Followup Study for Infant Feeding Practices Study II

0910-NEW

SUPPORTING STATEMENT

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe is all women who participated in the Infant Feeding Practices Study II and completed at least two questionnaires after their infants were born. The total number of women who qualify is 2,847. It is expected that the contractor will be able to find current contact information for 2,562 of these mothers, and that 2,051 will answer the questionnaire (80%) either by mailed questionnaire or by telephone interview.

Data analysis will be conducted using SAS 9.1 statistical software. A statistical power analysis based on Casagrande, 1978 and Fleiss 1981 via the calculations at the website http://department.obg.cuhk.edu.hk/researchsupport/Sample_size_Comp2Prop.asp

indicates that if we test with 95 percent confidence, we will have 80 percent power to detect differences in two groups of 2.5 to 4 percent with about 900 respondents in each group when the overall prevalence of an outcome is 10 percent or less, which is likely to be the case for a number of health outcomes. We will have 80 percent power to detect a difference of 5 percent between two groups of about 1,000 respondents each when the overall prevalence of the outcome is 22.5 percent.

Specific information used for the power analysis is listed below. Because power depends in part on how many respondents are in each of the groups compared, we have first listed the percentage in various feeding characteristic groups, as found in the IFPS II.

Feeding characteristic	Prevalence In IFPS II (%)	Number in each dichotomous group in the Follow Up Study based on total sample size of 2051
Fed cow milk at 10-1/2 months	17	349/1702
Fed other allergenic foods at 10-1/2 months	30	615/1436
Exclusively breastfed at 3 months	36	738/1313
Fed infant expressed milk	60	1231/820
Breastfed at least 6 m	50	1025/1026
Fed breast milk as 100% of milk feeds at month 9	27	554/1497
Put to bed with a bottle (10-1/2	20	410/1641

m)		
Fed less than 1 daily serving of either fruit or vegetable in late infancy	15	308/1743

The table below shows the minimal detectable difference between select groups for various outcomes. The two feeding characteristics chosen for display are the one with half of the sample in each group (breastfed at least six months) and the one with the greatest difference in the size of the groups (fed less than 1 daily serving of fruit or vegetable in late infancy). The minimal difference for the other feeding characteristics will lie between these two. References for the prevalence estimates are given below the table.

Outcome	Prevalence in children (%)	Minimum detectable difference	
		Breastfed at least 6 months	Fed <1 daily fruit or vegetable
Food allergy, parent-reported symptoms	35 (a)	6	9
Food allergy, diagnosed	6 (a)	4	4
Asthma	6 (b)	4	4
Atopy	15 (a)	5	6.5
Childhood obesity	19 (c)	5	6.5
Inadequate intake of fruit	74 (e)	5.5	8
Poor psychosocial development (Parent reports at least some difficulties on the Strengths and Difficulties Questionnaire	45 (d)	6.5	9

a. Lee, LA and Burks, AW. Food allergies: prevalence, molecular characterization, and treatment/prevention strategies. *Annu Rev Nutr*. 2006;26:539-565.

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c. Ogden, CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA*. 2006;295(13):1549-1555.

d. Kramer MS, Fombonne E, Igumnov S et al. Effects of prolonged and exclusive breastfeeding on child behavior and maternal adjustment: evidence from a large, randomized trial. *Pediatrics* 2008;121:E435-E440.

e. Lorson, BA, Melgar-Quinonez, HR, Taylor, CA. Correlates of fruit and vegetable intakes in US children. *J Am Diet Assoc*. 2009;109:474-478.

2. Procedures for the Collection of Information

Data for this study will be collected in two ways. Most respondents will complete mailed questionnaires, but those who do not respond will be administered a telephone interview if possible. A number of contacts are planned with the respondents, and different versions of the materials will be needed depending on whether the person is a member of the mail or the internet panel because the incentive structure is a little different for the mail and internet panel members. The incentive description, and therefore material that mentions the incentive, will also be different if the respondent is a former panel member (i.e., currently a non-panel member). The contact points and materials for each subsample are listed in Appendix A.

All eligible participants from the Infant Feeding Practices Study II (IFPS II) will be sent a personalized pre-notification letter. If the participant is still a panel member, the letter will be signed by the panel spokeswoman alias, Marie Brighton. If the person is not a current panel member, the letter will be signed by the Vice President of Synovate. This letter will serve two purposes. First, it will inform the respondents about the nature and purpose of a questionnaire that will be sent to them shortly thereafter and will encourage their cooperation. Second, returned letters will give the contractor a list of people who have changed addresses since the last data collection of the IFPS II so that their current contact information can be traced. The contractor will use commercial tracing organizations to find updated contact information. The expected successful contact rate is 90% of the total eligible sample. The pre-notification letters are shown in Appendix B.

An introductory letter (Appendix C) will be mailed to the sample with the questionnaire (see Appendix D for the pilot version of the questionnaire) and a short demographic survey (Appendix E) for women who are no longer panel members. Two weeks later, post card reminders will be mailed (Appendix F). One month after the initial questionnaire mailing, a second complete package will be sent to non-respondents, along with a revised introductory letter **(**Appendix G**).**

The completed mail questionnaires will be sent by respondents directly to the contractor, who will scan them and import them into Fast and Accurate Questionnaire Scanning System (FAQSS) to capture the data. FAQSS is used by the Census Bureau and is regarded as the best data capture system available. It can read marks in check boxes and numeric responses. Use of this system eliminates error from human data entry. Verbatim comments by respondents will be hand-entered by scanning operators and then coded in collaboration with FDA's Project Officer.

Two weeks after the second mailing, non-respondents will be contacted for a telephone interview to collect the same information that was requested in the mail questionnaire, including the demographic data if necessary. (See Appendix H for the introduction to the telephone interview.) The telephone interview will be based on the mailed questionnaire, which will be used to program a computer assisted telephone interview. Specially trained professional interviewers will conduct the telephone interviews. Quality control will be assured by periodic monitoring of on-going interviews throughout the study. The telephone interview data will be entered into a data base during the interview.

~~Data analysis will be conducted using SAS 9.1 statistical software. A statistical power analysis based on Casagrande, 1978 and Fleiss 1981 via the calculations at the website http://department.obg.cuhk.edu.hk/researchsupport/Sample_size_Comp2Prop.asp~~

~~indicates that if we test with 95 percent confidence, we will have 80 percent power to detect differences in two groups of 2.5 to 4 percent with about 900 respondents in each group when the overall prevalence of an outcome is 10 percent or less, which is likely to be the case for a number of health outcomes. We will have 80 percent power to detect a difference of 5 percent between two groups of about 1,000 respondents each when the overall prevalence of the outcome is 22.5 percent.~~

3. Methods to Maximize Response Rates and Deal with Non-response

Because this is a follow up study with a sample based on respondents to a previous study, each respondent is critically important to the success of the data collection. As noted in B2, all sample members will be mailed a pre-notification letter as the first contact for this study. The total sample will be mailed a post card reminder two weeks after the initial mailing of the survey packet. Those who are non-respondents will be sent a second complete package one month after the initial questionnaire mailing, and two weeks after the second mailing, the remaining non-respondents will be contacted for a telephone interview. The number of responses is expected to be 2,051, which is a response rate of 80 percent based on the 2,562 mothers on whom we expect to obtain current contact information.

Our estimate that we will be able to find contact information for 90% of the respondents to the IFPS II is based on several factors. First, the IFPS II sample was relatively stable in their residence, given that they were on a consumer opinion panel and that a very large percentage of them answered numerous questionnaires by mail when their child was an infant. It is likely that most will continue to be residentially stable and therefore easier to trace than some elements of the US population. Second, the panel administration has contact information for all of them that was current about five years ago because the IFPS II continued through the child's first birthday. In some instances, the panel will also have names of other family members.

A description of the tracing procedures follows. Drawing upon Experian/MSG's in-house Business and Household databases, its GENESYS system provides sample/list

enhancement services specifically focused on the needs of researchers. Computerized forward and reverse matching appends phone numbers, addresses, and demographic information to lists. We plan to use Experian/MSG's Enhanced Match, which, on average yields 10-15% more matches. To conduct the Enhanced Matching, MSG uses 4 databases to append addresses and phone numbers. The first database is the TARGUS database. TARGUS has hundreds of data sources and a unique membership in the U.S. Telecommunications Network. The database is updated several times daily. Any records that do not return a match are run against the 3 consumer databases MSG has in-house including: InfoUSA, Experian, and Acxiom to locate a match. These databases are compiled from various sources including white page listings, public information, and other proprietary sources.

As an additional step, Synovate will verify the mailing address for each sample member by performing a look-up of name and address records with the National Change of Address (NCOA) files. ZIP codes will be updated on existing addresses, and street name designations will be brought into compliance with Postal Service requirements, increasing the deliverability and thereby increasing the contact rate. We will also obtain and append telephone numbers for sample members, where available.

We have several reasons for assuming that this study will have a response rate of 80 percent. The first reason is that these same people had high response rates in the infant part of the sample, which occurred during a time that most mothers find challenging. The response rates were 82.9% for the birth screener, 76.9% for the neonatal (first month) questionnaire, and 83.1% for the month 2 questionnaire. In the IFPS II, 76.6 percent of respondents answered at least seven of the total twelve questionnaires. We believe that many respondents will be more inclined to respond because they were part of the earlier study, i.e., because they have already committed time to the study. They all have experience answering the type of questionnaire we will send and doing so by mail. In addition, the current response rate for telephone surveys in the panel is relatively high and will be able to obtain data from many of those who do not answer by mail.

This vendor's current average panel response rate for mail studies is about 40% without an incentive and its response rate for telephone studies is about 80%. The contractor estimated a higher than average mail response rate (60%) because we are offering an incentive, because respondents should find this survey more interesting than average, and because of the past experience respondents have with this study. They estimated a lower than average telephone response rate [(513/1024) = 50%] because the questionnaire is longer than most they administer and because they will be calling respondents who were unable or unwilling to answer by mail.

The incentive offered for this study, either $10 or $15, is about average for a 20 minute survey. The incentive usually offered depends on the survey topic and the expected respondent interest in the subject. For this study, interest is expected to be high and therefore the incentive will be adequate even for the respondents that take a little longer to complete it.

4. Test of Procedures or Methods to be Undertaken

The questionnaire is based on previously used questions to the extent possible, modified as necessary for written administration. This decision will enable us to compare some estimates with nationally representative data and will reduce the amount of time needed for developing questions and pre-testing. In all cases, we have determined that the questions are in the public domain or we have explicitly obtained permission to use them. Table 3 shows the source of the questions for each topic.

Table 3. Source of questions for Follow Up Study, IFPS II

Topic	**Source of questions or style of questions**
Outcomes	
Psychosocial development	National Survey of Children's Health (NSCH); National Health Interview Survey (NHIS); Strengths and Limitations Questionnaire (used in the PROBIT study (Kramer et al., 2007)) and in the Millennium Cohort Study (Sacker et al., 2006) ; new questions
Child overweight or obesity	National Health and Nutrition Examination Survey (NHANES); new questions
Dental caries	NSCH; new questions
Child health, asthma	NSCH; custom analysis of 20 most frequent reasons children 6 to 7 years old visited physician offices in 2008 (National Ambulatory Medical Care Survey); NHIS; NHANES
Physical development	NSCH
Child food allergy	Infant Feeding Practices Study II (IFPS II); Food Safety Survey; new questions
Food group consumption	NHANES diet screener; IFPS II; Harvard Children's Nutrition Questionnaire, new questions;
Maternal overweight or obesity	IFPS II
Confounders	
Child care arrangements	NSCH
School arrangements	New questions
Cognitive stimulation at home	HOME questionnaire (Bradley et al., 2001)
Dental hygiene	New questions
Physical activity of child and mother	NSCH; new questions
Screen time	NSCH; new questions
Sleep patterns	New questions

Eating environment	Youth Physical Activity and Nutrition Survey (YPANS)
Child Eating Behavior	Child eating behavior questionnaire (Wardle et al., 2001)
Maternal control of child's eating	Child Feeding Questionnaire (Birch, et al., 2001)
Presence of pets	New question
Exposure to inhaled contaminants other than cigarette smoke	New questions
Family medical history	IFPS II; new questions
Maternal depression	NHANES (10 item) (Radloff 1977)
Exposure to cigarettes	IFPS II
Pregnancies subsequent to sample child	National Maternal and Infant Health Survey follow up
Maternal employment	IFPS II; new questions
Health insurance	New question
Participation in government nutrition programs	NSCH

During the questionnaire development phase, cognitive interviews were conducted with six respondents to test the new and modified questions. Although many of the questions are from previous data collection instruments, the total questionnaire will present the questions in a different context from the original, and for many questions, the form of collection will be changed from an in-person interview to a written questionnaire or a telephone interview. Therefore, a pilot study of 91 mail and 9 telephone respondents will be conducted to test the questionnaire after OMB approves the data collection. It is expected that the pilot test will refine some of the questions but not result in substantial changes in the questionnaire. The materials for the pilot study are included in the Appendices showing each specific material for the main study, except that the debriefing questionnaire is shown in Appendix I.

The method for the pilot test will be similar to that of the main study with a few exceptions because of the different sample and different purpose. The contractor will select the sample to match the IFPS II sample on the demographic characteristics of race, income, education, region, household size, and age plus 6 years (because the IFPS II sample will be contacted six years after the prenatal questionnaire, on which we asked age). The contractor will identify 250 female panel members that match the above demographic characteristics and that have a 6-year-old child (because the IFPS II sample will be contacted when the target child is 6 years old). A low response rate has been assumed for the pilot study because it is urgent to obtain the target sample size of 100 completed questionnaires in a short period of time.

A prenotification letter (Appendix B) will be sent to the selected sample. Half of the sample will be offered an incentive of $10 value in points and half will be offered $15

in points value so that we can test whether a higher incentive yields a higher response rate. The panel administrators recommended the two different points values based on the length of the survey. A few weeks after the prenotification letter, the sample will be sent an introduction letter (Appendix C) along with the pilot questionnaire (Appendix D) and the debriefing questionnaire (Appendix I). Note that the estimated burden for the pilot study is greater than for the main study because we are asking them to complete the debriefing questionnaire in addition to the study questionnaire. Two weeks after the questionnaire mailing, a post card reminder (Appendix F) will be sent to all sample members. A week later, nine sample members who have not responded will be contacted for a telephone interview to collect the same information that was requested in the mailed questionnaire, using the telephone introduction shown in Appendix H. These mailings and the telephone interview timing are like those proposed for the main study except that in the main study, we will have in addition a second mailing of the questionnaire.

The unedited data from the pilot study will be made into a SAS data base and analyzed for amount of item non-response, inconsistent responses between and within questions, incorrect skips, and multiple responses given to questions that request only one response. The responses to the debriefing questionnaires will be read and coded manually.

We will obtain the following information from analyzing the answers to the pilot test:

- whether the skip instructions are clear (by analyzing those who should have skipped compared with those who did skip each question)
- whether any questions generate a large amount of non-response (by reviewing the number of missing responses for each question)
- whether different questions that ask similar information result in inconsistent responses (by checking the responses of such questions against each other)
- whether questions with multiple responses have inconsistent responses or have a written response in the "other" category that is the same as one of the listed responses
- whether any response options are given by either no one or everyone
- whether items that we believe should have only one answer receive multiple responses.

If we find that any skip instructions are not clear, we will consider using larger or bolder font for the instructions, rearranging questions to minimize the number of questions to be skipped or the location of the place to begin after a skip, or work with the contractor to identify other possible remedies.

If any questions receive a large amount of non-response, we will examine the characteristics of the non-responders to determine whether the question might not apply to their situation; we will examine the placement of the item (for example, was it the beginning of continuing after a skip, or did it have other such placement characteristics that might cause nonresponse?); we will examine cognitive interview responses to the

question to determine whether they indicate a lack of clarity that we had not addressed. The remedy we decide on will depend on what we determine to be the cause of the non-response.

If similar questions generate inconsistent responses, we will evaluate whether respondents might misinterpret one of the questions by reviewing the context of the two questions and by examining the characteristics of the respondents with inconsistent responses; we will examine cognitive interview responses to the question to determine whether they indicate a lack of clarity or possible multiple interpretations that we had not addressed. The remedy may be a rewording of one of the items or a rearrangement of one of the questions. We will use similar procedures if responses within a multiple response question are inconsistent (for example, the respondent chooses an option and also chooses "none of these").

If some response options are chosen by no one, we will evaluate whether the option is likely to be needed in a larger sample. If experts agree that it probably will have a very low or zero frequency in the main sample, we will delete the response option. Because more white space is better in a written questionnaire, there is a cost to keeping options that are not needed. However, if the item measures a low incident condition of importance, we will keep it. If some questions are answered the same by everyone, we will evaluate the need for the question in the main study. If the characteristic is obvious and not likely to vary, we will delete the question.

If some items that we thought should have only one answer receive multiple answers, we will evaluate the combinations of responses chosen and the characteristics of the respondents who give the response to determine whether the question needs to be revised to a "mark all that apply" type of response or if it should be clarified or be given additional response options.

We will obtain the following information from the debriefing questionnaire sent with the pilot questionnaire. Most of this information was obtained from the respondents to the cognitive interviews, but we want to know for a larger number of mothers:

- Range of length of time it takes respondents to answer the total questionnaire (self-reported in response to a specific question on the debriefing questionnaire)
- whether most mothers in this sample have a scale for measuring a person's weight at home and what they did about answering the child's weight question if they did not have a scale
- what percent of mothers in the pilot sample had difficulty with the instructions for measuring height
- what percent of mothers found it hard to remember over the 12 month reference period
- what kinds of situations mothers have that cause any questions to be hard to answer.

If we find that the questionnaire takes longer than the 20 minutes on average that we expect, we will consider the following possible actions: Increase the response burden estimates we have given in the supporting statement; increase the incentive; delete some questions to shorten the questionnaire. If we believe that we must shorten the questionnaire, we will consider deleting items with these characteristics: request details about some low prevalence conditions, have no variation in the pilot data; ask for lower priority information.

If we find that some mothers do not have a scale and that those who did not own a scale also did not have access to a scale (for example, at a friend's or relative's home), we will first evaluate whether the level of missing data that will be caused by this lack is acceptable. If the number missing a scale is too large, we will consider the possibility of adding money to the contract to fund obtaining permission from the mothers and then contacting their health care providers about the child's weight. This option will require additional review by FDA's Research Involving Human Subjects Committee. Because all six of the respondents to the cognitive interviews had scales, we expect that nearly all mothers will have a scale.

If mothers have difficulty with the instructions for measuring height, we will simplify the instructions and then test the new instructions with several mothers whom we will obtain from the panel in the same manner as the cognitive interviews. Because none of the six respondents to the cognitive interviews had difficulty with the instructions, we believe that nearly all mothers will be able to follow them easily.

If mothers indicate that that they had difficulty remembering over the 12 month reference period or write in other problems with some questions, we will evaluate the respondent characteristics, the reason for the difficulty, if given, and the details of the mother's special situation, if given. We will determine how likely it is that the difficulty applies to many other mothers and whether we can clarify the question without changing it substantially before changing the item. The mothers in the cognitive interviews were able to recall information over the reference period.

We will compare response rates between the two groups that receive the different incentive amounts to see if the larger incentive leads to a higher response rate for this type of respondent (by comparing response rates of the groups that receive the $10 and the $15 incentive). With a sample size of 50 in each group, and assuming an overall 80 percent response rate, we will be able to detect a significant difference of 23% or greater at $p<.05$ and 80 percent power. If the two incentive levels yield a similar response rate, we will use the lower amount for the main study.

The telephone interview part of the pilot test will show us how long the questionnaire takes when administered orally, give an indication of whether respondents react favorably to being called about a questionnaire they received in the mail but did not complete in writing, and show whether any of the questions need to be re-worded in order to obtain the information orally. For example, some of the multiple response questions may be better understood if each response is answered. We will ask the telephone

interviewers to give their general impressions of how well each interview went and whether they recognized any particular problems. However, their training is for consistent administration of a questionnaire, not for probe questions as one would do in a cognitive interview, and therefore, we will not ask them to follow up with any questions in addition to those in the questionnaire. An additional reason not to add questions to the telephone interview is that we want to test the length of the oral administration of the questionnaire. Because we are looking for areas between the two types of data collection that may have large differences, we believe that we can obtain the information we need from a small number of telephone respondents.

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

The data will be collected by Synovate under a task order, and social scientists from FDA and Centers for Control and Prevention will conduct the data analysis. The names and contact information for the individuals who have consulted on statistical aspects of the study are listed in the table below.

Name	Title	Organization	Telephone number	Email
Valerie DiPaula, Ph.D.	Project director	Synovate	703-663-7243	Valerie.fuller@synovate.com
Sara B. Fein, Ph.D.	Consumer Science Specialist	FDA/CFSAN	301-436-1824	Sara.fein@fda.hhs.gov
Cary Chen, MPH	Staff Fellow	FDA/CFSAN	301-436-1844	Cary.chen@fda.hhs.gov
Ann DiGirolamo, Ph.D., MPH	Senior Technical Advisor, Early Childhood Development and HIV/AIDS	CARE USA	404-979-9119	Adigirolamo@care.org
Rouwei Li, M.D., Ph.D.	Epidemiologist	CDC/Division of Nutrition, Physical Activity, and Obesity	770-488-8126	Ril6@cdc.gov
Laurence Grummer-Strawn, Ph.D.	Branch chief	CDC/Division of Nutrition, Physical Activity, and Obesity	770-488-5702	Lxg8@cdc.gov

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