Feeding My Baby and Me: Infant Feeding Practices Study III

New

Supporting Statement B

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September 2, 2020

TABLE OF CONTENTS

ATTACHMENTS

5a. Recruitment and enrollment flow chart
5b. Social media recruitment messages
5c. Telephone and voicemail script for eligible respondents
5d. Study consent
5e. Request for notification of child's birth
5f. Survey invitation email/text
5g. Survey reminder email/text
5h. Survey thank you email/text
5i. Missed survey email/text
5j. Study removal email/text
5k. Participant follow-up letter
5l. Children's books
5m. Sample screenshots of website
5n. Frequently Asked Questions website
6. Confidentiality and non-disclosure statement

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The overall purpose of the Feeding My Baby and Me: Infant Feeding Practices Study III (FMB&M- IFPS III) is to understand the current state of mothers' intentions, behaviors, feeding decisions, and practices from pregnancy through their child's first two years of life and how these change. It will also assess the impact of these practices on the child's feeding and health outcomes during the first two years, and explore emerging issues related to infant and toddler feeding practices.

Respondent universe: FMB&M- IFPS III is a longitudinal study. The respondent universe for this study are women in the United States who are between the ages of 18–49 years and are 20 to 37 weeks gestation with a single baby (i.e., no multiples). The United States recorded 3.88 million live births in 2016 among women 18–49 years [1] which translates to an average of about 324,000 births per month. Under the assumption that U.S. birth rates remain at about this same rate when IFPS III is underway, about 1,944,000 women would be in the second half of their pregnancy in any given month.

Sampling approach: FMB&M- IFPS III will use a non-probability quota-based sampling approach. Pregnant women will be recruited using paid social and digital media (Attachment 5b). Three equal groups of non-Hispanic white, non-Hispanic black, and Hispanic women will be recruited to ensure adequate sample size at the end of the study (24 months) to detect differences between subgroups as explained in "Sample Size Estimates".

Although a representative probability sample of pregnant women would be preferable for statistical inference, identifying women in the second half of pregnancy would require enormous screening costs. As such, IFPS I and IFPS II utilized a sample drawn from a mailed consumer opinion panel ("Infant Feeding Practices Study," OMB No. 0910-0220, exp. 6/30/1998; "Infant Feeding Practices Study II," OMB No. 0910-0558, exp. 12/31/2007). However, this sampling strategy had limited numbers of women who were African American or Hispanic [2]. These groups are a particular focus of the Centers for Disease Control and Prevention's (CDC) programmatic efforts at the state and community level (e.g., "State Physical Activity and Nutrition (SPAN)

Program" and "Racial and Ethnic Approaches to Community Health (REACH)) and efforts in hospitals to support implementation of evidence-based maternity care practices. These racial/ethnic subgroups are a focus because of lower breastfeeding rates, poorer dietary practices among children, and risks for adverse health outcomes [3, 4].

A non-probability sampling approach has been used before successfully in Evaluation of Essentials for Parenting Toddlers and Preschoolers ("Evaluation of Essentials for Parenting Toddlers and Preschoolers," OMB No. 0921-1086, exp. 10/31/2017), a longitudinal study that followed parents of young children over the course of 18 weeks. This study used an Internet-based recruitment method by posting information about the study on Facebook and on parenting blogs and websites. The study aimed to enroll 200 parents. During a 6 week recruiting time period, nearly 1,200 parents were screened, via an on-line screener, to be eligible for the study. When recruitment was finished, there were still 982 interested parents on the waitlist. Overall, the study achieved a sample with 32% of participants with household incomes <$50,000, 12.5% African American, 8.0% multiracial, and geographic representation among four regions that ranged from 17% to 35%. This study aimed to have a sample that was diverse in geography, socioeconomic status, and race/ethnicity.

Sample size estimates: CDC determined that a sample size of 2,500 participants at the end of the study would meet our goals. In determining the sample size for FMB&M- IFPS III, CDC had two objectives:

- The primary objective was to compare estimates between racial/ethnic groups (non-Hispanic white vs. non-Hispanic blacks, non-Hispanic whites vs. Hispanics, and non-Hispanic blacks vs. Hispanics). A large number of comparisons are expected over the course of the study. In order to maximize our ability to determine differences between racial/ethnic groups, we assumed a prevalence estimate of 50% for one group and wanted to be able to detect differences of 7.1%.
- A secondary objective was to include a smaller sample of women of any other race or ethnicity to allow for their inclusion.

In order to detect a difference of at least 7.1% at a prevalence estimate of 50%, approximately 800 women in each group are required. This would

result in a sample of 2,400 women. To meet our secondary objective, we would include an additional 100 women of other race and ethnicities.

Estimated sample sizes do not account for losses due to ineligibility, nonresponse, or attrition. CDC estimates that approximately 4,239 respondents are needed for enrollment to ensure 2,500 respondents remain at the 24 month interview. Table 2-1 provides estimates for enrollment sample sizes, based on the following assumptions:

- Final sample size is 2,500 at the 24 month interview.
- The number of non-Hispanic white, non-Hispanic black, and Hispanic women are equal.
- Post-enrollment ineligibility rate is 15% for non-Hispanic blacks and 10% for all other race/ethnicities.
- Response rate of 67% and is constant across subgroups.

The ineligibility rate is based on preterm birth rates. It is expected that some women will enroll in the study but will be ineligible due to a preterm birth (i.e., the infant is born before 37 weeks gestation) or the infant has to stay in the Neonatal Intensive Care Unit (NICU) for ≥ 3 days. Ineligibility for non-Hispanic black women was estimated at a slightly higher percentage to account for higher preterm birth rates than other race and Hispanic origins [1]. The ineligibility rate was inflated by ~1% point above the preterm birth rate by race and Hispanic origin to account for any infants who had to stay in the NICU for ≥ 3 days or for mothers who may be unable to feed their newborn for ≥ 1 week due to a severe medical problem.

The response rate of 67% was estimated based on response rates from other longitudinal studies among young children. Specifically, estimates were used from the following studies:

- US Department of Agriculture's (USDA) Infant and Toddler Practices Study-2 which had a 63% response rate at the 24 month survey ("WIC Infant and Toddler Feeding Practices Study-2 (WIC-ITFPS-2)," OMB No. 0584-0580, exp. 3/31/2022),
- CDC's and Food and Drug Administration's (FDA) Infant Feeding Practices Study II which had a 64.5% response rate for the 12 month survey [2] ("Infant Feeding Practices Study II," OMB No. 0910-0558, exp. 12/31/2007), and
- Evaluation of Essentials for Parenting Toddlers and Preschoolers which had an 83% response rate at the end of 18 weeks ("Evaluation of

Essentials for Parenting Toddlers and Preschoolers," OMB No. 0920-1086, exp. 10/31/2017).

Given that the assumed response rate does not meet OMB's guideline of 80 percent, it will be necessary to do a nonresponse bias analysis. This will be done by comparing responding and nonresponding participants based on information available from those participants who screen eligible for the study. Demographic characteristics will be included for these comparisons. Additionally, for respondents who complete a prenatal or other monthly survey, additional characteristics used in the nonresponse bias analysis may include feeding practices, attitudes, and intentions.

Table 2-1. Target number of enrolled women needed to attain target numbers of completed 24-month interviews under varying overall response rate assumptions

	Target # completed interviews at 24 months	Assumed ineligibility rate	Expected overall response rate at 24 months					
			30%	40%	50%	60%	67%	70%
Total	2,500		9,434	7,076	5,661	4,717	4,239	4,043
Non-Hispanic Black	800	15%	3,138	2,353	1,883	1,569	1,448	1,345
Hispanic	800	10%	2,963	2,223	1,778	1,482	1,368	1,270
Non-Hispanic White	800	10%	2,963	2,223	1,778	1,482	1,368	1,270
Other	100	10%	371	278	223	186	171	159

NOTE: Ineligibility rates account for expected exclusions after enrollment due to premature births, spending 3 or more days in the NICU, or mothers unable to feed their newborn for ≥ 1 week due to a severe medical problem. Due to rounding, details may not sum to totals.

B2. Procedures for the Collection of Information

As described in Section B.1, this study uses a non-probability quota-based sampling approach. This sampling approach does not allow for national estimates nor any generalizability to the U.S. population. Additionally, any findings coming from this study would need to include information on the sampling limitations. This data collection effort does not have any unusual problems requiring specialized sampling procedures. All data collection activities will occur within a 36 month period. The study design requires that respondents are surveyed at multiple time points as described below. The contractor, Westat, will conduct the recruitment, data collection, data cleaning, and analysis.

Data Collection: Study recruitment, enrollment, and data collection efforts will be done electronically using the Internet and web-based surveys, except for the initial phone contact to confirm eligibility and enroll the participants. The following describes study enrollment and data collection efforts.

Pregnant women who are eligible based on their completed online screener, will be contacted by phone to confirm eligibility and then enrolled (Attachment 4a, Attachment 5c, and Attachment 5d). At the time of enrollment, eligible participants must be (1) between 20 to 37 weeks gestation, (2) not pregnant with multiples, and (3) between the ages of 18 and 49. Women who do not qualify for the study because their due date places them before 20 weeks gestation will receive a message inviting them to return and complete the screener again when they are within the eligible timeframes. After giving birth, 10–15% of enrolled participants may no longer be eligible to remain in the study. After birth eligibility includes delivering a live, singleton, full-term (≥37 or more weeks' gestation), healthy (has not stayed in the NICU for ≥ 3 days) infant. Mothers who have a severe medical problem that has prevented them from feeding their newborn for ≥ 1 week will also be excluded (Attachment 5a).

Recruitment will continue until the target enrollment of 4,239 women is reached and enrollment maintains the race/Hispanic origin quotas. Ideally, participants will also be distributed across geography and income levels. Any remaining participants who completed the screener but were not contacted for enrollment will be notified that they will not be able to participate. Data collected from participants who complete the screener but are not enrolled will be deleted from the system at the end of the recruitment period. All enrolled participants will complete an online consent form (Attachment 5d). The form will indicate that the study will contact them using their preferred mode of communication during the study. Respondents can request an electronic copy of their signed consent form.

Participants will complete 14 total web-based surveys over 24 months (Attachments 4b – 4p). The frequency and timing of surveys is based on the rapidly changing development of infants in the first months of life. Because of this rapid development, feeding practices and behaviors change very quickly which necessitate frequent data collection to ensure these changes are accurately and timely identified. The first survey is completed prenatally. After the baby is born, surveys are completed monthly for the first 6 months, every other month through 12 months, and then every 3 months through 24 months of life. Surveys will take between 2 minutes (birth screener) to an average of 15 minutes (monthly surveys).

To capture when the baby has been born and set the schedule for the follow-up surveys, participants will receive automated short weekly emails or texts every week starting when the mother is 37 weeks pregnant. These messages will ask the mother to complete a Birth Screener (Attachment 5e and Attachment 4c).

The timing of each survey windows is based on the need to ensure that each monthly survey is unique and does not occur during the succeeding month survey (i.e., month 1 does not get completed when the child is 2 months of age). The survey window increases in length as children get older and practices and behaviors are not changing as rapidly. Each survey has a window of time in which it must be completed; respondents may start and stop surveys during each survey window.

- Prenatal surveys must be completed before the child is born.
- For months 1 to 5 of the follow up surveys, the survey window will be a 2 week period with the survey opening on the month anniversary of the baby's birth to 2 weeks after.
- For months 6 to 10 of the follow up surveys, the survey window will be 3 weeks (from the month anniversary of the baby's birth to 3 weeks after).
- For months 12 to 24 of the follow up surveys, mothers will have a 4 week window to complete the survey (from the month anniversary of the child's birth to 4 weeks after).

Participants will receive reminders (Attachment 5g) to complete the monthly surveys on the following schedule:

- For survey months 1 to 5 (survey open 2 weeks):
    - The first reminder will occur 1 week after the initial survey invitation.
    - A second reminder will occur the day before the window closes.
- For survey months 6 to 10 (survey open 3 weeks):
    - The first reminder will occur 2 weeks after the initial survey invitation.
    - A second reminder will occur the day before the window closes.
- For survey months 12 to 24 (survey open 4 weeks):
    - The first reminder will occur 2 weeks after the initial survey invitation.

- The second reminder will occur 3 weeks after the initial survey invitation.
- A third reminder will occur the day before the window closes.

In addition, mothers will complete an on-line assessment of dietary intake using an online, automated, self-administered tool developed by the National Cancer Institute called the ASA24 shortly after the prenatal survey and around the 3 month follow up survey (Attachment 4q). A sub-sample of ~15% of participants will be asked to complete a second dietary intake at each time point during the first year. The ASA24 will take 24 minutes to complete. These recalls are unscheduled, meaning that the participant will not know the day they are to complete the survey until they receive an automated message. Participants will be invited to complete their recall up to 3 times within a 1 week period. Once the recall is started, participants have 24 hours to complete the ASA24.

All surveys will be hosted on a secure Westat server. Participants will receive a text or email invitation (Attachment 5f), depending on the mode of communication they prefer, with a unique PIN code for each survey. This ensures that participants do not need to recall a PIN for the entire study. Each survey will start on a screen that requires respondents to enter their assigned PIN code. PIN entry will be required each time a respondent accesses their survey online, and partially completed surveys will resume on the last question completed. If a respondent has any questions during a survey, she may call a toll-free number for the study and receive assistance. For the dietary recalls, participants will log onto the ASA24 website using the link provided in the text or email message and report consumption of foods, beverages and dietary supplements for the previous day.

B3. Methods to Maximize Response Rates and Deal with No Response

To maximize response rates, CDC will follow best practices for engaging and retaining survey participants using the framework of Dillman's Tailored Design Method [5]. This approach calls for activities to be tailored for the target population. For example, all surveys and correspondence with participants will be personalized. Overall, CDC will increase the benefits of

survey participation, decrease the burden of participation, and establish trust between the participant and researcher to maximize response rates for each survey and to minimize attrition.

The benefits of survey participation include:

- *Providing monetary tokens of appreciation*: Participants will receive monetary tokens of appreciation of $30 for each completed monthly survey and $50 for each dietary recall. A detailed discussion of why monetary tokens of appreciation are needed and how they will increase the response rate is provided in Supporting Statement A Section 9.

- *Providing non-monetary tokens of appreciation*: All participants will receive three free, age appropriate, e-children's books available on CDC's website. Electronic thank you notes will be sent after each survey to demonstrate appreciation for participants' efforts to help others by providing useful information (Attachment 5h). Thank you notes reinforce the notion that participants are doing an activity for more than just the incentive money. Electronic birthday cards will be sent for the child's birthday.

- *Encouraging a feeling of helping others*: Participants will be given the rationale behind this study and how the data will be used to improve the health and wellbeing of babies and their families in the future.

Decreasing the burden associated with participation include:

- *Minimizing survey length*: Monthly surveys take an average of 15 minutes to complete. This was based on testing by nine mothers with children less than 24 months of age and used a skip patterns that would ensure the most questions were answered. The median time to complete the ASA24 is 24 minutes [6].

- *Making participation convenient*: Participants will receive embedded links to the survey website in emails or texts. A unique PIN code for each survey will be provided. Clear deadlines will be communicated for each survey. Brief automated reminders sent via text or email will be sent to make compliance easier.

- *Utilizing effective visual design principles*: Adaptive designs will be used. Surveys will be optimized to display based on the type of device being used (i.e., laptop, tablet, or mobile phone). Testing of the programmed survey across different devices and web browsers will be done to ensure that the survey questions are visually appealing on different devices and perform appropriately.
- *Providing easy updating of contact information*: Contact information will be updated at the end of each survey. This will reduce the risk of risk of losing participants whose contact information changes during the study period. Multiple methods of contact information (i.e., electronic and phone) will be collected. A secondary mode of contact will be used only if the preferred contact method fails. Lastly, a participant will receive a follow-up letter to update contact information if primary and secondary modes of contact bounce back (Attachment 5j).

Establishing trust between the researcher and the participant includes:

- *Providing sponsorship information*: Participants will be informed that this study is sponsored by the Centers for Disease Control and Prevention.
- *Providing clear expectations*: Participants will be given clear and consistent communication about responsibilities during the study (i.e., the number, length, and timing of surveys; and short electronic reminders at expected intervals about when survey requests will be issued or when a survey was missed) (Attachment 5g and Attachment 5i). Participants will be informed that all information provided will be confidential and information that identifies them will not be included in any data files.
- *Providing contact information*: Participants can contact the data collection contractor, Westat, via a help desk to answer any questions. Information on how to reach the help desk will be displayed on the bottom of the survey screens and on their personal webpage on the study website.

- *Providing a way to stop participation*: Participants can opt out of the study by calling a phone number that is on each survey invitation. If a participant asks to leave the study, the reminder messages will stop immediately, and the status will be noted in the study management system. The participant will receive a refusal conversion letter (Attachment 5k).

Estimates of response rates and rationales for expected response rates have been previously discussed in Section B1.

All non-response will be tracked for each survey. At each survey, the different types of non-response (i.e., asked to be dropped from the study, did not complete the survey within the designated timeframe, could not be reached to be informed about the survey, etc.) will be assessed. Analyses of non-responders can occur at each survey time point to determine if this impacts findings.

The proposed sample is not nationally representative.

B4. Tests of Procedures or Methods to be Undertaken

The survey questions in FMB&M- IFPS III are similar to the IFPS II questions ("Infant Feeding Practices Study II," OMB No. 0910-0558, exp. 12/31/2007) with some modifications as well as additions of new questions on different topic areas. A sample of new or modified questions have been cognitively tested with nine women who had children 24 months of age or younger. Based on cognitive findings, questions were modified to address any problems with question comprehension or misinterpretation of the questions' intent. In addition, usability testing was conducted with nine women who had children less than one year old. Usability testing was done on multiple device modes (e.g., laptop, mobile phone, or tablet) to determine if question format was efficient and effective on the different types of electronic devices. Usability testing indicated that mobile phones were the preferred device and question formatting was taken into consideration to aid the participant in answering (e.g., provide pre-populated numbers in a question that requires a numeric response). The web pages will be designed using a responsive design approach that will detect the screen size of the respondent's screen and facilitate completion of the surveys on laptops, mobile phones, and tablets.

The ASA24 uses a multiple-pass approach to guide participants through the survey. This approach is based on the United States Department of Agriculture's Automated Multiple-Pass Method which has been validated [7]. The system asks standardized, detailed questions about the form, preparation and additions to foods, and uses images to assist participants in reporting portion size. The ASA24 participant website is 508-compliant, offering usability with assistive technologies, is available in English or Spanish, and is accessible using a computer, tablet, or a mobile device. The ASA24 displays a brief user orientation the first time a participant accesses the site, and provides optional help screens throughout the survey.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The survey instruments, data collection procedures, and statistical analysis plan were designed in collaboration with researchers at Westat. The following individuals from Westat were involved:

- Nancy Weinfield, *no longer with Westat*
- Crystal MacAllum, *now retired*
- Jill DeMatteis, JillDeMatteis@westat.com
- Amelia Burke-Garcia, AmeliaBurke-Garcia@westat.com
- April Fales, AprilFales@westat.com

Westat will conduct FMB&M- IFPS III including data collection and analysis, in consultation with CDC. Ms. Janice Machado will serve as Westat's Project Director, Dr. Christine Borger will serve as the Deputy Project Director for analysis, Ms. Bibi Gollapudi will serve as the Deputy Project Director for survey operations and Dr. Jill DeMatteis will serve as the statistician. Their contact information is:

- Janice Machado, JaniceMachado@westat.com
- Christine Borger, ChristineBorger@westat.com
- Bibi Gollapudi, BibiGollapudi@westat.com
- Jill DeMatteis, JillDeMatteis@westat.com

CDC collaborated on all aspects of the study design and development. The following individuals were involved:

- Heather Hamner, hfc2@cdc.gov
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