WIC Infant and Toddler Feeding Practices Study: protocol design and implementation

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ABSTRACT
The federal Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which began in the 1970s, has undergone revisions in the past several years, including revision to contents of the supplemental food “packages” in 2009 based on recommendations provided by an Institute of Medicine (IOM) committee of The National Academies. In 2010, the IOM held a workshop to examine and recommend research priorities for the program. The overall purpose of the current (ie, second) WIC Infant and Toddler Feeding Practices Study (ITFPS-2) is to conduct a nationally representative, longitudinal study of contemporary WIC infant and toddler feeding practices. This study will update earlier studies and collect information on variations in WIC program components. The study will also assess ways in which WIC may address obesity in early childhood and examine changes in feeding practices that may stem from the 2009 food package revisions. The sample is drawn from the universe of WIC sites nationally, excluding only those with an insufficient volume of eligible participants. Eligibility for the study includes the ability to be interviewed in English or Spanish. Approximately 8000 women and infants are being sampled, and ~4000 are expected to participate. Eligible women are invited to participate during their WIC enrollment visit, and informed consent is sought. The design includes a core sample to be followed until the infant reaches age 2 y and a supplemental sample to be used in some cross-sectional analyses to ensure adequate representation of groups that might be underrepresented in the core sample. Participants will complete up to 11 interviews (core sample) or 4 interviews (supplemental sample) each except for the prenatal interview, which includes a quantitative 24-h recall of food intake for the infant. Eighty sites have been sampled across 26 states and 1 territory. Instruments have been developed and pretested in both English and Spanish, and interviewers have been rigorously trained. Recruitment and interviewing began in July 2013. This study will provide the only current large-sample longitudinal feeding data available on a nationally representative sample of infants in low-income families, and results will be available to inform the 2020 Dietary Guidelines for Americans for the 0- to 24-mo age group. This study was registered at clinicaltrials.gov as NCT02031978.

INTRODUCTION
The Birth to 24-mo (B-24) Project is a collaborative effort between the USDA and the Department of Health and Human Services that seeks to develop dietary recommendations for children from birth to 24 mo of age. The efforts of the B-24 project will fill an important gap and provide consistency in maternal, infant, and toddler nutrition advice given across government and external organizations. The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) serves a large segment of the population of interest to the B-24 project, and the data gathered via the present study (the second WIC Infant and Toddler Feeding Practices Study, ITFPS-2) will provide a basis for evidence-based decision making that will inform the project.

WIC is administered by the Food and Nutrition Service (FNS) of the USDA. The WIC program was established in 1972 by an amendment to the Child Nutrition Act of 1966. WIC has greatly expanded since its inception. In fiscal year 2011, WIC served 9 million participants at an annual cost of $7.1 billion (1). WIC is funded by grants to state agencies subject to annual appropriation, ie, it is not an entitlement program.

WIC was designed to improve the health of nutritionally at risk, low-income pregnant, breastfeeding, and postpartum women, infants, and children up to 5 y of age. Program participants receive food supplements and referrals to health and social services, and the child care providers receive nutrition education. WIC encourages breastfeeding as the best source of infant nutrition and currently allocates funds for breastfeeding promotion and support activities.

To receive WIC benefits, an individual must be categorically eligible; that is, the person must be a pregnant, breastfeeding, or postpartum woman; an infant up to the age of 1 y; or a child aged

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3 Supported by contract no. AG-3198-B-11-0020 from the Food and Nutrition Service, USDA.
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5 Abbreviations used: B-24, Birth to 24-mo (Project); FDA, Food and Drug Administration; FNS, Food and Nutrition Service; IFPS-1, First WIC Infant Feeding Practices Study; IFPS-2, Infant Feeding Practices Study II; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

First published online January 29, 2014; doi: 10.3945/ajcn.113.073585.
WIC PARTICIPANTS

Using data from the WIC Participant and Program Characteristics 2010 report (1) and a project on estimating the number of WIC-eligible individuals (2), the USDA estimates that ~40% of women having live births in the United States participated in WIC during pregnancy. In addition, WIC provides support to half of the infants as well as ~40% of 1-y-olds in the United States (2). Almost 70% of WIC participants reside in households with an income below the federal poverty level. The average annual household income of WIC participants is $16,449 (1). Additional facts about pregnant women who are served by WIC include the following: ~10% are <18 y of age, 28.9% of pregnant WIC participants have less than a high school diploma or General Education Development test, 39% are Hispanic or Latina; approximately one-third (32.7%) of pregnant women receiving WIC identify their race as other or multiracial (3).

NEED FOR THE STUDY

This study is needed to update information in the WIC Infant Feeding Practices Study (IFPS-1), which was conducted in the fall of 1994, and collected data only on infants (4). Since that time, WIC infant feeding practices may have changed in important ways, particularly because the new WIC food packages were introduced in 2009 following recommendations from an Institute of Medicine committee for revision of the supplemental foods provided (5), and the program has instituted a greater emphasis on nutrition education and breastfeeding.

Recent infant and toddler feeding studies such as the Nestle Nutrition Institute’s Feeding Infants and Toddlers Study (FITs 2008) (6) and the Food and Drug Administration’s (FDA’s) Infant Feeding Practices Study II (IFPS-2) (7) have collected important data; however, they did not focus on the WIC population, which is unique for several reasons, including being low income and at nutritional risk. The WIC program reaches >50% of all infants born in the United States, and thus representative data on this population are important for setting policy. One analysis (8) has compared WIC participant infants and toddlers to nonparticipants within the Feeding Infants and Toddlers Study and found, similar to previous data, that WIC participant children were less likely than nonparticipants to be breastfed, that the proportion with inadequate nutrient intakes was extremely low, and that mean energy intakes exceeded mean energy requirements with WIC participant children having the greatest excess.

Several recent studies (9–11) have compared the pre- and post–food package changes in behaviors of WIC families. One, based in Connecticut, compared access to healthy foods based on store inventories in late 2009 and early 2010 (9) and found increases in access to healthy foods (defined as whole grains, fruit and vegetables, and lower-fat milk) after food package changes. Another study (10) more directly assessed the diets of WIC participants in New York State in 2008 and 2011 and identified favorable changes in breastfeeding initiation; delayed introduction of solid foods; increased fruit, vegetable, and whole-grain consumption among children; and shifts from whole milk to low/nonfat milk for 2- to 4-y-olds. The third study (11) directly surveyed diets of WIC families before and after the late 2009 change; this study was limited to California but involved 2 large cross-sectional samples (~3000 each) from September 2009 and March 2010; differences were significant in the expected directions, with increased whole-grain consumption, less whole-fat milk and more reduced-fat milk consumption for women and children ≥2 y old, and small but significant increases in fruit and vegetable consumption.

A recent Institute of Medicine workshop on planning a WIC research agenda (12) recommended a national dietary study in WIC participant infants and toddlers, and the present study is a direct outgrowth of the recommendations from that workshop. The primary contractor is Westat (Rockville, MD) with partnerships with the University of California (Los Angeles and Berkeley) and the Altarum Institute. This study was registered at clinicaltrials.gov as NCT02031978.

STUDY OBJECTIVES

The purpose of the study is to design, conduct, and report, using a longitudinal design, on a nationally representative sample of WIC infants from birth to their second birthday. The study will focus on WIC infant and toddler feeding practices. The study objectives include the following:

- Conduct new data collection to update and expand on the information in WIC IFPS-1 on the feeding practices and behaviors of WIC infants and toddlers
- Compare and contrast the new findings with those from WIC IFPS-1 and other studies of infant and toddler feeding
- Collect information on the nutrition education (recommended feeding patterns and behaviors) and breastfeeding promotion and support provided by WIC and other sources to the caregivers
- Assess behaviors in overfeeding and overconsumption during early infancy and childhood
- Identify aspects of WIC nutrition education that could influence feeding practices to address the problem of high body weight among young children in WIC and obesity status
- Identify any changes in feeding practices and behaviors stemming from the implementation of the new WIC food package revisions, including baby foods for the infants and fruit, vegetables, and whole grains for toddlers.

MATERIALS AND METHODS

An extensive amount of planning has gone into this study. We have coordinated with the national WIC program managers at the USDA, and with the FDA, Economic Research Service, CDC, the National WIC Association, and all state/territorial agencies that have been sampled into the study.

Two theoretical models have been developed, in collaboration with the study’s Peer Advisory Panel, to guide analyses focusing on infant feeding decisions and early weight gain (Figures 1 and 2).
These serve as draft templates for modeling analyses. Of course, these models will be controlled for relevant demographic variables. Recruitment time “windows” have been randomized across sites; during a “window” (time period varying), a Westat recruiter invites an eligible potential participant (enrollees at their first WIC visit for this pregnancy or child, either prenatally or with an infant <2.5 mo of age if the mother has not participated prenatally) to participate in the study, and signed informed consent is sought. Participants are assigned to the core or supplemental sample in sequential order, assuming that they are

**FIGURE 1.** Infant feeding practices model. BF, breastfeeding; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

**FIGURE 2.** Early childhood weight model. GWG, gestational weight gain; HBW, high birth weight; LBW, low birth weight; PG, pregnancy; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.
outcome variables will be as follows: 1) will include subgroup comparisons of various types. The main
provided to the sponsor (and available for public access). These
Statistical analysis

The telephone interviews for the core sample will take place
prenatally (for those enrolling prenatally) and at 1, 3, 5, 7, 9, 11,
13, 15, 18, and 24 mo of the child’s age (11 interviews possible)
and at 1 or 3 mo and 7, 13, and 24 mo for the supplemental
sample (4 interviews possible). Each interview (except for the
prenatal interview) will include a quantitative 24-h recall of the
child’s dietary intake using the USDA Automated Multiple Pass
method (13). Infant/child weights and lengths will be obtained
from hospital and WIC records; in cases in which these mea-
sures are not available, we will send a home health service nurse
to collect the information in the home. We are aware of the error
inherent in hospital birth length records and will account for this
in statistical analyses; subsequent measures will be performed
with standardized methodology and equipment. The type of food
package provided to the mother and infant/child will be obtained
from WIC administrative records. Interviews will include the abbreviated (6-item) US Food Security module at 5 time points.

Ethics

This study has been approved by the federally certified insti-
tutional review boards of Westat and of the University of
California, Los Angeles; in addition, the study has been reviewed
and approved by all state health department and local WIC agency
review boards that are in the sample and that have review
requirements.

Incentives are provided to participants in the amount of $50 for
initial enrollment and $20 for each completed interview; they will
be reimbursed $10 when they use their own cell phones for the
interviews. In the rare instances in which the participant has no
telephone access, a cell phone with enough minutes is provided to
complete study participation.

Statistical analysis

An extensive number of bivariate tables will be produced and
provided to the sponsor (and available for public access). These
will include subgroup comparisons of various types. The main
outcome variables will be as follows: 1) breastfeeding decisions
(intent to breastfeed, first hospital feeding, breastfeeding at
hospital discharge); 2) for those who breastfeed, use of breast
pump, time until formula supplementation, and time until breast-
feeding cessation; 3) other infant feeding practices (number of
feedings per day, time until cereal, time until baby foods (by type),
duration of bottle use, and timing of feeding transition; and 4) nutrient intake and weight outcomes (foods eaten by type, energy
intake/kg body weight, usual nutrient intakes relative to Es-
timated Average Requirements, Adequate Intakes, and Upper
Limits (Tolerable Upper Intake Levels), as appropriate; nutrient
densities; weight-for-length; weight gain at 0–6 mo and at 6–12
mo). Variance estimations will be conducted for all analyses.

A key set of independent variables of interest is the mother’s experience with the WIC program. We will undertake a series of qualitative interviews with key informants at the state agency
and local delivery site levels to assess variability in the following
aspects of the experience: education offered, breastfeeding peer counseling, provision and support for breast pumps,
food package composition, and time participating in the WIC
program. The goal here is to learn from the best practices and
generalize the information throughout the program. In addition,
we will conduct multivariate modeling to explore the various
aspects of the conceptual models presented as Figures 1 and 2.

RESULTS

Eighty WIC sites located in 26 state agencies and 1 US terri-
tory have been selected into the sample. We have obtained
institutional review board approvals at all levels; Office of
Management and Budget approval has been obtained, and field
data collection began in midsummer of 2013. The WIC com-

We acknowledge the significant contributions of Shannon Whaley of Pub-
Health Enterprises WIC program, Irwindale, CA; Loren Bell, Altarum
Institute; Lorrenne Ritchie and Patricia Crawford, University of California,
Berkeley; Westat professional staff Nancy Weinfield, Laurie May, Crystal
MacAllum, and Jill Montaqua; May Wang and Dena Herman (University of
California, Los Angeles); consultants Jane Heining, University of California,
Davis; Leann Birch, Pennsylvania State University; Betsy Frazao, Economic
Research Service; Sara Fein, formerly FDA; Ruowei Li, CDC; Lisa
Southworth and Valery Soto, FNS WIC staff; Renee Arroyo Lee-Sing,
FNS; and Peer Advisory Panel members Zoe Neuberger, Peggy Trouba,
Suzanne Murphy, Maureen Black, Sally Findley, and Larry Grummer-
Strawn. We also appreciate the many state and local WIC program staff
who are doing a great deal to support implementation of the study.
The authors’ responsibilities were as follows—GGH: was responsible for
drafting the manuscript and final approval. JDH and TAO: wrote the
background information on the program; SWM: wrote the research plan on which the Materials and Methods section is based; and LES: designed the qualitative methods for program documentation. All of the authors read and approved the final manuscript. None of the authors declared a conflict of interest.

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