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FOOD ASSISTANCE

The National WIC Evaluation: Reporting and Follow-Up Issues





United States
General Accounting Office
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**Resources, Community, and
Economic Development Division**

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The Honorable Tony P. Hall
Chairman, Select Committee on Hunger
House of Representatives

The Honorable Tom Harkin
United States Senate

The Honorable Augustus F. Hawkins
House of Representatives

The Honorable James M. Jeffords
House of Representatives

As requested, this report provides information on the U.S. Department of Agriculture's (USDA) handling of the National WIC Evaluation and its current plans for a follow-on study of WIC's impact on children.

This report discusses the problems USDA encountered in performing the National WIC Evaluation, which added to its cost and delayed its issuance; the reasons USDA cancelled a follow-up study of WIC's effects on children; and the status of USDA's plans for a redesigned study of children. It also includes factors USDA may want to consider in planning and conducting future evaluations in order to produce less costly, more timely results.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 7 days after the date of this letter. At that time, we will send copies of this report to the appropriate House and Senate committees and subcommittees; interested members of the Congress; the Secretary of Agriculture; and other interested parties.

If you have any questions on the material in this report, please call me on (202) 275-5138. Major contributors are listed in appendix IV.

John W. Harman
Director, Food and
Agriculture Issues

USDA's compendium of results contains errors and misleading statements about some of the data and deletes the study team's overall conclusions regarding the WIC Program's impact on participants. In contrast, the original executive summary used appropriate methodology, was accurately presented, and reported the study's main conclusions: that WIC improves the diet of pregnant women and children, adds to maternal weight gain, increases the use of prenatal care, and reduces preterm deliveries.

In 1983, USDA proposed a study to assess WIC's impact on the physical and mental development of children born to mothers who had participated in the National WIC Evaluation. It withdrew the proposal, in 1984, because it believed that the response rate would be too low. Since the response rate would probably have been higher than USDA reported, GAO believes that USDA acted prematurely in canceling its plans for the follow-up study.

USDA is currently determining whether to pursue a study of WIC's impact on a different group of children, which its contractors concluded could feasibly be done in about 5-1/2 years at an estimated cost of \$16 million to \$22 million. USDA is currently contemplating a limited field test before committing itself to the study.

Principal Findings

Several Factors Delayed Publication of the Evaluation

The National WIC Evaluation—originally planned to be a 2-1/2-year effort at an expected cost of about \$3.9 million—took 6 years to complete and cost about \$5.9 million. Publication of the final report was delayed because (1) USDA replaced the study's principal investigator and redesigned the study, (2) the research team could not produce a product acceptable to USDA and the study's advisory panel within the time frames estimated, (3) USDA's review of the report was protracted because it wrote a compendium of results to replace the study team's executive summary, and (4) unforeseen printing problems were encountered.

When the study design was submitted for review, the advisory panel recommended that a medical researcher be appointed as principal investigator and that the study be redesigned to better meet the study's objectives. USDA hired a medical researcher as the new principal investigator.

passage of time, it becomes more difficult to separate WIC effects from the effects of schooling and other factors.

USDA Is Considering a New Child Impact Study

Because of continuing interest in determining WIC's impact on children, USDA contracted for a feasibility report to examine the effects of WIC on the physical and mental development of children. This report, completed in February 1989, concluded that a longitudinal study, which collects data about WIC's impact on children over a specified period of time, was feasible. The report recommended a 5-1/2-year project to assess such impacts. USDA has estimated that such a study would cost \$16 million to \$22 million. Because it has some unresolved concerns about both the technical feasibility of conducting the study and its proposed costs, USDA intends to field-test aspects of the recommended design and alternatives before committing itself to the full research. Completing the study as recommended could affect other WIC research if the \$3-million annual ceiling on WIC research spending is not raised.

Recommendations

GAO is making no recommendations because this is an informational report. However, factors that USDA should consider before undertaking future WIC evaluations are discussed in chapter 4.

Agency Comments

USDA said that GAO was accurate in describing the events discussed in this report. USDA did not always agree with the intent it says GAO ascribed to the events or with GAO's conclusion that the proposed National WIC Evaluation follow-up was prematurely cancelled in 1984. USDA also suggested several factual changes which GAO incorporated into the report where appropriate.

This report does not discuss USDA's intent in deleting the study team's chapter and executive summaries and replacing them with its compendium of results. GAO does conclude, however, that the compendium of results contains errors and misleading statements about the study's data and deletes the study team's conclusions regarding the WIC Program's impact on participants. GAO also continues to believe that USDA's decision to cancel the follow-up study was premature. (See app. III.)

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Abbreviations

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| FNS | Food and Nutrition Service |
| GAO | General Accounting Office |
| GPO | Government Printing Office |
| OMB | Office of Management and Budget |
| PEMD | Program Evaluation and Methodology Division |
| RCED | Resources, Community, and Economic Development Division |
| USDA | U.S. Department of Agriculture |
| WIC | Special Supplemental Food Program for Women, Infants, and Children |

the program. However, infants under 6 months may be certified up to 1 year of age.

In fiscal year 1989, USDA estimated that an average of about 3.4 million persons were enrolled in the program each month at an annual cost of approximately \$1.93 billion. Because WIC has to operate within congressional funding levels, not every eligible woman, infant, or child can participate in the program. According to a 1987 USDA study, based on 1984 data, about 10 million people met the WIC program's criterion for family income.¹ The Department estimates that only 40 to 50 percent of these people are participating in the program.

Each participating woman, infant, or child receives individually prescribed packages of foods high in protein, iron, calcium, and vitamins A and C. The food packages contain items such as infant formula, milk or milk products, iron-fortified cereal, juice, eggs, and dried beans or peanut butter. WIC foods are intended to be a supplement to foods normally purchased by participants through other means such as family income or benefits received from other feeding or welfare programs.

The National WIC Evaluation

Beginning in 1976, many studies of the effectiveness of the WIC program were attempted. However, insufficient information was available in 1978 to make any general or conclusive judgments regarding the WIC program's effectiveness.² As part of the 1978 reauthorization of the WIC program, the Congress directed that an evaluation of the WIC program's impact on the health and nutritional status of participants be conducted. The objective of the National WIC Evaluation, which began in 1979 and was issued in 1986, was to provide a reliable estimate of the effects of participation in the WIC program on nutrition and health during pregnancy and early childhood.

The National WIC Evaluation consists of four component studies. The Historical Study of Pregnancy Outcomes estimated changes in fetal and infant mortality attributable to WIC, from 1972 to 1980, in 19 states and

¹Estimation of Eligibility for the WIC Program, USDA, July 1987.

²WIC Evaluations Provide Some Favorable but No Conclusive Evidence on the Effects Expected for the Special Supplemental Program for Women, Infants and Children (GAO/PEMD-84-4, Jan. 30, 1984).

researchers expected that data from one of the other studies would provide useful additional information. However, this information must be used appropriately because differences in study design cause differences in the ability to detect effects of the program. The ability to detect program effects is referred to as the “power” of a study. Studies with low power require larger effects before such effects can be determined to be statistically “significant.” For this reason, one study might conclude that a result is not statistically significant while another study might find that it is significant.

For example, while the Longitudinal Study of Pregnant Women and the Historical Study of Pregnancy Outcomes both examine WIC impact on fetal mortality, the design of each study is different. The Longitudinal Study compared birth outcomes of a national sample of 5,205 WIC participants with a control group of 1,358 nonparticipants.⁴ The Historical Study made its evaluation by estimating the WIC program’s effect on birth outcome over a 9-year period for all births in 19 states and the District of Columbia. The Historical Study found a statistically significant reduction of 2.30 deaths per 1,000 births in the late fetal death rate on the basis of the 9-year data it analyzed. The Longitudinal Study found no statistically significant effect on fetal death rate in the sample it analyzed. These findings are not inconsistent and do not conflict in any way since the studies had differing abilities (power) to detect these effects.

Objectives, Scope, and Methodology

The former Chairman of the House Select Committee on Hunger, Senator Tom Harkin, and Representatives Jim Jeffords and Augustus Hawkins asked us to evaluate USDA’s policy and procedures governing evaluations of the WIC program. After discussion with the requesters’ offices, we agreed to answer the following questions:

- What were the reasons for the delay in releasing The National WIC Evaluation? How did USDA determine the number of copies of the report that should be produced? (See ch.2.)
- Does USDA’s compendium of results accurately present the results of the National WIC Evaluation? (See ch.2.)

⁴The socioeconomic status of the WIC and control groups were different. Women in the control group were more often white and married and had higher incomes and higher status jobs than WIC participants. This meant that, for statistical significance, WIC program effects had to be large enough to compensate for pre-existing differences between the groups that could not be statistically controlled. Since the control group members were initially better off than the WIC group, the National WIC Evaluation results probably underestimate program effects. Thus a nonsignificant outcome in the study could simply mean that the larger effect required for statistical significance was not achieved.

USDA's National WIC Evaluation Contracting and Reporting Process

The 1978 congressional requirement to evaluate the impact of the WIC program on the health and nutritional status of participants led to FNS awarding a contract for the National WIC Evaluation, in 1979, to the Research Triangle Institute. This study, which was originally expected to cost about \$3.9 million and take 2-1/2 years to complete, was designed to estimate the effects of the WIC Program on nutrition and health during pregnancy and early childhood. The final study, released in January, 1986 took nearly 5-1/2 years to complete and cost \$5.9 million. Almost immediately, the principal investigator and Members of Congress raised concerns regarding the manner in which the study was reviewed and reported. Specifically, they were concerned that

- USDA had not released the study in a timely manner and
- chapter and executive summaries, written to make the report useful to the Congress and lay readers, had been removed from the report and had been replaced by a misleading compendium of results written by USDA.

USDA Extended Time and Cost Limits to Complete the National WIC Evaluation

Publication of the final report was delayed about 4 years and cost \$2 million more than originally expected. The report was delayed because (1) USDA replaced the study's principal investigator and redesigned the study 2 years after the National WIC Evaluation began, (2) USDA changed the report format after the initial draft was completed and it took the contractor longer than estimated to produce a final draft, (3) policy reviews—which included rewriting the research team's executive summary—took about 6 months longer than such reviews usually take at USDA, and (4) the report was printed twice because of a defective initial printing.

Principal Investigator Replaced and Study Redesigned

In 1977 FNS established an advisory panel to develop a model for the evaluation of the WIC program. With this input and other technical and programmatic information, FNS developed a preliminary design for the National WIC Evaluation. On the basis of this design, USDA awarded a 2-1/2-year contract, in 1979, for a \$3.9-million national evaluation of the WIC Program. The objective of this evaluation was to estimate the effects of WIC participation on nutrition and health during pregnancy and early childhood.

About 2 years into the study, when the design of the National WIC Evaluation was submitted for review, the Evaluation's advisory panel had concerns about the ability of the proposed design to meet the National

report, with four additional volumes of technical reports and appendixes, instead of separate reports on each component study as originally planned.

Acting on the advisory panel's recommendation, in the summer of 1984 USDA extended the National WIC Evaluation contract twice, at a cost of about \$349,000. These modifications were the 14th and 15th made to the contract. They raised the total contract price from about \$5.51 million to \$5.86 million, and allowed the study team until September 19, 1984, to deliver a second draft report and until November 19 to deliver a final draft report.^{1,2} The second draft, while an improvement over the first version, was unacceptable to USDA because it required additional technical and writing refinements. According to the principal investigator, neither this second draft nor any subsequent version of the National WIC Evaluation was submitted by USDA to the Advisory Panel for its comment.

An acceptable final draft of the National WIC Evaluation report was submitted to USDA in February 1985 approximately 9 months behind the original due date of May 1984.

Protracted Policy Review Delayed Report Issuance

Generally, a major evaluation such as the National WIC Evaluation receives extensive review at the technical level within USDA. After the report has been amended to respond to all technical comments, it passes to the Administrator, FNS, and the Assistant Secretary, Food and Consumer Services, for policy review. According to a USDA official, policy review by the Administrator, FNS and the Assistant Secretary, Food and Consumer Services usually requires about 8 weeks.

For the National WIC Evaluation, USDA took 3-1/2 months to give the final draft report its first policy review, by the Administrator, FNS. On June 3, 1985, the final draft was submitted to the Assistant Secretary's Office with a recommendation from the Administrator, FNS, that it be released to the public.

¹Simultaneously with redrafting the report, the research staff was continuing to analyze the data it had collected. The increases in the contract cost covered this continuing data analysis as well as efforts to rewrite the report.

²As of October 1989 the National WIC Evaluation contract was in the process of being closed out. Final invoices had been received from the contractor and the total contract cost was about \$5.87 million.

favorable light than was justified by the study's data. After discussing the matter with the Assistant Secretary, the Special Assistant drafted the "U.S. Department of Agriculture Compendium of Results of the National WIC Evaluation." With input from other staff, this document became the approved executive summary of The National WIC Evaluation. It replaced the executive and chapter summaries written by the research team.

USDA's compendium had methodological flaws and a few reporting errors that could contribute to misinterpretations about the evaluation's main findings. The compendium understated the generally positive impacts that the National WIC Evaluation found were attributable to the WIC program because, unlike the executive summary, it did not contain any conclusions regarding WIC's impact on participants. It implied, incorrectly, that most measures studied in the National WIC Evaluation were unaffected by WIC participation and did not report the conclusions regarding WIC's impact on participants that are found in the body of the report. In contrast, the research team's executive summary used appropriate methodology, was accurate, and summarized the report's main conclusions that WIC improves the diet of pregnant women and children, lengthens gestation and reduces the likelihood of preterm deliveries, increases the weight gain of pregnant mothers and their use of prenatal care. These issues are discussed in more detail in the following sections.

Executive Summary Was Accurate

The research team's executive summary contains appropriate conclusions regarding the major effects that the WIC program had on participants. Generally, the team was careful to accurately qualify its results and to report the conclusions explained in the 5-volume report. In one instance, however, when reporting on a statistically significant increase in infants' mean birthweight, the team did not properly qualify its results as limited to white infants. We also found that the team did not summarize all the tested outcomes that appeared unaffected by the WIC program. This is appropriate because the component studies were designed differently and thus varied in their abilities to detect effects on participants. For this reason we believe the research team's de-emphasis of nonsignificant results was appropriate. If the study team had reported all nonsignificant outcomes in its summary, the reader might infer that the WIC program had no effect on those outcomes. This inference could be incorrect because the study's design, in some instances, made it unlikely to detect any effect. After comparing the results reported in the research team's executive summary with the detailed findings in the technical volumes of The National WIC Evaluation, we

others combined two subissues, or represented new organizational categories that did not match anything found in The National WIC Evaluation report.

For example, instead of retaining the National WIC Evaluation's assessment structure for the diet issue, as shown in list 2.1, which used three subissues and numerous indicators, USDA's compendium used a completely different structure. The USDA compendium addressed only the major diet issues. Instead of reporting on the subissues or the numerous indicators that were assessed to determine the dietary intake of the three groups, the compendium reported that only five indicators were examined by the National WIC Evaluation.³ (See list 2.2.)

³Because a secondary analysis of the National WIC Evaluation was beyond the scope of our review, we did not seek to define, identify, and count all the indicators used in the National WIC Evaluation. However, the number of indicators of diet examined by the National WIC Evaluation numbered well over 100, not the 5 reported in USDA's compendium.

evaluation structure also enables the reader to weigh the relative importance of study results at each of these levels. For example, USDA's compendium, which lists a total of 49 indicators it says were evaluated by the National WIC Evaluation, reports that the study measured 8 "psychological indices for children" but only 6 indicators of health service use and 5 of diet. These numbers are incorrect and misleading. They give the reader the impression that the National WIC Evaluation's design considered assessing WIC's impact on psychological indices (8 indicators) as more important than WIC's impact on health services (6 indicators) or diet (5 indicators). The opposite is true. The National WIC Evaluation examined WIC impacts on health services and diet as two of the study's six major issues. The impacts of WIC on health services and diet issues were assessed using several subissues and hundreds of indicators of those subissues, while WIC's impact on the "psychological indices of children" (the subissue called "improved cognitive and behavioral development" by the National WIC Evaluation) was examined as one of three subissues of the larger issue of infant and childhood health and development. Lists 2.3 and 2.4 portray, respectively, the hierarchical design of the National WIC Evaluation and the Evaluation's design as reported by USDA's compendium.

List 2.4: National WIC Evaluation Design
as Reported in the USDA Compendium

Grouping Category

1. Adequacy of Prenatal Care
(e.g., first trimester registration)
2. Adequacy of Gestation
(e.g., incidence of very premature delivery)
3. Infant Characteristics
(e.g., mean birthweight)
4. Fetal & Infant Mortality
(e.g., fetal death rate)
5. Dietary Intake of Pregnant Women
6. Anthropometric and Hematologic
Changes for Pregnant Women (e.g., maternal weight gain)
7. Behavioral Changes for Pregnant Women
8. Dietary Intake of Infants
9. Dietary Intake of Children
10. Anthropometric Indices for Children
11. Use of Health Services for Infants and Children
12. Psychological Indices for Children
13. Family Food Expenditures

Source: "USDA Compendium of Results of the National WIC Evaluation." USDA, Table 2 (Washington, D.C.: 1986).

USDA's Compendium Calculated
Meaningless Summary Statistics

To develop meaningful statistical results that summarize the National WIC Evaluation's findings, indicators should be (1) independent of one another and (2) similar in kind (e.g., of equal importance or relevance) before they can be meaningfully aggregated in the manner attempted by USDA. However, USDA's compendium aggregated indicators without assuring that these criteria were met. Therefore, USDA's summary statistics are inaccurate.

USDA reported in its compendium that the units of analyses it used were "indicators measured." USDA did not disclose how it defined "indicator measured." Without an explicit explanation of what "indicator measured" means, the reader is led to assume that USDA's "indicator" is the same "indicator" used by the National WIC Evaluation. The Evaluation's indicator is the lowest building block in the National WIC Evaluation hierarchy. It is the factor that was studied to determine whether or not the WIC program had any effect in the area being examined.

In some instances USDA's indicators either are not independent or are inconsistent with the National WIC Evaluation's indicators. For example, the indicator "Combined Forward and Backward Memory Test" is calculated from two other indicators—"Forward Numerical Memory Test"

because the studies were designed differently and thus had differing abilities to detect effects. In general, a failure to find statistical significance by itself does not imply that there is no program effect.

For example, both the Historical Study of Pregnancy Outcomes and the Longitudinal Study of Pregnant Women sought to measure WIC's effect on the adequacy of prenatal health care. Both of these studies sought to determine if WIC participation influenced pregnant mothers to obtain an adequate number of prenatal visits. However, the studies had different abilities to detect this effect.

The Historical Study sought to make its determination by looking at the effectiveness of WIC over its entire history, from 1972 to 1980. To accomplish this, it used data on 11 million births from 1,392 counties in 19 states and the District of Columbia. To determine whether WIC participation had a statistically significant impact, the study linked the proportion of eligible pregnant women served by the WIC program, in each county and year, to levels of maternal prenatal care, for the same county and year.

In contrast, the Longitudinal Study sought to determine WIC impact during a single pregnancy. It examined and interviewed 6,563 women—5,205 first-time WIC applicants and 1,358 first-time registrants for prenatal care who were not WIC participants. A field staff of 98 interviewers administered questionnaires covering diet; past pregnancies; social, demographic, and economic status of the household; expenditures for food; and the use of health care services. Additionally, the field interviewers took height, weight, arm circumference, and skinfold thickness measurements. All this information was gathered twice for each woman.

The Historical Study concluded that WIC participation (over the history of the program from 1972 to 1980) significantly increased the proportion of women who had an adequate number of prenatal visits. The Longitudinal Study concluded that WIC participation did not significantly affect the number of prenatal visits once the woman was registered for care. By stating that a conflict exists in the results of these studies, USDA misconstrues the meaning of statistical significance. A conflict does not exist between the results of the two studies because the studies had different objectives and methodologies. Therefore, results cannot be considered to be in conflict merely because they arrive at different conclusions regarding the statistical significance.

Table 2.1: National WIC Evaluation Results on the Use of Health Services for Children

| Area | Child's age at WIC inception | | | | |
|--------------------------------|------------------------------|------------|-------------|------------|---------|
| | Prenatal | 0-3 months | 4-11 months | 12+ months | Unknown |
| Regular source of medical care | S | S | S | NS | NS |
| Use of preventive health care | NS | NS | NS | NS | NS |
| Immunization card available | NS | NS | NS | S | NS |
| Measles immunization | NS | NS | NS | S | NS |
| Adequate DPT immunization | S | S | S | NS | NS |
| Adequate polio immunization | NS | S | NS | NS | NS |

Legend

S = statistically significant

NS = not statistically significant

Source: The National WIC Evaluation, USDA, Vol. VI (Washington, D.C.: 1986), p. 73.

Table 2.2: USDA Compendium Results on the Use of Health Care Services for Children

| Area | Finding |
|---------------------------------|--|
| Regular source of medical care | Not Reported |
| Preventive health care services | NS |
| Immunization card available | Not Reported |
| Measles immunization | S (only for those recruited into WIC after age 1) |
| DPT immunization | S (only for those recruited into WIC before age 1) |
| Polio immunization | NS |

Legend

S = statistically significant

NS = not statistically significant

Source: USDA Compendium. USDA Table 2, (Washington, D.C.: 1986), pp. 10-11.

Report Copies Limited and Delayed

USDA technical staff determine how many copies of research reports will be produced for initial public distribution. USDA has no criteria or policy to guide the technical staff in this process. Because of this lack and the staff's perception of the limitations on the number of copies it could have printed by a commercial printer, USDA met its initial distribution requirements by providing requesters copies of the summary volume,

printing and binding regulation makes between “copying and duplicating” and “printing and binding” when they made the decision to have the report printed commercially.

Senior USDA officials we talked to were unanimous in recognizing The National WIC Evaluation as a major work with high congressional and public interest. However, after satisfying its initial distribution—principally to senators, representatives, and state WIC officials—USDA had about 20 copies of the summary volume available for the press, the public, and other researchers. The shortage of immediately available copies raised questions from some Members of Congress regarding USDA’s limited copy production.

There was no statutory requirement for USDA to produce any specific number of copies of The National WIC Evaluation report. According to USDA officials, predicting how many copies of its research reports should be printed is difficult. While USDA wanted to produce sufficient copies for initial distribution to those with a legitimate interest in their products, it did not wish to assume the role of a report distribution facility. Reprints and microfiche copies of The National WIC Evaluation report can be purchased from the National Technical Information Service by any one who wants a copy.⁵

USDA also had problems with the commercial printer. Although USDA had estimated that a commercial printer could print and bind the report in 3 weeks, the printer required 8 weeks to produce an acceptable product. The initial printing was unreadable because the ink used in the report smudged. The second printing produced acceptable results, with USDA receiving the reports in January 1986 approximately 5 weeks later than it anticipated. USDA released The National WIC Evaluation on January 10, 1986, within hours after the volumes were delivered to it by the printer.

Conclusions

The National WIC Evaluation provided an estimate of the effects of WIC participation on the nutrition and health of pregnant women and infants. The study cost \$5.9 million and took more than 6 years to complete—\$2 million and nearly 4 years more than originally anticipated. Issuance of the report was delayed because of several unrelated factors. These factors included replacing the principal investigator and redesigning the study 2 years into the project, underestimating the time required

⁵The National Technical Information Service catalogs this report as PB86192929. It is available in a printed version for \$92.95 and on microfiche for \$29.00.

Proposed Child Follow-Up Study

In 1983, at the conclusion of data collection for the National WIC Evaluation, USDA proposed to conduct a follow-up study to address research questions that were beyond the scope of that evaluation. The proposed study would have examined the continuing effects of the WIC program on a select group of children born to mothers who had participated in the National WIC Evaluation. However, USDA's concern that obtaining a representative sample of this select group would not be possible caused it to cancel a follow-up of the children of original study participants. This concern flowed from a confidentiality pledge made to participants that restricted the government's access to the names and addresses of National WIC Evaluation study participants. After completing a technical review of the follow-up proposals in December 1983 and exploring the legal, contracting, and technical issues involved in the follow-up, USDA decided to cancel the proposed study in July 1984, concluding that it was not practical.

The National WIC Evaluation Identified Areas for Further Study

The National WIC Evaluation was designed to analyze a broad spectrum of potential WIC effects on women, infants under 1 year of age, and children under 5 years of age. While performing that study, the research team found indications of WIC program impacts on children, including improved head and, perhaps, improved brain growth, and potential improved behavioral and cognitive performance that were beyond the scope of the study. For example, the research team found that the head sizes of the WIC babies were significantly larger than those of a comparison group of non-WIC babies, while the total weight of the infants was approximately the same. Some believe that these findings may indicate increased brain growth that would lead to better cognitive development in childhood. However, the scope and milestones of the National WIC Evaluation did not provide an opportunity to determine whether greater infant head size resulted in improved cognitive development in the children.

In 1983, USDA and the research team discussed the benefits that might be derived from a follow-up study. USDA was convinced of the usefulness of a follow-up effort and therefore developed plans to fund such a study. The proposed study would have compared the development of children whose mothers received WIC benefits during pregnancy with a comparison group of children of eligible non-participants. Both groups had participated in the National WIC Evaluation. USDA intended to study these children in several assessments or "waves" beginning 13 months after birth.

is no universally accepted wording for a confidentiality pledge. For the National WIC Evaluation, the contractor made its standard confidentiality pledge, which guarantees the complete confidentiality of all information supplied by participants. This pledge assured participants that their WIC benefits would not be affected by participating in the study since neither USDA, the agency that grants WIC benefits, nor any third party would have access to the information.

The contractor told us that other wording could have been used in the pledge that would have permitted the contractor to share all the information collected with USDA. However, USDA did not request this wording, and the contractor thought that a pledge that permitted the disclosure of personal information to USDA would probably have reduced the participation rate and the honesty of responses.

USDA's request for proposals for the follow-up evaluation stated that,

"Within one year of birth, the women [who participated in the Longitudinal Study of Pregnant Women] will be recontacted by the FNS contractor conducting the National WIC Evaluation to confirm their mailing address and their willingness to participate in further FNS study activities."

USDA never completed this task. Had it done so, written consent which permitted sharing the updated participant list with the winner of the follow-up contract could have been obtained by the contractor.

A former USDA official responsible for managing the National WIC Evaluation project told us that his staff was unfamiliar with the provisions of the contractor's confidentiality pledge because they had not been with the project since its inception in 1979. According to the official, USDA expected to have unrestricted access to the names and addresses of National WIC Evaluation participants and the data collected from them. With such information USDA could have obtained full and open competition on the child follow-up contract. Any research firm that won the contract would have the information it needed to conduct the study.

Although a confidentiality pledge was drafted in 1979, the final pledge was not made until 1982, after Dr. Rush's redesign of the study was approved. The key project staff responsible for the follow-up request for proposals in 1983 were working with the National WIC Evaluation in 1982. The wording of the request for proposals recognizes that consent was required for a follow-up evaluation and that the original contractor

Concerns About the Number of National WIC Evaluation Participants Recontacted for Follow-Up Study

Under the existing National WIC Evaluation contract, USDA instructed the contractor, in May 1984, to verify the names and addresses of approximately 6,000 National WIC Evaluation participants. USDA intended this step to provide it with an estimate of the probable success in obtaining new consent forms. USDA prescribed the methodology that the contractor used to verify names and addresses. The initial phase involved direct contact by mail or telephone. The contractor mailed business reply postcards to all WIC participants in the sample and made up to three attempts (day, evening, and weekend) to telephone participants from whom return postcards were not received. If participants could not be contacted by postcard or telephone, the contractor sent a certified letter. Additionally, friends and relatives were used to verify names and addresses for those participants who could not be contacted by postcard, telephone, or certified letter.¹

A memo dated June 21, 1984, from USDA to the contractor described the schedule for completing the address verification tasks. The contractor was to recruit and train staff and complete both telephone and certified mail surveys by July 31, 1984. USDA was to receive weekly status reports on the progress of the verification effort, beginning in late June.

According to the Assistant Secretary for Food and Consumer Services, USDA decided not to undertake the proposed Child Follow-up study on July 15, 1984, 16 days before the end of the verification project. The Assistant Secretary recalls that the decision was based on the interim results of the address verification task. In the opinion of USDA technical staff, the verification rate was too low to provide confidence in any resulting study. The Assistant Secretary cited USDA's calculation of a 45-percent response to the address verification task to support the decision that the expected participation in a follow-up study was too low to undertake the study. However, USDA's action came 2 weeks before the contractor's July 30th final report. In that document the contractor reported an 82-percent verification rate using the methodology USDA had prescribed.

¹Persons named by participants in the National WIC Evaluation as always knowing how to contact them.

certified letter, the contractor believed more time was needed to obtain final responses.

On the basis of its research experience, the contractor stated that it disagreed with USDA's assessment that National WIC Evaluation participants whose addresses were verified by friends and relatives were less likely to participate in a follow-up evaluation than those whose addresses were verified by personal contact. According to the contractor's staff, whether a subject can be relocated becomes the determinant of future participation. The contractor told us that if participants can be recontacted, there is a good chance that they will be willing to participate in another study. A member of the contractor's staff who had worked on the WIC evaluation told us that researchers generally develop a trust and rapport with their subjects. This facilitates obtaining their consent for follow-up research. Additionally, because the follow-up topic—WIC's impact on improved physical and mental development of their children—would be of great interest to the participant mother, researchers told us they expected a higher-than-normal desire to participate in the follow-up.

Expected Participation Rate for the Follow-Up Study

Although the ability to verify the address of a participant in the National WIC Evaluation does not directly translate into a willingness to participate in a follow-up study, both USDA and the contractor estimated participation rates using these data. USDA considered that only the 45 percent of the original sample directly contacted were likely to participate in the follow-up. In effect, USDA counted as unsuccessful all addresses verified by a friend or relative. It further assigned to these women the same zero likelihood of participating in the follow-up study as someone whose address could not be verified at all. USDA officials told us that they had no empirical basis for this belief.

A USDA official told us that the agency decided not to pursue the follow-up study, before the address verification task was completed, because even if the contractor directly contacted all the remaining sample participants, the response rate would be too low to permit the follow-up study. The official told us that the OMB would have required a 75-percent participation rate before granting approval for research studies.

OMB was unable to find any guidance in effect in 1983-84 that directed executive branch agencies to achieve any specific response rate prior to undertaking research studies. Notwithstanding the lack of specific OMB standards, a 70- to 80-percent response rate is generally desired in social

using such techniques, the contractor expected that it would obtain consent for a follow-up study from about 90 percent of the eligible participants, or about 82 percent of the WIC sample.

The contractor cited two examples of successful follow-up research after a lapse of 12 or more years. For one study it succeeded in locating 87 percent of children receiving low doses of iodine treatment after a lapse of 12 years or more. In its recently completed Vietnam Veterans Readjustment Study, the contractor used data that were over 20 years old to contact 95 percent of its sample and to achieve a participation rate of 83 percent of those eligible to participate in the study. The participation rate achieved in a WIC follow-up would probably have been different from the rate achieved in the veterans study. The rate would probably be different because the veterans group has different demographic characteristics than the WIC sample. For example, while the veterans are both male and female, the WIC sample is all female and therefore more likely to change surnames. This difference makes tracking the WIC sample more difficult. On the other hand, the basic information needed to contact the veterans was 20 years old while information collected on the WIC sample was less than 1 year old when the WIC follow-up was proposed. This difference would make it harder to recontact the veteran participants. On balance, the contractor stated that because the National WIC Evaluation focused on young, poor women who were mobile and subject to name changes through marriage or divorce, the WIC sample group overall would be slightly more difficult to trace than the veterans. According to the contractor, this net assessment of the relative difficulties of obtaining participation between the two studies was the basis of the contractor's lower estimated participation rate for a WIC follow-up.

In September 1987 the Ford Foundation asked four research analysts (from Harvard, Cornell, and Johns Hopkins Universities and the University of California) to analyze a similar WIC child follow-up proposal. Their unanimous conclusion was that the study, which would have used the same sample population rejected by USDA, was practical and should be done. The Ford Foundation lacked the resources to fund the project, however.

Conclusions

USDA cancelled the initial request for proposals for the follow-up study because it believed the contractor's response rate was too low to provide

that the basic difference between its position and ours is in the calculation of the response rate, specifically the number used in the denominator. As we discuss in this chapter, USDA divides the number of people successfully contacted by 6,563, the number of women in the National WIC Evaluation sample. USDA's contractor divides the successful contacts by a smaller number, 5,954—which is the number of addresses that USDA asked it to verify and the number of women eligible to participate in the follow-up. While we believe both positions have merit—USDA's denominator provides an estimate of the percentage of the original National WIC Evaluation sample that might participate in a follow-up, and the contractor's denominator provides an estimate of participation of National WIC Evaluation participants who were eligible to participate in the follow-up study—the difference in denominator alone is not a critical factor in our conclusion that USDA acted prematurely in withdrawing the follow-up. The effect of using the USDA's denominator is to reduce the contractor's reported response rate from 82 percent to 74 percent.

A far more significant factor is the 45-percent response rate that USDA consistently reported to the Congress to support its decision not to conduct the follow-up. This figure reflects only the addresses that were updated by personal contact, not all the addresses that were updated. USDA arrived at the 45-percent figure by not including 1,648 address verifications made by relatives or close friends. USDA concluded, without testing its assumption or having any empirical support for its position, that participants whose addresses were verified by a relative or friend were “improbable candidates for a follow-up.” We disagree. One reason participants may not respond to mail or telephone contacts is if they had moved since the National WIC Evaluation and did not have a forwarding address on file with the Postal Service. This fact does not tell us anything about those people's willingness to participate in a follow-up study. They may be willing to participate in such a study if asked. The contractor had updated names, addresses, and telephone numbers for these participants, but USDA elected not to contact them to determine their willingness to participate in a follow-up study.

In addition, USDA cancelled the follow-up evaluation in mid-July, 2 weeks before the 6-week long address verification task was to conclude. During those 2 weeks, 281 more addresses were verified, and the contractor advised that more certified mail responses were expected to be received after the original July 31, 1984, completion date. USDA commented that waiting these additional 2 weeks would not have changed the outcome of its decision. We agree that having already discounted 1,648 successful

Finally, USDA states that among the studies we cited as examples of the high follow-up rates that are achievable in social science research only the Continuing Survey of Food Intake of Individuals has a population similar to the WIC population. We disagree that only one of these studies examines a population similar to the WIC Program's. While no group will be identical to the WIC population, we believe that the participants in the Department of Housing and Urban Development's Experimental Housing Allowance Program, who were usually younger, nonwhite families with income less than \$4,000 per year and headed by women, were similar to the WIC group and thus would present similar challenges to follow-up studies. At the three sites we examined in our follow-up study of this group, we achieved a 74-percent average participation rate.

Because of these factors and the 1987 conclusion of a Ford Foundation review panel that a WIC child follow-up study based on the same group of participants was still feasible, we conclude that USDA acted prematurely in making its 1984 decision to withdraw its plans for a child follow-up study.

- legal barriers to obtaining National WIC Evaluation participant names and addresses remained, and
- an alternative sample of participants would yield a superior design.

The consultants recommended that a new study be conducted to assess WIC's impact on infants and children. Since the National WIC Evaluation documented the prenatal effects of WIC, the new Child Impact Study was to focus on postnatal effects. The primary objective of the panel's recommended study was to assess the short- and long-term impacts of WIC on infants and preschool children's growth and development.

The consultants proposed that two longitudinal studies be conducted concurrently over a 5-year period. The first study design would randomly assign people who qualified for WIC benefits to treatment groups (in which they would receive their WIC benefits) and control groups (in which they would receive no benefits). Such a study was recommended for one or two locations receptive to this type of experimentation. A second, much larger study, which would involve neither controlling WIC benefits nor making random assignments to treatment and control groups, was proposed to study infants and children of WIC and non-WIC mothers.

USDA decided to begin the process of investigating WIC's impact on children with a feasibility study. FNS officials believed that a feasibility study would not only bring forward innovative approaches to determining WIC's impact, it would also highlight methodological problems so that they could be resolved or accepted early in the research process. In requesting proposals for the feasibility study, USDA posed several questions that researchers were to respond to in their proposals. These questions focused on various issues, including determining WIC's impact on children's

- physical growth,
- mental development,
- anemia and other blood problems,
- diet, and
- use of health care services.

(A complete listing of these research questions appears in app. I.)

In August 1987, USDA advertised this research opportunity in several ways. It published the legally required notice in the Commerce Business Daily; wrote approximately 150 letters to individual academics; schools

collection methods. For example, USDA could have data collected for it as part of the National Health and Nutrition Examination Survey or the National Maternal and Infant Health Survey, or use other existing data bases. However, use of existing data bases may limit the scope of the research for a variety of reasons. For example, the data base's population may not be similar enough to the WIC population, data may not be collected on all areas of interest, and data collection procedures cannot be controlled by USDA's researchers, thereby limiting the accuracy of results. Modification of the contractor's proposal is the approach USDA took on the National WIC Evaluation. When that study was redesigned in 1982, the incoming principal investigator presented USDA with five to six possible studies that could be included in the evaluation. It chose three of his studies and added a fourth of its own. USDA intends to conduct a field test of the proposed design and some alternative approaches before it makes its final decision on the Child Impact Study.

USDA is not legally bound to conduct a Child Impact Study. However, senior USDA officials told us that because of clear congressional interest in this research and the implicit importance of the issue, the Department is committed to conducting some form of a Child Impact Study. A USDA official told us that if the procurement proceeds as hoped, a contract for the Child Impact Study could be awarded by the first quarter of fiscal year 1990.

Funding the Child Impact Study Could Affect Other WIC Research

WIC legislation limits the amount that USDA can spend on WIC research to one-half of 1 percent of the amount appropriated for the WIC program. Since WIC was funded at about \$1.93 billion in fiscal year 1989, this formula would have allowed about \$9.65 million to be spent on WIC research. However, the legislation further limits WIC research to an annual ceiling of \$3 million. Any funds designated for WIC research that are not spent at the end of the fiscal year revert to the states as increased grants that may be used to serve additional qualified recipients.

During fiscal years 1987 and 1988, the actual WIC research budget approved by the OMB was \$2.1 million, \$900,000 below the legislated ceiling. In fiscal year 1989, this budget was raised to the \$3-million ceiling to fund eight ongoing and four new research projects. According to the FNS Administrator, this increase was made principally to finance two congressionally mandated studies—the WIC Medicaid Cost Study and the Study of Program and Participant Characteristics.

including medical research, WIC administration, and research methodology—was an effective method for ensuring that each group's viewpoints and interests were considered in designing and implementing the evaluation. Use of such a panel should prove useful in future WIC evaluations.

USDA and its contractors have been unrealistically optimistic when establishing time goals for research, analysis, and reporting on study results. The analysis and report writing took nearly 9 months longer than estimated to complete. Part of this time was consumed in altering the report's format from separate reports on each component study to a single integrated summary report with additional volumes of technical reports and appendixes. USDA should be able to reduce the time required to produce a final report by deciding on its report format before the initial draft is prepared.

Reporting time and controversy might also be reduced if USDA states its disagreements with research findings in a separate letter rather than reanalyze and rewrite the study team's summary and conclusions; the separate letter is an option that the Assistant Secretary told us he has used successfully on reports processed after the National WIC Evaluation. During the National WIC Evaluation, USDA required almost 9 months to review the report and rewrite the executive summary into its compendium. Departmental review normally required 2 months. By using the Assistant Secretary's approach, USDA can express its opinion on study findings and policy implications, ensure timely review and publication of study findings, and allow all parties involved to air their views on the issues being studied.

During the final processing phase of the National WIC Evaluation, to expedite printing USDA decided to produce fewer copies of The National WIC Evaluation than were warranted by the significance of the study and public interest in its results. In the future USDA may want to determine the number of copies to be produced before the final report is drafted. In making its initial distribution determination, the needs of legitimate audiences including the Congress, WIC officials, active researchers, academia and the public should be considered along with the significance of the study and its findings. This information is important not only in determining the quantity of reports to be produced but also in determining how the reports will be printed.

For future reports where USDA believes printing time is a critical factor, it could determine the number of copies to be produced and solicit the

Chapter 4
Current Efforts to Assess WIC's Impact on
Child Development

names and addresses released to a third party for follow-on research purposes only.”

WIC Research Projects Requiring Fiscal Year 1990 Funding

A. Ongoing Projects

1. WIC Participant and Program Characteristics Study 1988, 1990, and 1992 (congressionally mandated)
2. National Maternal and Infant Health Survey 1988, 1990 (support for Department of Health and Human Services survey)
3. WIC Medicaid Cost/Benefit Study (congressionally mandated)
4. WIC training, technical, and miscellaneous assistance
5. WIC Child Impact Study
6. WIC Vendor Issues
7. WIC Farmers' Market Process Evaluation

B. Proposed Fiscal Year 1990 New Starts

1. WIC Analytic Research Projects II (proxy indicators of nutrition risk)
2. State Variations in WIC Food Packages
3. WIC Program Structure and Links with the Medical Community
4. WIC Farmers' Market Impact Evaluation (congressionally mandated)
5. WIC Dietary Assessment Techniques

In addition to the above studies, WIC research funds are also used to pay for computer time at the Washington Computer Center and the Food and Nutrition Information Center. The Food and Nutrition Service is also in the process of completing 11 other WIC research studies. These studies were funded in prior years and now consume staff resources but not WIC research funds.

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of Agriculture

Mr. John W. Harman

2

Advisory Panel recommended such a dramatic staffing change and study redesign, has such an extended review been required by the Office of the Assistant Secretary, or has such an extensive revision been made of the final report. While the Agency has cancelled procurements in the past, it has never progressed to the final technical review stage before cancellation, as it did in the NWE follow-up study. Thus, while problems were encountered in carrying out the NWE and the proposed follow-up, these were not typical of USDA's WIC research or USDA's evaluation process.

USDA disagrees with GAO's conclusion that a premature decision was made not to conduct the evaluation. The information that was used in making this decision is not completely presented in the GAO report. It is extensive and is therefore included as an enclosure. Also discussed in the enclosure are comments on the factors which GAO believes should be considered in future WIC evaluations. USDA agrees with all of the factors, and most are routinely included in all WIC research.

While GAO has criticized some aspects of USDA's oversight of NWE, the Department believes that such criticism will not detract from the merit of the study or the data resulting from the effort presented in USDA's five-volume final report, and more recently published in the American Journal of Clinical Nutrition. The NWE remains the most comprehensive study of the WIC Program to date. Each of its four component studies have shed light on aspects of the program, and have played an important role in many programmatic decisions and in subsequent Departmental and University studies.

In addition to the discussion of the NWE follow-up decision and factors for future WIC evaluations, the enclosure cited above contains specific technical comments which we hope you will consider.

Thank you for this opportunity to respond.

Sincerely,

Ann Chadwick

Ann Chadwick
Acting Assistant Secretary for
Food and Consumer Services

Enclosure

See agency comments,
ch.3

See comment 1.

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Table 1. File Maintenance Task

| | | |
|----|---|-------|
| | Original sample | 6563 |
| | Unusable cases due to incomplete data | 609 |
| 1. | Mailed postcards returned by respondent | 628 |
| 2. | Telephone contact with respondent | 2278 |
| 3. | Certified letter sent to respondent; card returned | 38 |
| | Total successful contacts with respondent | 2944 |
| | as percent of total respondents (6563) | 44.9% |
| 4. | Telephone call to collateral person named in interview as always knowing how to contact respondent. | 1648 |
| | as percent of total respondents (6563) | 25.1% |
| | Total verifications of respondent addresses | 4592 |
| | as percent of total respondents (6563) | 70% |

To arrive at the NWE contractor's claim that 82 percent of the respondent's address could be verified, one must ignore the 609 cases of the original sample that were unusable because of incomplete data from the NWE, and use 5,954 in the denominator instead of the original sample of 6,563. Not to use the original sample size in the denominator of the calculation of response rate misrepresents the follow-up sample and distorts interpretation of the results of the follow-up. To obtain their response rate the NWE contractor also had to count collateral contacts as successful, that is, those contacts that were made to persons identified in NWE interviews as those knowing how to contact the study participants. USDA regards these cases as fundamentally different from those verified by contact with respondents themselves, and improbable candidates for a follow-up study. These participants did not respond to the initial mail request, three attempted phone calls, and a certified letter.

Waiting the additional 2 weeks to make the decision would not have changed the outcome. GAO reported that in the 2-week period following FNS' decision, 271 additional women were successfully contacted. Even if these women were added into the FNS calculation (using 6563 in the denominator and not counting collateral contacts), the address verification rate would still be below 50 percent.

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these additional contacts). Given the delay that resulted from the failure of the NWE contractor to release the names and addresses to a USDA designee, if the follow-up was implemented, the data collection would have occurred between 15 and 27 months after the original NWE data collection.¹

While USDA agrees that participation rates are higher when there is an inherent interest in the research questions on the part of the participants, there is no reason to believe that there is any difference between parents interest in their children's dietary intake, physical, or psychological development.

II. GAO's Considerations for future WIC evaluations.

GAO has recommended several factors for USDA to consider in conducting WIC research in the future. In general, USDA agrees with these factors and they are inherent in the current research and evaluation process. Each of the factors is presented with USDA comments below:

1. USDA should carefully select the proposed Child Impact Study's design and principal investigator.

To guarantee the choice of the best possible design and study staffing, both items are included as part of the technical criteria for evaluating all of the proposals for WIC research. These criteria receive a great deal of weight in the technical evaluations and are often points of negotiations before making a contract award.

2. Decide on the report format before the initial draft of the final report is prepared.

It is standard procedure for USDA WIC project officers to give extensive guidance on format and content to contractors prior to their drafting of a report. Such guidance is based on the objectives of the study, the anticipated audience and preliminary study results. Based on a review of the initial draft of a report, however, consultants and advisory panel members sometimes have suggestions for how a report might be enhanced. Indeed, a major role of these experts is to optimize the presentation of the results for the targeted WIC audience. USDA will thus continue to request this input for enhancing the final

¹Data collection for NWE occurred between May 1 and November 30, 1983. The address verification task was completed in July 1984. If the contract was awarded in August 1984, the contract schedule would have called for data collection to occur between February 1 and July 31, 1985. Thus, between 15 and 27 months would have elapsed between contacts.

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See comment 2.

Specific comments on text²

Executive Summary

- o The description of the WIC program omits the provision of services to children up to age 5 and postpartum as well as pregnant and breastfeeding women. (p. 1)
- o The statement is made that WIC costs over \$1.9 billion annually. The current appropriation for Fiscal Year 1989 is 1.9 billion. However, the cost of the program was \$1.8 billion in fiscal year 1988, as stated in the body of the report. (p. 1)
- o The date of the completion of the WIC Child Impact Design Feasibility Study is inaccurately reported in the Executive Summary and throughout the body of the report. The date the final report was submitted was December 9, 1988 and revised February 9, 1989.
- o The \$16 - \$22 million total (including both direct and indirect costs) estimated for full implementation of the design proposed by UNC and RTI is a USDA estimate, based on the direct costs given in the final design feasibility report. (p. 4)

Report

See comment 3.

- o Congressman Leland is missing from the list of requestors for this review. (p. 5)
- o USDA disagrees with the logic used by GAO in suggesting that the number of indicators used in addressing an issue reflects its importance. It is more probable that the number of indicators reflect the difficulty of measuring the issue. For example, iron deficiency may be addressed using one or two indicators (e.g., hemoglobin, hematocrit), while cognitive development may require several indicators (e.g., of vocabulary, verbal, and analytic skills, along with a total score). (p. 19)
- o The report states the proposed follow-up to the NWE would have compared children of WIC mothers to children of "similar economic status" whose mothers did not participate in the program. This is inaccurate. The mothers of the children in the comparison group were not economically similar. In fact, the women in the comparison group differed from the WIC women along a variety of socioeconomic factors, including income, race, marital and occupational

See comment 4.

²Page numbers refer to those in the draft review copy.

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See app. II

A. Ongoing Projects

WIC Participant and Program Characteristic Study
(Congressionally mandated)
1988 National Maternal and Infant Health Survey (Support for
the Department of Health and Human Services survey)
WIC-Medicaid Cost/Benefit Study (Congressionally mandated)
WIC Benefit Targeting Study
WIC Breastfeeding Promotion Study and Demonstration
WIC Vendor Management Study
WIC Analytic Research Projects (WARP I)
WIC Income Verification Study
CDC-FNS Cooperative Project on Smoking Cessation During
Pregnancy
Wayne County, Michigan - Health Clinic Smoking Reduction
Project
Illinois Vendor Demonstration Project
WIC training and technical assistance
Computerized Food Package Modeling System

B. 1989 Awards

Study of Appropriate Methods of Drug Education in WIC
(Congressionally mandated)
WIC Farmer's Market Process Evaluation
WIC Child Impact Study: Field Test
WIC Vendor Issues Study

C. Proposed Fiscal Year 1990 New Starts

WIC Analytic Research Projects (WARP II)
State Variations in WIC Food Packages
WIC Program Structure and Link with the Medical Community
WIC Farmer's Market Impact Evaluation (Congressionally
mandated)
1990 Longitudinal Follow-up of the National Maternal and
Infant Health Survey
WIC Dietary Assessment Techniques

not use number of indicators in this way, USDA's compendium did. We state, in chapter 2, that USDA's compendium does not preserve the hierarchical design that the National WIC Evaluation used to reach its findings and that USDA did not correctly report the number of "indicators" which the National WIC Evaluation team examined. The National WIC Evaluation addressed six major research questions and divided them into subissues composed of indicators. USDA mixed these hierarchical levels in arriving at the number of indicators which it says the study team examined. While the number of indicators which USDA reports is generally fewer than the number of indicators that the study team examined, we disagree with USDA's mixing of subissues and indicators—two different levels of analysis.

5. Appendix 2 of this report presents a listing of WIC research projects which require fiscal year 1990 funding. To fund these projects USDA has asked the Congress to raise the FY-90 limit on WIC research funds from \$3 million to \$5 million. The difference between our appendix and the list USDA included with its comments is 11 projects which it is in the process of completing. While these projects require the use of staff resources, no additional research funding is required.

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GAO Comments

1. USDA stated that the National WIC Evaluation was the most comprehensive study of the WIC program to date, and pointed out that the study required a great deal of care due to the complexities of the issues and methodologies needed to study the issues. Although USDA stated that we accurately described the events concerning the study, it added that it is important to understand the context and reasons for the study delays and the uniqueness of the study. We agree with USDA that the National WIC Evaluation was a complex and comprehensive study of the WIC Program. The data resulting from the effort, presented in USDA's five-volume report and the American Journal of Clinical Nutrition republication, has shed light on some aspects of the WIC program. The National WIC Evaluation was an important step in understanding the effects of WIC participation on the nutrition and health of program participants. We believe that our report adequately summarizes the reasons for the study's delays when we discuss USDA's rationale for appointing a new principal investigator and redesigning the study, the advisory panel's input regarding reformatting of the report, and USDA's decision to replace chapter and executive summaries in the report with its own compendium. The majority of these changes generally produced an improved final product, albeit a less timely and more expensive one. USDA's compendium did not improve The National WIC Evaluation report. As discussed in chapter 2, regardless of USDA's intent, the compendium does not accurately portray the data collected by the evaluation team, the conclusions reached in the National WIC Evaluation, or the information presented in the written chapter and executive summaries submitted by the study team.

2. USDA's specific comments on the report text have been incorporated in the report text as appropriate.

3. Congressman Leland was not omitted from the list of requesters for this review. His request was made to us as the Chairman, House Select Committee on Hunger and he is listed by that title. Because of Chairman Leland's recent death, this report is being addressed to his successor, Representative Tony B. Hall, Chairman of the Select Committee on Hunger as well as to the other requesters.

4. Regarding our discussion on the structure USDA's compendium used to report National WIC Evaluation findings, USDA states that it, "...disagrees with our logic in suggesting that the number of indicators used in addressing an issue reflects its importance." We make no such suggestion. We agree with USDA that the number of indicators examined is not an accurate measure of the importance of a research area. While we did

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status. (p. 34)

- o The timespan of the study recommended by UNC and RTI is 5 1/2 to 6 1/2 years (65 months for the basic study, plus an optional 15 months for an additional cognitive measure), not 6 1/2 to 8 years, as stated in the draft report. (p. 45)
- o The report states that USDA began to develop alternative methods for a child impact study because of the continuing interest of Congress. Other groups besides Congress have continued to urge USDA to pursue a child impact study, including the National Association of WIC Directors and the National Advisory Council on Maternal, Infant and Fetal Nutrition. (p. 45)
- o The report mentions that USDA has the option to completely accept or reject the design recommended by UNC and RTI, and "could modify the study in a number of ways including amending its scope or design or choosing less costly data collection methods." The less costly data collection option includes analysis of existing data bases (GAO suggests that one such data base is the National Health and Nutrition Examination Survey). USDA is exploring existing data bases, the National Center for Health Statistics' National Maternal and Infant Health Survey, in particular. However, it is important to note the limitations of such a strategy. The sample for these data bases is in most cases drawn to represent the population of the United States, not the population of WIC. Therefore, the number of WIC women and children may be limited, and subanalysis by such factors as race/ethnic group and birthweight may be impossible. A second limitation of the use of such surveys is that their format is not always conducive to addressing all areas of interest (i.e., physical and mental development, hematological status, health care utilization, and dietary intake). (p. 49)
- o USDA's proposed WIC research budget for fiscal year 1990 is \$5 million. (p. 51)

Appendices

- o The question "Does WIC decrease child medical or Medicaid costs?" was dropped from the design feasibility study since it is being addressed in USDA's WIC-Medicaid Cost/Benefit study.
- o The list of WIC Research Projects in appendix II does not include all of the current or planned studies. A more complete list occurs below.

See comment 5 and app. II

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draft in every way possible.

3. State USDA disagreements with research findings in a separate letter rather than include them as part of a report.

As the former Assistant Secretary for Food and Consumer Services stated in his interview with GAO staff, this strategy has been used in several reports released since NWE, including the report on the WIC Child Impact Design Feasibility Study.

4. Determine the number of copies of the final report needed before the report is drafted.

USDA agrees that this should be estimated as precisely as possible.

5. When appropriate, solicit Joint Committee on Printing approval for expedited printing at the Government Printing Office or request permission to use a private printer.

USDA agrees that this approval should be obtained when appropriate.

6. Confidentiality pledges should include provisions for all data collected during the study to be furnished to USDA.

The RFP for the WIC Child Impact Study Field Test currently requires that contractors word the confidentiality pledge in such a way that a follow-up is possible and data may be relinquished to a USDA designee.

However, while the use of a weaker pledge has theoretical appeal (i.e., follow-up utility), it may present formidable practical barriers to data collection. For example, the Department recently attempted to use a weaker confidentiality pledge in the 1988 WIC Participant and Program Characteristics Study (PC88) and the results were mixed. Specifically, we asked PC88 participants to sign a pledge that allowed a USDA contractor to recontact them to obtain information for a subsequent study, the WIC Income Verification Study. Some States strongly objected to the use of a weaker confidentiality pledge and the National Association of WIC Directors also protested its use. Support of both States and the Association is essential to obtaining data. Thus, in some cases it may be necessary to use a stronger confidentiality pledge, even if it limits USDA research activities.

See comment 2.

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As GAO points out, address verification was only the first step in obtaining data from children. The next step would be to recontact all of the potential follow-up participants, obtain parental consent for study participation, and take the proposed measures. At each step in this research process, there is a loss of participation, so that the final response rates are only a percentage of the total number of candidates with addresses verified. Based on USDA's and others' experience in studies of the low-income population, the final participation rate for the NWE would have been below what GAO states is "generally desired in social science research."

Even if USDA had included the 271 additional women successfully contacted and all of the collateral contacts were counted as success at verifying address, the verification rate for the first step would have been 74 percent of the original total. The response rate for the next step of the process, obtaining consent forms, would still decrease this rate below GAO's stated range for acceptability (70 - 80 percent). The NWE contractors estimate of the success rates and costs of obtaining new consent forms is used here to illustrate this point. Their estimate was included in a memorandum to USDA on March 15, 1984. The NWE contractor's estimate for consent form response rates ranged from 45 to 80 percent, depending on the consent procedure used (e.g., face to face contact, telephone and mail methods). Even if USDA was to use the most effortful and expensive contact procedure, face to face contact (estimated to cost \$186,000), and the inflated 74 percent verification rate, the response rate at this next step would have yielded only 59 percent of the original sample.

GAO cites several studies that had fairly high response rates to support their conclusion that USDA's decision in cancelling the follow-up study was inappropriate. However, only one of these, the Continuing Survey of Food Intake of Individuals (CSFII), had a low-income sample similar to the population in the NWE. That is, the women included in the particular sample of CSFII were low-income women between the ages of 19 and 50, with children aged 1 - 5.

This population is extremely difficult to recontact, since they are highly mobile and often change their names due to marriage or divorce. USDA believes that the response rate for CSFII is thus the most accurate as an estimate of the NWE follow-up of those presented in the GAO report. The other studies are of less mobile populations (e.g., veterans), represent all ranges of income, or represent households as opposed to individuals. If anything, the CSFII rates are optimistic since the WIC Program serves an even younger, more mobile group (under 19 years of age) and since, unlike the NWE participants, the CSFII sample was contacted about every other month for a year (and had agreed to

USDA Comments on the GAO Report,
Food Assistance: The National WIC Evaluation
and Follow-up Issues (GAO/RCED-89-124)

I. Decision not to conduct the follow-up to the National WIC Evaluation (NWE).

USDA asserts that its decision not to conduct the NWE follow-up study was appropriate. The decision was reached after thorough consideration of the data and careful analysis. The basic difference between USDA's analysis and the analysis supported by GAO was the number used to as a comparison figure in calculating the response rate (i.e., the number used in the denominator). USDA used the original sample size as this comparison figure, and believes that using other than this number misrepresents the follow-up sample and compromises the study results. The decision was made before the address verification task was fully completed, but the data obtained in the additional two weeks would not have changed the decision.

As described in the GAO report, USDA had intended to competitively award a contract to conduct a follow-up of the children participating in the NWE. When the NWE contractor notified USDA that it would not release the names of the study participants to another contractor, USDA funded the NWE contractor to recontact the study sample to verify and update current addresses of participants and to estimate probable success in obtaining new consent forms. USDA cancelled the follow-up procurement when the results of this effort showed that an insufficient number of the original sample could be contacted for a valid study.

The fundamental difference between USDA's and the NWE contractors calculation of a response rate (45 vs 82 percent) is whether or not the number in the original sample is used as a reference point, and not whether the decision was made 16 days in advance of the completion of the task. At the time that the decision was made not to conduct the follow-up, the responses were as follows:

Comments From the U.S. Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

JUL 12 1989

Mr. John W. Harman
Director, Food and Agriculture Issues
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Harman:

This letter is in response to the General Accounting Office (GAO) report entitled, Food Assistance: The National WIC Evaluation Reporting and Follow-up Issues. The United States Department of Agriculture (USDA) finds that, for the most part, the events described in this report are accurate. However, USDA does not always agree either with the intent ascribed to the Department for these events or with the conclusions drawn.

See comment 1.

The National WIC Evaluation (NWE) was the most comprehensive study of the WIC Program to date. A great deal of care was required at each step of the research process due to the complexity of the issues under study and the methodologies necessary to support the design, field implementation, and report preparation. While GAO's report of the delays in the NWE publication is factually correct, it is important to understand the context and the reasons for the delays. The naming of the new Principal Investigator and redesign of the study, and the extensive report revisions required to produce an acceptable report were the result of USDA and the Advisory Panel's efforts to optimize the validity and utility of the evaluation.

See agency comments
ch 2

USDA agrees with GAO's technical criticisms of the USDA compendium. However, the intent of this document was not to understate the results nor to mislead the reader in any way. It was written out of a genuine concern that the summary submitted by the contractor did not accurately characterize the results of NWE. Nonetheless, while the Department has continued to present its concerns with more recent research efforts, it has not issued anything similar to the compendium since the NWE. The policy has been to express USDA's concerns in a separate cover letter attached to the contractor's report.

See comment 1.

Not discussed at all in GAO's report, but of notable importance in such a review, is the uniqueness of the NWE. It was--and remains--an atypical evaluation when compared with all other studies that have been carried out under the direction of the Food and Nutrition Service. In no other instance has an

Research Questions Considered in the Child Impact Feasibility Study

Outcomes

1. Does WIC improve children's growth?
2. Does WIC improve children's mental development?
3. Does WIC decrease anemia or other blood problems?
4. Does WIC improve children's diets?
5. Does WIC increase children's health care utilization?

Comparisons

6. What are effects of WIC participation during pregnancy, versus infancy, versus childhood?
7. What effects are attributable to WIC rather than other assistance?
8. Does WIC help certain groups more than others (e.g., low birth-weight babies, black children, etc.)?
9. What are the relative effects of the components of WIC (food, nutrition, education, and access to health care)?
10. What local operational factors are associated with better outcomes?

Joint Committee on Printing for an expedited printing at the Government Printing Office or request permission to use a private printer. By using this procedure USDA will be able to issue the appropriate number of report copies which are consistent with the significance and public interest in the report.

Although a national study of WIC's impact on children, if conducted, is expected to be a comprehensive effort, it is important to consider follow-on uses of the study in making decisions about such things as granting confidentiality pledges. Because of the wording of the confidentiality pledge given to participants of the National WIC Evaluation by the contractor, USDA did not have access to the names and addresses of study participants to facilitate a follow-up evaluation. For the proposed Child Impact Study, USDA may want to consider whether the confidentiality pledge given to participants should include provisions for all data collected during the study to be furnished to USDA. In making a decision on the confidentiality pledge, USDA may want to consider the effect that such a decision would have on the participation rate and the quality of participation response. Alternatively, USDA may want to consider including a final file maintenance task in the overall study design. Such a task could include updating participant names, addresses and phone numbers and assessing participant willingness to have their names and addresses released to a third party for follow-on research purposes only.

Agency Comments and Our Evaluation

In commenting on a draft of this report, USDA stated that, in general, it agrees with the factors we believe USDA should consider in future WIC evaluations. USDA said that most of these factors are inherent in its current research and evaluation process. In its comments USDA stated that we recommended its, "confidentiality pledges should include provisions for all data collected during the study to be furnished to USDA." USDA summarized the practical barriers to data collection that such a pledge would present. We believe, however, that USDA misunderstood our discussion of this factor. While we made no recommendation to USDA, our report states that:

"For the proposed Child Impact study, USDA may want to consider whether the confidentiality pledge given to participants should include provisions for all data collected during the study to be furnished to USDA. In making a decision on the confidentiality pledge, USDA may want to consider the effect that such a decision would have on the participation rate and the quality of participant response. Alternatively, USDA may want to consider including a final file maintenance task in the overall study design. Such a task could include updating participant names, addresses, and phone numbers and assessing participant willingness to have their

USDA's proposed WIC research budget for fiscal year 1990 is \$5 million, which exceeds the legal ceiling for WIC research by \$2 million. Included in this proposed budget is \$1.2 million for the Child Impact Study. If the ceiling is not raised, USDA will have to defer some or all of the research it planned to begin in fiscal year 1990. USDA has asked the Congress to increase the legal ceiling to \$5 million, in the fiscal year 1990 WIC research budget. The additional funds would allow USDA to complete studies legislatively mandated, currently underway, or planned to begin in fiscal year 1990, according to the Administrator, FNS. This amount would also include funding the fiscal year 1990 portion of the WIC Child Impact Study. Appendix II contains a full listing of WIC research projects requiring fiscal year 1990 funding.

Factors to Consider in Future WIC Evaluations

The Child Impact Study as proposed is likely to be an expensive effort. Although FNS's Office of Analysis and Evaluation, which would manage such a study, has gained a great deal of experience—through the National WIC Evaluation and Child Impact Feasibility Studies—in managing complex WIC research projects, there are several factors it may want to consider when undertaking complex WIC research in the future. These factors include taking steps to (1) keep the study's implementation within time and financial constraints; (2) reduce the administrative review process in order to communicate results to the Congress, policymakers, and the public in a more timely fashion; and (3) ensure that the production and distribution of the report match the study's significance and interest to the public.

As experience with the National WIC Evaluation shows, replacing the principal investigator and redesigning an ongoing evaluation are costly and time consuming events. Although the National WIC Evaluation was anticipated to take 30 months and cost \$3.9 million, by the time USDA replaced the original principal investigator 24 months had elapsed and \$3.23 million had been obligated for the study. Eventually 56 months and \$5.51 million were required before the first draft of the National WIC Evaluation was completed. Because of the expense, in time and money, of replacing a principal investigator and redesigning a national study, USDA should carefully select the proposed Child Impact Study's design and principal investigator. Producing a study whose methodology and findings are accepted by the scientific community and other constituencies concerned with the WIC program has been a goal of USDA's past WIC research and should be continued. The National WIC Evaluation's use of an advisory panel—composed of members with various backgrounds

of public health; current, former and prospective contractors; public and private research groups; research foundations; and active WIC researchers. It also announced its interests in two nutrition and research-related newsletters. USDA expected to fund up to three research designs during the feasibility study phase. Although 167 individuals and research institutions requested application packages for the child impact feasibility study, only 4 submitted proposals. USDA officials told us that they were surprised and disappointed with the small number of submittals.

USDA and outside experts formed a technical review panel to examine the technical merits of each proposal. Because of technical weaknesses in three of the four proposals, the review panel unanimously recommended that only one feasibility study award be made. In March 1988, USDA contracted with the University of North Carolina at Chapel Hill to do the study.

Feasibility Study's Findings

The purpose of the feasibility study was to (1) design a longitudinal study to answer as many of the research questions as possible, (2) determine if that study design is practical, and (3) estimate the direct costs (excluding contractor profit and indirect costs and expenses) to conduct the study. The feasibility study, which was completed in February 1989, concluded that the Child Impact Study was feasible and estimated that the direct costs would be about \$10 million. USDA staff estimates that the total cost of the study will be \$16 to \$22 million, with the addition of the contractor's fee, indirect costs, and general administrative expense, over a 5-1/2- to 6-1/2-year period.

The Child Impact Study recommended by the contractor consists of a Base Study that would assess WIC's impact on the mental and physical growth and development of children, a Sibling Study to assess whether non-WIC siblings in the same household benefit indirectly from WIC, a centralized assessment of cognitive development of an 800-child sample, and a WIC Program Assessment Study to identify WIC program factors associated with better outcomes.

USDA has some unresolved concerns about the technical feasibility of conducting the study and its projected costs: From a technical perspective, can a valid comparison group be obtained? Will vital statistics be available in a timely fashion, and can they be used to select a study sample? USDA could either completely accept or reject the contractor's recommended approach or modify it. USDA could modify the study in a number of ways, i.e., amending its scope or design or choosing less costly data

Current Efforts to Assess WIC's Impact on Child Development

In February 1989 a USDA contractor completed a study on whether it was feasible to conduct a national study to assess WIC's impact on child development. This study concluded that a national Child Impact Study is feasible and recommended a multiyear design for the project. The Child Impact Study differs from the follow-up proposal discussed in chapter 3 in two important respects. First, a new group of people will be selected to participate in the research. Second, the study will probably be more comprehensive and more expensive than the follow-up study proposed in 1983. The Child Impact Study recommended by the contractor would cost between \$16 and \$22 million, over a 5-1/2-to 6-1/2-year period, and could adversely affect other WIC research in USDA if the agency's \$3-million annual ceiling on WIC research spending is not raised by the Congress. USDA has some unresolved concerns about both the technical feasibility of conducting the study and its costs. It therefore intends to field-test some aspects of the design before determining whether it should conduct a Child Impact Study.

Preliminary Design and Approach of the Child Impact Study

Because of the continuing interest of the National Association of WIC Directors, the National Advisory Council on Maternal, Infant and Fetal Nutrition, Members of Congress and others in determining WIC's impacts on children, USDA began to examine, early in 1987, alternative methods for completing a Child Impact Study. USDA reaffirmed its decision not to follow-up on the National WIC Evaluation sample and instead solicited new research designs from a large number of institutions and individuals. USDA had planned to fund up to three separate research projects, known as feasibility studies. However, only one of the four proposals submitted was judged by USDA to have sufficient technical merit to warrant funding.

In February 1987 USDA officials met with two consultants to determine whether a new child impact evaluation should be undertaken. At that meeting USDA presented alternative study designs to the consultants for their comments and recommendations. One of the alternatives was the design that USDA had rejected in 1984.

The consultants concurred with USDA's decision not to conduct, in 1987, the originally proposed follow-up evaluation. The consultants' rationale for rejecting the follow-up study design proposed in 1983 was that

- it was not practical (in 1987) to find and recruit participants from the original sample,

address verifications, the loss of 281 more would not have affected USDA's decision. However, we believe that USDA should not have discounted the 1,648 addresses verified by relatives and friends and that it should have completed the address verification task and waited beyond July 31 for the results of the certified mailings. The results of USDA's actions were to discount 1,929 verified names and addresses—over 29 percent of the National WIC Evaluation sample—that should have been factored into its decision regarding the practicality of completing a follow-up evaluation. With these successful address verifications, the names and addresses of 74 percent of the National WIC Evaluation sample (82 percent of those eligible to participate in the follow-up) were updated, not “below 50 percent” as USDA claims in its comments on this report.

As we pointed out earlier in this chapter, address verification is only a first step in determining the number of people that will participate in a follow-up study. Participants must be recontacted, informed about the study, and asked to consent to participate. The percentage of people who agree to participate is usually less than 100 percent. Had USDA decided to do the follow-up study, it would probably have used more rigorous tracing techniques to update more participant addresses in an effort to seek consent.

The contractor, in a letter to USDA in March 1984—3 months before it was asked by USDA to update participant addresses—estimated that the final consent rate for the follow-up would be 45 to 80 percent, depending on whether it attempted to obtain consent via mail and telephone (lower rate) or by personal contact (higher rate). In commenting on our draft report, USDA has erroneously treated the contractor's percentages as numbers by which the percentages of addresses verified in July 1984 would have to be multiplied to calculate the final participation rate. The contractor's March letter was written before USDA had decided to perform an address verification task. These percentages were the contractor's estimate of the final number of people who would finally consent to the follow-up. The estimate assumed that all of the eligible participants would be contacted for their consent. Contractor officials told us that the 6-week address verification step was simply a first step toward contacting all participants. They believe that the results of the effort, verifying the addresses of 74 percent of the original sample and 82 percent of eligible participants within 6 weeks, show that reaching almost the entire eligible participant group was achievable, if USDA were interested in performing the follow-up study.

any confidence in the study's results. However, we believe USDA's calculation of the response rate was flawed and that it made its decision prematurely. The number of names and addresses of National WIC Evaluation participants verified by the contractor indicates that the follow-up study may have been possible in 1984. We reach this conclusion based on the following:

- The contractor verified the names and addresses of 4,873 of the 5,954 women eligible to participate in the follow-up (74 percent of the entire National WIC Evaluation sample and 82 percent of those who were eligible to participate in the follow-up study) within 6 weeks with minimal effort. A higher success rate was likely if more time had been allowed to obtain responses to the certified mailing sent by the contractor.
- The contractor's estimate, based on its experience with similar research studies, indicates that about 80 percent of the original 6,563 participants would ultimately agree to participate in the follow-up. Even the contractor's lowest estimate met the response rate generally desired in social science research.
- An important objective of the proposed follow-up, to determine if WIC participation led to improved health and nutrition or physiological or psychomotor development in their infant children, would probably have been of strong interest to participants. Research objectives which clearly benefit participants generally produce higher participation rates.
- Because only about 1 year has elapsed since data were collected for the National WIC Evaluation, tracing and recontacting participants would be a task more easily and successfully accomplished than studies with longer lapses between the original and follow-up research.

In 1987, research analysts, selected by the Ford Foundation from four major universities, concluded that it was still practical to conduct a follow-up study similar to the one proposed in 1983 and using the same population. With each passing year it becomes increasingly difficult to pursue a research design using the children born to participants of the National WIC Evaluation. These children have now entered school, and the elapsed years make it more difficult to separate the effects of WIC participation on their mental development from the effects attributable to the educational system and other factors.

Agency Comments and Our Evaluation

In commenting on a draft of this report, USDA stated that it disagrees with our conclusion that it made a premature decision in 1984 not to conduct the child follow-up study that it proposed in 1983. USDA states

science research. One USDA official believes that the recent 61- to 77-percent response rates achieved in the Human Nutrition Information Service's Continuing Survey of Food Intakes by Individuals are good estimates of what the National WIC Evaluation follow-up study might have achieved. We achieved a higher participation rate in a follow-up study of low-income people that we conducted in the late 1970s. Using a public accounting firm to make follow-up contacts, we achieved a 74-percent average participation rate at the three sites we examined during our follow-up study of participants of the Experimental Housing Allowance Program.

Other follow-up research has achieved response rates of 70 to 80 percent or more, especially when the research objective is perceived as being important to the participant. For example, researchers at the Office of Research and Evaluation of the Philadelphia School District and the National Academy of Sciences found that under such conditions participation rates range between 70 and 80 percent. Because one of the purposes of the proposed follow-up study—to determine if WIC participation led to improvements in health and nutrition or physiological or psychomotor development in their infant children—is of inherent interest to National WIC Evaluation participants, we believe USDA could have achieved a higher rate of participation in a follow-up study and that it prematurely decided not to undertake the follow-up study. Without empirical evidence indicating significantly different participation rates between women whose addresses were verified by direct contact and those whose addresses were verified by friends and relatives, the available evidence indicates participation rates would have been higher than USDA estimated.

The contractor estimated that, in general, after obtaining permission for a first study, at least 85 to 90 percent of the people it contacts agree to participate in a follow-up study. Using this figure, the contractor estimated that the lower bound of the final participation rate for the study would be 70 to 74 percent of the eligible sample.³ Moreover, the contractor noted that it had verified participant addresses with minimal tracing effort. If USDA decided to pursue a follow-up study, it would use more sophisticated techniques to trace participants and to obtain their written consent to participate in the follow-up study of WIC children. By

³This rate is calculated by multiplying the 85- to 90-percent rate by the 82 percent of the eligible sample for which the contractor had verified addresses by July 30, 1984.

USDA and the Contractor Calculate Address Verification Rate Differently

In reporting the results of the verification effort, USDA and the contractor have consistently reported different figures. USDA has reported an address verification rate of 45 percent. This figure represents the percentage of participants of the National WIC Evaluation's Longitudinal Study whose addresses were verified directly with the participants by July 15, 1984. It is calculated by dividing the 2,944 directly verified participant addresses by the entire 6,563-person sample.

USDA's calculation of a 45-percent response rate was based on address verifications made only through direct contact as reported in interim progress reports supplied to it by the contractor. Although USDA instructed the contractor to verify addresses through friends and relatives when direct contact could not be made—which could occur, for example, if the participant had moved since the last data collection and the local post office did not have a forwarding address—it did not count these contacts in reporting the success rate of the address verification effort. Although USDA's contractor had updated address data on participants whose addresses were verified by both direct contact or through friends and relatives, its evaluation staff told us that the participants whose addresses were verified through third parties were less likely to participate in a follow-up study. In making its decision not to pursue the follow-up study USDA concluded without any empirical support that these WIC participants were “undoubtedly different in characteristics of interest in the study from those who would have participated,” and would have biased the remaining follow-up sample.

The contractor's figure of an 82-percent address verification rate was calculated by dividing the 4,873 addresses it verified, through the direct and third party contacts that USDA had prescribed, by the 5,954 women eligible to participate in the follow-up study.² This represents 74.2 percent of the original 6,563-woman sample. In its final report, dated July 30, 1984, the contractor told USDA that it expected more responses would be received after the cutoff date for its report. The contractor expected additional responses to certified letters that it had mailed to participants. Because the postal service makes three attempts to deliver each

²During the National WIC Evaluation's Longitudinal Study of Pregnant Women, two interviews and medical evaluations were attempted for each participant. One of these interviews/evaluations was conducted when the women first entered the WIC Program or first sought prenatal care and the other during the eighth month of pregnancy. For 609 women only one interview/evaluation was completed. Because both pieces of data were needed for the follow-up study, these women were not eligible to participate. Because of this ineligibility, USDA directed the contractor not to attempt address verification for these women. Thus the contractor attempted address verification for only the 5,954 women (90.7 percent of the original sample) eligible to participate in the follow-up.

would be responsible for updating the names and addresses on the participant list and obtaining consent for the follow-up study. In February 1984 the contractor reminded USDA that without written consent of participants it could not release the names, addresses, and telephone numbers of study participants to a third party. The contractor's position was supported by the written opinion of its legal counsel and subsequently supported by USDA and Department of Justice attorneys.

Lacking these data, USDA had several options it could pursue to complete the study: it could (1) obtain written consent from the study group participants to participate in the follow-up and release their names to USDA or another researcher, as was originally contemplated; (2) award the entire study to the National WIC Evaluation contractor; or (3) redesign the study using a new group of participants.

Under the first option, to obtain written consent, USDA would have had to enter first into a sole-source contract with the National WIC Evaluation contractor or add an additional task to the National WIC Evaluation contract. This contractor would have been required to recontact the original participants, determine if they would be willing to participate in a follow-up study, and obtain written permission to release their names for the purpose of a follow-up study. The National WIC Evaluation contractor estimated the cost of this effort at \$50,000, while USDA officials estimated the cost at \$200,000 to \$300,000. Under the second option, USDA could award the entire study to the National WIC Evaluation contractor, thereby eliminating the difficulties of recontacting participants. However, FNS officials told us that their office had never awarded a sole-source contract, and it was reticent to do so. USDA's third option was to redesign the study so that a new group of participants could be evaluated. The new design could examine additional areas that the National WIC Evaluation did not address and could be structured so that a follow-up study could be facilitated. (Option three was selected. For further discussion of this option, see ch. 4.)

Prior to pursuing any of these options, USDA decided to determine if the follow-up study using the original participants would be feasible. To do this it asked the National WIC Evaluation contractor to verify the current addresses of a sample of original participants and estimate the probable success in obtaining new consent forms.

The follow-up study was to address several questions:

- What factors affect WIC participation in children?
- What effects do WIC prenatal and postnatal participation have on the health status, nutritional status, and psychomotor development of 1-year olds?
- Does WIC participation affect dietary intake and feeding patterns during infancy, including the incidence and duration of breast-feeding, and the use of WIC foods?
- What is the preventive and curative health care utilization of infants?
- What are the preventive and curative health care costs of infants and their mothers during pregnancy?

In addition to addressing these questions, the study was to develop and test methodologies useful in future annual follow-ups of the children through age 5.

The researchers and USDA officials believed that proving WIC benefits improve cognitive development in children could have far-reaching implications for the WIC program. Historically, most WIC funds target pregnant women. If WIC benefits were shown to significantly improve the brain's functional development in early childhood, targeting more WIC benefits to infants and children might be desirable. According to a USDA official, very little is known about WIC's impact on the cognitive development of children because no research studies have examined this issue.

To conduct the proposed child follow-up study, researchers working for USDA would have to contact mothers who had participated in the National WIC Evaluation and had subsequently borne children. To do this, they would require access to the names, addresses, and telephone numbers of the former participants. In August 1983, USDA announced a request for research proposals for an 18 month study known as the Follow-up Study of WIC Children. USDA completed technical reviews of the proposals in December 1983 and began discussions with potential contractors. During this process the issue of a confidentiality pledge made by the contractor to the National WIC Evaluation participants became a contentious issue between USDA and the contractor.

Confidentiality pledges encourage participation in research studies by promising that participant responses will be kept private. For some studies, use of a confidentiality pledge is the only ethical way to obtain desired data. Although pledges are often used in survey research, there

to produce an acceptable draft report, rewriting the study team's executive summary as part of a protracted administrative review process, and printing the report twice because of an illegible initial printing. While the timing of some of these factors was within the control of USDA, the timing of others, such as printing problems, was influenced by circumstances beyond USDA's control.

The compendium of results written by USDA to replace the research team's chapter and executive summaries was methodologically flawed. USDA used invalid methods in its synthesis of the National WIC Evaluation's findings by (1) focusing its analysis on a level that did not preserve the original study design, (2) using inconsistent criteria to summarize the study's results, (3) incorrectly reporting conflicts in the statistical significance of outcomes, and (4) incorrectly reporting some of the study's results. The combined effects of these shortcomings is to understate the effects of the WIC program and mislead the readers regarding the National WIC Evaluation's findings.

Agency Comments and Our Evaluation

In commenting on a draft of this report, USDA stated that it generally agreed with the facts presented in the report, including our technical criticisms of the compendium, but that it did not always agree either with the intent which it says we ascribed to the Department's actions or with the conclusions we drew. USDA stated that the intent of the compendium was not to understate the results of the National WIC Evaluation or mislead the reader. We do not discuss USDA's intent in deleting the study team's chapter and executive summaries and replacing them with its compendium. We do conclude that the compendium contains errors and statements that may mislead the reader about the study's data and deletes the team's overall conclusions regarding the WIC Program's impact on participants. (See app. III for the text of USDA's comments and for our additional responses to them.)

not the complete five volume report. After making its initial distribution, USDA had only 20 copies of the summary report available for free distribution to interested parties.

In June and July 1985, while the Assistant Secretary's office was reviewing the final draft of the National WIC Evaluation, USDA technical staff were making plans for printing the final report. At this time USDA had made initial distribution commitments for 230 copies of the report. Because publication of the report was behind schedule, USDA technical staff wanted the report printed and distributed as soon as possible. On the basis of its past experience with the Government Printing Office (GPO), USDA staff estimated that it would take GPO 5 to 7 months to print the report. Since commercial printing was expected to take 3 weeks, USDA officials wanted the report to be printed commercially.

Generally, by law, government printing must be done by or through the Government Printing Office. USDA believed that the Government Printing and Binding Regulations provided an exception which would allow it to have The National WIC Evaluation printed commercially. The exception provides that a contractor providing services, such as research, to the government can duplicate up to a total of 25,000 pages of a report. Therefore, to shorten printing time and to take advantage of this exception, USDA designated each report volume as a separate job. Consequently, USDA printed a different number of copies of each volume to assure that it did not exceed the 25,000-page limit for each job. For example, volume I, the summary and smallest volume, contained 74 pages and was printed in 250 copies, for a total of 18,500 pages. However, volume IV, a technical appendix and the largest volume, contained 489 pages. USDA was able to print only 50 copies (a total of 24,450 pages) of this volume. As a result, USDA printed only 50 copies of the complete 5-volume report for initial distribution.

We believe USDA misinterpreted the Government Printing and Binding Regulations when it produced the report. USDA used the terms "Printing and Binding" in describing the process it used to publish the report. Sections 1-1 and 2-1 of the Government Printing and Binding Regulations distinguish between "copying and duplicating" and "printing and binding." Section 35-3 of these regulations allows a research contractor to duplicate the pages of a report up to a limit of 25,000 pages without having to use the Government Printing Office. The regulations contain no comparable provision concerning printing. USDA officials involved in printing the report told us that they were unaware of the distinction the

By reporting differences as conflicts not resolved by the research team, USDA's treatment of statistical significance in the compendium gives the reader the misimpression that component studies of the National WIC Evaluation came to opposing conclusions regarding the effect of WIC on program participants. This encourages the reader to underestimate the program effects found by the research team. For example, the compendium reports a conflict between the findings of the Historical and Longitudinal Studies regarding WIC's impact on late fetal death. By reporting that the Historical study found a statistically significant effect while the Longitudinal Study found effects that were not statistically significant, the reader is led to assume that the National WIC Evaluation could not conclude that WIC participation affected late fetal death. Actually, the National WIC Evaluation reported a significant reduction, 2.3 deaths per 1,000 (33 percent) in late fetal deaths attributable to WIC participation. That is, it gave more weight to results from the Historical Study noting that the Longitudinal Study's design was not sufficiently powerful to detect significance of the effect.

Inaccurate Reporting on Health Services

Finally, USDA's compendium contained some important reporting errors concerning the issue of health services. Although few in number, these errors are important because of USDA's method of counting outcomes, which makes omissions of them more important than they otherwise might be. These omissions may lead a reader to assume that researchers found a much weaker WIC effect in that area than was actually the case. Table 2.1 is a condensed version of a similar table in The National WIC Evaluation. As table 2.1 shows, the evaluation examined six indicators of these services for each of four age-specific groups and a fifth group of unknown age when WIC benefits began.

USDA's compendium reported results as shown in table 2.2. USDA did not report the significant impact WIC benefits had on attaining a "regular source of medical care" for three age groups and immunization card availability for one age group. These positive impacts were not mentioned at all by USDA. Further, USDA reported that WIC had no significant impact on improving polio immunization. Actually, the WIC program had a positive impact on polio immunization for those infants receiving WIC benefits during their first through third months of life. Overall, in its compendium USDA reported on only four of the nine age groups and health care services categories for which researchers found positive WIC impacts. The result of these omissions is to lead the reader to think that WIC's impact on the use of therapeutic health services for children was weaker than was actually found by and reported in The National WIC Evaluation.

and "Backward Numerical Memory Test." USDA counted these as three separate indicators in its compendium. This is not statistically valid because the combined test is dependent on the other two tests and therefore is not independent. In other instances where USDA's indicators are independent, they are not similar in kind. In some instances USDA's indicators are a collection of National WIC Evaluation indicators, for example, pregnant women's dietary intake of specific nutrients; in others it is a single indicator, for example, infant head circumference (an indicator of improved newborn development); while in still other cases, National WIC Evaluation indicators were not listed or counted at all.

Because USDA used indicators that were not independent of each other and applied inconsistent criteria when choosing the indicators it used to report National WIC Evaluation results, the compendium (1) reported that the evaluation examined 49 indicators instead of the hundreds that were examined, (2) summarized aggregated indicators that were meaningless, and (3) generally understated WIC's impacts on program participants.

USDA Incorrectly Reported Conflicts in the Significance of Outcomes

USDA incorrectly reported conflicts in the significance of outcomes reported by the National WIC Evaluation. Statistical significance is a statement that the likelihood, or probability, of program effects exceeds a pre-established criterion. Because of differences in research, design studies differ in their abilities to detect effects.⁴

The results of two differently designed studies do not conflict if one study finds a statistically significant effect and the other determines that the effect is not statistically significant. The latter study can be thought of as providing inconclusive evidence of program impacts.

USDA identified a total of 49 indicators purportedly measured in the National WIC Evaluation. It classified each as statistically significant or not significant and calculated the number with similar results. It also noted apparent agreement or lack of agreement in the significance of results between component studies of the National WIC Evaluation. In this process USDA's compendium treated statistical significance as a "Yes/No" characteristic of an outcome. This led USDA to conclude incorrectly that outcomes that were significant in one and not significant in another of the component studies were in "conflict." This is incorrect

⁴Studies with a low ability to detect effects require larger effects before the results can be determined to be statistically significant, that is, due to the effects of the program and not due to chance.

**List 2.3: Hierarchy of Design of the
National WIC Evaluation-Potential WIC
Program Impacts**

I. (Issue) Diet

Increased intake of specific nutrients
Better balanced diets
Use of WIC foods

II. (Issue) Food-Purchasing Patterns

III. (Issue) Use of Health Services

Earlier/regular prenatal care
Use of therapeutic health services for children

IV. (Issue) Maternal Health/Growth

Appropriate weight gain
Reduced anemia
Reduced likelihood of preterm labor

V. (Issue) Fetal/Newborn Health and Development

Fetal mortality
Birthweight
Length/head size
Neonatal mortality

VI. (Issue) Infant/Childhood Health and Development

Frequency of breast-feeding
Improved physical growth
Improved cognitive and behavioral development

Source: The National WIC Evaluation, USDA, Vol. I (Washington, D.C.: 1986), pp. 19-21.

List 2.1: National WIC Evaluation Issues, Subissues, and Indicators Hierarchy for Assessing Diet

I. (ISSUE) Diet

A. (Subissue) Nutrient intake

The nutrient intake of 3 groups (pregnant women, infants, and children) was assessed for the following 15 nutrients (indicators):

| | | | |
|-------------------|------------|------------|-------------|
| Calcium | Iron | Protein | Vitamin B6 |
| Calories (energy) | Magnesium | Riboflavin | Vitamin B12 |
| Carbohydrates | Niacin | Thiamin | Vitamin C |
| Fat | Phosphorus | Vitamin A | |

B. (Subissue) Nutritional status (better balanced diets)

1. The percentage of 3 groups (pregnant women, infants, and children) with nutrient consumption significantly less than the recommended daily allowances for the following 13 nutrients (indicators) were assessed:

| | | | |
|-------------------|------------|-------------|-----------|
| Calcium | Niacin | Thiamin | Vitamin C |
| Calories (energy) | Phosphorus | Vitamin A | |
| Iron | Protein | Vitamin B6 | |
| Magnesium | Riboflavin | Vitamin B12 | |

2. Nutrient density—the intake of nutrients adjusted for calories—was assessed for the same 3 groups for the following 14 nutrients (indicators):

| | | | |
|---------------|------------|------------|-------------|
| Calcium | Magnesium | Riboflavin | Vitamin B12 |
| Carbohydrates | Niacin | Thiamin | Vitamin C |
| Fat | Phosphorus | Vitamin A | |
| Iron | Protein | Vitamin B6 | |

C. (Subissue) Use of WIC foods

Nutrient intake from potential WIC foods in 4 food groups—juice, cereal, dairy, other—was assessed for 3 groups (pregnant women, infants, and children) for the following 15 nutrients (indicators).

| | | | |
|------------------|------------|------------|-------------|
| Calcium | Iron | Protein | Vitamin B6 |
| Calories(energy) | Magr esium | Riboflavin | Vitamin B12 |
| Carbohydrates | Niacin | Thiamin | Vitamin C |
| Fat | Phosphorus | Vitamin A | |

List 2.2: USDA Compendium's Treatment of the Diet Issue

| Category | Number of indicators |
|----------------------------------|----------------------|
| Dietary intake of pregnant women | 1 |
| Dietary intake of infants | 2 |
| Dietary intake of children | 2 |
| Total indicators assessed | 5 |

USDA's selection of categories is potentially misleading to the reader because it removes the structure that permits the reader to understand that the Evaluation's conclusions regarding major issues were based on the analysis of smaller components—the subissues and indicators. The

concluded that, overall, the team's summary correctly reported strong, positive impacts of the WIC program whereas USDA's compendium, because of the weaknesses discussed below, did not.

USDA's Compendium Had Two Weaknesses

USDA's compendium had two weaknesses—methodological flaws and reporting inaccuracies—that serve to generally understate the benefits of WIC participation and that could serve to mislead the reader regarding the study's actual conclusions. USDA's synthesis of the National WIC Evaluation's results included inappropriate methodological steps and reporting inaccuracies. The compendium

- did not preserve the original research design of the National WIC Evaluation,
- used inconsistent criteria to define outcomes that made its aggregation of results meaningless,
- incorrectly reported conflicts in the statistical significance of outcomes across component studies, and
- incorrectly reported the National WIC Evaluation's findings on the use of therapeutic health services.

The Compendium Did Not Preserve the National WIC Evaluation's Design

The National WIC Evaluation was designed in a hierarchical fashion, with the six major research issues being divided into subissues. Conclusions regarding the subissues were formulated by examining certain indicators (or measures) of those subissues. For example, in order to form conclusions regarding the impact of the WIC program on diet, the National WIC Evaluation assessed three subissues—nutrient intake, nutritional status, and use of WIC foods. WIC's effect on each of the subissues was determined by examining the impact of various nutrients (indicators) on 3 major groups—pregnant women, infants, and children. For example, the nutrient intake subissue was assessed by examining up to 15 nutrients for each of the 3 groups. The dietary issue as a whole was assessed by examining more than 100 indicators. (List 2.1 depicts the issue, subissue, and indicator hierarchy the National WIC Evaluation used for assessing the diet issue.)

USDA's compendium eliminated the issue, subissue, indicator hierarchy and reported results using categories created by USDA. Such a change results in a new or secondary analysis of results, not a summary of original results. Additionally, USDA was not consistent in selecting its categories. Some of USDA's categories were National WIC Evaluation subissues,

The review of the final draft report in the Assistant Secretary's office took 5 months, primarily because the chapter summaries were removed and the executive summary was rewritten. The Assistant Secretary completed his review and approved the report for printing in November 1985—9 months after it was submitted to USDA.

We discussed this process with the Assistant Secretary, who had just assumed his position when the final draft of the National WIC Evaluation was submitted to his office. He said his current practice is to expedite the review of reports as much as possible. Retrospectively, he said the review process for The National WIC Evaluation took too long. He told us that if he could redo the policy review of that report, he would expedite the process by sending it to the Congress with an attached cover letter that set forth his concerns with the research team's summary, rather than delaying the report to redraft the executive summary. The Assistant Secretary said that he now uses this process on all the reports he reviews. He also told us that he was unaware that the summary, written by an assistant in his office, contained inaccuracies such as we discuss in the following section.

To expedite report printing, USDA chose to use a commercial printer rather than the Government Printing Office. Problems with the commercial printer delayed report distribution 5 weeks beyond USDA's expectations. Use of the commercial printer limited the number of copies of the report that could be printed. These issues are discussed later in this chapter.

Compendium of Results Less Accurate Than the Executive Summary

USDA's compendium of results was written in the Assistant Secretary's office to replace the research team's executive summary. The rewriting occurred because a reviewer in the office believed the conclusions in the executive summary portrayed the WIC program in a more favorable light than was justified by the study's data. However, we found the compendium's reporting of the results of the National WIC Evaluation was less accurate than the research team's executive summary.

When the final draft report of the National WIC Evaluation was received in the Assistant Secretary's office, a Special Assistant to the Assistant Secretary reviewed the executive summary written by the research team. He compared it with the summary report volume and the technical reports of The National WIC Evaluation and concluded that there were factual discrepancies between these documents. According to the Special Assistant, these discrepancies cast the WIC program in a more

WIC Evaluation's objectives. It, therefore, informed USDA that the results of the study would have more credibility with the medical community if the effort was redesigned and a medical doctor was appointed as principal investigator. USDA agreed with the advisory panel's suggestion and as a result named Dr. David Rush, a pediatrician, epidemiologist, and medical researcher, principal investigator for the study in late 1981. At the time Dr. Rush joined the National WIC Evaluation, USDA increased the amount obligated for the study from \$3.23 million to \$4.14 million. This increase was needed to fund the final research design and the operational and analyses plans for the study. Dr. Rush joined the evaluation team with the freedom to redesign the study as he considered appropriate. He redesigned the evaluation in the fall and winter of 1981-82. After USDA received the Office of Management and Budget's (OMB) approval for the research, actual field data collection began in the summer of 1982, nearly 3 years after the contract was awarded. To support this effort, in September 1982 USDA increased funding for the project by \$536,000 bringing the total to about \$4.67 million. Most of the data were collected in 1983, and by the end of that year, the data collection effort was virtually complete; the cost of the National WIC Evaluation had reached about \$5.51 million.

In September 1982, 3 years after awarding the contract, USDA revised its reporting requirements for the National WIC Evaluation. It required the contractor to produce four reports—one for each of the National WIC Evaluation's component studies: the Longitudinal Study of Pregnant Women, the Study of Infants and Children, the Food Expenditures Study, and the Historical Study of Pregnancy Outcome. Final versions of these reports were to be provided to USDA by May 1, 1984. The contractor was not able to meet this date for delivery of a final draft. However, an initial draft of all components of the report was produced and submitted to USDA for review by May 1984.

For the technical review, USDA relied on the National WIC Evaluation advisory panel and its own program and technical staff. The panel reviewed each report draft, raised questions, and suggested changes. These changes and those suggested by USDA staff were incorporated into revised drafts. According to USDA officials, the initial draft of the National WIC Evaluation report was incomplete, and its sections were not well integrated. As a result of these shortcomings, in May 1984, the National WIC Evaluation Advisory Panel unanimously recommended that the contract be extended to complete data analyses and the production of a comprehensive final report. This comprehensive report was to integrate the results of the four component studies into a single summary

- Why did USDA withdraw its initial request for proposals for a follow-up study of children born to mothers who had participated in the National WIC Evaluation? (See ch.3.)
- Did USDA subsequently redesign the follow-up study based on an entirely new sample group? (See ch.4.)
- If so, what is the status of USDA's plans to conduct a study of WIC's impacts on children and what are its likely costs? (See ch.4.)

To address the questions (1) why USDA delayed in issuing the report, (2) how it determined the number of reports to produce, and (3) whether the USDA compendium accurately reflected the findings of the National WIC Evaluation, we examined the official National WIC Evaluation contract files of the prime contractor, the Research Triangle Institute, and USDA; interviewed current and former USDA officials who were involved in the report review process; reviewed USDA and contractor records and correspondence; discussed the issues with members of the research team; and analyzed USDA and the contractor's versions of the report summary, comparing them to The National WIC Evaluation.

To address the question on USDA's withdrawal of the proposed follow-up study, we reviewed official USDA records, congressional correspondence, and information in the contractor's files; discussed the issue with current and former USDA officials, a USDA consultant, and members of the National WIC Evaluation research team; and analyzed the data USDA relied on in deciding whether a follow-up study was technically feasible.

To address the questions on whether USDA redesigned the follow-up study using a new sample group and the status of USDA's efforts to study the effects of the WIC program, we examined the official USDA cooperative agreement with the University of North Carolina at Chapel Hill for developing a Child Impact Feasibility Study; interviewed USDA technical staff, senior officials, and project staff; and reviewed drafts of the feasibility study.

For each question, we compared documents obtained from governmental and private sources, analyzed discrepancies, and questioned knowledgeable officials to resolve such differences. Our work was conducted between April 1988 and October 1989 in accordance with generally accepted government auditing standards, principally at the Food and Nutrition Service, Alexandria, Virginia; Office of the Assistant Secretary for Food and Consumer Services, Washington, D.C.; Research Triangle Institute, Research Triangle Park, North Carolina; and the University of North Carolina, Chapel Hill, North Carolina.

the District of Columbia using WIC program data and state vital statistics.³ The Longitudinal Study of Pregnant Women compared dietary intake, weight gain, duration of pregnancy, and other factors between a representative national sample of WIC participants and a control group of non-participants. The Study of Infants and Children examined WIC's impact on dietary intake, anthropometry—the measurement of body size and proportions—and psychological development. The Food Expenditures Study estimated the impact of WIC on family grocery and other food expenditures.

According to the National WIC Evaluation summary report, the first 2 years of the study were used to assess the types of information needed by potential users of the study, evaluate past literature, interview all WIC operating agencies, and field-test data collection instruments and procedures. This work was reviewed by the National WIC Evaluation advisory panel of outside experts. The advisory panel's expertise covered a variety of areas including WIC administration, medical research, and research methodology.

In mid-1981, in order to focus the National WIC Evaluation on WIC's effects on nutrition and health, the advisory panel recommended that the original principal investigator, a social scientist, be replaced. In the fall of 1981 USDA acted on this recommendation, naming a physician and medical researcher as the new principal investigator. The new principal investigator subsequently redesigned the study into its final form. Actual implementation of the study (field data collection) began in the summer of 1982 and continued throughout 1983. Analysis of data and report writing were completed by the research team in 1985 and USDA released the study in January 1986. As published by USDA, all four of the component studies are summarized in a one-volume summary report. Four additional volumes—two technical volumes and two appendixes—provide more detailed information on the evaluation's findings and methodology. More recently, in August 1988, the American Journal of Clinical Nutrition published a reanalysis of the National WIC Evaluation in a 130-page supplemental volume.

According to the principal investigator, while each study was designed to provide a definitive answer to one or more research questions,

³The Commodity Supplemental Food Program originally served a target population similar to WIC. Throughout this report GAO refers to all data collected from these two programs between 1972 and 1980 as WIC program data.

Introduction

The Special Supplemental Food Program for Women, Infants, and Children (WIC) is a federally funded nutrition assistance program that provides supplemental foods, nutritional education, and access to health services to low-income pregnant, breast-feeding, and postpartum women; infants; and children up to 5 years old.

Authorized in September 1972, as an amendment to the Child Nutrition Act of 1966, the WIC program originated as a 2-year pilot project and has grown since. WIC's underlying premise is that substantial numbers of pregnant, breast-feeding and postpartum women, infants, and children from low-income families are at risk because of inadequate nutrition, inadequate health care, or both. The program's food assistance aspect was intended to operate as an adjunct to ongoing prenatal and pediatric health care, thereby reducing nutrition-related health problems of pregnancy, infancy, and childhood.

How the Program Operates

At the federal level, WIC is administered by the U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS). FNS provides cash grants to authorized agencies of each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, the Northern Marianas Islands, Trust Territory of the Pacific Islands, Guam, and Indian groups recognized by the Department of the Interior, and the Indian Health Service of the Department of Health and Human Services. The state agencies then provide funds to local agencies, such as public or private nonprofit health and human service organizations, that certify program eligibility and provide services to WIC participants. Although WIC program funds are not used to pay for health services, the program encourages WIC participants to make use of existing services, such as prenatal and postpartum medical supervision, and preventive therapeutic infant and child care.

To qualify for the WIC program, potential participants must be individually certified by a competent professional (such as a nutritionist, dietitian, nurse, or physician) to be nutritionally at risk because of medical reasons or an inadequate diet. Participants must also meet income requirements. A family's gross annual income cannot exceed 185 percent of the nonfarm poverty income defined by the Office of Management and Budget. State WIC agencies may set more stringent eligibility requirements (but not less than 100 percent of the poverty level) as long as the income requirements correspond to the state's income standards for free or reduced price health care. Generally, WIC participants (except for pregnant women) must be recertified every 6 months to continue in

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He redesigned the evaluation in 9 months. In mid-1982, collection of field data began. The research team needed until February 1985, 9 months later than stated in the contract, to complete data analyses and draft a final report. Concluding that there were discrepancies between the executive summary and the findings, USDA wrote a compendium of results that it substituted for the research team's executive summary. Final policy review of the report, including writing the compendium, took USDA 6-1/2 months longer than its usual 8-week review time. Printing the report took 2 months—5 weeks longer than anticipated—delaying report issuance until January 1986.

USDA Summary Is Misleading

Unlike the executive summary it replaced, USDA's compendium contained no conclusions on WIC's impact on program participants. The compendium's analysis (1) did not preserve the original study design, (2) used inconsistent and different criteria to summarize the study's results, (3) improperly aggregated measures of program outcome, and (4) incorrectly reported the Evaluation's findings on using therapeutic health services. Therefore it understated—and could serve to mislead the reader about—the study's findings of the generally positive effects of the WIC program.

Premature Decision Not to Conduct Child Follow-Up Study

Although the National WIC Evaluation was designed as a one-time study, research officials found indications that WIC had effects on children that included improved head size and, perhaps, improved brain growth and potential improvement in behavioral and cognitive performance. The research team and USDA officials were convinced that a follow-up study of these issues was warranted. USDA solicited such a study in 1983 but withdrew the request in 1984 principally because it believed that the confidentiality pledge given participants, which restricted the government's access to their names and addresses, made completing the study impractical.

USDA's decision was premature. Available evidence—including the results of a partially completed effort to verify the addresses of National WIC Evaluation participants, the lapse of less than 1 year since collection of the last data from these participants, and the participation rates achieved in similar follow-up research—indicates that participation in a 1984 follow-up study could have been adequate. In 1987 research analysts employed by the Ford Foundation analyzed a similar proposal, which would have followed up on the same sample population, and concluded that such a study was still feasible. However, with the

Executive Summary

Purpose

The Special Supplemental Food Program for Women, Infants, and Children (WIC) provides nutritional supplements and education to needy pregnant and breast-feeding mothers and children up to age 5 at a cost of about \$1.93 billion annually. In 1986, the U.S. Department of Agriculture (USDA) published the results of its study estimating WIC's effects on participants' nutrition and health. Almost immediately, the study's principal investigator and Members of Congress questioned how the study was reviewed and reported. The Chairman of the House Select Committee on Hunger and three other Members of Congress asked GAO to address, among other issues, the following questions:

- What factors were involved in the delay in releasing The National WIC Evaluation?
- Does USDA's compendium of results accurately present the results of the National WIC Evaluation?
- Why did USDA withdraw its initial request for proposals for a follow-up study of children born to participants in the National WIC Evaluation?
- Did USDA subsequently redesign the follow-up study using an entirely new sample group, and if so, what is the status and likely cost of that study?

Background

The cost of the WIC program and the number of participants have grown since the program began in 1972. Because insufficient information on the effectiveness of WIC benefits was available, the Congress, in 1978, directed USDA to study the program's effectiveness. In January 1986, The National WIC Evaluation, a 6-year, \$5.9-million comprehensive analysis of the program, was released by USDA. A second study—of the children served—was proposed in 1983 and then withdrawn by USDA. In 1987 USDA announced plans to conduct a feasibility study to determine if it is possible to assess WIC's impact on preschool children.

Results in Brief

Publication of The National WIC Evaluation was delayed because of changes in the study—including redesigning the study and replacing the principal investigator after 2 years, overly optimistic time frames, protracted USDA review times, and printing problems. USDA deleted the original chapter and executive summaries and replaced them with its compendium of results because, officials told GAO, the research team's conclusions portrayed the WIC program more favorably than justified by the data.

