

Birth Defects Study to Evaluate Pregnancy exposures

Justification for the development of the Infections, Travel History, and Marijuana Use Sections

Infections:

In the BD-STEPS CATI, there are several questions regarding sexually transmitted diseases, such as chlamydia, HPV, herpes, syphilis, genital warts, and gonorrhea. Additionally, in the “Chronic Disease Catch-All Question”, the participant is asked whether she had been diagnosed with Hepatitis (the type was not specified), but other chronic infections such as Lyme disease are possibly not reported, because it will only be reported if the participant responds that she had “other” conditions. It has been shown previously that maternal recall, particularly regarding medication use, is directly related to the specificity of the questions asked (<https://academic.oup.com/aje/article-abstract/123/4/670/72770>).

Because the potential teratogenic effects of maternal infections, such as Zika virus, is an area of emerging concern, the sexually transmitted disease questions were removed from the Genitourinary Infections section and a new Infections section was added. In addition to questions about the previously mentioned STDs, questions in the Infection section ask about the diagnosis and treatment of the following infections of interest: Zika virus, Chikungunya, Dengue, Lyme disease, Malaria, West Nile, Lyme disease, and Hepatitis (specific types). Please see questions below (page 2) or **Attachment F** Section T: Infections (page 91).

Travel History:

Due to the Zika virus epidemic, there is a heightened awareness that travel just prior to conception and during the first trimester of pregnancy occurs frequently and is a potential source of exposure to teratogens, such as Zika virus infection. Questions in the new Travel History section regarding travel dates, locations, travel-associated illness and symptoms were adapted from other federal studies, primarily, the US Zika Infant and Pregnancy Registry Maternal Health History Form. This section also includes medication exposure questions that are asked in other parts of the BD-STEPS CATI. Please see questions below (page 5) or **Attachment F** Section U: Travel History (page 94).

Marijuana Use:

As the prevalence of exposure in the general population to marijuana increases with legalization of recreational and medicinal marijuana use, marijuana use during early pregnancy is a topic of emerging concern. Although recent studies have not reported an increase in adverse pregnancy outcomes resulting from marijuana exposure, co-use of other substances is common (<https://www.ncbi.nlm.nih.gov/pubmed/29627409>) and there have been few recent epidemiologic studies studying the association between specific birth defects and marijuana use during pregnancy. CDC leveraged existing questions from a number of federal studies, including PRAMS, BRFSS, and YRBSS, to develop the questions regarding the route of ingestion/use, frequency, and reason for use of marijuana in this section. Please see below (page 9) or **Attachment F** Section BB: Marijuana (page 140).

Section T: INFECTIONS

INFECTIONS – Gateway Table

(FOLLOW-UP QUESTIONS FOR EVERY “YES” RESPONSE BEGIN IN NEXT TABLE)

Has a doctor or other health care provider <u>ever</u> told you that you had any of the following infections?		IF YES, ASK FOLLOW-UP QUESTIONS	IF NO, ASK NEXT CATEGORY	IF DK, ASK NEXT CATEGORY	IF RF, ASK NEXT CATEGORY
		YES	NO	DK	RF
T1.	Zika virus				
	Chikungunya				
	Dengue				
	Lyme disease				
	Malaria				
	West Nile				
	Hepatitis A				
	Hepatitis B				
	Hepatitis C				
	HIV				
	Syphilis				
	Chlamydia				
	Gonorrhea				
	Human papillomavirus (HPV)				
	Any other sexually transmitted disease, such as herpes or trichomoniasis?	What was it?			

For each infection that the mother reported, ask the following questions:

T2.	When was your infection first diagnosed?	a. MM/DD/YYYY OR b. Age in years c. DK d. RF
T3.	Did you have any symptoms during the 3 months before your pregnancy through the end of your [pregnancy with [NOIB]; TAB: the pregnancy that ended on [DOIB/DOPT]], that is from [B3] to the end of your pregnancy? Please note that this is a longer time period than most of my other questions.	a. YES → CONTINUE TO T4 b. NO → SKIP TO T5 c. DK → SKIP TO T5 d. RF → SKIP TO T5
T4.	During which months did you have symptoms?	a. B3 b. B2 c. B1 d. P1 e. P2 f. P3 g. T2 h. T3 i. DK j. RF

T5.	Did you take any medications or remedies for [INFECTION] during the 3 months before your pregnancy through the end of your [pregnancy with [NOIB]; TAB: the pregnancy that ended on [DOIB/DOPT]]?	a. YES → CONTINUE TO T6 b. NO → SKIP TO NEXT INFECTION/SECTION c. DK → SKIP TO NEXT INFECTION/SECTION d. RF → SKIP TO NEXT INFECTION/SECTION
T6.	What did you take? Did you take anything else? [LIST ALL]	a. Medication: _____ b. DK c. RF
T7.	Did you use [MEDICINE] for the entire time from 3 months before your pregnancy through the end of your [pregnancy with [NOIB]; TAB: the pregnancy that ended on [DOIB/DOPT]]?	a. YES → SKIP TO T11 b. NO → CONTINUE TO T8 c. DK → CONTINUE TO T8 d. RF → CONTINUE TO T8
T8.	When did you start using [MEDICINE] for the first time during this period? [CAN USE DK OR RF FOR MM OR DD OR YY]	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
T9.	When did you use [MEDICINE] for the last time during this period? [CAN USE DK OR RF FOR MM OR DD OR YY]	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
T10.	OR How long did you take it?	a. AMOUNT: _____ i. Days ii. Weeks iii. Months b. DK c. RF
T11.	How often did you use [MEDICINE] during the 3 months before your pregnancy through the end of your [pregnancy with [NOIB]; TAB: the pregnancy that ended on [DOIB/DOPT]]? You can say the number of times per day, per week, per month, or during the entire period.	a. AMOUNT: _____ i. Per Day ii. Per Week iii. Per Month vi. Per Time Period [<i>Note to interviewers that this refers to B3-end of pregnancy; e.g., if the mother only took the medication once during that entire time period they would put AMOUNT=1 per time period</i>] b. DK c. RF
T12.	Did you take the same dose of medicine each time you took it throughout [B3] to [DOIB/DOPT]? That is, for example, the same number of milligrams of medicine in each dose?	a. YES → CONTINUE TO T13 b. NO → SKIP TO T14 c. DK → CONTINUE TO T13 d. RF → CONTINUE TO T13
T13.	What dose of [MEDICINE] did you take each time you took it?	a. AMOUNT: _____ → SKIP TO NEXT MEDICINE/INFECTION/SECTION i. UNITS: _____ b. DK → SKIP TO NEXT MEDICINE/INFECTION/SECTION c. RF → SKIP TO NEXT

		MEDICINE/INFECTION/SECTION
T14.	How many different dosage amounts do you remember taking? [If mom knows she took more than one dosage, but can't remember how many, select 1 for the number of dosages and report the dosage information she does remember. You may put additional details in a comment field.]	a. AMOUNT: _____ b. RF
T15.	What dose of [MEDICINE] did you take the [1 st , 2 nd , etc.] time?	a. AMOUNT: _____ i. UNITS: _____ b. DK c. RF
T16.	When did you begin taking that dose?	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
T17.	When did you stop taking that dose?	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
T18.	OR How long did you take it?	a. AMOUNT: _____ i. Days ii. Weeks iii. Months b. DK c. RF

Section U: TRAVEL HISTORY

The next questions are about places you may have traveled before and during your pregnancy.

U1. Did you spend any time outside the continental United States during the time period from 3 months before pregnancy through the end of pregnancy, that is from [B3] TO [DOIB/DOPT]? We are interested in travel you took to other countries, to Hawaii, or to U.S. territories such as Puerto Rico or the U.S. Virgin Islands. [Note to interviewers: We are not interested in travel to Alaska in this question, even though it can be considered outside of the continental United States.]

- a. YES → CONTINUE TO U2
- b. NO → SKIP TO NEXT SECTION
- c. DK → SKIP TO NEXT SECTION
- d. RF → SKIP TO NEXT SECTION

U2. Where did you travel to? Anywhere else?

[Interviewer guidance will be provided that multiple locations (e.g. different cities) within a trip to a country/U.S. territory would only be recorded as a single location here.]

Location [1]:

Location [2]:

Location [3]:

Etc...

ASK QUESTIONS U3 - U11 FOR EACH LOCATION, IF MULTIPLE TRIPS TO THE SAME LOCATION, RECORD EACH TRIP SEPARATELY

U3. What date did your trip to [Location[N]] start?

- a. MM/DD/YYYY or MM/YYYY
- b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3)
- c. DK
- d. RF

U4. What date did your trip to [Location[N]] end?

- a. MM/DD/YYYY
- b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3)
- c. DK
- d. RF

OR

U4a. How long was your trip?

- a. AMOUNT: _____ DK RF
 - i. Days
 - ii. Weeks
 - iii. Months

U5. Did you get sick during your trip to [Location[N]] or within 2 weeks of your return to the U.S.?

- a. YES → CONTINUE TO U6
- b. NO → SKIP TO NEXT SECTION
- c. DK → SKIP TO NEXT SECTION
- d. RF → SKIP TO NEXT SECTION

U6. Did you have any of the following symptoms with this illness:

- a. Rash: YES / NO / DK / RF
- b. Conjunctivitis or “pink eye”: YES / NO / DK / RF
- c. Pain behind eyes: YES / NO / DK / RF
- d. Joint pain: YES / NO / DK / RF
- e. Body pain in your muscles or bones: YES / NO / DK / RF
- f. Chills: YES / NO / DK / RF
- g. Headache: YES / NO / DK / RF
- h. Persistent vomiting: YES / NO / DK / RF
- i. Diarrhea: YES / NO / DK / RF
- j. Nasal congestion: YES / NO / DK / RF
- k. Cough: YES / NO / DK / RF
- l. Sore throat: YES / NO / DK / RF
- m. Difficulty breathing: YES / NO / DK / RF
- n. Fever: YES / NO / DK / RF

U7. Did you have any other symptoms with this illness?

- a. YES → CONTINUE TO U7a
- b. NO → SKIP TO U8
- c. DK → SKIP TO U8
- d. RF → SKIP TO U8

U7a. What other symptoms did you have?

Symptom 1: _____

Symptom 2: _____

[allow them to report as many additional symptoms as they had]

DK

RF

U8. Did you receive a diagnosis from a doctor or other healthcare provider?

- a. YES → CONTINUE TO U9
- b. NO → SKIP TO U10
- c. DK → SKIP TO U10
- d. RF → SKIP TO U10

U9. What diagnosis did they give you?

Diagnosis: _____

DK

RF

U10.	Did you take any medications or remedies for this illness in the 3 months before pregnancy through the end of pregnancy?	a. YES → CONTINUE TO U10a b. NO → SKIP TO NEXT SECTION c. DK → SKIP TO NEXT SECTION d. RF → SKIP TO NEXT SECTION
U10a.	Did you already tell me about the medications you took for this illness?	a. YES → SKIP TO NEXT SECTION b. NO → CONTINUE TO U11 c. DK → CONTINUE TO U11 d. RF → CONTINUE TO U11
U11.	What did you take? Did you take anything else?	a. Medication: _____

	[LIST ALL]	b. DK c. RF
U12.	Did you use [MEDICINE] for the entire time from the 3 months before pregnancy through the end of pregnancy?	a. YES → SKIP TO U16 b. NO → CONTINUE TO U13 c. DK → CONTINUE TO U13 d. RF → CONTINUE TO U13
U13 .	When did you start using [MEDICINE] for the first time during this period? [CAN USE DK OR RF FOR MM OR DD OR YY]	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B1, P1, P2, P3) c. DK d. RF
U14.	When did you use [MEDICINE] for the last time during this period? [CAN USE DK OR RF FOR MM OR DD OR YY]	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B1, P1, P2, P3) c. DK d. RF
U15.	OR How long did you take it?	a. AMOUNT: _____ i. Days ii. Weeks iii. Months b. DK c. RF
U16.	How often did you use [MEDICINE] during the 3 months before pregnancy through the end of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.	a. AMOUNT: _____ i. Per Day ii. Per Week iii. Per Month vi. Per Time Period [<i>Note to interviewers that this refers to B3-end of pregnancy; e.g., if the mother only took the medication once during that entire time period they would put AMOUNT=1 per time period</i>] b. DK c. RF
U17.	Did you take the same dose of medicine each time you took it throughout [B3] to [DOIB/DOPT]? That is, for example, the same number of milligrams of medicine in each dose?	a. YES → CONTINUE TO U18 b. NO → SKIP TO U19 c. DK → CONTINUE TO U18 d. RF → CONTINUE TO U18
U18.	What dose of [MEDICINE] did you take each time you took it?	a. AMOUNT: _____ i. UNITS: _____ b. DK c. RF
U19.	How many different dosage amounts do you remember taking? [If mom knows she took more than one dosage, but can't remember how many, select 1 for the number of dosages and report the dosage information she does remember. You may put additional details in a comment field.]	a. AMOUNT: _____ b. RF
U20.	What dose of [MEDICINE] did you take the [1 st , 2 nd , etc.] time?	a. AMOUNT: _____ i. UNITS: _____ b. DK

		c. RF
U21.	When did you begin taking that dose?	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
U22.	When did you stop taking that dose?	a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B3, B2, B1, P1, P2, P3, T2, T3) c. DK d. RF
U23.	OR How long did you take it?	a. AMOUNT: _____ i. Days ii. Weeks iii. Months b. DK c. RF

Section BB: MARIJUANA

The next questions are about marijuana use. Marijuana is sometimes called pot, weed, cannabis, or hash. Marijuana is usually smoked but can be added to foods or drinks. Marijuana can be used for both medical and non-medical reasons.

BB1. At any time from 1 month before you became pregnant to the end of your third month of pregnancy, that is from [B1] to [P4(-1)] did you use any form of marijuana? [PROBE: Even if you did not use any of these products the whole time, we are interested in whether you used any of them at all during this time period.]

- a. YES → CONTINUE TO BB2
- b. NO → SKIP TO NEXT SECTION
- c. DK → SKIP TO NEXT SECTION
- d. RF → SKIP TO NEXT SECTION

BB2. During the month before through your third month of pregnancy, did you use marijuana in any of the following ways [SELECT ALL THAT APPLY]

- a. Smoke it, for example in a joint, bong, pipe, or blunt → IF YES, ASK BB4
- b. Eat it, for example in brownies, cakes, cookies, or candy → IF YES, ASK BB5
- c. Drink it, for example in tea, cola, or alcohol → IF YES, ASK BB6
- d. Vaporize it, for example in an e-cigarette-like vaporizer or another vaporizing device → IF YES, ASK

BB7

- e. Dab it, for example, using waxes or concentrates → IF YES, ASK BB8
- f. Some other way? → CONTINUE TO BB2a.

BB2a. How did you use it? → CONTINUE TO BB3

- g. DK
- h. RF

BB3. On average, how often did you consume marijuana through [RESPONSE TO "OTHER"] during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:
 - i. PER DAY
 - ii. PER WEEK
 - iii. PER MONTH
 - iv. PER ENTIRE 4 MONTH PERIOD

BB4. On average, how often did you smoke marijuana during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:
 - i. PER DAY
 - ii. PER WEEK
 - iii. PER MONTH
 - iv. PER ENTIRE 4 MONTH PERIOD

BB5. On average, how often did you eat foods containing marijuana during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:
 - i. PER DAY
 - ii. PER WEEK
 - iii. PER MONTH
 - iv. PER ENTIRE 4 MONTH PERIOD

BB6. On average, how often did you consume drinks containing marijuana during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:
 - i. PER DAY
 - ii. PER WEEK
 - iii. PER MONTH
 - iv. PER ENTIRE 4 MONTH PERIOD

BB7. On average, how often did you vape marijuana during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:
 - i. PER DAY
 - ii. PER WEEK
 - iii. PER MONTH
 - iv. PER ENTIRE 4 MONTH PERIOD

BB8. On average, how often did you dab marijuana during the month before through the third month of pregnancy? You can say the number of times per day, per week, per month, or during the entire 4 month period.

- a. Enter frequency:
- b. Select time period:

- i. PER DAY
- ii. PER WEEK
- iii. PER MONTH
- iv. PER ENTIRE 4 MONTH PERIOD

BB9. Why did you use marijuana products during this 4 month time period? [READ ALL OPTIONS; SELECT ALL THAT APPLY]

- a. To relieve nausea
- b. To relieve vomiting
- c. To relieve stress or anxiety
- d. To relieve symptoms of a chronic condition
- e. To relieve pain
- f. For fun or to relax
- g. Some other reason
 - i. SPECIFY: _____