

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title

OMB NO. 0920-0010

Expiration Date 02/28/2023

Summary:

Briefly summarize changes

We propose to modify questions in the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) interview to gather additional details about COVID-19 infections and vaccinations. New questions will gather information on COVID-19 infections diagnosed using an at-home test, repeat infections, and the level of treatment received for each infection. We also propose to gather information on booster doses of COVID-19 vaccine. The current version of the COVID-19-related infection questions only ask about the occurrence of one infection that was diagnosed by a doctor or other healthcare provider and the vaccination questions only ask about the primary series of COVID-19 vaccinations.

Description of change

The current version of the computer-assisted telephone interview (CATI) asks participants about the occurrence of 16 possible infections (including COVID-19), with follow-up questions about symptoms and medication use (e.g., duration, frequency, and dose) in the three months before to the end of pregnancy. This non-substantive change is being made so that we can gather additional follow-up information about all COVID-19 infections during pregnancy, rather than just one, and includes ascertainment of COVID-19 infections not diagnosed by a healthcare provider. In addition, new COVID-19 follow-up questions ask about the level of care received for COVID-19 (e.g., hospitalization) and prompts recall of medications specific to COVID-19 (e.g., monoclonal antibodies, paxlovid, etc.).

The current version of the COVID-19 vaccination questions ask only about the first two doses of COVID-19 vaccination. Our proposed change will allow us to capture all doses of COVID-19 vaccinations, including booster doses.

These changes are being made to both the English and Spanish version of the BD-STEPS CATI (**Attachment C1**).

Reason for change

These changes are being made so we can more accurately capture all COVID-19 infections and vaccinations before and during pregnancy among our study population of women who were pregnant during the SARS-CoV-2 pandemic.

Background & Justification:

Brief explanation for the change requested, including the reason (purpose or benefit) for the requested change

While studies have shown that pregnant women and their infants are at increased risk for adverse outcomes following COVID-19 infection during pregnancy, research is still needed to understand the full spectrum of impacts, particularly with respect to birth defects. It is equally important to understand any potential impacts of the COVID-19 vaccines for women who receive it during pregnancy.

BD-STEPS, as the largest ongoing case-control study of birth defects in the United States, is uniquely poised to conduct such studies, but the questionnaire must be modified to capture accurate and comprehensive data on COVID-19 infections and vaccinations. Mothers of control infants (liveborn infants born without any major birth defects) are representative of the general population of pregnant women in our study areas. Information about

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COVID-19 exposure and COVID-19 vaccination during these pregnancies will allow us to assess risk for adverse pregnancy outcomes in addition to birth defects, including preterm delivery and low birth weight.

Effect of Proposed Changes on Current Approved Instruments:

- Show a crosswalk of the changes in table below

Form	Current/Question Item	Requested Change
AttC1a_Core_CATI	<p>T1. Has a doctor or other health care provider <u>ever</u> told you that you had any of the following infections?</p> <ul style="list-style-type: none"> - Coronavirus or COVID-19 a. YES → Ask Follow-up Questions b. NO → Ask next category c. DK → Ask next category d. RF → Ask next category 	<p>T19. Have you <u>ever</u> had a coronavirus/COVID-19 infection or tested positive for COVID-19?</p> <ul style="list-style-type: none"> a. YES → CONTINUE TO T20 b. NO → SKIP TO NEXT SECTION c. DK → SKIP TO NEXT SECTION d. RF → SKIP TO NEXT SECTION
		<p>T20. How many coronavirus/COVID-19 infections have you had? You may have received more than one positive test for one infection. If you recovered from COVID-19 and then were infected with COVID-19 again that would count as a separate infection. [IF DK NUMBER, SELECT 1 AND ASK MOM FOR DETAILS ABOUT 1 INFECTION SHE REMEMBERS.] [ASK T21-T40 FOR EACH INFECTION LISTED.]</p> <p>a. NUMBER: _____</p>
	<p>For each infection that the mother reported, ask the following questions:</p> <p>T2. When was your infection first diagnosed?</p> <ul style="list-style-type: none"> a. MM/DD/YYYY OR b. Age in years OR c. Time period ago d. DK e. RF 	<p>I'm going to ask you a set of questions about your [1st/2nd/3rd/etc.] COVID infection.</p> <p>T21. When was your infection first diagnosed?</p> <ul style="list-style-type: none"> a. MM/DD/YYYY OR b. Age in years OR c. Time period ago d. DK e. RF
		<p>T22. Did a doctor or other healthcare provider tell you that you had COVID?</p> <p>[If diagnosed by a drive-through testing site or pharmacy technician select "Yes"]</p> <ul style="list-style-type: none"> a. Yes

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		<p>b. No e. DK f. RF</p>
		<p>T23. Did you test positive on a home test? a. Yes b. No e. DK f. RF</p>
		<p>T26. How would you describe the level of care you received? If you contacted a healthcare provider through email or phone or telemedicine select that you received medical care. [READ OPTIONS A-C]: a. Did not seek medical care b. Received medical care but was not hospitalized c. Was hospitalized and not admitted to ICU d. Was hospitalized and admitted to ICU i. DK j. RF</p>
	<p>T6. What did you take? Did you take anything else? [LIST ALL] a. Medication: _____ b. DK c. RF</p>	<p>T28. What did you take? / Did you take anything else (such as monoclonal antibodies, steroids, antibiotics, ivermectin, or hydroxychloroquine)? PROBE: READ LIST IF NECESSARY NAME: _____ DK → SKIP TO NEXT SECTION RF → SKIP TO NEXT SECTION LIST (select if 'Yes'): COVID MEDICATION PROMPTS: Acetaminophen Advil Ibuprofen Motrin Tylenol Remdesivir Paxlovid OTHER, SPECIFY:</p>
	<p>V620. During this time period, did you take any medications,</p>	<p>V620. During this time period, did you take any medications,</p>

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	<p>remedies, or treatments that we haven't already talked about? Any others?</p>	<p>remedies, or treatments that we haven't already talked about (such as over the counter or prescription medications for constipation (for example, prucalopride)? We will ask you about any COVID vaccines later./Any others?</p>
	<p>V633. Did you get the COVID-19 vaccine <u>the month before</u> through the end of your pregnancy? a. YES → CONTINUE TO V634 b. NO → SKIP TO NEXT SECTION c. DK → SKIP TO NEXT SECTION d. RF → SKIP TO NEXT SECTION</p>	<p>V639. Have you ever received a COVID vaccine? a. YES → CONTINUE TO V640 b. NO → SKIP TO NEXT SECTION c. DK → SKIP TO NEXT SECTION d. RF → SKIP TO NEXT SECTION</p>
	<p>V634. Do you know what type of COVID-19 vaccine you received? a. YES → CONTINUE TO V634a b. NO → CONTINUE TO V635</p>	<p>V640. How many COVID-19 vaccine doses do you remember getting? This includes any boosters you may have received. a. Number: _____ [IF DK NUMBER, SELECT 1 AND ASK MOM FOR DETAILS ABOUT 1 VACCINE SHE REMEMBERS.] [ASK V641-V642 FOR EACH VACCINE DOSE LISTED.]</p>
		<p>For each vaccine dose that the mother reported, ask the following questions:</p> <p>V641. When did you get the [1st/2nd/3rd/etc.] vaccine dose? a. MM/DD/YYYY or b. Before B1 OR c. MONTH OF PREGNANCY (B1-P9) d. After P9 OR e. HOW LONG AGO (with units for days, weeks, months, years) f. Age in years OR g. DK h. RF</p>
		<p>V642. Do you know what type of COVID-19 vaccine you received? a. YES → CONTINUE TO V642a. b. NO → RECORD NEXT DOSE INFORMATION OR GO TO NEXT SECTION</p>
		<p>V642a. Which brand of COVID-19 vaccine did you receive? a. Pfizer-BioNTech b. Moderna</p>

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		<p>c. Johnson and Johnson (Janssen)</p> <p>d. One of the brands that require two initial shots, but not sure which brand</p> <p>c. Other (SPECIFY): _____</p> <p>d. DK</p> <p>f. RF</p>
	<p>V634a. What was it? SPECIFY _____</p>	
	<p>V635. Did the type of vaccine you received require 2 doses?</p> <p>a. YES → CONTINUE TO V636</p> <p>b. NO → CONTINUE TO V638</p> <p>c. DK → CONTINUE TO V636</p>	
	<p>V636. Did you receive 2 doses?</p> <p>a. YES → CONTINUE TO V637</p> <p>b. NO → CONTINUE TO V638</p>	
	<p>V637. When did you get the 1st dose?</p> <p>a. Before B1 or</p> <p>b. MM/DD/YYYY or</p> <p>c. MONTH OF PREGNANCY (B1-P9)</p> <p>d. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>e. DK</p> <p>f. RF</p>	
	<p>V637a. When did you get the 2nd dose?</p> <p>a. After P9 or</p> <p>b. MM/DD/YYYY or</p> <p>c. MONTH OF PREGNANCY (B1-P9)</p> <p>d. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>e. DK</p> <p>f. RF</p> <p>SKIP TO NEXT SECTION</p>	
	<p>V638. When did you get your dose of vaccine?</p> <p>a. MM/DD/YYYY or</p> <p>b. MONTH OF PREGNANCY (B1-P9) or</p> <p>c. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>d. DK</p>	

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	e. RF SKIP TO NEXT SECTION	
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Effect on Burden Estimate:

This proposed change would not impact the burden.