psychological services' notes, and consultations. In addition, birth defect (i.e. congenital anomalies) information is also collected on the standard U.S. birth certificate. Hospital records should be reviewed to determine if a reportable defect is present. Each reportable condition is coded separately according to the 6 digit code. These codes are based on ICD-9 codes but provide more specific diagnostic information. If reportable birth defects are diagnosed, check 'Yes' and abstract all diagnoses onto the EPS Date Abstraction Form and the HARS case report form. Also include discrepant diagnoses and those mentioned once in the chart that have not been specifically 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 as to whether a diagnosis is a birth defect and should be reported please call the Enhanced Perinatal Surveillance Coordinator. For reference, you may request the full copy of the Metropolitan Atlanta Congenital Defects Program Procedure Manual from the EPS Coordinator.

Another source of information would be a HARS match with the local birth defects surveillance registry.

Q. 51 IF CHILD DECEASED, FROM DEATH CERTIFICATE, LIST: Legibly print the causes of death in the appropriate space provided exactly as it appears on the death certificate. If the ICD-9 or ICD-10 code is included on the death certificate that you review you should include those on the abstraction form. If codes do not appear on the death certificate, the causes of death will be assigned an ICD-9 or ICD-10 code at CDC. **Do not, however, code these causes of death yourself.**

Note: The last listed cause of death in part 1 of the death certificate is usually the underlying cause of death.

Last Updated on October 17, 2006

Procedural Guidance for Enhanced HIV/AIDS Perinatal Surveillance FY2006-FY2009

HIV/AIDS Incidence and Case Surveillance Branch
Division of HIV/AIDS Prevention
August 2006

CONTENTS

I. Introduction
    A. Purpose of EPS
    B. Background of Advancing HIV Prevention
    C. History of EPS
    D. Purpose and Use of EPS Procedural Guidance

II. Goals and Objectives

III. Partners in Cooperative Agreement
    A. CDC
        1. Project Officer
        2. Project Coordinator
        3. Data Manager
        4. Analysis Working Group
    B. State and Local Health Departments
        1. Project Director
        2. Project Coordinator
        3. Abstractors/Data Entry Staff
        4. Community Planning Groups/Prevention Program Partners

IV. Methods
    A. Project Design
    B. Project Sites
        1. HIV Exposure Reporting
        2. Non-HIV Exposure Reporting
    C. Case Eligibility/Ascertainment
        1. Cohort Birth Year
        2. State/City of Birth Hospital v. State/City of Residence
        3. Eligible Mother-Infant Pairs
        4. Case Ascertainment
        5. Case Finding
            a. Active surveillance
            b. Passive surveillance
        6. Vital Statistics Birth Registry Match
        7. Other Methods of Case Ascertainment
    D. Data Collection
        1. Data Sources
        2. Data Collection Instruments
            a. Historical changes to data collection form
            b. Integration with HARS case reports
            c. Abstracting data from medical records
            d. Site-specific questions
        3. Data Collection Procedures
            a. Timing of collection
            b. Attainment of records

c. Completeness of reporting
d. Notation of abstraction procedures & anomalies
e. Follow-up of children

E. Data Management (Electronic Data Entry & Transfer)
1. Structural Requirements
2. Process Standards
a. Data entry
b. Edits
c. Processing follow-ups, corrections, and deletions
d. Documentation
3. Data Files
4. Data Analysis Files
5. Data Management Procedures
a. System backup
b. Computer virus protection
c. Quality control
d. Security and access to abstractions and computer files
e. Quarterly report generation

F. Data Quality
1. Structural Requirements
a. Procedure manuals, coding manuals, and other documentation
b. Edits and data processing
2. Process Standards
a. Adherence to data standards
b. Training
c. Quality control activities
d. Outcome measures

G. Data Analysis
1. Preparation for Analysis
a. Data complete for analysis
b. Data accuracy
c. Security and confidentiality
2. Features of Analyses
3. Site-Specific Analyses
4. National/CDC Analyses

H. Dissemination of Results
1. Ways to Use EPS Data
2. Ways to Disseminate EPS Data
3. Authorship Principles with CDC, Partners & External Researchers
4. Review of Abstracts and Manuscripts

I. Limitations of EPS data

V. Project Time Line
A. Ongoing activities

VI. Protection of Human Subjects
A. IRB Approval

B. Informed Consent
C. Protecting Privacy of EPS Data (Confidentiality and HIPAA)

References

Appendices

A. EPS Supplemental Medical Record Abstraction Form
B. Technical Guidance for HIV/AIDS Surveillance Programs: Pediatric HIV/AIDS Case Reporting
C. EPS User's Guide
D. Site-Specific Questions
E. Technical Guidance for HIV/AIDS Surveillance Programs: Access to Source Data and Completeness of Reporting
F. Technical Guidance for HIV/AIDS Surveillance Programs: Data Quality
G. NCHSTP Determination of Applicability of Human Subjects Regulations
H. Example from New York City - IRB Approval for Site Specific Surveillance of Mother/Infant Pairs
I. Assurance of Confidentiality

I. Introduction

A. Purpose of EPS

The purpose of the Enhanced Perinatal Surveillance (EPS) project is to target and follow the progress toward maximal reduction of perinatal HIV transmission. This project addresses the new strategies for a changing epidemic developed at the Centers for Disease Control and Prevention called "Advancing HIV Prevention": Further decrease perinatal HIV transmission.

B. Background of Advancing HIV Prevention (AHP)

One of the goals of Advancing HIV Prevention, CDC's recently launched initiative, is to further decrease perinatal HIV transmission (*1*). Strategies for accomplishing this goal include (a) working with prevention partners to disseminate recommendations and support implementation, (b) providing training for providers and health departments in conducting prenatal testing, (c) promoting universal prenatal HIV screening according to the opt-out approach (e.g. HIV testing is part of the routine battery of prenatal tests unless a woman declines), and (d) promoting routine rapid testing during labor and delivery for women whose HIV status is still unknown. These and other strategies will be necessary to further reduce perinatal HIV transmission in the United States.

Progress towards this goal may be measured through surveillance efforts of HIV-exposed infants.

C. History of EPS

In February 1994, the Pediatric AIDS Clinical Trial Group Protocol 076 demonstrated that zidovudine (ZDV) could reduce the risk of mother-to-child HIV transmission from 25% to 8% (*2*). As a result, a United States Public Health Service (USPHS) task force issued recommendations in August 1994 for the use of ZDV to reduce perinatal HIV transmission. Included are treatment options for HIV-infected pregnant women and for infants born to HIV-infected women and recommendations for the medical monitoring of pregnant women and of infants who receive ZDV (*3*). In July 1995, the USPHS published recommendations for HIV counseling and voluntary testing for all pregnant women, which include advice to health care professionals on educating women about the importance of knowing their HIV status and the steps to preventing mother-to-child transmission (*4*). Revised recommendations for HIV screening for pregnant women, which further emphasized HIV testing as a routine part of prenatal care, including rapid testing during labor and delivery, were published in 2001 (*5*).

With the emphasis on the importance of preventing perinatal HIV transmission, the CDC implemented activities targeted at further reducing perinatal transmission of HIV in high prevalence areas. The Enhanced Perinatal Surveillance (EPS) Project was created as an extension of routine surveillance activities.

D. Purpose and Use of EPS Procedural Guidance

The EPS Procedural Guidance will serve as a standardized approach to the collection, management, analysis and dissemination of data on HIV-exposed infants in the funded project sites. CDC provides guidance in the EPS Procedural Guidance to address approaches in conducting EPS in name-based and code-based sites as well as population and facility-based sites.

II. Goals and Objectives

The goals and objectives of the EPS project are to allow State and local health departments to evaluate: 1) the impact of implementation of efforts to maximally reduce perinatal HIV transmission; 2) prevention failures for perinatal HIV transmission; 3) the efficacy of zidovudine (ZDV) and other antiretroviral medications in preventing perinatal HIV transmission; 4) potential adverse outcomes of perinatal and postnatal antiretroviral therapy; and 5) the Public Health Service recommendations for opportunistic infection prophylaxis by:

A. Conducting medical record reviews of mother/infant pairs and longitudinal follow-up of all HIV exposed children to ascertain: (i) knowledge of maternal HIV infection status before birth; (ii) HIV incidence; (iii) AIDS incidence; (iv) death; (v) the use of maternal and neonatal zidovudine (ZDV) and other antiretroviral medications; and (vi) efficacy of these medications in preventing HIV transmission.
B. Conducting medical record reviews to evaluate recommendations for opportunistic infection prophylaxis and initiation of HIV evaluation and treatment in children.
C. Assessing potential adverse outcomes of exposure to antiretroviral medications among infected and uninfected children in the short term (e.g., birth defects, ascertained through record reviews and registry matches) and in the long term where there is a retention of records on exposed infants (e.g., by matching to tumor registries).
D. Matching HIV/AIDS registries to birth registries to ensure complete ascertainment of mother/infant pairs.
E. Collaborating with CDC to track progress towards the maximal reduction of perinatal HIV transmission.

III. Partners in Cooperative Agreement

A. Centers for Disease Control and Prevention (CDC)

The following is the CDC staffing pattern for the EPS Project as of January 2006. All staff members are located in the National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention:

1. Project Officer

Suzanne Whitmore, DrPH is the CDC Project Officer for EPS. She is responsible for the overall management of the project and oversees the administrative aspects of EPS.

2. Project Coordinator

Nan Ruffo is the CDC Project Coordinator for EPS. Her duties are to act as liaison for all day-to-day project issues, provide feedback on issues related to data collection procedures and participate in the analysis of EPS data.

3. Data Manager

Nan Ruffo is the CDC Data Manager for EPS. She is responsible for all data management activities including data entry, edit checks, processing follow-ups, corrections and deletions in the data system, data quality, evaluation and analysis for data dissemination.

4. EPS Analytical Working Group

Tonji Durant, PhD
Lorena Espinoza, DDS, MPH
Alpa Patel-Larson, MPH
Nan Ruffo
Suzanne Whitmore, DrPH

This working group is tasked with developing and analyzing EPS data from all participating sites.

B. State and Local Health Departments

Record reviews and data abstraction will be conducted by State and local personnel responsible for HIV/AIDS surveillance activities as deemed appropriate by State, local, and CDC staff. Although several people at State and local health departments may be involved in perinatal

surveillance activities, one individual from each State/local health department will serve as primary coordinator and contact person for this project.

1. Project Director

The duties and responsibilities of the Project Director:

- Oversee administration of EPS and supervise staff
- Act as liaison with CDC
- Assure compliance with the EPS Procedural Guidance
- Provide CDC with annual progress reports

2. Pediatric Surveillance Project Coordinator(s)

The duties and responsibilities of the Pediatric Surveillance Coordinator:

- Primarily responsible for the day- to day activities for EPS
- Oversee data collection procedures
- Oversee all data management procedures
- Train staff and participate in EPS training and meetings
- Oversee the development of the procedural guidance's site-specific sections and data collection form's site specific questions
- Apply and track Institutional Review Board (IRB) approval and inform IRB of any changes
- Participate in the analysis of EPS data
- Prepare and renewal all cooperative agreement applications and annual progress reports
- Responsible for maternal and child health linkages with other datasets
- Assure quality control of data entry and data collection by conducting process and outcome evaluation activities

3. Abstractors/Data Entry Staff

The responsibilities for Abstractors include:

1. Conduct medical record reviews and abstraction of data for the EPS Project.
2. Inform the coordinator of EPS data collection activities
3. Assist with operational activities

The responsibilities for Data Entry staff include:

1. Enter EPS data into data entry system

4. Community Planning Groups / Prevention Program Partners

The community planning groups and prevention partners will serve to aid in the development of site-specific questions and advise surveillance staff on the analysis and dissemination of EPS data. The Surveillance Coordinator should provide updates the community planning groups and prevention partners at least once a year.

IV. Methods

A. Project Design

This project constitutes an integrated HIV/AIDS population-based or facility-based surveillance system for HIV-infected mothers and their perinatally exposed children. Data will be collected using both the HIV/AIDS case report form and the supplemental EPS abstraction form (*Appendix A*). HARS records will be updated on an ongoing basis as needed.

The data to be collected include: maternal prenatal care usage, maternal HIV test history, prenatal and neonatal antiretroviral therapy, other interventions to prevent transmission, receipt of prophylaxis and treatment by the infant, appropriate follow-up care of the mother and child, and other interventions relevant to the evaluation of recommended public health actions to prevent perinatal HIV transmission.

Enhanced perinatal surveillance constitutes additional case ascertainment methods, linking of mother-infant pairs and review of supplemental medical records. Supplemental medical record reviews will include both the mother's and child's medical records (mother's HIV clinic chart, prenatal records, labor and delivery records, newborn hospital and pediatric clinic charts, birth and death certificates, and laboratory reports) to assess testing, prenatal care, and treatment, longitudinal follow-up to assess infection status of infants, initiation of HIV-related care, and long-term outcomes. States without named HIV infection reporting may have authority (based on Institutional Review Board (IRB) assurance, relevant State public health laws, statutes, rules, etc.) to access HIV-infected mother's and HIV-exposed infant's medical records at medical facilities and to collect data from these records.. The specific methods for collecting data on HIV-infected mothers and their HIV-exposed infants will vary depending on the HIV reporting laws and policies of each State. Unless prohibited by reporting laws or regulations, matching HIV/AIDS and birth registries will be conducted to help ensure that all mother/infant pairs are identified and the data are representative of all HIV-infected pregnant women. Where feasible, additional registry matches (i.e. birth defects and tumor registries) will be conducted to assess potential adverse outcomes of antiretroviral exposure among infected and uninfected children in the short and long term.

The HIV-exposed infants identified through enhanced perinatal surveillance will be followed up by the health department every 6 months for up to 18 months until their HIV infection status is determined, and, if they meet the HIV/AIDS case definition, will continue to be followed to determine their vital status. At each six month interval, HARS (the HIV/AIDS surveillance software reporting system) will be updated with new information. Children found to be HIV-uninfected will be maintained in HARS as a perinatal exposure (unless prohibited by State law).

B. Project Sites

Applicants funded for the Enhanced Surveillance for Perinatal Prevention Project in 2006 are: Chicago; Connecticut; Delaware; Georgia; Houston; Los Angeles; Louisiana; Maryland; New Jersey; New York; New York City; Philadelphia; Puerto Rico; South Carolina; and Texas, or their bona fide agents.

1. HIV Exposure Reporting

CDC and the Council of State and Territorial Epidemiologists (CSTE) recommend that all states and territories conduct surveillance for perinatal HIV exposure with follow-up to determine HIV-infection status of the infant and progression to AIDS (*6-8*). Sites should conduct population-based perinatal HIV exposure surveillance for infants born to HIV infected mothers and follow the infants until 18 months of age or until status is determined. Refer to *Appendix B* for *Technical Guidance for HIV/AIDS Surveillance Programs: Pediatric HIV/AIDS Case Reporting*.

Perinatal exposure reporting differs from reporting of pediatric cases of HIV among children <13 years of age, as exposed infants may or may not be infected with HIV. Antibody tests may be positive at birth regardless of the infant's true HIV status due to the transplacental transfer of maternal antibodies. Common ways that mother-infant pairs are often identified include active HIV/AIDS case finding, reports of HIV-infected pregnant women to surveillance, reports of HIV-exposed or HIV-infected infants to surveillance, birth registry linkages (e.g. programs can match HIV cases in women of child-bearing age with the birth registry database annually), and hospital discharge summaries.

The specific methods for collecting data on HIV-infected mothers and their HIV-exposed infants will vary depending on the HIV reporting laws and policies of each State. Sites that have HIV exposure reporting laws have the authority (based on relevant State public health laws, statutes, rules, etc) to access HIV-infected mothers' and HIV-exposed infants' medical records and to collect data from these records to be stored at the State/local health department.

2. Non-HIV Exposure Reporting

States without HIV exposure reporting will be able to access HIV-infected mothers' and HIV-exposed infants' medical records and to collect data from these records, based on separate IRB assurance. The specific methods for collecting data on HIV-infected mothers and their HIV-exposed infants will vary depending on the HIV reporting laws and policies of each State. Unless prohibited by reporting laws or regulations, matching HIV/AIDS and birth registries will be conducted to help ensure that all mother/infant pairs are identified and the data are representative of all HIV-infected pregnant women.

C. Case Eligibility/Ascertainment

1. Cohort Birth Year

All project areas should collect data on HIV-exposed infants (and their mothers) born in 2005-2008. Data for these birth years previously abstracted on the January 2003 EPS abstraction form will be updated using the 2006 EPS abstraction form to obtain data collected exclusively on the new form.

2. State/City of Birth Hospital v. State/City of Residence

Case eligibility will be determined by the site. If the site is facility-based, the EPS data abstraction form will be completed on all infants identified in the selected facilities. If the site is population-based, the EPS data abstraction form will be completed for all infants born within the project area. In these instances, sites in which the birth occurred should coordinate abstraction efforts with the project site of residence to obtain all needed data. For states with a separately funded city, case eligibility will be based on case ownership established through core HIV/AIDS surveillance activities.

3. Eligible Mother-Infant Pairs

Mother-infant pairs meeting any of the following criteria are eligible for inclusion in EPS:

a. Women who were known to be HIV-infected in pregnancy (tested before or at delivery) and delivered in the data collection birth years
b. Women who were not known to be HIV-infected in pregnancy, but whose child was reported to surveillance (either as indeterminate, infected, or seroreverter) and was born in the data collection birth years
c. All children reported to surveillance who were born to HIV-infected mothers and were born in the data collection birth years.

4. Case Ascertainment

In HIV exposure reporting sites, ascertainment of mother-infant pairs will consist of all infants born to HIV-infected mothers within the geographic area defined by the project. These sites will conduct the project as though it is part of core surveillance activities. See Appendix B

Project sites without HIV exposure reporting will conduct these activities in selected facilities serving large numbers of HIV-infected women (e.g., delivery hospitals or high-risk prenatal clinics) and HIV exposed children (e.g., specialty pediatric clinics, pediatric HIV clinics). Thought should also be given as to whether other facilities and certain sites conducting prevention activities should also be targeted. Mother-infant pairs will consist of all HIV-exposed infants born to HIV-infected mothers within these selected facilities in the geographic area defined by the project. In addition, these sites will need to complete the following:

a. Must obtain State and facility IRB approvals

b. Must submit IRB approved protocols to CDC. Procedural Guidance should include how facilities were chosen for inclusion and a timeline for the project.
c. ***<Sites should explain their plans to obtain additional data for mother-infant pairs who received care outside of the participating facilities>***

<Include plans for case ascertainment and selected facilities. Project area should include discussion of how they select facilities/sites (i.e., SCBW data, hospitals where at least one HIV-positive birth has occurred during a certain time period)>

5. Case Finding

EPS project staff should identify report sources including HARS, laboratory reports, birth certificates, death certificates, and case management records. Ascertainment of mother-infant pairs should occur through both active and passive surveillance.

a. Active surveillance

EPS project staff should regularly contact reporting facilities or have an active reporting system established with delivery hospitals and clinics to identify potential/suspect HIV/AIDS perinatal exposure cases. HIV-infected women should be identified during pregnancy by surveillance staff and the infant should be investigated until the infection status is known. ***<Site describes site-specific active surveillance>***

b. Passive surveillance

Reporting systems with laboratories, pediatric clinics, and HIV clinics should be established to receive testing results on exposed infants, including all positive and negative polymerase chain reaction tests. ***<Site describes site-specific passive surveillance>***

6. Vital Statistics Birth Registry Match

A registry match between the HIV/AIDS registry and the birth registries is critical for ascertaining all possible mother/infant pairs so that data is representative of all HIV-infected pregnant women who were known to be HIV-infected during pregnancy. A registry match occurs when a woman's information on the HIV/AIDS registry matches the maternal information on the infant's birth certificate. ***<Site describe plans for registry matches – include timeline >***

7. Other Methods of Case Ascertainment

<Site identifies additional methods for case ascertainment>

D. Data Collection

1. Data Sources

a. Prenatal care records
b. Maternal HIV clinic records
c. Labor and delivery records
d. Pediatric birth records
e. Pediatric HIV medical records
f. Pediatric medical records (non-HIV clinic/provider)
g. Birth certificate
h. Death certificate
i. Health department records
j. Other records

2. Data Collection Instruments

a. Historical changes to data collection form

The EPS data collection form has been revised based on information availability and reliability in the medical records. It was also revised to better collect data of interest and to improve analysis capacity. For information on what and how information should be abstracted, refer to *Appendix C* (*EPS User's Guide*).

b. Integration with HARS case reports

The EPS abstraction form will be completed for every mother/infant pair in addition to the HARS case report forms. Every infant included in the Enhanced Perinatal Surveillance system must have a State of report and a State number. These two pieces of information are required for inclusion in the EPS data entry system. If the project site is code-based, a project ID number will be established in place of the code. No coded ID numbers will be sent to the CDC.

Both the HARS case report form and EPS form should be abstracted at the same time. If a HARS report already exists within the system, EPS variables collected on the HARS case report form should be re-abstracted to assure accuracy. Any discrepancy should be addressed in the HARS database.

c. Abstracting data from medical records

Data will be collected from various reporting sources including health care providers, hospitals and clinics, laboratories, and vital statistics records (birth and death certificates). Medical records that will be accessed to complete the HIV/AIDS case report form and the supplemental data collection form include those listed in the above Data Sources section. All pediatric medical records should be reviewed six weeks postpartum or later so that data on neonatal antiretroviral

use, breastfeeding, etc. will be available. However, timely collection of these data is essential for identification of missed prevention opportunities, and targeting of prevention activities.

The standard pediatric surveillance case report form includes data on mother's HIV status; demographic and risk factors; the timing of the mother's HIV test with respect to the child's birth; the timing of first prenatal care visit and the total number of visits; use of ZDV to prevent transmission (prenatal, intrapartum, and neonatal); mother's use of other antiretrovirals; type of delivery; use of PCP prophylaxis in child and date started; use of antiretrovirals for treatment for child and date started; breast feeding; birth defects; vital status; child's primary medical reimbursement provider; and the type of care in which the child has been enrolled.

The supplemental data abstraction form will collect more specific and additional data on timing and receipt of prenatal care; HIV diagnostic testing history; illicit drug use and STD history during pregnancy; immunologic testing; and clinical status. The form will also collect information on receipt of ZDV and other antiretroviral agents by the woman during pregnancy; labor and delivery; and receipt of antiretrovirals by the newborn. Information on mode of delivery; determination of the HIV status of infant; receipt of prophylaxis and treatment by the infant; breast feeding; birth defects; and assessing follow-up care of the mother and child is also collected. It is also important to know if documentation of mother's HIV status is found in labor and delivery records and in the infant's medical record.

The pediatric HIV/AIDS case report form and the supplemental data abstraction form will be completed for each child. A woman may give birth more than once over the abstraction period. For such women, each pregnancy should be abstracted on a separate form. The maternal information pertinent to each pregnancy must be included. If a woman has twins or triplets, a separate data abstraction form should be completed for each infant. Once data are entered in the HARS and EPS systems, these data should be merged and selected variables will be sent to the CDC EPS data manager.

d. Site-specific questions

States have the opportunity to supplement the standard questions with questions that address additional issues of particular importance for their individual site. Site-specific questions are developed and pre-tested by the site, and are incorporated into the site-specific portion of the abstraction form. These questions will be entered into the EPS data entry system using the variable names SSQ1 – SSQ10. Sites will submit site-specific questions to the CDC for approval prior to data collection. Refer to *Appendix D* for site-specific questions.

3. Data Collection Procedures

a. Timing of collection

Abstraction forms should be completed as the mother-infant pairs are identified and in accordance with the sites' core surveillance procedures. Minimum timeliness standard of ≥ 66%

of cases for a diagnosis year are reported within 6 months of diagnosis, assessed at ≥ 85% completeness 12 months after the diagnosis year.
For detailed guidance on timeliness of reporting refer to *Appendix E* (*Technical Guidance for HIV/AIDS Surveillance Programs: Access to Source Data and Completeness of Reporting*).

b. Attainment of records

<Site includes method(s) of attaining records>

c. Completeness of reporting

Completeness of HIV/AIDS case ascertainment can be calculated by comparing the number of cases diagnosed and reported to the surveillance program for a diagnosis year with the number of cases expected to be diagnosed during that year.

Completeness can be assessed for cases that meet the project requirements. Checks on case ascertainment include:

- Case-finding audits
- Capture-recapture analyses
- Regular assessments of reported vs. expected number of cases received from a reporting source, e.g., electronic lab reporting (determine frequency at least quarterly), with feedback to the reporting source. Possible data sources include state based Survey of Childbearing Women data, laboratory reporting data, AIDS Drug Assistance Program, and Medicaid.

Completeness of case ascertainment for a diagnosis year is measured at 12 months after the diagnosis year, comparing the number of cases diagnosed and reported to the surveillance system for a given year to the number of cases expected to be diagnosed during that year. The standards for completeness are

- Minimum performance standard: ≥ 85% of expected number of cases for a diagnosis year are reported by 12 months after the diagnosis year.
- Target performance standard: ≥ 95% of expected number of cases for a diagnosis year are reported by 12 months after the diagnosis year.

For detailed guidance on completeness of reporting refer to *Appendix E* (*Technical Guidance for HIV/AIDS Surveillance Programs: Access to Source Data and Completeness of Reporting*).

d. Notation of abstraction procedures & anomalies

<Site provides abstraction methods and procedures>

e. Follow-up of children

All infants and children born to HIV-infected mothers, including perinatally-exposed and infected children, reported to surveillance will be followed up at 6-month intervals. According to

routine pediatric surveillance guidelines (*Appendix B*), infants are followed to document the following events: i) confirmation of infection or seroreversion; ii) referral to appropriate clinical follow-up and receipt of drug therapies; iii) onset of AIDS; and iv) confirmation of vital status. Children should be followed until they are determined to be uninfected or until they reach 18 months of age.

The uninfected children should remain in the HARS database. If HIV exposures are not reportable, a HARS database separate from that which maintains case reports on HIV-infected persons could be established. These HIV-exposure registries should be maintained in accordance with State laws. They are essential for follow-up and investigating outcome measure related to exposure to antiretroviral drugs. If consideration is being given to delete these HIV-uninfected children from the database, prompt notification to CDC should be made before any deletions occur.

A proposal to revise the pediatric HIV surveillance case definition was approved by the CSTE in 2006 (*9*). These new criteria should be used in determining the child's HIV infection status. All AIDS diagnoses should be reported in accordance with the 1987 pediatric AIDS case definition (*10*). The clinical guidelines for *Pneumocystis* pneumonia (PCP) prophylaxis for children (*11*) and the use of antiretroviral agents for pediatric HIV infection (*12*) may also be used as a reference when conducting follow-up activities.

E. Data Management (Electronic Data Entry & Transfer)

A web-based data entry system is currently being developed. This system will allow project sites the ability to enter their own data at the site level thus making the data more readily available for ongoing prevention and care planning. All data will be reported to CDC in a secure manner using CDC-provided forms and software.

1. Structural Requirements

The structural requirements for data management include hardware and software that allow searching for existing cases, importing of data and linkage to other databases, transmission of data, data quality functions, and report generation in a secure environment. Further, staff must receive adequate training (initial training and continuing education) in data processing to assure consistency.

2. Process Standards

The processes for data management must be documented in procedures manuals and kept up-to-date to maintain an adequately functioning system and to train staff. The documentation may include manuals for the data entry software as well as documentation of processes specific to the local health department.

a. Data entry

Paper documents received by EPS Coordinators or other designated EPS staff should be marked with the date of receipt and, after visual editing (proofreading), data items from these documents should be entered into the EPS software. Local programs should develop written procedures for handling and storage of paper and electronic documents, including an acceptable time frame from document receipt to data entry. Some verification of keyed data should be in place, such as duplicate data entry to compare original and duplicate documents for discrepancies (*See Data Quality*).

b. Edits

Data edits are automatically applied when information is entered into the system and are applied to all data on a routine schedule (*See Data Quality*). The edits are described in the EPS software documentation. Each document should be retained as originally received. If data edits indicate incorrect information in a particular document, EPS staff should verify that the information was correct as indicated by the source records. However, information in a document should not be changed based on information from other medical records. The rules for abstracting multiple records described in the User's Guide should be applied to select the best value for a data element, or to override information from a document that is proven to be incorrect (*Appendix C*).

c. Processing follow-ups, corrections, and deletions

In many instances, follow-up is required to obtain all necessary information on a case. Information obtained from a source during follow-up for missing information on a case may range from one particular data item (e.g., risk factor information) to many data items; this information is recorded on a new EPS data abstraction form if the follow-up information is obtained after the case has been entered into the EPS software. If the follow-up is prior to data entry, the additional information may be recorded on the original form. When information is gathered on a new EPS form during a follow-up investigation, this form must be marked as a follow-up report; this information is also entered into the EPS software.

In some instances, information is found to be incorrect (e.g., a data edit revealed an invalid value and the report source is re-contacted or re-visited and the correct information is obtained). Then the information should be corrected on paper and electronic forms. Changes to original documents should only occur if verification is obtained. If information is incorrect on a document but known to be correct based on information obtained through another medical record, staff can correct the original form if not previously entered into the EPS software. If case has been entered into the EPS software, the correct value and infant identifiers should be written on a new EPS form for data entry updates. Any errors created during data entry should be corrected in the software.

Cases may also need to be deleted after they have been entered into the EPS software (for example, infant is found to have a duplicate record). After a document or record for an infant is marked for deletion and the updated information is sent to CDC, final deletion occurs after feedback from CDC is received that the case deletion was noted and was also deleted in the

national database. Paper forms should also be marked as deleted with the reason for deletion in the software.

d. Documentation

Data management processes—data collection, additions, changes, deletions, and the like—should be documented, including the staff performing the action, the date, and the action (e.g., changed sex from male to female). In addition, data management reports should be routinely created and shared with the appropriate parties. Such reports include:

- Reports of database and surveillance operations (e.g., staff access to data, changes/deletions, workflow [e.g., cases by process completed such as visual editing, follow-up investigations], and listing of cases missing critical data items)
- Reports of cases reported
- Reports of timeliness and completeness of reporting to provide feedback to data abstractors
- Reports on quality control operations (*See Data Quality*)

Comment [n1]: Would like to be able to include these types of reports, but we currently don't know if the system will allow for these. I will update the guidance once the system is in place.

3. Data Files

4. Data Analysis Files

5. Data Management Procedures

a. System backup

b. Computer virus protection

c. Quality control

d. Security and access to abstractions and computer files

e. Quarterly report generation

Comment [n2]: Need system information to complete these sections.

F. Data Quality

1. Structural Requirements

a. Procedure manuals, coding manuals, and other documentation

The surveillance program must document all procedures, coding of information, and data edits, and this documentation must be available to all staff. The documentation must be aligned with the policies and standards for CDC's HIV/AIDS Reporting System. This documentation should also include the site's quality assurance plan (checks on case ascertainment and checks on data quality), staff training, and quality control activities.

b. Edits and data processing

Computerized data edits that check for item validity and internal consistency based on logic rules are generally part of the EPS software. At a minimum, the standard data edit checks must be available (the edits are described in the EPS software documentation). Information from edit procedures should be retained and analyzed on a regular basis to detect and correct problems with specific data sources, abstractors, or instruction manuals.

The software system should allow duplicate data entry and the preparation of reports comparing the original and duplicate entry.

The EPS software system should allow a sample of records to be selected for audits or special studies. In addition, the system should allow original data to be compared with data from re-abstraction studies. Either through built-in functions of the EPS software, or through other analytic packages, quality control personnel must be able to produce reports to measure data quality standards. Standard methods must be used to produce the outcome measures.

Comment [n3]: Again, we don't know if this will be allowed in the new system.

2. Process Standards

a. Adherence to data standards

Data items should be collected according to standard codes as defined in the EPS User's Guide (*Appendix C*). Using standard codes allows data exchange between local sites and aggregation of data on the national level. Adherence to standard codes is assessed with standard data edits.

b. Training

Training is an essential component to assuring accurate, consistent, and complete data collection. Training for registry staff should include:

- Reporting requirements, including frequency of reporting, mechanism of reporting, and required data items
- Data collection, including reportable events, case-finding procedures, coding, and follow-up procedures

- Quality control, including visual and computer edits and feedback regarding edit results
- Data processing, including data entry

c. Quality control activities

The quality control activities described in this section primarily address the accuracy of the data collected. Checks on case ascertainment (accuracy of case counts, completeness of reporting) and timeliness of case reporting are described in *Data Collection Procedures*.

Data quality control activities include:

- Visual editing (proofreading) of hard copy case report forms (all forms, all data items, and all comments) before data entry, if possible by a person other than the person completing the form. This includes checking readability, consistency, and coding, and verifying any inconsistent or unclear responses.
- Duplicate data entry (all or at least 10% of hard copy forms). An alternative option is to select 10% - 20% of cases and cross-reference them with the hard copy. Any discrepancies identified in reports of the results from duplicate data entry (i.e., the comparisons of the original and duplicate documents) should be resolved, and the results should guide training efforts regarding data entry.
- Electronic edit checks of the consolidated case-based records (all standard data edits [SAS program will be provided by CDC] are applied to all records before data transfers to CDC, but at least quarterly), and resolution of errors.
- Duplicate abstracting (*Appendix F*).
- Data analysis and use: Inconsistencies in the data are often discovered during data analyses. These problems should be communicated to the quality control staff for follow-up and improvements of procedures.

d. Outcome measures

The validity and accuracy of estimates derived from individual data elements may be limited if these data elements contain errors or a large proportion of information is missing or unknown for them. Standards for individual data elements are measured by edits (proper values, internal consistency), the percentage of missing information, and re-abstraction studies.

Outcome standards are set to indicate the minimum at which data can be reliably used for analyses and should be assessed for each diagnosis year at the specified time for all cases meeting the HIV/AIDS case definitions. The results should be used to improve surveillance processes.

- Edits: The minimum standard for passing data edits is that ≥ 97% of case records pass all standard data edits. The target standard is that 100% of case records pass all standard data edits. The edits for the standard include those variables most important for data analysis. The standard is assessed for the most recent diagnosis year at 12 months after that diagnosis year.
- Missing/Unknown Information: The proportion of case records missing information is assessed for infant's soundex, mother's date of birth, mother's race/ethnicity, receipt of

prenatal care, antiretroviral therapy during pregnancy, labor/delivery, and neonatal period, timing of maternal HIV testing, mother's most advanced disease classification during pregnancy, infant's HIV infection status, type of birth, delivery method, birth weight, receipt of PCP prophylaxis, and infant's date of death (for those known to be dead). The target is 0% missing information.

Note: Percentage of missing information is measured for each data item at 12 months after the diagnosis year. While a code of "unknown" or "indeterminate" is not the same as a code for missing value, the percentage of "unknown" or "indeterminate" is also calculated. A separate standard addresses missing information for mother's transmission category.

- Re-abstraction Studies: Agreement rates are calculated from re-abstraction studies as an indicator of data quality. No standards have been set for agreement rates.

G. Data Analysis

Data analysis will occur both at the project site (i.e., the State and/or city health department) and on a national level at CDC. Results will be disseminated through standardized reports, Supplemental HIV/AIDS Surveillance Reports (CDC), MMWR publications, professional peer-reviewed journals, and at appropriate meetings and conferences. These data will be made available for timely use by prevention partners for planning, targeting, and evaluation purposes. Data can also be used to assess and evaluate guideline implementation, quality control of data, and progress on Advancing HIV Prevention goals of decreasing perinatal transmission in the U.S.

1. Preparation for Analysis

a. Data complete for analysis

Sites should use the variable 'Information Complete for Analysis' found on the EPS data collection form to determine whether or not a case should be included in the analysis dataset. The response should be given based on the definition of completeness defined by the EPS Coordinator, Surveillance Coordinator, or another designee. Sites should use the following guidelines to help determine if the data are ready for analysis:

1. 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.
2. Information through the birth history should have been obtained.
3. Completeness should be judged based on what information is abstracted that is most useful to the site in performing any particular analysis.

Sites should create a definition incorporating these guidelines and use it consistently for all analyses during the project period.

b. Data accuracy

As described in *Data Quality*, edit checks for item validity and standard edits for all case-based data will be applied to the dataset being used for each analysis. This will ensure data accuracy across all analyses within the site and across the project sites for national level analyses.

c. Security and confidentiality

Analysis databases or datasets that are released to individuals who work outside the secured area must be held securely until the data are approved for release. For example, health department epidemiologists or statisticians who do not work in the secured area often use analysis databases for routine analysis. The computers used in these circumstances must have protective software (e.g., user ID and password protection) to maintain data securely. Other robust authentication methods also may be used since the examples described are only the minimum required. Encryption software is not required with analysis databases because they are considered much less sensitive than those that contain names or other personal identifiers. Analysis data are still considered sensitive, since it may be possible to identify individuals by using particular combinations of reporting system variables. For that reason, analysis data should not be taken home, and all the results of all analyses performed by using reporting system variables must be approved for release as outlined in the surveillance unit's data release policy.

If the occasion should arise that it is necessary to include identifying information in a dataset, the EPS Coordinator should refer to the Access Control section in the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines (13)*.

2. Site-Specific Analyses

At the beginning of the project period, sites should define their specific data needs and how EPS data will be analyzed to meet these needs. A Site-specific analysis plan should be developed to use as a guide for planning and conducting all analyses using EPS data. As data needs change, this plan can be modified to meet these changes.

The Site plan should cover these basic areas:

- A list of data needs for the site for the three-year project period. Data needs include data for funding requests, health department policy changes, legislative requirements, needs assessments, prevention and care program needs, and process monitoring. Sites should collaborate with prevention program staff to establish local data needs.
- A list of EPS questions that would be used to address the data needs
- A listing of proposed analyses as well as a rationale and plan for dissemination
- A policy for review of reports, manuscripts, and presentations
- A policy for access to data by external researchers. External researchers are persons not part of the state/local health department research team.
- A policy on authorship.

- A list of individuals from the state/local health department who will be analyzing EPS data
- A timeline for completing the data analyses

EPS sites should also provide CDC with final copies of any major presentations and publications written by state/local EPS staff or external researchers. Examples include presentations at major external conferences (e.g. National HIV/AIDS conference), major internal meetings (e.g. state/local planning groups), and journal articles.

4. National/CDC Analyses

CDC is responsible for descriptive and analytic studies using aggregated data. CDC will obtain written permission from the individual EPS project sites when plans are made to conduct any analyses that will identify specific sites. Types of CDC analyses include periodic surveillance reports, descriptive and analytic studies using aggregated data for publication in journals or presentation at national meeting, descriptive articles for MMWRs, and analyses of EPS methodology.

H. Dissemination of Results

The dissemination of EPS data is essential to a successful surveillance system. For data to be used effectively for prevention and care needs, they must be disseminated effectively.

1. Ways to Use EPS Data

Ways to use EPS data include:

- Evaluating care and prevention strategies and programs
- Monitoring progress toward state and local health objectives
- Supporting legislation
- Assessing needs
- Informing care and prevention programs/community planning groups
- Developing or modifying prevention and care programs
- Linking EPS data to other maternal and child health data sources

2. Ways to Disseminate EPS Data (Past, Present, Future)

Ways to disseminate EPS data include:

- Presentations at national and state/local conferences and community planning group meetings
- Publications (abstracts, manuscripts) and reports in national and state/local journals and in the MMWR

- Website posting of data
- Fact sheets
- Media messages
- Local newsletters using mailing lists of data users, program planners, health care professionals, and state/local provider associations.
- Epidemiologic profiles/Perinatal Epidemiologic profiles
- HIV/AIDS Surveillance Summaries
- Slide sets
- Data requests for Title IV and V grants of the Ryan White CARE Act

3. Authorship Principles with CDC, Partners & External Researchers

Sites should establish written authorship principles in accordance with their state/health department guidelines on authorship. CDC has established some guiding principles for CDC authors. For further information on CDC Authorship Guidelines: http://www.cdc.gov/od/foia/policies/author.htm

Authorship issues need to be addressed prior to data analysis. An individual involved in this process should be recognized as an author or be identified in the acknowledgement section of the publication. The minimum basis for authorship requires participation in the following:

- The conception or design, data collection, and/or data analysis and interpretation of data
- Drafting the manuscript or reviewing/revising critical sections
- Assume responsibility for the final version of the manuscript

Authors must be an active participant in the planning, writing, and reviewing of the publication as well as publicly defend the project if such need occurs. Authors should also be decided upon and put into writing during the planning stages of the publication. The first author is the individual that writes the first draft of the paper and coordinates the writing and editing processes. Secondary authors should be listed in order of their contribution to the publication. No one should be listed as an author without his or her knowledge and consent. Persons that make contributions to the publication or participate in EPS but do not meet the criteria for authorship can be included in the acknowledgement section of the publication.

For publications where CDC persons collaborated with state/local groups, that individual should be listed in the authorship line. If there is no CDC author, please include an acknowledgement to the "Centers for Disease Control and Prevention."

For state/local publications, recipients should place an acknowledgement of Public Health Support (PHS) for recipients of this funding: This publication was made possible by grant number PS-06-607 from the Centers for Disease Control and Prevention."

For publications where external researchers have contributed to the publication, the individual should be listed in the authorship line.

4. Review of Abstracts and Manuscripts

If CDC personnel are listed in the authorship line, publications must undergo a minimum clearance process through the CDC division level. Please allow a minimum time frame of at least four weeks for clearance processes.

I. Limitations of EPS Data

Data collected as part of the EPS project may not be representative of all HIV-exposed infants in each site, since unreported cases of HIV-infected mothers are not abstracted. Some sites are able to collect data at the population-level; however, some sites are only able to obtain IRB approval from a certain group of facilities in the specified geographic area serving high-risk populations. In addition, data linkages for case identification may be different for code-based reporting sites compared to name-based reporting sites.

Completeness of reporting ascertained by using the 1994 Survey of Childbearing Women (or later if sites used local budgets to conduct a serosurvey) may under- or overestimate the number of births to HIV infected women. For further information, refer to the Completeness of Reporting section of this document. For antiretroviral treatment, EPS data cannot ascertain compliance with prescribed regimens and can only note what was prescribed.

V. Project Time Line

Start-up

December 21, 2005 – Program announcement

February 13, 2006 – Application deadline

March 1, 2006 – Objective review panel

April-May 2006 – Funding decision made

June/July 2006 – Approval of data abstraction form, CDC and site-specific procedural guidance; Approval by site-specific IRB, if needed

June 2006- EPS Start-up meeting

July 2006 – Start-up for collecting 2005 data (abstraction, entry & transfer)

A. Ongoing Activities

Conference Calls: Bi-monthly

Updated procedural guidance: Annual basis

Data entry quality controls: Prior to every data transfer

Data transfer on secure data-network: Monthly

VI. Protection of Human Subjects

A. IRB Approval

This project has been exempt from CDC IRB review because the activity is not research but constitutes data collection for the purposes of disease surveillance and program evaluation (*Appendix G*). Individual project areas may need local IRB approvals (See *Appendix H* for an example). Sites with code-based reporting will need separate IRB approval with each facility. In addition, some sites may need IRB approval depending on local/state reporting laws that affect the collection of protected data.

B. Informed Consent

No informed consent is needed for this enhanced surveillance activity. For this project, data are abstracted from existing medical and ancillary records. There will be no contact with individual patients. However, grantees must forward to the Surveillance Branch, DHAP-SE, NCHSTP written documentation of their authority to access HIV-infected mother's and HIV-exposed infant's medical records and to collect data from these records (i.e., HIV reporting laws, IRB assurance, relevant State public health laws, statues, rules) (*Appendix G*).

C. Protecting Privacy of EPS Data (Confidentiality and HIPAA)

Provisions for protecting the security and confidentiality of information collected for this project will be the same as that provided for standard HIV/AIDS surveillance (*13*). HIV/AIDS case surveillance data are currently collected under an assurance of confidentiality under Sections 306 and 308(d)of the Public Health Service Act (42 U. S. C. Sections 242k and 242m(d)). Information collected in HIV/AIDS surveillance system that would permit identification of any individual is collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 306 and 308 (d) of the Public Service Act. Data for this project (including data on HIV perinatally exposed children) will be collected as part of routine surveillance and will be covered by existing Assurance of Confidentiality (*Appendix I*).

In addition to the assurance of confidentiality, additional protections include physical security of files and computer safeguards. The CDC security and confidentiality standards for the protection of HIV/AIDS data have been published in the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines*. Data will be collected by trained health department personnel. No personally identifying information will be transmitted to CDC, and all data will be transmitted to the CDC as an encrypted file through the Secure Data Network.

References

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APPENDIX A

EPS Supplemental Medical Record Abstraction Form

APPENDIX B

Technical Guidance for HIV/AIDS Surveillance Programs: Pediatric HIV/AIDS Case Reporting

APPENDIX C

EPS User's Guide

APPENDIX D

Site-Specific Questions

APPENDIX E

Technical Guidance of HIV/AIDS Surveillance Programs: Access to Source Data and Completeness of Reporting

APPENDIX F

Technical Guidance of HIV/AIDS Surveillance Programs: Data Quality

APPENDIX G

NCHSTP Determination of Applicability of Human Subjects Regulations

APPENDIX H

Example from New York City - IRB approval for Site Specific Surveillance of Mother/Infant Pairs

APPENDIX I

Assurance of Confidentiality