

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 ask women about receipt of a COVID-19 vaccine in the month before through the end of the pregnancy. The current version of the question asks about COVID-19 vaccine only through the third month of pregnancy.

Description of change

The computer-assisted telephone interview (CATI) asks participants if they received any of 10 specific vaccines in the month before through the third month of pregnancy. This non-substantive change is being made so that we can extend maternal reporting of the receipt of COVID-19 vaccination through the end of the pregnancy. If the participant reports that they received a COVID-19 vaccination during this exposure period, the month before through the end of the pregnancy, they will continue to be asked whether they know the type of vaccine they received (e.g., Pfizer, Moderna); and the dates of each dose. This change is being made to both the English and Spanish version of the BD-STEPS CATI.

Reason for change

This change is being made so we can capture information on receipt of COVID-19 vaccination through the end of the pregnancy, extending the period of interest beyond just the first three months of pregnancy, in our study population of women who were pregnant during the SARS-CoV-2 pandemic.

Attachments:

- Att18_BDSTEPS_CATI_V8.0
- Att18_BDSTEPS_CATI_V8.0_SPAN

Background & Justification:

To date, two vaccines against COVID-19 have been approved in the United States. Although pregnant women were not included in the randomized controlled trials that determined the efficacy of the vaccine, these vaccines are not contraindicated during pregnancy. Therefore, it is important to understand any potential impacts of the vaccine for women who receive it during their entire pregnancy. BD-STEPS provides a unique opportunity to capture this important information.

Effect of Proposed Changes on Current Approved Instruments:

Form	Current/Question Item	Requested Change
Att18_BDSTEPS_CATI_V8.0 Att18_BDSTEPS_CATI_V8.0_SPAN	V156: [If they report receipt of any vaccines in the month before through the third month of pregnancy] Which vaccines did you get? PROBE: READ LIST IF NECESSARY <ul style="list-style-type: none">- COVID-19- Chickenpox Vaccine- Flu Vaccine- Hepatitis A Vaccine- Hepatitis B Vaccine	V156: [If they report receipt of any vaccines in the month before through the third month of pregnancy] Which vaccines did you get? PROBE: READ LIST IF NECESSARY <ul style="list-style-type: none">— COVID-19- Chickenpox Vaccine- Flu Vaccine- Hepatitis A Vaccine- Hepatitis B Vaccine

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	<ul style="list-style-type: none"> - HPV Vaccine (Human Papillomavirus) - Measles, Mumps, Rubella Vaccine) - Meningococcal Vaccine - Pneumococcal Vaccine, Polyvalent - Shingles Vaccine <p>V156a: [Only for those who report getting the COVID-19 vaccine]: Do you know what type of COVID-19 vaccine you received? What was it?</p> <p>V157: When did you get [NAME OF VACCINE]?</p> <ul style="list-style-type: none"> a. MM/DD/YYYY or b. MONTH OF PREGNANCY(B1, P1, P2, P3) or c. HOW LONG AGO (with units for days, weeks, months, years) d. DK e. RF <p>V157a: [Only for those who report getting the COVID-19 vaccine]: When did you get your second dose of vaccine for COVID-19?</p> <ul style="list-style-type: none"> a. Did not receive 2nd dose or b. MM/DD/YYYY or c. MONTH OF PREGNANCY(B1, P1, P2, P3) or d. HOW LONG AGO (with units for days, weeks, months, years) d. DK e. RF 	<ul style="list-style-type: none"> - HPV Vaccine (Human Papillomavirus) - Measles, Mumps, Rubella Vaccine) - Meningococcal Vaccine - Pneumococcal Vaccine, Polyvalent - Shingles Vaccine <p>V156a: [Only for those who report getting the COVID-19 vaccine]: Do you know what type of COVID-19 vaccine you received? What was it?</p> <p>V157: When did you get [NAME OF VACCINE]?</p> <ul style="list-style-type: none"> a. MM/DD/YYYY or b. MONTH OF PREGNANCY(B1, P1, P2, P3) or c. HOW LONG AGO (with units for days, weeks, months, years) d. DK e. RF <p>V157a: [Only for those who report getting the COVID-19 vaccine]: When did you get your second dose of vaccine for COVID-19?</p> <p>a. Did not receive 2nd dose or</p> <p>b. MM/DD/YYYY or</p> <p>c. MONTH OF PREGNANCY(B1, P1, P2, P3) or</p> <p>d. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>d. DK</p> <p>e. RF</p> <p>V633. Did you get the COVID-19 vaccine the month before through the end of your pregnancy?</p> <ul style="list-style-type: none"> a. YES b. NO c. DK d. RF <p>V634. Do you know what type of COVID-19 vaccine you received?</p> <ul style="list-style-type: none"> a. YES b. NO <p>V634a. What was it?</p> <ul style="list-style-type: none"> - Specify: _____
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		<p>V635. Did the type of vaccine you received require 2 doses?</p> <p>a. YES b. NO c. DK</p> <p>V636. Did you receive 2 doses?</p> <p>a. YES b. NO</p> <p>V637. When did you get the 1st dose?</p> <p>a. Before B1 or b. MM/DD/YYYY or c. MONTH OF PREGNANCY (B1-P9) d. HOW LONG AGO (with units for days, weeks, months, years) e. DK f. RF</p> <p>V637a. When did you get the 2nd dose?</p> <p>a. After P9 or b. MM/DD/YYYY or c. MONTH OF PREGNANCY (B1-P9) d. HOW LONG AGO (with units for days, weeks, months, years) e. DK f. RF</p> <p>V638. When did you get your dose of vaccine?</p> <p>a. MM/DD/YYYY or b. MONTH OF PREGNANCY (B1-P9) or c. HOW LONG AGO (with units for days, weeks, months, years) d. DK e. RF</p>
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Note: Changes will be applied to both the English and Spanish versions of these documents.

Effect on Burden Estimate:

Discuss and include a table comparing to previously approved burden

- *Include a burden table and identify changes, or, if the burden isn't changing, state there is no change*

This proposed change would not impact the burden as presented in our last approved OMB package