

ATTACHMENT D6: INITIAL BREASTFEEDING INTERVIEW

APPROVED
OMB# 0920 -XXXX
OMB EXP. DATE / /

SUBJECT ID# _____
DATE OF INTERVIEW / /

Ask these questions only after informed consent for participation has been obtained and the enrollment interview has been completed.

If the initial infant interview has already been completed, obtain the infant's sex from that interview before beginning this interview.

Infant's sex _____

If this interview is being conducted on the same day as the infant follow-up interview, skip the paragraphs below and go directly to Section A.

Note: Read only the wording that appears in regular font when conducting the interview. Wording in italics contains instructions to the interviewer and should not be read.

Hello. May I speak with <Name of the woman>? This is <Project coordinator's name> from the <Name of teratology information service>. I am calling about the project to learn about the safety of medicines during pregnancy and breastfeeding that we are conducting with the Centers for Disease Control and Prevention. You completed the most recent interview for this study on <Date of last interview>. It is now time for the next interview. This will take about 20 minutes. Is now a convenient time for me to conduct that interview? *(Circle one)*

Yes

No

If no, go to tracking form.

I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer. I also want to remind you that whether or not you complete the entire study will not affect the medical care you receive or your use of the <Name of teratology information service>. You can call the service at any time to obtain information and counseling about medicines or other exposures while you are pregnant or breastfeeding regardless of whether you participate in the study.

Before we begin, do you have any questions for me about the study?

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

Section A

I'd like to ask some questions about your baby and breastfeeding. This includes both nursing your baby at the breast, and pumping your breast and feeding the baby breast milk through a bottle or tube. All of your answers will be kept private and you can choose not to answer any question you do not want to answer.

If the initial infant interview has been completed, skip Questions 1-5 and begin with Question 6.

1. Is your baby a boy or a girl?
 - a. Boy
 - b. Girl
 - c. Don't know or refused

2. When was he/she born? ____/____/____ ____ Don't know or refused

3. How much did he/she weigh at birth?
_____ pounds _____ ounces ____ Don't know or refused

4. How much did he/she weigh the last time he/she was weighed?
_____ pounds _____ ounces ____ Don't know or refused

5. When was that? (*Complete the one that best reflects the answer given; probe for specifics if she is unsure*)
 - A. Date ____/____/____
 - B. Number of days ago _____
 - C. Number of weeks ago _____
 - D. Number of months ago _____
 - E. Baby's age _____
 - F. Other response _____
 - G. Don't know or refused

6. On average, how often does your baby breastfeed?
 - a. Every _____ hours.
 - b. Number of times in 24 hours _____
 - c. Other response _____
 - d. Don't know or refused

7. Do you also give your baby formula?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Section B.

8. How old was your baby the first time he/she received formula?
 - a. Days of age _____
 - b. Weeks of age _____
 - c. Months of age _____
 - d. Other response _____
 - e. Don't know or refused

9. On average, how often does he/she receive formula?
 - a. Every _____ hours.
 - b. Number of times in 24 hours _____
 - c. Other response _____
 - d. Don't know or refused

Section B

Next, I'd like to ask about medicines you took at any time while you were breastfeeding. This includes prescription medicines that you got from a doctor or pharmacy, over-the-counter medicines such as Tums or Tylenol, vitamins, herbals, and other supplements. I'll be asking about how much you took and how often you took them.

Sometimes it is helpful to have the medicine bottles, or a calendar or other reminder, in front of you when answering these questions. Do you want to take a minute to collect these items?
(If yes, wait for her to collect the items, then continue)

Again, I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer.

1. What medicines have you taken while you were breastfeeding? List all the medicines you can think of even if you took them for a short time or only occasionally when needed.
(Ask for both trade and generic names of each medicine; If the medicine has a name that is common to multiple preparations, such as Tylenol, ask her for the exact name of the preparation, e.g., Tylenol PM, Tylenol Sinus, Tylenol Arthritis, etc.)

_____ Don't know or refused

2. First/Next, let's talk about (name of the first/next medicine). What were you taking it for?
_____ Don't know or refused

3. When did you first have (name of the condition)? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
 - A. Date ____/____/_____

- B. If before conception, days, weeks, months, or years before _____
C. If during pregnancy, weeks or months of gestation _____
D. Baby's age at onset _____
E. Mother's age at onset _____
F. Other response _____
G. Don't know or refused
4. When while you were breastfeeding did you first/next take (name of the medicine)?
(Complete the one that best reflects the answer given; probe for specifics if she is unsure)
A. Date ____/____/_____
B. Baby's age _____
C. Other response _____
D. Don't know or refused
5. How many (name of the medicine) pills/teaspoons did you take at a time the first/next/that time you took it? _____ Don't know or refused
6. How many milligrams were in each pill/teaspoon? _____ Don't know or refused
7. How often did you take that dose? For example, how many times per day, per week, or per month? *(Complete the one that best reflects the answer given)*
a. Number of times per day _____
b. Number of times per week _____
c. Number of times per month _____
d. Other response _____
e. Don't know or refused
8. Did the dose of (name of the medicine) or how often you took it change (again) while you were taking it that time?
a. Yes
b. No
c. Don't know or refused
- If no or don't know/refused, go to Question 10 in this section.*
9. When did the dose of (name of medicine) change? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
A. Date ____/____/_____
B. Number of days or weeks after starting the medicine _____
C. Baby's age _____
d. Other response _____
e. Don't know or refused

Go to Question 5 in this section.

10. Are you still taking (name of the medicine) now?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 12 in this section.

11. And are you still taking (read the dose and frequency from the last response to Questions 6 and 7)?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes or don't know/refused, go to Question 14 in this section.

If no, ask her to clarify when she started taking her current dose. Then go to Question 14 in this section.

12. When did you stop taking (name of medicine) that time? For example, how many days or weeks did you take it, or how old was your baby when you stopped?
- a. Number of days _____
 - b. Number of weeks _____
 - c. Number of months _____
 - d. Baby's age _____
 - e. Other response _____
 - f. Don't know or refused

13. Have you taken (name of the medicine) again since then?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 4 in this section.

14. Did you notice any changes in your milk supply while you were taking (name of the medicine) or right after you stopped taking it?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 16 in this section .

15. What changes did you notice? List all you can think of. _____
_____ Don't know or refused

16. Did you notice any physical or behavioral changes in your baby while you were taking (name of the medicine)? Examples might include a change in appetite, more sleepiness, irritability, or change in the frequency or consistency of bowel movements?
- Yes
 - No
 - Don't know or refused

If no or don't know/refused and there are more medicines on the list, go to Question 2 in this section for the next medicine. If there are no more medicines on the list, go to Question 18 in this section.

17. What changes did you notice? List all you can think of.

_____ Don't know or refused

If there are more medicines on the list, go to Question 2 in this section for the next medicine. If there are no more medicines on the list, proceed with Question 18 in this section.

18. Have you taken any other medicines at any time while you were breastfeeding? This includes things like Tylenol, cold medicine, extra vitamins, or dietary supplements.
- Yes
 - No
 - Don't know or refused

If no or don't know/refused, go to Section C.

19. What other medicines did you take during the time from one month before you became pregnant until now? List all the medicines you can think of even if you took them for a short time or only occasionally when needed.
(Ask for both trade and generic names of each medicine; If the medicine has a name that is common to multiple preparations, such as Tylenol, ask her for the exact name of the preparation, e.g., Tylenol PM, Tylenol Sinus, Tylenol Arthritis, etc.)

Go to Question 2 in this section for the first/next medicine on the list.

Section C

Next, I'd like to ask about any other medical conditions you had while you were breastfeeding that we haven't already talked about, even if you did not take medicine for them. Examples might be a sore throat or sinus infection, asthma, depression, high blood pressure, or diabetes.

Again, I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer.

1. Have you had any (other) medical conditions while you were breastfeeding?
 - a. Yes
 - b. No
 - c. Don't know or refused.

If no or don't know/refused, go to Section D.

2. What conditions have you had? List all you can think of.

_____ Don't know or refused
_____ (If she doesn't know the name of the condition, ask her to describe it and its symptoms)
If refused, go to Section D.

3. First/Next, let's talk about (name of the first/next condition). When did you first have <name of the condition>? (Complete the one that best reflects the answer given; probe for specifics if she is unsure)

- A. Date ____/____/____
- B. If before conception, days, weeks, months, or years before _____
- C. If onset during pregnancy, weeks or months of gestation _____
- D. Baby's age at onset _____
- E. Mother's age at onset _____
- F. Other response _____
- G. Don't know or refused

4. Did you take any medicine for <name of the condition> while you were breastfeeding that we haven't already talked about?
 - a. Yes
 - b. No
 - c. Don't know or refused.

If yes, go to Section B, Question 1.

If no or don't know/refused and there are other conditions on the list, go to Question 3 in this section. If there are no more conditions on the list, proceed with Section D.

Section D

Finally, I'd like to ask about some other exposures that you might have had while you were breastfeeding. I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer.

1. While you were breastfeeding, did you smoke a cigarette at any time?

- a. Yes
- b. No
- c. Don't know or refused

If no or don't now/refused, go to Question 4 in this section.

2. On average, how many cigarettes did you smoke per day? (1 pack = 20 cigarettes, half a pack = 10)
- a. Number of cigarettes _____
 - b. Number of packs _____
 - c. Other response _____
 - d. Don't know or refused
3. When was the last time you smoked a cigarette? (Complete the one that best reflects the answer given; probe for specifics if she is unsure)
- A. Date ____/____/____
 - B. Days, weeks or months since delivery _____
 - C. Other response _____
 - D. Don't know or refused
4. Did others in your home or workplace smoke while you were breastfeeding?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 6 in this section.

5. How many people in your home or workplace smoked while you were breastfeeding? (Do not include the woman herself)
- _____ Don't know or refused
6. While you were breastfeeding, on average how often did you have a drink of alcohol? (Complete the one that best reflects the answer given; probe for specifics if she is unsure)
- a. Number of times per day _____
 - b. Number of times per week _____
 - c. Number of times per month _____
 - d. Didn't drink
 - e. Other response _____
 - f. Don't know or refused

If she didn't drink or doesn't know/refused, go to Question 10 in this section.

7. On average, how many drinks did you have at one time while you were breastfeeding? One drink is equal to one glass of wine like you would have at a restaurant, one bottle or can of

beer, or 1 ounce of hard liquor either in a mixed drink or straight up. *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- a. Number of drinks per day _____
- b. Number of drinks per week _____
- c. Number of drinks per month _____
- d. Other response _____
- e. Don't know or refused

8. What was the most number of drinks you had on any one occasion while you were breastfeeding?
_____ Don't know or refused

9. When was the last time you had a drink? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- A. Date ____/____/____
- B. Days, weeks, or months since delivery _____
- C. Other response _____
- D. Don't know or refused

10. While you were breastfeeding, did you use any (other) recreational drugs?

- A. Yes
- B. No
- C. Don't know or refused

If no or don't know/refused, go to End of Interview.

11. What (other) recreational drugs did you use? List all you can think of.

_____ Don't know or refused

12. While you were breastfeeding, on average how often did you use <name of the first/next drug>? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- a. Number of times per day _____
- b. Number of times per week _____
- c. Number of times per month _____
- d. Other response _____
- e. Don't know or refused

13. When was the last time you used <name of the drug>? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- A. Date ____/____/____
- B. Days, weeks, or months since delivery _____
- C. Other response _____
- D. Don't know or refused

If there are more drugs on the list, go to Question 12 in this section for the next drug. If there are no more drugs on the list, proceed with Question 14 in this section.

14. Did you use any (other) recreational drugs while you were breastfeeding?
- Yes
 - No
 - Don't know or refused

If yes, go to Question 11 in this section.

If no or don't know/refused, go to End of Interview.

End of Interview

That is the end of this interview. I truly want to thank you for taking the time to complete it. Your contribution to this study is very important. Before we hang up, do you have any questions for me? _____

Your next interview is scheduled for about 1 month from now. That will be approximately
<Calculated date based on date of this interview>.

Go to tracking form.