REPORT TO THE CONGRESS

Observations On Evaluation Of The Special Supplemental Food Program Food And Nutrition Service

Department of Agriculture

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

FED-75-310

DEC 12 1974

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-176994

To the Speaker of the House of Representatives
and the President pro tempore of the Senate

This is our report on observations on evaluation of the Special Supplemental Food Program administered by the Food and Nutrition Service, Department of Agriculture. We issued a previous report on this program on September 28, 1973 (B-176994).

This report is required by section 17(e) of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1786(e)). We are sending copies of this report to the Director, Office of Management and Budget, and to the Secretary of Agriculture.

Elmer B. Staats

Comptroller General
of the United States

Contents

ABBREVIATIONS

CDC	Center for Disease Control
FNS	Food and Nutrition Service
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NBS	National Bureau of Standards

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

OBSERVATIONS ON EVALUATION OF THE SPECIAL SUPPLEMENTAL FOOD PROGRAM
Food and Nutrition Service
Department of Agriculture

D I G E S T

WHY THE REVIEW WAS MADE

The Child Nutrition Act of 1966, as amended, authorizes a Special Supplemental Food Program for women, infants, and children through fiscal year 1975 and requires the Secretary of Agriculture and the Comptroller General to provide the Congress with preliminary and final evaluation reports on the program.

This is GAO's second report; its first was sent to the Congress on September 28, 1973. The final reports, which are to contain recommendations on the program's continuation, are to be submitted by March 30, 1975.

To assist in its work, GAO hired consultants with expertise in nutrition, biochemistry, pediatrics, obstetrics, and biostatistics. The consultants' opinions are included in the opinions GAO expresses throughout the report.

FINDINGS AND CONCLUSIONS

The program provides cash grants to the States to provide supplemental foods through health clinics to pregnant or lactating women and to infants and children up to 4 years of age determined by competent professionals to be nutritional risks because of inadequate nutrition and income.

As of October 29, 1974, there were 254 approved projects. These projects have approved caseloads totaling about 440,000 women, infants, and children. (See p. 6.)

The program is managed by the Food and Nutrition Service, Department of Agriculture.

Design and implementation of program evaluations

Evaluations of the program are to determine (1) the medical benefits of the nutritional assistance provided, including any benefits in combating and abating any mental as well as physical damage that might otherwise be caused to infants due to malnutrition, and (2) the cost efficiency of various methods of distributing the foods. (See p. 1.)

Under a contract with the School of Public Health of the University of North Carolina at Chapel Hill, the Food and Nutrition Service has a detailed medical evaluation underway at 19 projects.

Data collection began in February 1974 and will continue through June 1975. According to the current schedule, the university's final report is due to the Service on October 1, 1975. (See p. 8.)

[illegible] evaluation [illegible]
[illegible] individual, [illegible] evalua-
tion of the [illegible] effective-
ness, [illegible]
food [illegible]
the program [illegible]
this evaluation [illegible]
Service [illegible]
plans [illegible]
[illegible]

[illegible]

Attempts [illegible] the [illegible] assistance [illegible] necessarily [illegible] problems:

--Lack of [illegible] of good health [illegible] nutri- [illegible] reliable [illegible] concerning the program's effect on overall health or nutritional status. (See p. [illegible])

--Lack of [illegible] nutrient [illegible] to maintain or improve [illegible] nutritional status [illegible] to [illegible] particular [illegible]

If [illegible] [illegible]ts, definition [illegible] need for [illegible] program [illegible] amounts of [illegible] known.

[illegible]

[illegible] how [illegible] the foods or [illegible] services contrib- [illegible] whether [illegible] changes would [illegible] supplemental [illegible] been provided.

[illegible] adequate indicator of mental development and of [illegible] known method to isolate [illegible] factors affecting [illegible] development which pre- [illegible] reliable conclusions on [illegible] program's effects on infants' [illegible] development. (See p. 16.)

[illegible] Service and the university [illegible] taken steps to [illegible] problems, they cannot practicably be overcome and must be recognized as preclud- ing a conclusive determination of the program's benefits.

[illegible] *limiting* [illegible]

[illegible] problems, a [illegible] could be useful [illegible] whether to continue the [illegible] reliable data were [illegible].

[illegible] such as the [illegible] to be accepted [illegible] must be of some [illegible] reliability. The [illegible] the responsibility [illegible] reliability.

[illegible] in training, [illegible] and procedures [illegible] quality, how- [illegible] the univer- [illegible] that standardized [illegible] and are being [illegible], nor can

BEST DOCUMENT AVAILABLE

they document the degree of data reliability.

Accordingly, GAO believes that the Service and the university will not be able to prove that the data is reliable. (See pp. 17 to 29.)

Because a large part of the data needed for the medical evaluation has already been collected under circumstances which raise serious doubts about the data's reliability, corrective action to improve quality control and insure the reliability of future data would not improve the validity and usefulness of the conclusions that might be drawn from the evaluation. (See p. 30.)

RECOMMENDATIONS

This report does not contain any recommendations to the Department.

AGENCY ACTIONS AND UNRESOLVED ISSUES

The Department outlined the steps the Service and the university had taken to deal with the inherent problems faced in all human nutrition evaluations (see pp. 13, 14, and 15), and the action taken to try to insure that reliable data is collected (see pp. 20, 23, 24, 27, and 28).

GAO believes that, with the steps taken to deal with the inherent problems, a useful evaluation could have been made if reliable data were collected. However, GAO believes that the action taken by the Service and the university to insure data reliability is not sufficient, and that further action would not be beneficial in improving the evaluation.

[illegible]

Because the medical and food distribution evaluations are not scheduled to be completed before June 30, 1975, when the program is due to expire, the Congress will not have the final evaluation results when considering whether to continue the program.

Conclusions which might reasonably be drawn from the medical evaluation, however, probably will be of questionable use in determining and evaluating the benefits of the nutritional assistance provided, as required by the act.

Considering the questionable credibility and usefulness of the evaluation and the savings which may still be possible through terminating the contract, the Congress may wish to advise the Secretary whether it wants the evaluation to be continued.

Should the Congress wish to predicate continuation of this program on some medical evidence of benefits to recipients, further study would be needed. Such a study could not be completed, however, before present authority for the program expires.

GAO believes it should be recognized that, although useful indicators might be obtained, certain inherent problems will continue to preclude the possibility of obtaining definitive answers concerning the medical benefits of the nutritional assistance provided.

If the Congress decides to order a further evaluation of the medical benefits of the program, greater safeguards need to be taken to insure that the methodology and timeframe for any such evaluation will be adequate to achieve reliable results.

The Congress may wish to consider assigning responsibility for any such evaluation to the Department of Health, Education, and Welfare, the agency primarily responsible for research related to maternal and child health. (See p. 32.)

CHAPTER 1

INTRODUCTION

Public Law 92-433 (86 Stat. 724), approved September 26, 1972, established section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) which authorizes the Special Supplemental Food Program. The program provides cash grants to States[1] to provide supplemental foods through health clinics[2] to pregnant or lactating women and to infants and children up to 4 years of age determined by competent professionals to be nutritional risks because of inadequate nutrition and income. The Food and Nutrition Service (FNS), Department of Agriculture, administers the program.

Subject to approval by the State agency and FNS, health clinics select the methods for distributing foods to participants. The primary methods being used are providing vouchers redeemable at retail stores and distributing foods at the clinics.

According to the act, the State and local agencies which operate the program are to maintain adequate medical records on program participants to enable the Secretary of Agriculture to determine and evaluate the benefits of the nutritional assistance provided. According to the conference report[3] on the authorizing legislation, the conferees expected that enough data would be obtained to medically identify and define the benefits that would be provided through this program in combating and abating any physical and mental damage that otherwise might be caused to infants due to malnutrition. The program's legislative history also indicates that an evaluation of the cost efficiency of the various methods of dis-

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[1] State agencies are the State health department or comparable agency; an Indian tribe, band, or group recognized by the Department of the Interior; or the appropriate area office of the Indian Health Service of the Department of Health, Education, and Welfare (HEW).

[2] Clinics are those operated by a State or political subdivision; by a private nonprofit organization; by an Indian tribe, band, or group recognized by the Department of the Interior; or by the Indian Health Service.

[3] H. Conf. Rept. [illegible], 92d Cong., 2d sess., Sept. 11, 1972.

tributing the supplemental foods should be made.

According to the act, the Secretary and the Comptroller General of the United States are required to submit to the Congress preliminary and final evaluation reports on the program. The final evaluation reports, containing recommendations on the program's continuation, are to be submitted by March 30, 1975.[1]

PARTICIPATION REQUIREMENTS

To be eligible for the program, pregnant or lactating women, infants, and children must:

--Reside within the geographic area served by a project. (A project is a clinic or a group of clinics at which the program is being operated.)

--Be eligible for services at less than the full cost customarily charged by the clinic. Income criteria for the program are not required unless a project customarily applies them.

--Be determined by a competent professional on the clinic's staff to need the supplemental foods. Uniform criteria for determining an individual's need for supplemental foods have not been established.

FNS instructions state that the eligibility criteria must also be applied to all infants born to mothers who participate in the program; such infants are not automatically eligible. Also, participants are not required to take part in the medical evaluation. Each individual, or guardian in the case of a minor, must give signed informed consent to participate in the medical evaluation.

FOODS PROVIDED

The act defines "supplemental foods" as those foods containing nutrients known to be lacking in the diets of populations at nutritional risk and, in particular, those foods and food products containing high

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[1]As enacted in Sept. 1972, the act required the final evaluation reports to be submitted by Mar. 30, 1974. Public Law 93-150 (87 Stat. 560), approved Nov. 7, 1973, advanced the date to Mar. 30, 1975.

quality protein, iron, calcium, vitamin A, and vitamin C. Also included are commercially formulated food products designed specifically for infants.

Program regulations define the types and maximum quantities of foods which can be distributed. They include milk and formulas, eggs, cereals (limited to those which meet FNS requirements for enrichment), and juices. Substitutions may be used, such as cheese for milk or dried eggs for fresh eggs. The regulations state that these foods can supply substantial percentages of the National Academy of Sciences' recommended dietary allowances for protein, calcium, iron, vitamins A and C, and calories.

FNS requires that food from all these food groups be available to the participants. FNS officials told us, however, that the professionals at each project, on the basis of an individual's nutritional needs, can determine whether or not each individual should receive the entire food package or part of it.

PROGRAM FUNDING

As originally authorized, the program was to be carried out during fiscal years 1973 and 1974 at a funding level of $20 million a year. Program expenditures for fiscal year 1973 totaled $30,000. A court order[1] issued in August 1973 required that the remaining fiscal year 1973 funds be carried over and be committed to the program in fiscal year 1974. Public Law 93-150, approved November 7, 1973, extended the program through fiscal year 1975 and made $40 million available for that year.

Public Law 93-326 (88 Stat. 286), approved June 30, 1974, increased the authorization for fiscal year 1975 to $100 million. A July 1974 court order[2] required that all unspent fiscal year 1974 funds be carried over and obligated during fiscal year 1975 and that the $100 million authorized for fiscal year 1975 also be obligated.

PREVIOUS GAO REPORT

In a preliminary report dated September 28, 1973 (B-176394), we reviewed FNS's progress in implementing the program and some

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[1]Dixon v. Butz, D.D.C., Civil Action 1210-73, Aug. 3, 1973.

[2]Dixon v. Butz, D.D.C., Civil Action 1210-73, July 19, 1974.

problems we believed would be encountered in the medical evaluation of the program as then planned. The major concerns reported were that, because of delays in starting the program, insufficient operating time would remain in which to conduct a valid medical evaluation and [illegible] of the program's effects on infants' mental development would be possible in the type of evaluation planned by FNS. Public Law 93-150 extended the program for 1 year, providing additional operating time. Plans for measuring infants' mental development were not changed.

In carrying out our responsibility for evaluating the program, we have maintained continuous communication with FNS officials responsible for administering and evaluating the program. To assist us in our work, we hired four consultants with expertise in nutrition, biochemistry, pediatrics, obstetrics, and biostatistics. (See app. I.) We discussed with them FNS's evaluation of the program and informed FNS of potential problem areas they noted. Our consultants' opinions are included in opinions we express throughout this report.

CHAPTER 2

PROGRESS OF PROGRAM IMPLEMENTATION

From September 1972, when the program was authorized, until early March 1973, the Department of Agriculture planned the program and negotiated with HEW regarding the feasibility of HEW's administering the program. On March 6, 1973, after HEW declined to administer the program, FNS established a task force to plan program operation and evaluation. Among other things, the task force wrote program regulations that became effective July 13, 1973.

In June 1973 a suit[1] was brought on behalf of certain prospective program beneficiaries asking that the Secretary and other Agriculture officials be enjoined from further delaying the program and from refusing to spend the total $40 million authorized for the program. The court order issued on August 3, 1973 (see p. 3), required the Secretary to process and approve applications which qualified for funding until $40 million was expended or until June 30, 1974, whichever occurred first.

PROJECT SELECTION AND IMPLEMENTATION

FNS began receiving project applications in August 1973. Program regulations required that applications include information on the poverty level of the area served, the incidence of nutritional risk, the method of food distribution, and the project's capabilities to collect the required medical data. FNS officials told us that this information was necessary for selecting projects and that, because most of the applications contained insufficient information on these matters, they spent considerable time obtaining the necessary information.

FNS approved the first project on August 29, 1973. On September 28, 1973, 13 additional projects were approved. In November plaintiffs in the June 1973 suit filed a motion to cite the Secretary and other officials in contempt of the August 1973 court order because FNS had only committed about $5.3 million to operation of the program. On December 3, 1973, the court issued an order[2]

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[1] Dotson v. Butz, D.D.C., Civil Action 1210-73.

[2] Dotson v. Butz, D.D.C., Civil Action 1210-73, Dec. 3, 1973.

which, although making no contempt citation, required that the full $40 million be committed to the program on or before December 31, 1973. On the same day, FNS approved 143 projects, and on December 28, 1973, it approved 53 projects, for a total of 216 projects (one of these projects is now recognized by FNS as being two separate projects).

The 217 projects represented a commitment of about $38 million for operation of the program at the State and local levels in fiscal year 1974. FNS set aside the remainder of the $40 million for program evaluation.

Many of the projects which had been granted funds for January to June 1974 did not begin operation until after January. Consequently, FNS reduced the funds available to these projects by 1 month's estimated budget and recommitted these funds on March 6, 1974, by approving 39 additional projects. In addition, 14 more projects were approved (11 on Aug. 16, 1974, and 3 on Oct. 8, 1974) bringing the total number of approved projects to 270. However, 9 projects have withdrawn from the program and 7 have combined with other projects, leaving a total as of October 29, 1974, of 254 approved projects. These projects have approved caseloads totaling about 440,000 women, infants, and children. FNS estimated that about 206,000 participants were enrolled in the program at the 240 projects in operation as of June 30, 1974.

1974	Total number of projects operating	Total end-of-month participation			
		Women	Infants	Children	Total
Jan.	24	300	307	102	709
Feb.	87	2,642	3,335	5,435	11,382
Mar.	122	7,687	11,577	18,429	37,693
Apr.	179	15,894	25,383	46,178	87,455
May	226				(a)
June	240				(a)
July	240				(a)
Aug.	[b]239				(a)
Sept.	240				(a)
Oct.	241				(a)

[a]As of Oct. 30, 1974, participation figures for these months were not available. As of that date, FNS estimated that 206,000 women, infants, and children had been enrolled by June 30, 1974.

[b]In Aug. 1974 some projects combined, resulting in a net decrease in the number of projects in operation.

EXPENDITURES FOR PROJECT OPERATIONS

Estimated expenditures for project operations in fiscal year 1974[1] totaled $12.2 million, far short of the $38 million which FNS had committed for this purpose. FNS officials told us that many projects began operating later than anticipated and that the number of participants enrolled in many projects did not reach the number on which the projects' budgets were based.

The $12.2 million spent in fiscal year 1974 for project operations consisted of $9.9 million for foods provided to participants, $1.1 million for administrative costs (limited to 10 percent of food costs plus administrative costs), and $1.2 million for clinic evaluation costs (costs projects incurred to supply data for the medical evaluation and to determine the medical needs of persons for the supplemental foods).

The 254 approved projects have been funded through June 30, 1975. FNS officials told us that all of the $100 million made available for fiscal year 1975 and about $19 million of the funds anticipated to be carried over from fiscal year 1974 have been committed. In announcing the additional projects on October 8, 1974, FNS noted that, when it determined the actual amount of the fiscal year 1974 funds to be carried over, it would consider funding additional projects or increasing caseloads or geographical boundaries of projects already approved.

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[1]All fiscal year 1974 expenditures are estimates provided by FNS on Oct. 30, 1974.

CHAPTER 3

DESIGN AND IMPLEMENTATION OF PROGRAM EVALUATIONS

To meet the statutory requirement to determine and evaluate the medical benefits of the nutritional assistance provided to program participants, FNS has underway a detailed medical evaluation. This evaluation is being made at 19 projects under a contract with the Department of Nutrition, School of Public Health, University of North Carolina at Chapel Hill.

Also, as called for in the program's legislative history, FNS, through an agreement with the Technical Analysis Division, National Bureau of Standards (NBS), Department of Commerce, is evaluating the efficiency and effectiveness of various food distribution methods used in the program.

MEDICAL EVALUATION

FNS contracted with the university on November 28, 1973, to make the medical evaluation. The current estimated cost under the cost-reimbursable contract is $1.7 million. Since FNS and the university are still negotiating some cost elements, this cost may change. FNS plans to charge all contract costs to fiscal year 1974 funds.

As the evaluation is designed, baseline data is being collected on all participants when they enroll in the program and prior to receipt of the supplemental foods. This baseline data will be the control data for the evaluation representing the health status of the program population prior to participation. Women, depending on their stage of pregnancy at enrollment, are being reexamined at a maximum of three followup visits scheduled at specific stages of pregnancy (24 to 28 weeks, 36 to 40 weeks, and 4 to 8 weeks after delivery). Infants and children are being reexamined 6 and 11 months after enrollment.

The university intends to obtain baseline data on at least 1,000 pregnant women at each of the four stages of pregnancy and followup data on about 2,500 women who, at the time of delivery, will have received the foods for at least 3 months. It also intends to obtain baseline data on about 27,500 infants and children and followup data on about 25,000 infants and children who received the foods for

6 months and about 16,700 infants and children who received the foods for 11 months.

Parameters to be analyzed for each woman include clinical measures of height, weight, and anemia (hemoglobin and hematocrit values) and various biochemical measures designed to determine whether the participants increased their consumption of iron, protein, and vitamin A during the course of program participation. Information on the outcome of pregnancy, such as the infant's birth weight, is also being collected. Parameters to be analyzed for infants and children include those for women, with the addition of head circumference and the exclusion of vitamin A.

The university is also collecting information it believes is necessary to properly interpret the clinical and biochemical data. Household data (such as family size, income, and participation in other feeding programs), selected medical history information, and dietary data (a recall of everything eaten in the previous 24-hour period and a dietary history of general eating habits) are being collected. The dietary data is being obtained for one-half of the women and one-quarter of the infants and children being evaluated.

The basic approach in the evaluation is a comparison of followup data with baseline data. Followup data on infants and children, subgrouped by age, will be compared with baseline data on infants and children of comparable age. For example, followup data collected on children who, at the age of 3, had participated in the program for 11 months would be compared with baseline data collected on children who, at the time of enrollment, were 3 years of age, to determine if the incidence of deficiencies was lower in the former group. Similarly followup data on women at four stages of pregnancy will be compared with baseline data on women at comparable stages of pregnancy to determine differences in the parameters measured.

The contract does not indicate what analytical questions are to be answered in the evaluation.

According to the original schedule in the contract, the university was to train personnel at the evaluation projects in January 1974 and the projects were to begin collecting medical data in February 1974. Data was to be collected through February 1975, and a final report on the evaluation was to be prepared by May 1975, 2 months after the March 30, 1975, required reporting date.

However, training was delayed at most of the 19 projects. According to FNS and university officials, the delays resulted primarily from a lack of sufficient staff and equipment at the projects to perform the medical evaluation and from delays in completing budgets for clinic evaluation costs. Training was conducted at the sites in 1- or 2-day sessions between January 23 and May 24, 1974. The projects began operating at various times between February and June 1974.

The university plans to carry on the evaluation for 13 months at each project. For example, at those projects which began operations in June 1974, final data will be collected at the end of June 1975. Thus, because of delays in starting the evaluation, all evaluation data will not have been collected for analysis until the end of June 1975. According to the current schedule, the university's final report is due to FNS on October 1, 1975.

In its comments (see app. II), the Department noted that it felt the university worked as expeditiously as possible to implement the medical evaluation. It noted the following obstacles which precluded a more timely initiation of the evaluation and which it noted were out of the control of the Department and the university.

> At the time the prospective contractor was selected, the program was not authorized for a period long enough to allow a 12-month evaluation, the minimum period required by the only prospective contractor in a position to carry out the evaluation. After legislation extending the program was passed on November 7, 1973, negotiations resumed and a contract was signed on November 28, 1973.
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> --On visits to project sites, university personnel determined that project facilities were far from adequate for obtaining the quality of data required. The contract was revised to allow the university to procure necessary standardized equipment for the projects. Adherence to State and Federal procedures as well as late shipments from suppliers caused some delays in procurement of the equipment.
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> --Delays also resulted from personnel shortages. Some projects had difficulty in recruiting personnel to collect medical evaluation data because of constraints imposed by the States and because of other personnel and administrative problems.

EVALUATION OF FOOD DISTRIBUTION METHODS

On November 8, 1974, FNS signed an agreement with NBS to evaluate the efficiency, effectiveness, and total cost of various food distribution methods used in the program. We plan to monitor this evaluation as it is implemented.

According to the agreement, a sample projects information is to be obtained on the project characteristics, such as facilities available and services offered; the characteristics and views of participants, former participants, and nonparticipants; the degree of satisfaction of State and project personnel with the foods and the program; the total State and local program costs as well as total food distribution costs; the extent of nutrition education and outreach efforts; and the program's effect on participation in other clinic services.

According to the current schedule, NBS is to submit a final report on this evaluation to FNS by June 30, 1975.

CHAPTER 4

PROBLEMS INHERENT IN HUMAN NUTRITION EVALUATIONS

Attempts to determine and evaluate the benefits of nutritional assistance to humans, such as that authorized by the act, are necessarily limited by certain inherent problems including

- --the lack of universally accepted health and nutrition standards,
- --the lack of a precise determination of the nutrients required to maintain or improve nutritional status,
- --difficulties and limitations in finding and using control groups, and
- --the lack of an adequate indicator of infants' mental development.

Although FNS and the university have taken steps to deal with these problems, they cannot practicably be overcome and must be recognized as precluding a conclusive determination of the program's benefits. These problems, however, do not necessarily preclude performance of a useful evaluation.

LACK OF UNIVERSALLY ACCEPTED HEALTH AND NUTRITION STANDARDS

Standards of what constitutes good health and adequate nutritional status have not been precisely defined by medical and other scientific research. It is not definitely known, for example, how low a hemoglobin value can be without affecting health or growth and development. Similarly, the ideal growth rate for children, compatible with the longest useful and healthy life, has not been definitely determined. Because such standards have not been precisely defined, professionals do not agree on the significance of various parameters (such as height and weight) in assessing overall health or nutritional status. This lack of agreement will limit the evaluation's conclusions to the program's effects on the particular parameters studied. The effects on overall health or nutritional status will not be known.

For example, a recent study[1] of the nutritional status of preschool children in the United States stated:

> "... to our knowledge there have been no definitive efforts to develop a system for 'rating' or 'scoring' the nutritional status of populations or of individuals. We do not have available any substantive data which allow us to group dietary, clinical or biochemical data (weighed or unweighed) to signify the degree of subclinical malnutrition. Certainly, the presence of two or more 'unacceptable' biochemical indices in some segment of a population does not necessarily denote severity of malnutrition or even of a greater potential for malnutrition to develop at some future time."

Also, HEW is conducting the Health and Nutrition Examination Survey to measure the nutritional status of the U.S. population and to monitor changes in this status over time. The Survey uses, among others, the same parameters being used in the medical evaluation. A January 1974 report[2] on the survey stated:

> "Not one of these measures is, in itself, sufficient to characterize nutritional status. Theoretically, some synthesis [combination] of the several separate sightings would provide the best measurement and, hopefully, a method for such synthesis ultimately may be developed. At present, however, in the absence of a definitive method of combining the separate measures, it is necessary to present the findings separately from each methodology."

The Department (see app. II) told us that it shared our concern about the lack of universal health and nutrition standards. It said that, although there were no universally accepted standards to measure subtle nutritional benefits, there were certain parameters which were generally used in nutrition studies of this kind. It also

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[1]George M. Owen, Kathryn M. Kram, Phillip J. Garry, Jay E. Lowe, and A. Harold Lubin, "A Study of Nutritional Status of Preschool Children in the United States, 1968-1970," Supplement to Pediatrics, Evanston, Illinois, Apr. 1974, p. 643.

[2]"Preliminary Findings of the First Health and Nutrition Examination Survey, United States, 1971-72: Dietary Intake and Biochemical Findings," HEW, Jan. 1974, p. 3.

said that the parameters chosen were recommended by its consultants as those most likely to be abnormal in the population being studied and most likely to be altered by 6 or more months of feeding intervention.

By using the parameters which are generally used in evaluations of this type, FNS and the university have dealt with the problem to the extent possible.

NUTRIENTS REQUIRED TO MAINTAIN OR IMPROVE NUTRITIONAL STATUS NOT PRECISELY DETERMINED

The types or quantities of nutrients necessary to maintain or improve a given nutritional status have not been precisely determined. For example, the recommended dietary allowances published by the National Academy of Sciences are only estimates--the best available--of the dietary intakes necessary to keep healthy people in good health. Although the foods chosen provide a high proportion of the dietary allowances of nutrients specified in the legislation, our consultants noted that the extent to which this food combination meets the dietary needs of the target population is not known.

Therefore, conclusive nutritional evaluation can address only the effects of the particular food combination and amounts made available in this program. If little or no benefit results, definitive conclusions on the need for a supplemental food program could not be made, because benefits which might have come from different foods or amounts of foods would not be known. Further, associating the foods provided with the findings will be difficult because of problems in determining whether other factors contributed to findings and whether the foods were consumed. (See pp. 15 and 23).

The Department (see app. II) said that the supplemental foods chosen for the program (see p. 2) provide a high proportion of the recommended dietary allowances of the nutrients of high-quality protein iron, calcium, vitamin A, and vitamin C specified in the legislation, as well as substantial quantities of [illegible], niacin, riboflavin, and vitamin D. It said that [illegible] are readily available and widely accepted.

The Department also noted that, although there was some disagreement among professionals on the [illegible] quantities of nutrients necessary to maintain [illegible], the Department's consultants believed that the [illegible] were the best estimates available on the [illegible] of nutrients.

By choosing foods which supply a high proportion of the dietary allowances of nutrients specified in the legislation, FNS has dealt with the problem to the extent possible.

DIFFICULTIES AND LIMITATIONS IN FINDING AND USING CONTROL GROUPS

If this evaluation was being made under ideal research laboratory conditions, control data would be collected on groups with similar health and dietary characteristics whose food intake would be continuously monitored and who would receive essentially identical care without the supplemental foods. Any changes in the two groups could then be compared, and any differences could be attributed with some degree of confidence to the presence or absence of the supplemental foods.

Without control groups, the evaluators will not be able to judge (1) how much the foods or other clinic services, such as nutrition education, health care, outreach, or patient followup, contributed to the findings or (2) whether any demonstrated changes would have occurred if the supplemental foods had not been provided.

In a study such as this, however, finding truly comparable control populations--comparable groups receiving the same services except for the supplemental foods--would be very difficult. Further, even if such populations could be found, their use might be inappropriate in a program designed to provide foods since it would be necessary to deny the supplemental foods to some individuals who would be identified as being at nutritional risk.

The Department (see app. II) noted that, primarily for the reasons described above, this evaluation was using baseline data--data collected on participants prior to receipt of foods--as control data. Followup data will be compared with this data to determine any changes. The Department noted also that, because of difficulties in finding truly comparable control groups, its consultants believed that, from a purely scientific standpoint, the "baseline-control" approach being used was the most appropriate for this study.

We believe that, given the difficulties and possible inappropriateness of using customary control populations in this evaluation, using reliable baseline information is a satisfactory alternative.

LACK OF AN ADEQUATE INDICATOR OF MENTAL DEVELOPMENT

The only parameter being used in the medical evaluation to measure infants' mental development is head circumference.

Our September 1973 report stated that FNS's medical consultants had (1) stated that the measure of head circumference was not by itself adequate, but neither were any of the mental development tests then in use, and (2) noted that accurate data on head circumference probably would not be obtained, unless those taking the measurements were very well trained. Our report also noted that other physicians and persons working in the fields of nutrition and child health had questioned whether any valid measure of mental development was possible in a study of this type.

According to our consultants, head circumference is an indicator of brain size but not of mental development because brain size does not reflect mental capacity and increases in brain size do not reflect mental growth. They also noted that there is no known method to isolate individual factors affecting mental development from all the socioeconomic factors which affect it.

An FNS official told us that FNS had concluded that no other available instrument for measuring mental development would be appropriate for the evaluation, and that the program's effect on mental development would be determined only to the extent that head circumference could be considered an indication of mental development.

CHAPTER 5

LIMITED USEFULNESS OF CONCLUSIONS TO BE DRAWN FROM MEDICAL EVALUATION

Despite the inherent problems discussed in the preceding chapter, which preclude any conclusive determination of the benefits of nutritional assistance provided, an evaluation such as the legislation calls for could be useful in deciding whether to continue the program if reliable data were collected. However, we believe that FNS and the university have not taken adequate steps to reasonably insure data reliability and, therefore, the conclusions drawn from the medical evaluation probably will be of questionable use in determining whether to continue the program.

According to our consultants, for evaluations such as this to be accepted as valid, the data must be of some known degree of reliability. The evaluator bears the responsibility for proving data reliability. This can be done, in part, through indirect steps to insure standardized procedures, such as insuring adequate training and monitoring of data collectors. In addition, since some degree of variance will always exist in this type of data collection--even with the best trained and supervised personnel, direct steps, such as use of known-value blood standards and height and weight remeasures, must be instituted to determine, in a more precise manner than can be done through indirect means, the variance or degree of data reliability.

We believe that FNS and the university cannot insure that data is reliable because they have not taken adequate steps to insure that standardized procedures are used and instituted steps to document the degree of data reliability. We also believe that attempts to improve data reliability would not be beneficial because a large part of the data has already been collected under circumstances which raise serious doubts about the data's reliability.

INADEQUATE QUALITY CONTROL PROCEDURES

Our consultants have stressed that standardized and controlled procedures for collecting data are important in research efforts to insure consistent data quality. Such standardization and control is especially difficult in this evaluation because data is being collected at several widely dispersed sites. Also, differences in local attitudes, motivations, resources, personnel, and abilities, which are very difficult to document and control, can be expected to affect data quality.

To help insure accurate and uniform data collection, the university took or planned to take several steps, including:

- Preparing a procedures manual for project use.

--Conducting training sessions at each project on collecting all data except dietary data. Training in dietary data collection was conducted in two workshops at the university

--Requiring the use of comparable supplies and equipment at each project.

--Requiring that each project complete a pretest in which all types of data and blood specimens were collected on a sample of participants and sent to the university for review and approval before starting the evaluation.

--Requiring that project personnel responsible for making hemoglobin and hematocrit determinations periodically make and record such determinations from both "known-value" standards and "unknown-value" blood specimens to check the accuracy of these determinations.

--Planning that university personnel would visit each project to monitor data collection.

If properly implemented, these steps could contribute to quality control. However, we believe that, because of the weaknesses discussed below in training, pretest procedures, and procedures for controlling data quality, quality control is not adequate to insure data reliability.

Training

We attended university-conducted training sessions at 6 of the 19 projects and 1 of the 2 dietary training workshops held at the university.

At the project training sessions, we noted the following weaknesses which we believe reduced the effectiveness of the training.[1]

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[1] At one project--one of the first at which training was held--each of these problems occurred. The university held a second training session at this project which we did not attend.

--At three projects, instructions for standardizing balance scales with standard weights were not given. Although the principal investigator said that it was very important to periodically check the accuracy of scales with standard weights, and although such weights are listed in the manual as required equipment, the manual does not give instructions on standardization.

--At five projects, demonstrations of the prescribed procedures for taking body measurements were cursory. At all six of the projects only a few project personnel practiced any of these procedures, primarily because the university staff gave little opportunity for practice. To better insure standardization, we believe that project personnel should have had a greater opportunity to practice under the direction of a university team member.

--At each project, the demonstration of drawing blood from the fingers or heels of infants and children included squeezing, or milking, the area while blood was being drawn. This squeezing can cause hemolysis--the mixing of destroyed blood cells with plasma--and/or dilution of blood with tissue fluids introducing error in biochemical readings. Although the need to avoid excessive squeezing was mentioned during most of the demonstrations, and although the university's procedures manual states that squeezing should be gentle, our consultants said that even gentle squeezing while blood is being drawn can result in inaccuracies in hemoglobin and hematocrit values and in some biochemical measures.

--At five of the six training sessions, some of the personnel did not attend (in many cases they had not been hired), although the university's procedures manual states that training sessions were to be arranged for all personnel who would be collecting data.

We also noted weaknesses at the dietary training workshop. For example, during interview practice sessions, there were variations in the ways questions were asked and dietary forms were filled out. The differences in interview techniques which we observed were not noted or corrected by those conducting the training session and, consequently, the usefulness of practice sessions for standardizing procedures was reduced.

In many cases, those attending the training were not those who would be collecting the data. Also some of those attending expressed reservations during the workshop about whether they understood the procedures well enough to adequately teach the clinic personnel, usually nutrition aides or other intermediate level personnel, who would be collecting dietary data.

The Department (see app. II) said that training was "individualized" to meet the needs and circumstances of each project. It noted that training sessions were usually organized according to four areas--general orientation; collection and recording of demographic, household, and medical data; clinical measurement procedures; and laboratory procedures. It said that

> --in projects where a number of new and inexperienced staff members were recruited for the evaluation, arrangements were made for the staff to practice taking and recording data in small groups during the training sessions, but
>
> --in projects where staff members with considerable experience were responsible for data collection, there was less need for practice and greater emphasis was given to discussing pitfalls in carrying out the procedures and precautions to be taken to eliminate or minimize these difficulties.

The Department also noted that the laboratory procedures usually presented the greatest challenge because many of the projects did not have qualified laboratory technicians on their teams. Accordingly, it said, considerable time was often devoted to practicing laboratory procedures.

According to our consultants, obtaining reliable data on clinical measurements for research purposes is very difficult, and much practice is necessary, regardless of previous clinical experience. They noted that, although some personnel might be experienced in taking the types of measurements used in this study, many of the specific procedures required for this evaluation were not those generally used in health clinics. For example, most of the projects did not have the equipment prescribed for obtaining length, head circumference, and hemoglobin determinations before the evaluation. Further, our consultants said that the precision required for research purposes is far greater than is generally obtained in a clinic setting.

We and our consultants believe that, to help insure that standardized procedures would be used for data collection, all personnel, regardless of experience, should have been given an opportunity to practice the prescribed procedures under the direction of a university team member.

The Department also noted that, when collecting blood from a finger, it was not unusual to find it necessary to apply a small amount of pressure to obtain a sufficient quantity. It said that it was not always possible through observation to judge when the amount of pressure was excessive and that hemolysis was not observed in the samples obtained when the university staff demonstrated the technique during the training sessions.

As stated on page 19, our consultants said that even gentle squeezing while blood is being drawn can cause hemolysis and introduce tissue fluids into blood specimens causing error in blood determinations. They also note that tissue fluids cannot be detected in blood or plasma samples by visual observation--the method the university told us was being used to check for hemolysis. The university said that no tests to determine the presence of tissue fluids were being made.

The Department agreed that, to insure standardization, the university's training all personnel who would be collecting dietary data would have been preferred. It said, however, that it was impossible to train all data collectors because of the time constraint and the large number of personnel to be trained. It said that, to provide the highest quality instruction, centralized training sessions were held instead for key nutritionists from each project who would be responsible for training the remainder of their dietary staffs.

The Department also said that members of the university's dietary faculty visited the projects, as needed, to clarify problems concerning procedures for collecting and recording dietary data. It said that these followup training sessions consisted of lecture-discussions and demonstrations and that participants in the sessions practiced interviewing and using food models in questioning respondents and in recording dietary information given by respondents.

Our consultants have noted that collection of reliable dietary data is perhaps the most difficult phase of the evaluation because standardization of interview techniques is extremely difficult and,

as with collection of clinical data, obtaining data sufficiently reliable for research purposes requires a great deal of instruction and practice, regardless of previous clinical experience.

Because of weaknesses we noted in the dietary training, our consultants believe that the training was not sufficient to insure that the key nutritionists were sufficiently familiar with standardized procedures to collect reliable data or to train others to do so.

The university did not provide the key nutritionists with instructions on the amount or type of training they should give their staffs. Moreover, the university did not have information on what training was actually given. A university team member said that the procedures manual has detailed instructions on standardized procedures.

Our consultants noted, however, that written instructions are not sufficient to insure reliable data collection; practice and instruction are necessary. They noted also that the dietary data will be questionable because the university cannot insure that comparable training was given to those actually involved in this phase of data collection.

Further, a university team member told us that project visits by the dietary staff did not, in all cases, include training sessions for all those involved in dietary data collection.

Pretests

Because the pretests were not appropriately monitored, we and our consultants believe that they were not sufficient to insure that projects would collect accurate data. Our consultants pointed out that, although the university could identify such things as inaccuracies in completing forms (e.g., questions skipped or values recorded in incorrect units of measure) and use of improper procedures for shipping blood samples, it would not [illegible] whether proper techniques were used to obtain data and to collect and process specimens. For example, although an individual's weight might be recorded properly, the university could not know if the height had been measured correctly. Likewise, the university could check to see that dietary forms were filled in properly, but could not determine whether the interviewer had followed the proper techniques for obtaining correct information on all foods eaten.

We and our consultants believe that the usefulness of the pretests in insuring data quality could have been improved if, for example,

--an evaluation team member would have been present during each pretest to insure that proper techniques and procedures were used and

--a quality control blood sample for which personnel did not know the correct values had been used so that university personnel could check the accuracy of the blood determinations.

The Department (see app. II) said that, upon completion of the training sessions, each clinic site was requested to practice and coordinate all procedures required by this study for several days before conducting a pretest. Because of this interval and the large number of clinic sites, it was impossible for university personnel to be present at each pretest. Training was proceeding at some projects while pretests were being conducted at others.

The Department also noted that

--university personnel did not consider it necessary to be present to monitor and determine the validity of each pretest;

--there were several other satisfactory ways to judge the quality of pretest data, including checks on the completeness of the forms, consistence of the information collected, number of errors in forms, frequency of "out of range" data, adherence to instructions about the packaging and shipment of materials, evidence of hemolysis in plasma, quantity of plasma, and the ratio or correlation of hemoglobin to hematocrit;

--university personnel used all of these procedures to evaluate the validity of the pretest data; and

--a number of problems were detected very early in the program and immediate corrective actions were taken in each case.

As noted above, procedures used to monitor pretest data were adequate to allow the university to determine the degree of accuracy with which forms were completed and to identify certain problems in collecting and shipping blood. However, because no procedures were required at the projects during the pretest to determine the reliability of data collected, the university could not determine the degree of accuracy or completeness of interview information, the degree of accuracy with which clinical measurements were made, or the adequacy of procedures followed in obtaining and processing blood specimens and the degree of accuracy of blood values.

Determining reliability of data collected

Body measurement data

In the report provided the Department for comment, we said that the information FNS had made available to us showed that the university was not making frequent, periodic visits to projects to monitor data collection and that we believed the reliability of the data would be impaired. According to our consultants, procedures to monitor the data collection phase of the evaluation should have at least included more frequent visits to all projects to determine whether prescribed procedures were being used.

In commenting on this matter (see app. II), the Department, on the basis of updated information supplied by the university, said that all projects had been visited at least once by a member of the university's primary staff and that all but one project had been visited by the principal investigator or his deputy. It noted that visits by university personnel would be repeated at intervals of approximately 3 months, or more frequently if necessary.

The Department said that, although these personal contacts had been very useful in clarifying details of program operations, they had proven to be of more limited value in quality control than originally envisioned. It noted that data collection was in progress in over 80 sites at the 14 projects, that problems involved in close monitoring of each project site directly by the university were considerable, and that an effective control program based primarily on visits to the projects would be prohibitively expensive in personnel and travel costs.

Therefore, the Department said greater reliance had been placed on effective local supervision. It said that each project was required to appoint a competent project director and that the directors participated in all aspects of the on-site training.

We and our consultants believe that, if properly implemented, the use of project directors to monitor data collection, in conjunction with periodic project visits by university personnel, is a valid method of providing control over data collection. For the following reasons, however, we and our consultants believe that, as used in this evaluation, this approach does not provide the quality control necessary to insure data reliability.

--Adequate steps were not taken to insure that comparable quality control procedures were implemented at all projects or to insure that project directors were familiar with adequate quality control procedures. Although project directors were given primary responsibility for insuring that proper data collection techniques were used, they were not given written instructions, except for laboratory procedures (see p. 26), on what they should do to carry out this responsibility.

--The project directors received inadequate training at the project training sessions. (See p. 18.) At two of the six training sessions we attended, the project directors did not attend major portions of the sessions.

--The degree and type of quality control procedures instituted at various projects differed. The principal investigator told us, for example, that he had asked project directors to remeasure a sample of participants (e.g., take a second height or weight measure) to check the accuracy with which project staffs are taking measures, but that the degree to which this was being done varied from project to project. He did not ask project directors to record results of these remeasures.

--Project directors are not required to document the quality control procedures they implement, and the university does not receive any systematic feedback on timing or extent of procedures which might have been implemented.

According to our consultants, if data in the evaluation is to be accepted as valid, the investigator must provide evidence of the extent to which the data can be considered accurate. They noted that, even with the best trained and most experienced personnel, some degree of variance will exist between measures, but that the degree of variance must be documented. They believe that procedures, such as frequent, systematic, and recorded remeasures, should have been instituted at each project.

Procedures to document the degree of reliability, however, have not been implemented. As noted above, project directors are not required to document or report the quality control procedures they implement, and they are not required to record the results of any quality control checks they make. Although the principal investigator told us that the university team members do some remeasuring at the projects they visit, they do not record the results of their remeasures.

Projects' blood determinations

As one of the quality control checks for hematocrit and hemoglobin determinations made at the projects, the university's procedures manual states that the university is to periodically send for testing stabilized blood specimens for which the correct hemoglobin and hematocrit values are unknown to project personnel. The university is then to check the projects' determinations for accuracy. In addition, at 3-month intervals each project was scheduled to receive from HEW's Center for Disease Control (CDC) vials containing stabilized blood suitable for measuring hemoglobin and hematocrit values. The university planned to prepare its unknown-value stabilized blood specimens for distribution to the project sites in the intervals between receipt of the CDC specimens.

As of November 4, 1974, however, the university had not signed an agreement with CDC for that agency to supply blood specimens. Moreover, the university did not begin sending the projects the unknown-value test specimens it had prepared until October 2, 1974. By that time the projects had been operating for periods ranging from 4 1/2 months to 7 months.[1] Because the university did not institute the use of this control at the beginning of data collection, we believe the reliability of the projects' blood determinations cannot be insured.

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[1] As of Nov. 4, 1974, the university had received results from these specimens from 11 of 14 projects.

According to the Department (see app. II), the principal advantage of sending quality control stabilized blood samples with unknown values is that the operator should not be able to distinguish them from regular specimens, eliminating observer bias due to special handling of the samples. The Department said, however, it very soon became apparent that this ideal was impossible in the program. The laboratory personnel at the project sites normally deal directly with the participants. They collect the blood samples from the participants and make their determinations on the site. They would immediately recognize any specimen brought to them as a quality control sample.

Therefore, the Department said university efforts had been focused on cooperating with project directors in the use of commercially prepared, known-value hemoglobin and hematocrit standards. The university's procedures manual lists the use of such standards as another type of quality control check for hematocrit and hemoglobin determinations made at the projects.

The Department said that the commercially prepared standards were being dispatched regularly to each project director for distribution to each project site. It said that, on the first clinic day of each week, all personnel taking hematocrit and hemoglobin samples were required to prepare a hemoglobin and hematocrit sample from the standard as they would normally do with a blood sample. According to the procedures manual, the readings from these samples are to be recorded and sent to the university. The Department said that, if the determined values fall outside the range given by the manufacturer, the tests are repeated. If the repeat values are also outside the appropriate range, the examiner reports the matter to the project director. The project director is required to contact the university immediately if he cannot find a satisfactory solution.

According to our consultants, the use of known-value and unknown-value quality control checks [illegible] possible benefits. They recommended that project [illegible] might consider the unknown-value specimens as quality control checks, but only after the correct value [illegible] known. However, the consultants saw the possibility of a problem associated with the known-value standards. As noted above, however, the university did not approve the first project site stabilized blood specimens for use [illegible] until [illegible].

Further, the first commercially prepared known-value standards were not sent to the projects until mid-May 1974 and, as of October 8, 1974, the university had received the readings on these standards from only 10 of the 19 projects. University faculty told us they did not know whether the other 9 projects had been performing the determinations. Of the 10 projects which had submitted readings, none had begun recording the readings before June. At the time these projects began recording the readings, eight had been in operation 2 or more months; three of these for 4 or more months.[1]

Both known-value standards and unknown-value specimens are needed to control and document the accuracy of the projects' blood determinations. However, because the standards and specimens have not been used from the beginning of data collection, the university does not have evidence of the reliability of data collected before their use. Consequently, a reliable comparison cannot be made of data on hemoglobin and hematocrit values collected before and after the standards and specimens were used.

Dietary data

To determine the effects of foods provided to program participants, evaluators must know whether the participants ate the foods and if eating the foods represented a change in their eating patterns. Our consultants said that strict controls on human food consumption are not possible except in ideal research laboratory conditions and that no practical method to accurately determine past consumption has been devised for use in large-scale studies.

The Department (see app. II) told us that dietary data being obtained from participants, although not precise on an individual participant basis, may be quite reliable in reflecting gross changes in consumption patterns when applied to a large population, and that the limitations of the techniques to be used for the dietary studies were considered when determining the number of participants to be included in these studies.

Our consultants have noted that in order for dietary data obtained through interview to reliably reflect gross changes in

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[1] On Nov. 4, 1974, a university faculty member told us that readings had been received from three additional projects. These projects had begun recording readings in October, after some preoperation of 7, and 8 months, respectively.

consumption patterns, even of large populations, such data must be of some known degree of reliability. They have also noted that insuring reliability of dietary data in the evaluation will be more difficult than in general dietary surveys because the provision of food itself introduces an additional bias factor. For example, a woman who shared program foods with other family members might be reluctant to tell the interviewer this because of fear of being dropped from the program or having the amount of food reduced.

The Department noted that the possibility of concealment and falsification was a constant factor in any research based on interview, but that it can be minimized by using competent interviewers and by existence of good rapport and understanding between interviewer and respondent.

However, as discussed on page 22, the university cannot provide assurance that the interviewers were adequately trained. Further, steps were not taken to insure that adequate control over dietary data collection was instituted at all projects. Neither project directors nor key nutritionists (who the procedures manual states have special responsibility for the quality of dietary data) were given written instructions on procedures to be implemented. Projects are not required to document any controls which are implemented and the university does not get any systematic feedback on the extent or timing of any such controls.

Our consultants believe reliability of dietary data will also be questionable because the university required little practice with the procedures before data collection began. They note that it is probable, therefore, that experience during data collection will allow substantial improvement in completeness of data collected and that, if this occurs, changes which are indicated by followup data would be at least partially due to the fact that incomplete data was obtained earlier.

The university agreed that improvement in interviewing techniques in the course of the study is a possibility, and stated that, if it occurs, it will be reflected in baseline data collected during the later part of the investigation. However, our consultants have noted that the university could not know if changes noted in baseline data were the result of improved techniques or the result of changed consumption patterns in the population--which the data is supposed to identify.

ATTEMPTS TO IMPROVE QUALITY CONTROL WOULD NOT BE BENEFICIAL

According to the latest information available from the university, a substantial percentage of the baseline dietary and medical data had been collected as of October 30, 1974. At that time, about 71 percent of the total expected baseline data on infants and children and about 39 percent on women had been collected.

Because a large part of the data has already been collected under circumstances which raise serious doubts about the data's reliability, attempts to improve quality control would not be beneficial. Even if quality controls sufficient to insure the reliability of future data were instituted, the degree of reliability of the previously collected data or of comparisons using such data would not be known.

CHAPTER 6

CONCLUSIONS AND MATTERS FOR CONSIDERATION BY THE CONGRESS

CONCLUSIONS

The analysis of data collected for the medical evaluation will not be completed until at least October 1975, and the evaluation of food distribution methods is not scheduled for completion until June 1975. Therefore, it will not be possible for the Secretary of Agriculture or the Comptroller General to submit a final report with recommendations on continuing the program by March 30, 1975, as required. We plan to issue our final report after these evaluations have ended.

Attempts to determine and evaluate the benefits to humans of nutritional assistance, such as authorized by the act, are necessarily limited by certain inherent problems:

- The lack of precise definitions of good health and adequate nutritional status, and the resultant lack of agreement on the significance of various parameters generally used to assess the health or nutritional status of a population which limit any conclusions to the program's effects on the particular parameters studied and preclude any reliable conclusions on the program's effects on the overall health or nutritional status of the population.

- The lack of a precise determination of the types or quantities of nutrients necessary to maintain or improve a given nutritional status which limits any conclusions to the effects of the particular foods provided. If little or no benefit results, definitive conclusions on the need for a supplemental food program could not be made because benefits which might accrue from different foods or amounts of foods would not be known.

- The lack of customary control groups which precludes reliable judgments about how much the foods or other clinic services, such as nutrition education, health care, outreach, or patient followup, contributed to the findings or whether any demonstrated changes would have occurred if foods had not been provided.

- The lack of an adequate indicator of mental development and of any known method to isolate individual factors affecting mental development precludes any reliable conclusions on the program's effect on participants' mental development.

Although FNS and the university have taken steps to deal with these problems, they cannot practicably be overcome and must be recognized as precluding a conclusive determination of the program's benefits.

Despite these problems, which preclude any conclusive determination of the program's benefits, a medical evaluation, such as the legislation calls for, would be useful in deciding whether to continue the program, if reliable data were collected. However, conclusions drawn from the medical evaluation probably will be of questionable use in determining whether to continue the program because FNS and the university cannot insure data reliability. Because of weaknesses in training, pretest procedures, and procedures for controlling data quality, FNS and the university cannot insure that standardized procedures have been and are being used, nor can they document the degree of data reliability.

Because a large part of the data is already being collected under circumstances which raise serious doubts about the data's reliability, improving quality control procedures to insure the reliability of future data would not improve the validity of the conclusions or their usefulness in deciding whether to continue the program.

MATTERS FOR CONSIDERATION BY THE CONGRESS

Because the medical and nutritional evaluations are not scheduled to be completed before June 30, 1978, when the program is due to expire, the Congress will not have the final evaluation results when it considers whether to continue the program.

Our last report on the program made to the Congress recommended that the medical evaluation not be undertaken until [illegible] determining whether to continue the program. Since that time, however, substantial progress has been made in developing procedures which could be used to collect reliable data. Although [illegible] the Congress may wish to consider whether the medical evaluation should be undertaken.

Should the Congress wish to predicate continuation of the program on some medical evidence of benefits to recipients, further study would be needed. Such a study could not be completed, however, before present authority for the program expires. As indicated in the foregoing chapters, we believe it should be recognized that, although useful indicators might be obtained, certain inherent problems will continue to preclude the possibility of obtaining definitive answers concerning the medical benefits of the nutritional assistance provided.

If the Congress decides to order a further evaluation of the medical benefits of the program, greater safeguards need to be taken to insure that the methodology and timeframe for any such evaluation will be adequate to achieve reliable results. The Congress may wish to consider assigning responsibility for any such evaluation to the Department of Health, Education, and Welfare, the agency primarily responsible for research related to maternal and child health.

CHAPTER 7

SCOPE OF REVIEW

We made our review at the Department of Agriculture headquarters in Washington, D.C.; at the University of North Carolina; and at eight projects included in the medical evaluation.

We reviewed the program's authorizing legislation and amendments, the legislative history, and agency records concerning planning and implementation of the program's operation and evaluation. We also discussed these aspects of the program with FNS officials and, where applicable, with members of the university's evaluation team, including the principal investigator.

We were assisted by four consultants with expertise in the fields of nutrition, biochemistry, pediatrics, obstetrics, and biostatistics.

APPENDIX I

CONSULTANTS UTILIZED DURING REVIEW

George G. Graham, M.D., Professor of International Health (Human Nutrition), School of Hygiene and Public Health, and Associate Professor of Pediatrics, School of Medicine, The Johns Hopkins University

Howard N. Jacobson, M.D., Professor of Community Medicine, College of Medicine and Dentistry of New Jersey, Rutgers Medical School

Formerly: Director, Macy Program, and Associate Professor at the Boston Hospital for Women, Department of Obstetrics and Gynecology, Harvard Medical School, Harvard University

Robert B. Reed, Ph.D., Professor of Biostatistics, Department of Biostatistics, School of Public Health, Harvard University

Jack L. Smith, Ph.D., Swanson Associate Professor of Biochemistry and Internal Medicine, The University of Nebraska Medical Center

Formerly: Associate Professor, Biochemistry and Nutrition, School of Public Health and Tropical Medicine, Tulane University

APPENDIX II

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD AND NUTRITION SERVICE

WASHINGTON, D.C. 20250

September 18, 1974

Mr. Henry Eschwege, Director
Resources and Economic Development Division
U.S. General Accounting Office, Room 7822
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Eschwege:

Thank you for your letter of September 13 and the draft of a report to the Congress pertaining to the Special Supplemental Food Program for Women, Infants and Children (WIC).

The considerable input of both your staff and your consultants is greatly appreciated. We find ourselves in basic agreement on a number of points and have attempted to clarify certain other issues. [illegible] a detailed response to the specific questions raised in [illegible].

Sincerely,

Carl Hampton

Carl [illegible]
[illegible] Administrator

APPENDIX II

RESPONSE TO GAO'S OBSERVATIONS
ON HEW'S EVALUATION OF THE
SPECIAL SUPPLEMENTAL FOOD PROGRAM

A review was expressly GAO's test because the final results of the medical evaluation will not be available until after June 30, 1975, when the legislative authority for the program expires, the Congress will not have final information available when considering program continuation.

[illegible] shared by the Department; however, the Department and UNC [illegible] only as possible to implement the detailed medical evaluation. The [illegible] that precluded a more timely initiation of the evaluation are presented below.

[illegible] the prospective contractor for the evaluation on September 27, [illegible] negotiations. The prospective contractor advised that an adequate medical evaluation could not be performed in less than a 12-month period. [illegible] program was authorized only through fiscal year 1974. Since [illegible] a medical evaluation of 12 months, the only offeror in a [illegible] the evaluation work declined to accept an award. However, [illegible] extending the program for another year was used as a basis [illegible] operations. Upon passage of P. L. 93-150, November 7, 1973, the [illegible] submitted a proposal for a 12-month medical evaluation on [illegible]. The contract between DHS and UNC was signed on November 28.

[illegible] final contract allowed the contractor two months start-up time for planning, [illegible] projects, [illegible] equipment, and training personnel. Between December 14, [illegible], [illegible], UNC personnel visited all detailed medical evaluation [illegible]. A major outcome of these visits was the recognition that project facilities were far from adequate for obtaining the quality of data required for the evaluation. The contract was consequently amended to allow UNC to procure additional equipment for the projects in order to better standardize data collection procedures.

[illegible] obtaining the necessary equipment were partially responsible [illegible]. The Purchasing Department of [illegible] State [illegible] government to follow certain procedures [illegible]. Adherence to these regulations caused some delay [illegible]. Furthermore, negotiation of this program took place at [illegible] which strongly affected this activity. Thus delays in equipment [illegible], several manufacturers were also unable to supply, [illegible] items due to a plastic.

[illegible] also failed from personnel shortages in [illegible] recruiting personnel necessary for [illegible] these restraints imposed by the States and [illegible] medical and [illegible] problems.

APPENDIX I.

[illegible] anticipated and which were [illegible]

[illegible] has expressed specific concerns regard[illegible] the validity and the usefulness [illegible] to be [illegible] the level of deficiencies because standards have [illegible]

[illegible]

1. [illegible] Health Criteria

[illegible] has been advised by its consultants that precise standards have not been established to define good health and adequate nutritional status. These consultants believe that in the absence of such standards, professionals do not [illegible] the parameters which should be studied in order to assess the [illegible] nutritional status of a population or of individuals.

[illegible]

[illegible] is stated by the Congress and was the subject of much debate [illegible] with [illegible] in formulating plans for the detailed [illegible] to be [illegible] this difficulty as well as [illegible] evaluation [illegible] mandated by P. L. 92 [illegible] who were [illegible] with the Report out in formulating [illegible] selected [illegible] schools [illegible] [illegible] health, nutrition, and welfare, such as the [illegible] (MCH), Maternal and Child Health, the National [illegible], the Health Services Administration. These [illegible] specialties: pediatrics, obstetrics, [illegible], biostatistics, [illegible]

[illegible] particularly [illegible]

[illegible] the [illegible]

[illegible] types and [illegible] which [illegible]

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was of poor quality

Response

Although there is some disagreement among professionals with regard to the types and quantities of nutrients necessary to maintain good nutritional status, the Department has followed the guidelines established by the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The Department's consultants believe that the Recommended Dietary Allowances (RDA) as established by this Board are the best estimates available regarding the optimum types and quantities of nutrients.

The types and quantities of foods authorized through the WIC Program were determined after considering many factors. The legislation specifies that the supplemental foods which are made available through this program must contain certain specified nutrients (high-quality protein, iron, calcium, vitamin A, and vitamin C). The food package that was selected provides a high proportion of the RDA for these nutrients. In addition substantial quantities of calories, thiamin, niacin, riboflavin, and vitamin D are also provided. The foods that were selected are readily available and widely accepted.

(See GAO note on p. 47.)

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(See GAO note on p. 47.)

[illegible] expressed specific concerns regarding the validity and usefulness of the [illegible] data.

[illegible]

Lack of local control data

(See GAO note on p. 47.)

(See AD note)

Data to be collected are for only those [illegible] potential [illegible] interaction, the extent of the [illegible] response to the participants. [illegible] of the household, and several [illegible] data from each participant. The parameters were [illegible] by the Department's consultants to be the most [illegible] study of this type. These parameters have been [illegible] being used in current studies such as the [illegible] Survey conducted by the Department of Health, [illegible] Welfare. The investigation is designed to assess the [illegible] marking differences that occur [illegible] service periods of feeding [illegible] participants started receiving [illegible]

The use of control groups whereby [illegible] surveyed and not served [illegible] socially unacceptable for [illegible] fully nutritionally [illegible] standpoint, it was the [illegible] control groups should [illegible] food project and [illegible] characteristics, such [illegible] forces, which direct the [illegible] external "[illegible]" characteristics [illegible] control is [illegible] study will [illegible] [illegible] [illegible] indirect factors.

[illegible]

[illegible]

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because "yesterday" may not have been an "average" day, may be quite reliable in reflecting changes in consumption patterns when applied to these populations. Whether there are significant changes as a result of the program in the [illegible] with it, for example, is the kind of question for which it is reasonable to expect an answer on the basis of the proposed dietary studies. Both of the techniques to be used for the dietary studies must be taken into consideration when determining the number of participants to be included in these studies.

The possibility of concealment or falsification of information is a constant factor in any research based on interview. It can be minimized by use of competent interviewers and the existence of good rapport and understanding between the interviewer and the respondent.

(See GAO note on p. 47.)

[illegible] specific [illegible] affecting the quality of data to be collected due [illegible] for [illegible].

[illegible]

[illegible] data

[illegible]

[illegible] who would be collecting [illegible] the [illegible] were [illegible] possible [illegible] the large [illegible] prepared [illegible].

Two centralized training sessions were held for nutritionists to enable UNC to provide the highest quality instructions. As an example, consultants who participated in the Ten State Nutrition Survey presented some of the training. Attending the training program at UNC were key nutritionists from each project who would be responsible for training the remainder of their dietary staffs.

Members of the UNC dietary faculty conducted follow-up visits to projects, as needed, to clarify problems concerning procedures for collecting and recording dietary data. These follow-up training sessions consisted of lecture-discussions and demonstrations centered on:

- Techniques of the dietary interview with emphasis on the research interview.
- Use of the food models in obtaining and recording dietary information on the 24-hour dietary recall forms.
- Obtaining accurate information through interview on the modified dietary history of a respondent, either a pregnant/lactating woman or the adult accompanying an infant or a child.

Participants in the sessions practiced interviewing and use of food models in questioning respondents and in recording dietary information given by respondents.

2. Inadequacies of project training sessions

Response

The local training program conducted for each project was "individualized" to meet the needs and circumstances of that particular project. These training programs were conducted by UNC personnel and were usually organized according to the following four areas:

a. General orientation. During this session the purposes of the WIC [illegible] evaluation, the study design, and the administrative organization were explained.

b. Collection and recording of demographic, household, and medical data. Each of the interview forms was discussed in considerable detail.

c. Clinical assessments. The procedures for taking height, weight and head circumference measurements were discussed and demonstrated by a member of the UNC faculty.

d. [illegible] procedures. The procedures for taking blood samples and [illegible] were discussed and demonstrated. [illegible] discussed safety, storage, packaging, and dispatching blood [illegible] discussed during these sessions.

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Each training session was [illegible] over a two-day period. However, the program was modified [illegible] each project. Thus training was completed in [illegible] depending on the [illegible] projects, especially when only one category of participants was [illegible], i.e., infants only or infants and children (no women). The number and type of project staff attending the training sessions also varied, depending on the size of the project and its method of operation. Thus, large projects had more staff at training sessions than smaller ones; and projects which used part-time staff or integrated WIC with other ongoing programs involved more staff in the training program than projects which operate WIC as an almost self-contained program. In those projects where a number of new and inexperienced staff members were recruited for the evaluation, arrangements were made for the staff to practice taking and recording data in small groups during the training sessions. In other projects where staff with considerable experience were responsible for data collection, such as in Maternal and Child Health projects, there was less need for practice; instead greater emphasis was given to discussion of the pitfalls in carrying out the procedures and the precautions to be taken to eliminate or minimize these difficulties. The laboratory procedures usually presented the greatest challenge since many of the projects did not have qualified laboratory technicians on their team. Accordingly, considerable time was often devoted to practicing the laboratory procedures.

(See GAO note on p. 47.)

[illegible] being vulnerable to [illegible] about [illegible] essential, it [illegible] crucial for trainees that the appli[illegible] sort of pressure may be [illegible] or [illegible]. [illegible] not always possible [illegible] the [illegible] to ignore [illegible] observed [illegible] [illegible] the [illegible].

3. Inadequacies of pretests as conducted by the projects

Response

Upon completion of the training sessions, each clinic site was requested to practice and coordinate all procedures required by this study for several days prior to conducting a pretest. Due to this interval between training and pretest and because of the large number of clinic sites required to conduct a pretest, it was impossible for UNC personnel to be present at each pretest. Furthermore, training was proceeding at some projects while pretests were being conducted at others.

More importantly, UNC personnel did not consider it necessary to be present in order to monitor and determine the validity of each pretest. There are several other satisfactory ways to judge the quality of these pretest data. These methods include: checks on the completeness of the forms, consistence of the information collected, number of errors in forms, frequency of "out of range" data, adherence to instructions about the packaging and shipment of materials, evidence of hemolysis in plasma, quantity of plasma, and the ratio or correlation of hemoglobin to hematocrit. All of these procedures were used by the UNC personnel to evaluate the validity of the pretest data.

A number of problems were detected very early in the program and immediate corrective actions were taken in each case. For example, a discrepancy was observed between the hematocrit and hemoglobin values. Upon investigating possible sources of error, it was discovered that a spectrophotometer was malfunctioning. Instructions for corrective action was telephoned to the appropriate project personnel

4. Inadequacies of monitoring procedures

Response

The procedures for evaluating the validity of the pretest data as presented under issue number 3 above continue for the day-to-day monitoring of all data and samples being received by UNC. In addition, all projects have been visited by the UNC dietary staff. Visits have also been made to all projects except one by the Project Director, who is a physician, or by the Project Co-Director, who is a biochemist

During visits made by the Project Director, the Project Co-Director, and the dietary faculty, all projects have been visited at least once during the initiation of data collection. Three projects have been visited three times, fifteen projects have been visited two times, and one project has been visited one time. On each of the visits the project personnel were observed at work. Many of the problems discussed and resolved were logis-

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The principal advantage of sending quality control stabilized blood samples with unknown values is that the operator should not be able to distinguish them from regular specimens so as to eliminate observer bias due to special handling of the samples. However, it very soon became apparent that this idea was impossible in the WIC Program. The laboratory personnel at the project sites normally deal directly with the participants. They collect the blood samples from the participants and make their determinations on the site. They would immediately recognize any specimen brought to them as a quality control sample. Therefore, CDC efforts have been focused on cooperating with project directors in the use of the commercially prepared hemoglobin and hematocrit standards.

(See GAO note.)

In addition to the above issues, the completion date for the delivery systems evaluation should be clarified. According to the current schedule, this evaluation should be completed by June, 1975.

GAO note: Comments have been deleted because of changes to final report.

APPENDIX III

PRINCIPAL OFFICIALS OF THE DEPARTMENT OF AGRICULTURE RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF AGRICULTURE:		
Earl L. Butz	Dec. 1971	Present
ASSISTANT SECRETARY, MARKETING AND CONSUMER SERVICES:		
Richard L. Feltner	Apr. 1974	Present
Clayton Yeutter	Jan. 1973	Apr. 1974
Richard E. Lyng	Mar. 1969	Jan. 1973
ADMINISTRATOR, FOOD AND NUTRITION SERVICE:		
Edward J. Hekman	Sept. 1969	Present