Attachment 4(d)

Adult and Pediatric HIV/AIDS Confidential Case Reports
for National HIV/AIDS Surveillance OMB No. 0920-0573

Supplemental Surveillance Activity 3: Enhanced Perinatal Surveillance (EPS)
Summary of Form Changes and EPS User Guide Instructions for Data Abstraction Form

Listing of Changes to EPS Form
5/26/2009

I. Summary of Changes

- **Title of form Enhanced HIV/AIDS Surveillance to Maximally Reduce Perinatal HIV Transmission** changed to: **Enhanced Perinatal Surveillance (EPS)**
- Burden statement will be updated to 60 minutes
- Format of the form was changed to include check boxes and clear delineation of sections
- Removed designation of HARS or M-HARS after specific variables
- Public burden statement moved to end of form from first page
- Addition of list of abbreviations to the last page

List of abbreviations

ACTG	AIDS Clinical Trials Group
ART	antiretroviral therapy
EIA	enzyme immunoassay
HARS	HIV/AIDS Reporting System
HMO	health maintenance organization
ICD-9	International Classification of Diseases, Ninth Revision
ICD -10	International Classification of Diseases, Tenth Revision
IFA	immunofluorescent assay
ND	not documented
NNRTI	nonnucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
NRR	no risk factor reported
OB-GYN	obstetric-gynecologic or obstetrician-gynecologist
PCP	*Pneumocystis jirovecii* pneumonia [*jirovecii* is now preferred to *carinii;* abbreviation is the same]
PI	protease inhibitor
PID	pelvic inflammatory disease
STAT	immediately (*statim*)
WB	Western blot

This report to the Centers for Disease Control and Prevention (CDC) is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV/AIDS. Information in CDC's HIV/AIDS surveillance system that would permit identification of any individual on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance on file at the local health department, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

II. Changes to specific questions (changes indicated in highlighted (yellow) areas)

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_____

Changed to:

1. Records abstracted (Required)

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

____ Prenatal care records
____ Maternal HIV clinic records
____Pediatric medical records (non-HIV clinic or provider)
____Birth certificate

____ Labor and delivery records ____Death certificate

____ Pediatric birth records ____Health department records

____Pediatric HIV medical records ____Other (Specify.)

Description of changes above:

The word FIELD was removed. 2=Attempted, but record not available,

Changed to 2 = Attempted—record not available;

___ Pediatric medical records (non HIV clinic/provider)
Changed to ___Pediatric medical records (non-HIV clinic or provider)

2. Infant

Soundex _____
Changed to Soundex code

Description of change above: The word code was added

Sex at Birth ____ (**HARS**)
Changed to

Sex at birth

❑ M ❑ F

Description of change above: Male and female options were added

3. Mother

Soundex _____
Changed to

Soundex code

Description of change above: The word code was added

4a. If Country is unknown, but Continent of birth is known, specify _____
Changed to
4a. If mother's country of birth is not specified, list continent of birth if known.

Description of change above: Minor changes in wording

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

❑Hawaiian/Pacific Islander

Changed to

❑ Hawaiian/Other Pacific Islander

❑ Other Race, specify _____

Changed to

❑ Other (Specify.) _____

Description of change above:

Other was added to Pacific Islander

Race was added to Other (Specify.) _____

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 _____

Changed to

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

❑ Injection drug use

Heterosexual contact with

- ❑ injection drug user
- ❑ bisexual male
- ❑ male with hemophilia with documented HIV
- ❑ transfusion recipient with documented HIV infection
- ❑ transplant recipient with documented HIV infection

Heterosexual contact with (cont)

- ❑ HIV-infected male, risk factor not specified
- ❑ Hemophilia with documented HIV
- ❑ Receipt of transfusion
- ❑ Receipt of transplant(tissue/organ or artificial insemination)
- ❑ Perinatal exposure (i.e. mother was perinatally infected)
- ❑ Unknown
- ❑ Other documented risk (Discuss with the NRR coordinator in your state.)

If Other, specify_____

Description of changes above: change in formatting and minor word changes not changing meaning of responses

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

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

Changed to:

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

❑ Yes ❑ No (**Go to 15**.) ❑ Not documented (**Go to 15**.) ❑ Unknown

Description of changes above: This question added an unknown option

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

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

Description of changes above: Prior to changed to before

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

13. Number of prenatal care visits (99 = unknown)

Description of changes above: e.g., visits specifically for prenatal care) was removed from this question

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

Changed to:

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

❑ 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
❑ Unknown

Description of changes above: This question added an unknown option

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	❑	__ __/__ __/__ __ __ __	❑	❑	❑

Changed to:

15. Was the mother screened for any of the following during pregnancy?
(Check test performed before birth, but closest to date of delivery or admission to labor and delivery.)

	Yes	Date (mm/dd/yyyy)	No	Not documented	Record not available	Unknown
Group B strep	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Hepatitis B (HBsAg)	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Rubella	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Syphilis	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑

Description of changes above: This question added an unknown option

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	❑	__ __/__ __/__ __ __ __	❑	❑	❑

Changed to:

16. Diagnosis (for the mother) of the following conditions during this pregnancy or at the time of labor and delivery
(See Instructions for Data Abstraction for definitions.)

	Yes	Date of diagnosis (mm/dd/yyyy)	No	Not documented	Record not available	Unknown
Bacterial vaginosis	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Chlamydia trachomatis infection	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Genital herpes	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Gonorrhea	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Group B strep	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Hepatitis B (HbsAg+)	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Hepatitis C	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑

PID	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Syphilis	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑
Trichomoniasis	❑	__ __/__ __/__ __ __ __	❑	❑	❑	❑

Description of changes above:
Chlamydia Changed to *Chlamydia trachomatis* infection

Pelvic Inflammatory Disease (PID)
Changed to
PID

Trichomonas
Changed to
Trichomoniasis

This question added an unknown option

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 ___/___	____	______________	__________	*HIV Status: [1] Infected [2] Uninfected [3] Indeter-minate [9] Not Documented
Sib 2	__ __/__ __/__ __	___:___ as of ___/___	____	______________	__________	
Sib 3	__ __/__ __/__ __	___:___ as of ___/___	____	______________	__________	
Sib 4	__ __/__ __/__ __	___:___ as of ___/___	____	______________	__________	
Sib 5	__ __/__ __/__ __	___:___ as of ___/___	____	______________	__________	
Sib 6	__ __/__ __/__ __	___:___ as of ___/___	____	______________	__________	

Changed to:

18. Complete the chart for all siblings.

Date of birth (mm/dd/yyyy)	Age (yrs: mos as of mm/yyyy)	HIV serostatus (See list.)	State No.	City No.
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________
__ __/__ __/__ __ __ __	___:___ as of __ __/__ __ __ __	____________	__________________	__________________

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

Description of changes above

Status changed to serostatus
Sib 1-Sib 6 was removed.
This question added an unknown option.

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)***

Changed to:

19. Was substance use during pregnancy noted in the medical or social work records?
❑ Yes ❑ No (**Go to 20**.) ❑ Record not available (**Go to 20**.) ❑ Unknown

Description of changes above: This question added an unknown option.

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		

Changed to:

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

❑ Alcohol	❑ Cocaine	❑ Marijuana (cannabis, THC,	❑ Opiates
❑ Amphetamines	❑ Crack cocaine	cannabinoids)	❑ Other (Specify.)
❑ Barbiturates	❑ Hallucinogens	❑ Methadone	_____
❑ Benzodiazepines	❑ Heroin	❑ Methamphetamines	❑ Specific drug(s) not documente
		❑ Nicotine (any tobacco product)	

Description of changes above
(Mark all that apply)
Changed to
(Check all that apply.)

□ Nicotine / Tobacco
Changed to
❑ Nicotine (any tobacco product)

□ Not Documented which drug(s)
Changed to
❑ Specific drug(s) not documented

19b. If any substances used, were any of the drugs injected?
□ Yes □ No □ Not Documented
Specify which substance(s) were injected: _____

Changed to:

19b. If substances used, were any injected?

❑ Yes ❑ No ❑ Not documented ❑ Unknown Specify injected substance(s).

Description of changes above:

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

Changed to

19b. If substances used, were any injected?

Specify which substance(s) were injected: _____

Changed to

Specify injected substance(s).

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

Changed to:

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

❑ Yes, positive result (Check all that apply.)

❑ Alcohol	❑ Cocaine	❑ Marijuana (cannabis, THC,	❑ Opiates
❑ Amphetamines	❑ Crack cocaine	cannabinoids)	❑ Other (Specify.)
❑ Barbiturates	❑ Hallucinogens	❑ Methadone	_____
❑ Benzodiazepines	❑ Heroin	❑ Methamphetamines	❑ Specific drug(s) not documented
		❑ Nicotine (any tobacco product)	

❑ Yes, negative result ❑ No ❑ Toxicology screen not documented

Description of changes above:

□ Nicotine / Tobacco

Changed to

❑ Nicotine (any tobacco product)

□ Not Documented which drug(s)

Changed to

❑ Specific drug(s) not documented

❑ Crack cocaine was added to be similar to the other drug questions

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, THC, cannabinoids)	□ Opiates
□ Benzodiazepines		□ Other, specify _____
□ Cocaine	□ Methadone	□ Not Documented which drug(s)

□ Yes, negative

□ No

□ Not Documented

Changed to:

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

❑ Yes, positive result (Check all that apply.)

❑ Alcohol	❑ Cocaine	❑ Marijuana (cannabis, THC, cannabinoids)	❑ Opiates
❑ Amphetamines	❑ Crack cocaine	❑ Methadone	❑ Other (Specify.) _____
❑ Barbiturates	❑ Hallucinogens	❑ Methamphetamines	❑ Specific drug(s) not documented
❑ Benzodiazepines	❑ Heroin	❑ Nicotine (any tobacco product)	

❑ Yes, negative result ❑ No ❑ Toxicology screen not documented

Description of changes above:

□ Yes, positive, please specify (Check all that apply):
Changed to
❑ Yes, positive result (Check all that apply.)

□ Yes, negative
Changed to
❑ Yes, negative result

□ Not Documented
Changed to
❑ Toxicology screen not documented

□ Nicotine / Tobacco
Changed to
❑ Nicotine (any tobacco product)

□ Not Documented which drug(s)
Changed to
❑ Specific drug(s) not documented

❑ Crack cocaine was added to be similar to the other drug questions

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

□ Yes □ No □ Not Documented

Changed to:

22. If the results of the toxocology screen indicated substance use, was the mother referred for treatment (during or after this pregnancy)?

❑ Yes ❑ No ❑ Not documented ❑ Unknown

Description of changes above:

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

Changed to

22. If the results of the toxocology screen indicated substance use, was the mother referred for treatment (during or after this pregnancy)?

This question added an unknown option.

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

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

Changed to:

23. Mother's HIV serostatus

❑ Mother refused HIV testing ❑ HIV-positive before child's birth, date unknown
❑ HIV-positive before this pregnancy ❑ HIV-positive after child's birth
❑ HIV-positive during this pregnancy ❑ HIV-positive, date unknown
❑ HIV-positive at time of delivery

Description of changes above:

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

Changed to

23. Mother's HIV serostatus

□ (Mother refused HIV testing)

Changed to

❑ Mother refused HIV testing

□ Before child's birth, exact period unknown

Changed to

❑ HIV-positive before child's birth, date unknown

 Before this pregnancy
Changed to
❑ HIV-positive before this pregnancy

 After the child's birth\
Changed to
❑ HIV-positive after child's birth

 During this pregnancy
Changed to
❑ HIV-positive during this pregnancy

 HIV-infected, unk when diagnosed
Changed to
❑ HIV-positive, date unknown

 At time of delivery
Changed to
❑ HIV-positive at time of delivery

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

Changed to:
24. Date of mother's first positive result from confirmatory testing (WB or IFA)
__ __/__ __/__ __ __ __ (mm/dd/yyyy)

Description of changes above: Minor changes in wording

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)*		
_____	_____	__ __/__ __/__ __ __ __

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

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

Changed to:

25. Results of moth **…ancy**

	Test (See list in 26.)	**Date** (mm/dd/yyyy)
25a. First screening		
_____	_____	__ __/__ __/__ __ __ __
25b. Second screening (if result was negative, or mother refused first screening)		
_____	_____	__ __/__ __/__ __ __ __
25c. Third screening (if result was negative, or mother refused second screening)		
_____	_____	__ __/__ __/__ __ __ __

Results
Positive
Negative
Indeterminate
Results not available
Not tested
Not tested but known to be infected
Refused
Unknown

Tests
Rapid
Expedited EIA
EIA
Not documented

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

Description of changes above:

(if negative or refused first screening)

Changed to (if result was negative, or mother refused first screening)

Results not found to Results not available

Added Expedited EIA

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

Change

26. Moth **or and delivery**

	Test (See list.)	**Date of results in labor and delivery** (mm/dd/yyyy)	**Time of results in labor and delivery** (See military time.)
26a. First screening			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __
26b. Second screening (if applicable)			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __
26c. Confirmatory test			
_____	_____	__ __/__ __/__ __ __ __	__ __:__ __

Results
Positive
Negative
Indeterminate
Results not available
Not tested
Not tested but known to be infected
Refused
Unknown

Tests
Rapid
Expedited EIA
EIA
Not documented

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

Description of changes above:
(see below)
Changed to
(See list.)

Date Results at L&D
(mm/dd/yyyy)
Changed to
Date of results in
labor and delivery
(mm/dd/yyyy)

Time† Results at L&D
(see below)
Changed to
Time of results in labor and delivery
(See military time.)

Results not found to Results not available

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	__ __/__ __/__ __ __ __

Changed to:

27. Were CD4 counts determined during pregnancy or within 6 months before pregnancy?

❑ Yes ❑ No (**Go to 28**.) ❑ Not documented (**Go to 28**.) ❑ Record not available (**Go to 28**.) ❑ Unknown

27a. If yes, list below. (If more than 3 counts in record, **prioritize** the CD4 counts, starting with the count closest to delivery. If CD4 counts were not determined during pregnancy, record CD4 counts within 6 months before pregnancy if possible.)

Example: CD4 count of 174 cells/µL, 12%, August 12, 2000, would be recorded as 174 cells/µL 08/12/2000

12 % 08/12/2000

CD4 result	**Unit**	**Date blood drawn** (mm/dd/yyyy)	**CD4 result**	**Unit**	**Date blood drawn** (mm/dd/yyyy)	**CD4 result**	**Unit**	**Date blood drawn** (mm/dd/yyyy)
___	cells/µL	__/__/____	___	cells/µL	__/__/____	___	cells/µL	__/__/____
__ __	%	__/__/____	__ __	%	__/__/____	__ __	%	__/__/____

Description of changes above:

27. Were CD4 counts obtained during pregnancy?

Changed to

27. Were CD4 counts determined during pregnancy or within 6 months before pregnancy?

(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.)

Changed to

(If more than 3 counts in record, prioritize the CD4 counts, starting with the count closest to delivery. If CD4 counts we determined during pregnancy, record CD4 counts within 6 months before pregnancy if possible.)

Count

Changed to

cells/µL

Percent was removed; % was retained.

This question added an unknown option.

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)
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __

Changed to:

28. Were viral quantification tests (ie, viral load) performed on the mother during pregnancy or within 6 months before pregnancy?
❑ Yes ❑ No (**Go to 29**.) ❑ Not documented (**Go to 29**.) ❑ Record not available (**Go to 29**.) ❑ Unknown

28a. If yes, list all results below. (If more than 3 in record, **prioritize** the results of viral load tests, starting with the result closest to delivery. If viral load tests were not performed during pregnancy, record viral loads within 6 months of pregnancy if possible.)

Result in No. of copies/mL	Result in logs	Date blood drawn (mm/dd/yyyy)
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __
_____	_____	__ __/__ __/__ __ __ __

Description of changes above:

28. Did mother have viral quantification tests performed (i.e., viral load) during pregnancy?
Changed to
28. Were viral quantification tests (ie, viral load) performed on the mother during pregnancy or within 6 months before pregnancy?

(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.)
Changed to
(If more than 3 in record, prioritize the results of viral load tests, starting with the result closest to delivery. If viral load
performed during pregnancy, record viral loads within 6 months of pregnancy if possible.)

This question added an unknown option.

Result in copies/mL #
Changed to
Result in No. of copies/mL

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
Changed to:
29. What was the mother's most advanced HIV serostatus during pregnancy?
❑ HIV infection, not AIDS ❑ AIDS, CD4 criteria only ❑ AIDS, indicator condition
❑ HIV-negative ❑ Not documented ❑ Record not available ❑ Unknown

Description of changes above:
29. What was mother's most advanced HIV classification during pregnancy:
Changed to

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

 HIV, not AIDS
Changed to
❑ HIV infection, not AIDS

 HIV negative
Changed to
❑ HIV-negative

 Not Doc
Changed to
❑ Not documented

 RNA
Changed to
❑ Record not available

This question added an unknown option.

30. Was mother's HIV status noted in her prenatal care medical records?
 Yes, Positive Yes, Negative No No prenatal care Record Not Available
Changed to:
30. Was the mother's HIV serostatus noted in her prenatal care medical records?
❑ Yes, HIV-positive ❑ Yes, HIV-negative ❑ No ❑ No prenatal care ❑ Record not available
❑ Unknown

Description of changes above:
Status
Changed to
serostatus

 Yes, Positive
Changed to
❑ Yes, HIV-positive

 Yes, Negative
Changed to
❑ Yes, HIV-negative

This question added an unknown option.

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)

Changed to:

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

❑ Yes (**Complete table.**) ❑ No (**Go to 31a.**) ❑ Not documented (**Go to 32.**) ❑ Record not available (**Go to 32.**) ❑ Unknown

Drug name (See list on p. 8.)	Other (specify)	Drug refused	Date drug started (mm/dd/yyyy)	Gestational age drug started (weeks; round down)	Drug stopped Yes	No	ND	Date stopped (if yes in preceding column) (mm/dd/yyyy)	Stop codes (See list on p. 8.)
i. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
ii. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
iii. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
iv. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
v. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
vi. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
vii. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____
viii. _____	_____	❑	__ __/__ __/__ __ __ __	_____	❑	❑	❑	__ __/__ __/__ __ __ __	_____

(**After completing table, go to 32.**)

Description of changes above:

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

Changed to

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

☐ RNA *(Go to Q32)*

Changed to

❑ Record not available (Go to 32.)

Other (specify) was added to drug name

Was Drug Refused
Changed to
Drug refused

Gestational Age Started
(weeks, round down)
Changed to
Gestational age drug started
(weeks; round down)

If yes, __ __/__ __/__ __
Changed to
__ __/__ __/__ __ __ __

Drug Stop Codes
Changed to
Stop codes
(See list on p. 8.)

This question added an unknown option.

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

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

Changed to:

31a. If no antiretroviral drug was prescribed during pregnancy, check reason.

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

Description of changes above:
31a. If no ARV was prescribed during pregnancy, indicate reason:
Changed to
31a. If no antiretroviral drug was prescribed during pregnancy, check reason.

□ Other reason, specify _____
Changed to
❑ Other (Specify.)

This question added an unknown option.

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

□ Yes, Positive □ Yes, Negative □ No □ Record Not Available

Changed to:

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

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

Description of changes above :

Status

Changed to

serostatus

□ Yes, Positive

Changed to

❑ Yes, HIV-positive

□ Yes, Negative

Changed to

❑ Yes, HIV-negative

This question added an unknown option.

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

Changed to:

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

❑ Yes (**Complete table.**) ❑ No (**Go to 33a.**) ❑ Not documented (**Go to 34.**) ❑ Record not available (**Go to 34.**) ❑ Unknown

	Drug Name (See list.)	Other (specify)	Drug refused	Date received (mm/dd/yyyy)	Time received (See military time.)	Type of administration: Oral	IV	Not documented
i.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
ii.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
iii.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
iv.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
v.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
vi.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑
vii.	_____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑	❑	❑

(**After completing table, go to 34.**) Military time: noon = 12:00; midnight = 00:00

Description of changes above:

31. Was mother prescribed any antiretroviral medication during labor and delivery? (HARS)

Changed to

31. Were antiretroviral drugs prescribed for the mother during labor and delivery?

□ RNA *(Go to Q32)*

Changed to

❑ Record not available (Go to 32.)

Other (specify) was added to drug name

Was Drug Refused

Changed to

Drug refused

This question added an unknown option.

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

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

Changed to:

33a. If no antiretroviral drug was received during labor and delivery, check reason.

❑ Precipitous delivery/STAT Cesarean delivery
❑ HIV serostatus of mother unknown
❑ Mother tested HIV-negative during pregnancy
❑ Other (Specify.) _____

❑ Prescribed but not administered ❑ Birth not in hospital ❑ Mother refused ❑ Not documented ❑ Unknown

Description of changes above:
33a. If no ARV was received during labor & delivery, indicate reason:
Changed to
33a. If no antiretroviral drug was received during labor and delivery, check reason.

Status

Changed to

Serostatus

□ Birth outside of hospital

Changed to

❑ Birth not in hospital

This question added an unknown option.

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)***

Changed to:

34. Was mother referred for HIV care after delivery?

❑ Yes ❑ No (**Go to 36**.) ❑ Not documented (**Go to 36**.) ❑ Record not available (**Go to 36**.) ❑ Unknown

Description of changes above: This question added an unknown option.

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

35a. CD4:

□ Not Done

□ Not Available

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

35b. Viral Load:

□ Not Done

□ Not Available

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

Changed to:

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

35a. CD4 result ❑ Not done ❑ Not available

Result	Unit	Date blood drawn (mm/dd/yyyy)
__ __ __ __	cells/µL	__ __/__ __/__ __ __ __
__ __	%	__ __/__ __/__ __ __ __

35b. Viral load ❑ Not done ❑ Not available

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

Description of changes above:
35. If yes, indicate first viral load and/or CD4 after discharge from hospital up to 6 months:
Changed to
35. If yes, indicate first CD4 result or first viral load after discharge from hospital (up to 6 months after discharge).

35a. CD4:
Changed to
35a. CD4 result

CD4 Result
Changed to
Result

Units
Change to
Unit

Result in copies/mL #
Changed to
Result in copies/mL

36. Type of birth: (HARS)
□ Single □ Twin □ Triplet or greater □ Record Not Available
Changed to:
36. Type of birth ❑ Single ❑ Twin ❑ ≥3 ❑ Record not available ❑ Unknown

Description of changes above:
□ Triplet or greater
Changed to
❑ ≥3

This question added an unknown option.

	Time*	**Date** (mm/dd/yyyy)

37. Birth information:
☐ Birth Outside Hospital
☐ Record Not Available

Onset of labor	__ __:__ __	__ __/__ __/__ __ __ __
Admission to L/D	__ __:__ __	__ __/__ __/__ __ __ __
Rupture of Membranes	__ __:__ __	__ __/__ __/__ __ __ __
Delivery	__ __:__ __	__ __/__ __/__ __ __ __

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

Changed to:

37. Birth information ❑ Birth not in hospital ❑ Record not available

	Time (See military time.)	**Date** (mm/dd/yyyy)		(See military time.)
Onset of labor	__ __:__ __	__ __/__ __/__ __ __ __	Rupture of membranes	
Admission to labor and delivery	__ __:__ __	__ __/__ __/__ __ __ __	Delivery	

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

Description of changes above:
☐ Birth Outside Hospital
Changed to
❑ Birth not in hospital

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)***

Changed to:
39. Mode of delivery
- ❑ Vaginal (**Go to 40**.) ❑ Unknown
- ❑ Elective Cesarean delivery
- ❑ Non-elective Cesarean delivery
- ❑ Cesarean delivery, unknown type

❑ Record not available (**Go to 41**.)

Description of changes above:
C-section
Changed to
Cesarean delivery

This question added an unknown option

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
- ☐ Fetal distress
- ☐ Placenta abruptia / previa
- ☐ Other (Herpes, disproportion, etc) specify _____

□ Personal / Physician's Preference □ Not specified

Changed to:

39a. If Cesarean delivery, mark all the following indications that apply.

❑ HIV indication (high viral load) ❑ Fetal distress

❑ Previous Cesarean (repeat) ❑ Placenta abruptia or p. previa

❑ Malpresentation (breech, transverse) ❑ Other (eg, herpes, disproportion)

❑ Prolonged labor or failure to progress Specify _____

❑ Mother's or physician's preference ❑ Not specified

Description of changes above:
C-section
Changed to
Cesarean delivery

transverse lie
Changed to
transverse

□ Personal / Physician's Preference
Changed to
❑ Mother's or physician's preference

40. Instrumentation used:

□ None
□ Forceps
□ Vacuum
□ Forceps and vacuum
□ Not specified

Changed to:
40. Instrument used **❑ None ❑ Forceps ❑ Vacuum ❑ Forceps and vacuum ❑ Not specified**

Description of changes above:
40. Instrumentation used:
Changed to
40. Instrument used

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

□ Yes, Positive □ Yes, Negative □ No □ Record Not Available

Changed to:

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

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

Description of changes above
Status
Changed to
serostatus

☐ Yes, Positive
Changed to
❑ Yes, HIV-positive

☐ Yes, Negative
Changed to
❑ Yes, HIV-negative

This question added an unknown option.

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

Changed to:

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

❑ Yes (**Complete table.**) ❑ No (**Go to 43a.**) ❑ Not documented (**Go to 44.**) ❑ Record not available (**Go to 44.**) ❑ Unknown

Drug name (See list on p. 8.)	Other (specify)	Drug refused	Date drug started (mm/dd/yyyy)	Time started (See military time.)	ART Completed? Yes No ND UNK	Stop date (if therapy not completed) (mm/dd/yyyy)	Stop codes (See list on p. 8.)
i._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
ii._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
iii._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
iv._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
v._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
vi._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____
vii._____	_____	❑	__ __/__ __/__ __ __ __	__ __:__ __	❑ ❑ ❑ ❑	__ __/__ __/__ __ __ __	_____

viii._____ _____ ❑ __/__/__ ___:__ ❑❑❑❑ __/__/__ _____	
Military time: noon = 12:00; midnight = 00:00	

Description of changes above:
43. Was child prescribed any antiretroviral medication during the first six weeks of life? (HARS)
Changed to
43. Were antiretroviral drugs prescribed for the child during the first 6 weeks of life?

□ RNA *(Go to Q32)*
Changed to
❑ Record not available (Go to 32.)

Other (specify) was added to drug name

Was Drug Refused
Changed to
Drug refused

Regimen Completed
Yes No ND
Changed to
ART Completed?
Yes No ND UNK

If no, __ __/__ __/__ __
Changed to
__ __/__ __/__ __ __ __

Drug Stop Codes
Changed to
Stop codes
(See list on p. 8.)

This question added an unknown option.

43a. If no ARV was prescribed during the first six weeks of life, indicate reason:
□ HIV status of mother unknown □ Other reason, specify _____
□ Mother known to be HIV negative during pregnancy □ Not Documented
□ Mother refused
Changed to:
43a. If no antiretroviral drug was prescribed during the first 6 weeks of life, indicate reason.
❑ HIV serostatus of mother unknown ❑ Other (Specify.) _____
❑ Mother known to be HIV-negative during pregnancy _____ ❑ Not documented

❑ Mother refused

Description of changes above:
43a. If no ARV was prescribed during the first six weeks of life, indicate reason:
Changed to:
43a. If no antiretroviral drug was prescribed during the first 6 weeks of life, indicate reason.

Status
Changed to
Serostatus

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

Changed to:

44. Infant's HIV antibody testing

	Results (See list.)	**Test** (See list.)	**Date blood drawn** (mm/dd/yyyy)
i.	_____	_____	__ __/__ __/__ __ __ __
ii.	_____	_____	__ __/__ __/__ __ __ __
iii.	_____	_____	__ __/__ __/__ __ __ __

Results
Positive
Negative
Indeterminate
Results not available
Infant not tested
Mother refused
Unknown

Tests
Rapid
Expedited EIA
EIA
Not documented

Description of changes above:
Results not found
Changed to
Results not available

Same for Q45

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)

Changed to:

46. What is the child's current HIV infection status?

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

Description of changes above :
HIV status? (HARS-modified)
Changed to
HIV infection status?

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

Changed to:

47. If child's HIV serostatus is indeterminate, indicate reason.

❑ Moved from state ❑ Lost to follow-up
❑ Provider out of state ❑ Died before serostatus determined
❑ Child <18 months of age ❑ Not documented

Description of changes above:
47. If child's HIV status is indeterminate, indicate why: (HARS-modified)
Changed to:
47. If child's HIV serostatus is indeterminate, indicate reason.

Status
Changed to
serostatus

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

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

Changed to:

48. Was PCP prophylaxis prescribed during the first year of life?

❑ Yes Date received __ __/__ __/__ __ __ __
❑ No ❑ Not documented ❑ Record not available ❑ Unknown

Description of changes above:
Yes, date started
Changed to
Date received

This question added an unknown option

49.Was child breastfed? (HARS)
□ Yes, duration ___ days ___ weeks ___not doc □ No □ Not Documented □ Record Not Available
Changed to:
49.Was child breastfed?
❑ Yes Duration _ days ___ weeks
❑ Duration not documented
❑ No ❑ Not documented ❑ Record not available ❑ Unknown

Description of changes above:
not doc
Changed to
Duration not documented

This question added an unknown option

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: _____._____
Changed to:

50. Were birth defects noted during the first year of life? ❑ Yes ❑ No (**Go to 51**.) ❑ Record not available (**Go to 51**.) ❑ Unknown	**50a. If yes, specify type(s).** _____ Code _____._____ Code _____._____ Code _____._____

Description of changes above: This question added an unknown option.

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.

Changed to:

51. If child is deceased, please obtain the following from the death certificate. (Print legibly. Include ICD-9 or ICD-10 codes only if code appears on death certificate.)

Cause of death

Immediate _____
Underlying _____
Underlying _____
Underlying _____
Contributing _____

Note. Please be sure that a date of death has been entered on page 1, under Demographic Information (2. Infant).

51. If child deceased, from death certificate, list (Please print legibly):
(Include ICD9 codes only if code appears on death certificate)

Changed to

51. If child is deceased, please obtain the following from the death certificate. (Print legibly. Include ICD-9 or ICD-10 codes only if code appears on death certificate.)

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.

Changed to

Note. Please be sure that a date of death has been entered on page 1, under Demographic Information (2. Infant).

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.

Changed to:

Please include comments or clinical information you consider relevant to the overall understanding of this child's HIV exposure or infection status. State the date and source of the information.

Antiretroviral Drugs and Stop Codes

Antiretroviral Drug List	**NRTI**	**PROTEASE INHIBITORS**	**OTHER**
NNRTI Delavirdine (Rescriptor) Efavirenz (Sustiva) Nevirapine (Viramune, NVP)	Abacavir (Ziagen, ABC) Combivir (AZT & 3TC) Didanosine (ddI, Videx) Lamivudine (3TC, Epivir) Stavudine (d4T, Zerit) Trizivir (AZT & 3TC & Abacavir) Viread (Tenofovir)	Amprenavir (Agenerase) Indinavir (Crixivan) Kaletra (Lopinavir, Ritonavir) Nelfinavir (Viracept) Ritonavir (Norvir)	Adefovir dipivoxil (bis-POM, PMEA, Preveon) Atripla (Efavirenz & Tenofovir & Emtricitabine) **If an antiretroviral drug**

	Zalcitabine (ddC, Hivid) Zidovudine (AZT, Retrovir)	Saquinavir (Fortavase, Invirase) Tipranavir (Aptivus)	**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

Changed to:

Antiretroviral drugs and stop codes

NNRTI	**NRTI** (cont)	**Protease inhibitor**	**Other**
Delavirdine (Rescriptor) Efavirenz (Sustiva) Nevirapine (Viramune, NVP) **NRTI** Abacavir (Ziagen, ABC) Combivir (AZT & 3TC) Didanosine (ddI, Videx) Emtriva (Emtricitabine or FTC)	Epzicom (Abacavir/3TC, Kivexa) Lamivudine (3TC, Epivir) Stavudine (d4T, Zerit) Trizivir (AZT & 3TC & Abacavir) Truvada (Tenofovir DF/Emtricitabine) Videx® EC (Didanosine) Viread (Tenofovir) Zalcitabine (ddC, Hivid) Zidovudine (AZT, Retrovir)	Amprenavir (Agenerase) Darunavir (Prezista) Indinavir (Crixivan) Kaletra (Lopinavir, Ritonavir) Lexiva (Fosamprenavir) Nelfinavir (Viracept) Reyataz (Atazanavir or ATV) Ritonavir (Norvir) Saquinavir (Fortavase, Invirase) Tipranavir (Aptivus)	Adefovir dipivoxil (bis-POM, PMEA, Preveon) Atripla (Efavirenz & Tenofovir & Emtricitabine) Fuzeon (Enfuvirtide or T20) Hydroxyurea (Droxia, Hydrea) Intelence Selzentry Isentress **If an antiretroviral drug not on this list, call CDC**

Stop codes (2 codes allowed; if more, choose the 2 most important)

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

Description of changes above:

S2 = (Blank for EPS)

Changed to

S2 = ART completed

S8 = Patient choice

Changed to

S8 = Mother's choice

S14 = Mother couldn't afford medications

Changed to

S14 = Mother couldn't afford drugs

The following drugs were added to the drug list:

Emtriva (Emtricitabine or FTC);Epzicom (Abacavir/3TC, Kivexa);Truvada (Tenofovir DF/Emtricitabine) ;Videx® EC (Didanosine) ;Darunavir (Prezista) ;Reyataz (Atazanavir or ATV);Fuzeon (Enfuvirtide or T20);Hydroxyurea;(Droxia, Hydrea);Intelence;Selzentry; Isentress

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. The Enhanced Perinatal Surveillance System (EPSS) and HARS/Ehars should be updated with information collected during abstraction. 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. 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, Health Department 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, non HIV clinic, other medical records)
	Death certificate

Abstraction of Mother's Records
- All maternal variables refer to information on the infant's biologic mother.
- If it is not possible to obtain any chart at all on the mother, the Enhanced Surveillance Form should still be filled out and Questions 1, 2, and 3 should be completed as much as possible.
- If information on the mother is available in the infant's chart but also in the mother's chart, use the mother's chart as the 'gold standard' for questions related to the mother's care.

Abstraction of Infant's Record
- Complete this form only for 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, birthweight, vital status, birth defects, etc). You will need to complete a new EPS form documenting the updates. On the additional EPS form you should complete the demographics section for both the mother and the infant and then only those portions of the form that need to be newly completed or updated (**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' should be checked or written in if you wish to indicate an unknown value for any question. Type of response is indicated on the form. Unknown should only be checked if the source records are not available.

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

Record Not Available
Record not available should only be 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, ' ' (blank) should be entered into the appropriate space (e.g., 02/../2005). No not use '99" to indicate unknown/missing dates**. 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: Initials of the Abstractor filling the form, Infant reporting state, Infant state number and Infant date of birth. **Initials of the Abstractor filling the form and infant state number are required fields in the EPSS application.** 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.

Text boxes

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

This introductory first section would include all identifying information (not sent to CDC) as well as information on the abstractor, whether the information was complete and if it is a new form or an updated form, information on how the infant was identified and what types of records were abstracted.

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: This is a required field. 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

This section details the basic demographics of the infant and mother, including reporting state, statenos, citynos, soundex, dates of birth and death, sex of the infant, mother's race/ethnicity, mother's marital status and mother's HIV transmission category.

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. Soundex should be entered in the EPSS application (will not be automatically generated by the system). The soundex should be the same as generated by HARS.

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, ' ' (blank) should be coded in appropriate field (e.g. 02/../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. EPSS has a dropdown menu to select the country. If specific name of US Dependency is not known, a selection on the dropdown menu which indicates "US Dependency" can be checked.

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.

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 'Other', then specify the documented risk.

II. Prenatal Care

Questions 9-18

This section on prenatal care provides information on whether the mother received prenatal care during her pregnancy, dates of first and last prenatal care visits and number of visits, type of prenatal care facility, prenatal care screenings and diagnoses of medical conditions, mother's reproductive history, and infant's sibling(s) information.

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 ' / / ' (all spaces should be left blank). If part of the date is unknown, ' ' (blank) should be coded in appropriate field (i.e., 02/ /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 ' ' (blank) 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.

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.

- **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. Screening for syphilis, gonorrhea, and chlamydia is done during prenatal care. Generally a diagnosis of an STD will show up in a number of places in the chart including progress notes, prenatal clinic visit summary sheet (which should include summary of lab tests for various sexually transmitted diseases), lab results section, or in Sexually Transmitted Disease Summary sheets (typical of public health clinics). Diagnoses may be presumptive or definitive depending on various signs, symptoms and lab tests. If a diagnosis is made either presumptively or definitively, note the answer as 'Yes'. Specific criteria for answering 'Yes' to this question are outlined below:

- **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.

III. Substance Use

Questions 19-22
This section on substance abuse provides information on whether substance abuse occurred during the mother's pregnancy, types of substances used, and information on toxicology screenings for the mother and infant.

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

This section provides information on the mother's HIV testing history and diagnosis of HIV. This includes when the mother was diagnosed, results of HIV screening during pregnancy and labor/delivery, dates of first and subsequent HIV tests, CD4 counts and viral loads during pregnancy, and information on the most advanced serostatus of the mother during pregnancy.

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.
- **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, ' ' (blank) 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 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). 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).
- **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). 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 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**.

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**.

- **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**.

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 and 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 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. 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

This section provides information on the types of antiretroviral therapies provided to the mother during her pregnancy and labor/delivery as well as CD4 counts and viral loads after pregnancy.

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 <u>DURING THIS PREGNANCY</u>: '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.

<u>Antiretroviral Drug List:</u> There is a reference list of antiretroviral drugs included at the end of the data abstraction form. In this list, the drugs are organized by drug category, NNRTI, NRTI, Protease Inhibitors, and Other, and within each category the drugs are listed in alphabetical order. As new drugs become available the drug list in the database will be updated. Call the Enhanced Perinatal Surveillance Coordinator at CDC to report drugs that are not included in the list.

- **Drug Name** - Using the antiretroviral drug list, note all antiretrovirals either used or refused during the pregnancy. COMBIVIR is a combination of ZDV (AZT) and 3TC. If combivir is discontinued during pregnancy but either ZDV (AZT) or 3TC (lamivudine) is continued, code Combivir as stopped and indicate that ZDV or 3TC was begun (as a single drug) and the date this change was made. If the woman received drug therapy as part of <u>ACTG 316</u>, receipt of <u>NEVIRAPINE</u> should not be indicated on the antiretroviral drug chart since it is not known whether the mother received the drug or the placebo. If the specific drugs she received or refused are unknown, complete the grid and write 'Unknown" in the 'Drug Name' column. Also, be sure to enter the receipt of 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 '99' for Unknown.
- **Drug Stopped** - If the drug was stopped (discontinued) **prior to** the birth of the infant but administered sometime **during the pregnancy**, indicate 'Yes', the drug was stopped.
- **Date Stopped** - Enter date (MM/DD/YYYY) the antiretrovirals were stopped if completely discontinued. If date is not documented then indicate 'ND'.
- **Drug Stop Code** - To answer this question, use the 'S' codes found at the end of the abstraction form. 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. Enter ' ' (blank) for unknown values (i.e., 03/ /2005 or ..:..)). **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 not in hospital** - If the birth occurred outside a hospital, in all likelihood ARV would not have been administered.
- **Mother tested HIV negative during pregnancy** - Some women may become HIV positive during pregnancy. The mother may have tested HIV negative at some point during pregnancy and was never retested and determined to be HIV positive. In this case she may not have been prescribed ARV during labor and delivery because she was believed to be HIV negative. There must be evidence of a negative test during pregnancy or at labor and delivery in the chart; do not use patient report.
- **Mother Refused** - Mother refused ARV at labor and delivery.
- **Other** - If 'Other' is indicated, be sure to specify why ARV was not prescribed.
- **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. 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'.

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'.

VI. Birth History

Questions 36-42
This section provides information on the birth history of the infant, including the type of birth, dates of labor/delivery, infant's gestational age, mode of delivery, and infant birthweight.

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 '**..:..**'. 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. 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.
- **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
This last section provides information on antiretroviral therapies and prophylaxis for the infant, results of infant antibody or DNA/RNA screening(s), current infant HIV infection status, breastfeeding information, types of infant birth defects (if any), and cause(s) of death if the infant is deceased.

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

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. 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.
- **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). 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

Q. 47 IF CHILD'S HIV STATUS IS INDETERMINATE, INDICATE WHY: This question is included on the pediatric HARS software (although 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.

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 January 8th, 2009