Supporting Statement

Survey of Food Safety and Nutrition Information Provided to Pregnant Women by Health Care Providers and WIC Educators

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Universe and Sampling

The sample universe for this study is practicing health care providers from four separate professions: 400 OB/GYNs, 200 nurse practitioners, 200 nurse midwives, 200 physician assistants, plus 200 WIC educators. The sample will include only those who, at the time of data collection, provide their services to pregnant women.

The respondents for each health care provider profession will be randomly selected from the best available, national lists. The lists for OB/GYNs, nurse practitioners, nurse midwives, and physician assistants will be purchased from Medical Marketing Services, a company that specializes in maintaining these lists.

The sample of OB/GYNs will be randomly drawn from the 31,100 practicing, office-based OB/GYNs listed in the American Medical Association's Physician Masterfile. Office-based OB/GYNs excludes those in teaching, administration, research, or a hospital setting.

This file includes all physicians practicing at least part time in the United States. This technique for sampling physicians was used in the 2002 FDA national telephone survey Assessment of Physician Attitudes Toward Direct-to-Consumer (DTC) Promotion of Prescription Drugs.

The sample of nurse practitioners will be drawn from a list derived from state registries, surveys, and conventions. The sample will include only the 7,790 specializing in obstetrics/gynecology.

The sample of nurse midwives will be drawn from the membership list of the American College of Nurse Midwives. This list includes 9,370 Certified Nurse Midwives (CNMs). CNMs are registered nurses who have received supplemental education and national certification in maternity and women's health care.

The sample of physicians' assistants will be drawn from the 900 members and non-members of the American Academy of Physician Assistants specializing in obstetrics/gynecology.

There is no comprehensive, national list of WIC educators. However, the USDA maintains a listing of the approximately 2,200 WIC agencies serving the United States, categorized by region and state. Therefore, to reach WIC educators the study will use a stratified two-stage sample.

Ten strata will be created for the sampling plan: New York City; Los Angeles; a

stratum composed of the next eleven largest cities based on the July 2005 Census estimates; and seven strata for the remaining portions of the regional groups used by the USDA to list WIC agencies. The strata were selected to overcome potential problems that could occur due to considerable heterogeneity in the size of WIC agencies across the country. For example, among the 13 largest cities, Los Angeles, Philadelphia, and Jacksonville have only one WIC agency each, while New York City has 45. In some rural areas (including Indian reservations), one educator may be the sole provider for multiple agencies. As such, stratification will be necessary to guarantee adequate representation of WIC educators from larger cities. In any given state, there tends to be many agencies throughout the state and relatively few agencies within the largest cities. If some city strata are not created, then there would be a problem whereby WIC educators from 12 of the 13 largest cities would have small probabilities of being selected in the survey.

The proportion of WIC participants per state will be used to estimate the size of each stratum. An estimate of the percentage of WIC participants in large cities will be made using the percentage of WIC participants in the state and adjusting on the basis of the ratio of city to state population. The goal will be to give each of the 10 strata a sample size that is roughly proportional to its proportion of U.S. WIC participants. The three city strata account for almost 10 percent of the U.S. population. The target sample sizes will be about 20 from the 3 city strata (5 from New York City, 4 from Los Angeles City, and 11 from the third cities stratum) and 180 from the remainder of the country.

In the first stage of sampling, 50 agencies (primary sampling units) will be selected using simple random sampling and an allocation per stratum that is roughly proportional to stratum workload. Each selected agency will then be asked to provide a list of all of its WIC educators. In the second stage, the educators (second stage sampling units) at each selected agency will be selected randomly. The first selected educator from an agency will be chosen using simple random sampling from that agency's list. Additional educators will be selected using probability proportional to remaining size (after one educator has been selected), where size is defined as the number of WIC educators at each agency. This can be achieved by combining all of the lists from a stratum into a single list and applying simple random sampling to the remaining educators on that list. This technique will also facilitate additional sampling that may be required to adjust for non-responses.

By guaranteeing that at least one educator is contacted from each agency that provides a list, the sampling plan design will reach as many agencies as possible, given budget constraints, and obtain better national estimates as it is likely that educators within a particular agency will have similar knowledge and follow similar practices.

B2. Procedures for Collecting the Information

Each respondent will answer questions provided via a mail survey. The questionnaire will take approximately 10 minutes to complete.

B.3 Methods to Maximize Response Rate and Deal with Non-Response

FDA plans to take a number of steps to ensure a high response rate for this survey.

- All physician offices will be called prior to sending the survey to let them know that a survey will be coming in the mail shortly.
- All surveys will be sent via priority mail. This will help ensure that the survey reaches the proper respondent and that it will be separated out from other mail.
- The survey package will include an introduction letter describing the purpose of the study and the importance of a response. When the final, approved survey instrument is available, we will request endorsement by the relevant health care provider professional organizations and National WIC Association and include this in the letter. We will also use the cognitive interviews to determine who at FDA should sign the introduction letter to health care providers and WIC educators to encourage participation in the survey.
- Each survey will be designed to ensure ease of completion.
- The survey will take no more than 10 minutes to complete.
- A stamped envelope with the return address already printed will be included, facilitating ease of returning the survey.
- The questions will be extensively pre-tested with both cognitive interviews and a pre-test to ensure that each sampled group finds the questions understandable and meaningful. A well worded questionnaire on topics of interest to the selected groups will help encourage participation.
- A follow-up survey and letter will be sent to all selected participants who have not returned the survey after 3 weeks. This will help response rate, by providing a second copy to those who may have misplaced the survey.
- Each respondent will be paid an incentive for returning the questionnaire. Previous research has shown that incentives are effective at increasing response rate for these groups.

B.4 Tests, Procedures or Methods Used

Both cognitive interviews and pre tests will be conducted prior to fielding the entire survey. These tests of procedures will help ensure that the questions are understandable and meaningful to respondents and the answer categories complete and mutually exclusive.

A total of 16 cognitive interviews will be conducted via the phone. Each interview will last no more than 45 minutes. Four of the interviews will be with practicing OB-GYNs, and the remaining 12 with an even mix of nurse practitioners, nurse midwives and physician assistants – all currently in practice and specializing in obstetric care –and with WIC dieticians. Cognitive interview participants will be recruited by the same lists used survey participants. Potential participants will be recruited by phone by the contractor. An incentive for participation will be offered to interviewees. The amount of incentive is approximately related to the opportunity cost of time for physicians ($250) and other health care providers and WIC educators ($150). A pretest that includes 15 completed surveys with each of the sampled populations will be completed. This pretest study will allow us to test the mechanism for sending out

surveys, receiving completed surveys and recording the data. The pretest data will be reviewed prior to conducting the full survey.

The data from the full survey will be tabulated and analyzed to address the issues covered in the questionnaire. Cross tabulation of results and comparison of mean responses between the groups of health care providers will be used to examine the advice health care providers give pregnant women, the sources from which they receive the information, and the sources from which they prefer to receive the information.

B.5 Consulting Statistician and Contractor

The contractor, Synovate, Inc. will collect the data for the Survey of Food Safety and Nutrition Information Provided to Pregnant Woman by Health Care Providers and WIC Educators on behalf of the Food and Drug Administration's Center for Food Safety and Applied Nutrition and the Environmental Protection Agency, as a task order under the Quick-Turn-Around Research Services contract. Leigh Seaver, Ph.D., is the Senior Study Director for Synovate, telephone (703) 663-7225. Conrad J. Choinière, Ph.D., HFS-727 is the Project Officer, telephone (301) 436-1844.

References

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