

ATTACHMENT D5: FOLLOW-UP INFANT INTERVIEW

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

SUBJECT ID# _____
DATE OF INTERVIEW / /

Ask these questions only if the enrollment, pregnancy, and initial infant interviews were completed on a previous date.

Before beginning the interview, obtain the following information from the last infant interview:

Date of the last interview _____

Infant's age at the last interview (calculated from the birth date) _____

Infant's sex _____

List of all infant complications she reported at the last interview _____

List of all infant surgeries she reported at the last interview _____

List of all of the infant's specialists she reported at the last interview _____

List of all postpartum visits she reported at the last interview _____

Breastfeeding status at the time of the last interview _____

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 takes about 15 minutes on average. Is now a convenient time for me to conduct that interview? *(Circle one)*

- Yes
- No

If no, go to tracking form.

Public reporting burden of this collection of information is estimated to average 15 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).

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?

Section A

First, I'd like to ask some questions to update our information about your baby since your last interview. As a reminder, your last interview was on <date of last interview> and at that time your baby was approximately <infant's age at last interview> weeks/months old.

1. Is your baby alive now?
 - a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 3 in this section.

2. When did your baby die?
 - A. Date ____/____/____
 - B. Baby's age at death _____
 - C. Other response _____
 - D. Don't know or refused

*If she reported complications during the last interview, go to Question 5 in this section.
If she did not report complications during the last interview, go to Question 10 in this section.*

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

5. *If she reported no complications at the last interview, go to Question 9 in this section.*

During your last interview, you said he/she had had (*read list of complications from last infant interview*). Has/Did he/she continue(d) to have this (any of these) condition(s) since your last interview?

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

If no or don't know/refused, go to Question 9 in this section.

If yes but only one condition is listed from the last interview, go to Question 7 in this section.

6. Which conditions has he/she continue to have since your last interview?
_____ Don't know or refused

7. First/Next, let's talk about (name of the first/next condition). When since your last interview did he/she first/next have (name of the first/next condition) again? (*Complete the one that best reflects the answer given; probe for specifics if she is unsure*)

- A. Date ____/____/_____
B. Weeks or months of age _____
C. Other response _____
D. Don't know or refused

8. What treatment was he/she given? _____ Don't know or refused

If there are more conditions on the list, go to Question 7 in this section for the next condition.

If there are no more conditions on the list, continue with Question 9 in this section.

9. Has/Did your baby had/have any (other) illnesses or complications since your last interview?

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

If no or don't know/refused, go to Question 13 in this section.

10. What illnesses or complications has/did he/she had/have? 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)

11. First/Next, let's talk about (name of the first/next illness). How old was your baby when (name of the condition) developed? _____ Don't know or refused

12. What treatment was he/she given? _____ Don't know or refused

*If there are more illnesses on the list, go to Question 11 in this section for the next illness.
If there are no more illnesses on the list, continue with Question 13 in this section.*

13. *If she reported no birth defects at the last interview, go directly to the question. Do not read the next sentence.*

During your last interview, you said he/she had *(read list of defects from last infant interview)*.

Has he/she been diagnosed with any (other) birth defects since our last interview? This would include physical, internal, or genetic conditions that are not due to a medical complication or illness such as prematurity or infection.

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

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

14. What kind of birth defects were they? List all you can think of.

_____ Don't know or refused

15. First/Next, let's talk about (name of the first/next birth defect). How old was he/she when it was diagnosed? _____ Don't know or refused

16. How was it diagnosed? For example, with x-ray, MRI or CT scan, blood test, or other procedure. _____ Don't know or refused

17. What treatments was he/she given for it? _____ Don't know or refused

*If there are more defects on the list, go to Question 15 in this section for the next defect.
If there are no more defects on the list, go to Section B.*

Section B

Next, I'd like to update our information about any surgery your baby had or any specialists he/she saw. 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.

If she reported no surgery at the last interview, go directly to Question 1 in this section.

During your last interview, you said he/she had had (*read list of surgeries from last infant interview*).

1. Has your baby had any (other) surgery since your last interview?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 5 in this section.

2. What kind of surgeries has he/she had? List all the surgeries you can think of.

_____ Don't know or refused

3. First/Next, let's talk about (name of the first/next birth defect). Why was it done? (*Skip this question if already answered in Question 2*) _____

_____ Don't know or refused

4. How old was your baby when the surgery was done?

_____ Don't know or refused

*If there are more surgeries on the list, go to Question 3 in this section for the next surgery.
If there are no more surgeries on the list, proceed with Question 5 in this section.*

5. *If she reported that her baby had not seen any specialists at the last interview, go directly to the question. Do not read the next sentence.*

During our last interview, you said your baby had been to see (*read list of specialists from last infant interview*).

Has he/she see any (other) doctor or specialist, other than his/her general pediatrician, family physician, or nurse practitioner, since your last interview? Examples include a geneticist, a cardiologist, an ophthalmologist or eye doctor, a neurologist, a hearing specialist, or other type of provider?

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

If no or don't know/refused, go to Question 8 in this section.

6. What kinds of doctors or specialists has he/she seen? List all you can think of.

_____ Don't know or refused

7. First/Next, let's talk about (name of the first/next specialist). Why did your baby see that specialist? _____

_____ Don't know or refused

If there are more specialists on the list, repeat Question 7 in this section for the next specialist.

If there are no more specialists on the list, proceed with Question 8 in this section.

8. *If she reported no postpartum visits at the last interview, skip the next sentence and go directly to the question.*

During our last interview, you said you had seen (read list of postpartum visits from last infant interview).

Have you had any visits with any (other) doctor or health care provider since your last interview? Examples could include visits with an obstetrician, nurse midwife, family practitioner, lactation consultant, psychologist, or other provider.

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

If no or don't know/refused, go to Question 11 in this section.

9. What kind of providers have you seen? List all you can think of.

_____ Don't know or refused

10. First/Next, let's talk about (name of the first/next provider). Why did you see that provider?

_____ Don't know or refused

If there are more providers on the list, repeat Question 10 in this section for the next provider.

If there are no more providers on the list, proceed with Question 11 in this section.

11. Are you currently breastfeeding?

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

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

12. Have you taken any medicines since our last interview 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.
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, proceed with Initial Breastfeeding Questionnaire.

End of Interview

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

Did you find it difficult or burdensome to participate in this study?

- Yes
- No
- Not sure

If yes or not sure, ask

How was it difficult or burdensome? _____
