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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

RESOURCES AND ECONOMIC
DEVELOPMENT DIVISION

MAR 5 1974

Mr. Edward J. Hekman, Administrator
Food and Nutrition Service
Department of Agriculture

Dear Mr. Hekman:

As part of our responsibility as set forth in Public Law 92-433 to evaluate and report on the Special Supplemental Food Program, we have engaged several consultants to assist us in monitoring the Food and Nutrition Service's (FNS) evaluation of the medical benefits of the program. On December 17 and 18, 1973, we met with our consultants to obtain their views on the evaluation design proposed by the University of North Carolina under contract to FNS.

Members of your staff involved with this evaluation attended a portion of the December meeting and have since been advised of all of the major concerns raised by our consultants. We have also received some informal reaction to these concerns, but at this time would appreciate receiving the agency's formal comments on the issues raised.

As a result of the discussion at our December meeting, we are concerned that the evaluation will not meet the congressional intent of providing sufficient conclusive data on which to base recommendations regarding continuation of the program.

Our consultants pointed out several obstacles to successful completion of the proposed evaluation. Some of these obstacles are inherent to the type of broadscale evaluation envisioned by the legislation and our consultants do not believe it is possible to overcome them. They must, then, be recognized as major limitations to the types of conclusions which can be drawn. These inherent obstacles are listed below.

1. The lack of accepted standards by which to measure nutritional "benefit" and the lack of conclusive data on the type and quantity of food necessary to maintain adequate nutritional status or for nutritional rehabilitation.

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2. The probability that little measurable benefit can be found among patients enrolled at health clinics because people with serious nutritional or other health problems often do not take advantage of available health services and programs.

3. The problems inherent in collecting data at several widely dispersed sites where differences in local attitudes, motivations, resources, personnel and abilities can be expected to affect the quality of data collected.

4. The difficulties in determining whether or not the food was consumed by the intended recipient.

With respect to the specific evaluation design as described in the proposal, they noted several other factors which they believe place additional limitations on the usefulness of the data which will be collected. Some of the limiting factors are basic to the evaluation design chosen (e.g. the use of cross-sectional comparisons instead of the use of customary control groups) and major modifications to the design would be necessary to overcome them. Our consultants confined their suggestions for changes to areas which would not require modification of the basic evaluation approach, but emphasized that limitations of the chosen design must be recognized. These are summarized below.

Because there is no requirement that patients enrolled in the program be at a specified level of "nutritional risk," they believe it is probable that only a portion of the sample evaluated will be seriously malnourished. Therefore they think it likely that little or no benefit will be shown in the total evaluation sample, even though some subgroup of the population might have benefited from the program.

They expressed great concern over the probability that little or no benefit will be demonstrated by this evaluation, and that it might be erroneously concluded that there is no need for a supplemental food program or that nutritious food is not important during pregnancy or early childhood. They do not believe that this kind of study could be a valid basis for either of these conclusions.

They also noted that, without the use of customary controls, if some measurable benefits are shown, for either the total population or some subgroup thereof, neither the food nor any other single factor (such as emphasis on nutrition education or more regular attendance at health clinics) could be isolated as the cause.

Our consultants felt, however, that if the evaluation is to be carried out, recognizing the above limitations, every effort should be made to increase the integrity and usefulness of the data obtained. In this regard, they had several suggestions. Since mid-December several changes have been made in the evaluation design which incorporate some of these suggestions. However, other concerns raised by them, especially those relating to training of clinic personnel and the need for quality control over collection of clinic data, have not to our knowledge been acted upon and appear to us to be critical to obtaining useful data.

We would appreciate your comments on our consultants' views and suggestions, which are discussed in more detail in the attached summary, giving special consideration to those matters noted above. Please advise us of any action taken or planned relating to the subjects discussed in the summary.

If further information or clarification is required we will be available to discuss these matters with you.

Copies of this report are also being sent to the Director, Office of Audit.

Sincerely yours,

Richard J. Woods

Richard J. Woods
Assistant Director

Attachment

Summary of Consultants' Comments
on USDA's Proposed Medical Evaluation
of the Special Supplemental Food Program

INTRODUCTION

Purpose of meeting

On December 17 and 18, 1973, representatives of the General Accounting Office (GAO) and selected consultants met to discuss the Food and Nutrition Service's (FNS) contract with the University of North Carolina for the medical evaluation of the Special Supplemental Food Program for Women, Infants, and Children. Copies of the contract and related documents had previously been provided the consultants.

Public Law 92-433 requires GAO as well as the Secretary of Agriculture to evaluate the benefits of the nutritional assistance provided by the program. Because it is not considered feasible for GAO to do a completely separate evaluation of the program, GAO is monitoring the Department of Agriculture's evaluation.

The consultants' comments regarding the feasibility of the planned evaluation as well as specific comments and suggestions regarding the evaluation are summarized below.

Participants in meeting

GAO

Resources and Economic Development Division:

Richard J. Woods, Assistant Director-in-Charge,
Agriculture Audit Group
Ted M. Rabun, Assistant Director

Richard L. Wilson, Audit Manager
William Epps, Jr., Supervisory Auditor
Ruth Ann Heck, Management Auditor
Lawrence R. Keller, Supervisory Auditor

Manpower and Welfare Division:

Murray Grant, M.D., Assistant Director

Financial and General Management Studies Division:

Herman B. Galvin, Assistant Director
(Systems Analysis).

GAO Consultants:

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

Howard N. Jacobson, M.D., Medical School, Harvard University (Obstetrics and Gynecology)

Robert B. Reed, Ph.D., School of Public Health, Harvard University (Biostatistics)

Jack L. Smith, Ph.D., School of Medicine and School of Public Health and Tropical Medicine, Tulane University (Biochemistry and Nutrition)

FNS (attended summarization only)

Juan J. del Castillo, Director, Food Distribution Division
Harold T. McLean, Deputy Director
Nancy M. Weik, Assistant to the Director
Paula D. Linch, Food Distribution Division
Fred Shank, Nutrition and Technical Services Staff
(Contracting Officer's Representative)

OVERALL FEASIBILITY OF STUDY

The consultants stated that the evaluation as described in the proposal would provide such insufficient and inconclusive data that soundly based recommendations regarding continuation of the program would not be possible.

They noted several major problems inherent in the broad scale evaluation envisioned by the legislation. These problems are not the result of any decisions made by the Department and, in their opinion, cannot be resolved. They are inherent to the type of evaluation envisioned by the legislation and must be recognized as limitations to any study of this type.

1. Medical and scientific research have not yet established the type and quantity of foods necessary to maintain adequate nutritional status or to accomplish nutritional rehabilitation. Existing norms and standards for health and nutritional status are so rudimentary that they almost preclude reliable assessments of change or "benefits". There is no agreement on the parameters that should be studied or the methodology that should be used to assess "benefit" to the nutritional status of a population or of individuals.

2. Although the clinics selected for participation in the program are in areas where it might be expected to find some significant incidence of undernutrition in the population, people with such problems often do not take advantage of available health services and programs and the number of such persons who are enrolled in a

clinic probably is not high. Thus, the clinics will probably be dealing with the highly motivated and best nourished members of the target populations and presumably the ones for whom benefits will be most difficult to find.

3. Because data will be collected at several widely dispersed sites, differences in local attitudes, motivation, resources, personnel, and abilities can be expected to affect the quality of data collected. For example, some local clinic personnel may resent the added work-load of data collection and reporting while others may be commited from the start to prove that the program is successful. These factors can have a definite effect on the validity of data and they are very difficult to document and control.

4. In any evaluation attempting to determine the effects of food on a population it is necessary to know whether or not the food was consumed and, if so, if this represented a change in consumption patterns. However, strict controls on human food consumption are not possible in other than research conditions, and no accurate and reproducible method to determine past consumption has been devised for use in large scale efforts such as this study. Therefore determining whether or not the food was consumed by the intended recipient is a difficult if not impossible task in this type of study.

In addition to these inherent problems, they made some general comments concerning limitations of this specific evaluation plan.

They expressed considerable concern over the strong possibility that a "false negative" might occur. In other words, they fear that if little or no measurable benefit can be shown, it might be erroneously concluded that there is no need for a supplemental feeding program or that nutritious food is not important during pregnancy and early childhood. They do not believe that this kind of study could be a valid basis for either of these conclusions.

Although the proposal discusses "control data," the consultants emphasized that this in no way constitutes "controls" in the customary sense of clinic populations with similar characteristics receiving essentially identical care but not receiving the supplemental foods. They noted that in some studies limitations resulting from lack of customary control groups can be partially overcome by obtaining sufficient description of local clinic procedures and practices (in this case such things as attitudes of personnel, type of treatments normally given, and extent of nutritional counseling) to allow informed judgments to be made about results and outcomes. They do not believe, however, that sufficient description is possible in this large scale study. Thus, they noted that, even if measurable benefit is found in this study, it will not be possible to isolate the supplemental food as the cause for the improvement. They pointed out that if

benefit is shown, it would not be known whether any one component of the program--food, nutrition education, outreach and patient follow-up at health clinics, etc.--was more beneficial than others, and thus whether it might be more effective to concentrate efforts in one of these other areas rather than on provision of foods.

Although they do not think that the data obtained will enable evaluators to draw firm conclusions concerning benefits and thus continuation of the program, they believe that information carefully collected might be useful, especially in improving nutrition services of the program. Therefore, they made several comments regarding specific aspects of the proposed evaluation and suggestions which they believe might improve the usefulness of the information that is obtained. These comments and suggestions are summarized below.

TIME FRAME

Consultants' comments

The time allowed in the schedule for planning, training and initiating the evaluation at the project level is very tight and, in fact, appears extremely optimistic. More time is considered advisable for proper execution of these phases of the evaluation. However, if collection of data must be completed before the legislated termination of the program on June 30, 1975, extending the time frame for early stages of the study will result in an

offsetting reduction in the length of time over which the supplemental feeding can be followed. Any reduction in this longitudinal aspect of the evaluation would impose further limits on the value of the data.

Suggested alternative

Seek an extension of the program as soon as possible to allow adequate time for implementation of initial phases of the study and to insure that feeding can be monitored for a minimum of 11 months as now planned in the proposal.

IDENTIFICATION OF THOSE AT "NUTRITIONAL RISK"

Consultants' comments

Although little measurable benefit is expected to be found in the total clinic population (as discussed in paragraph 2, p. 3), some benefit might accrue to a subgroup of the population which is at some higher level of "nutritional risk" than the general clinic population. It is possible that this benefit will not be identified in this study for the following reasons. (1) Participation will not necessarily be limited to this subgroup (that is, a group at some identifiable level of nutritional risk). The regulations issued for the program require that a qualified professional determine that each individual admitted into the program is "at nutritional risk." However, no national standard for determining nutritional risk is prescribed, and, considering the lack of agreed upon standards for nutrition evaluation (as discussed in paragraph 1, p. 3)

it is possible that local definitions of nutritional risk may vary greatly. It is important to note, therefore, that all those determined "at nutritional risk" by local definitions will not necessarily be sub- or mal-nourished and many may not be deficient in any of the parameters being measured by this study. (2) The evaluation proposal does not indicate that any attempt will be made to identify and analyze data on this subgroup separately.
If data on all participants (those deficient and those who are not) are analyzed together, results will most likely show little benefit since "improvement" would not necessarily be shown in those who were not deficient at the beginning, although substantial improvement might have occurred in the subgroup of the clinic population that was deficient at enrollment.

Suggested alternatives

1. Establish standard criteria for determining nutritional risk for the program at all project sites to insure that all participants are at some recognizable level of nutritional risk.

2. Establish some standard criteria to identify those participants who at enrollment are at "most severe risk." To better insure that any measurable benefit which might result from the program is identified, data for this group of participants should then be analyzed separately as a subsample to determine what benefits, if any, accrue.

SAMPLE SIZE AND SELECTION

Consultants' comments

The sample cannot be considered "representative." However, no sample in a study of this kind could be truly representative. Thus during the study the sample will have to be monitored to try to determine how "nonrepresentative" it is.

The sample as described in the proposal is believed to be greatly overstated in all categories. Because it is probable that the 50 percent attrition discussed in the proposal will occur, an adequate beginning sample size is extremely important. It is also possible, considering this expected attrition rate, that meaningful data will not be obtained from some of the small project sites.

For women especially, the sample size appears overly optimistic because experience shows that a very small percentage of women enroll at health clinics prior to the 16th week of pregnancy. It does not seem probable, therefore, that 1,000 women will be enrolled in the "control" group at 12-16 weeks of pregnancy or that 8,000 women less than 16 weeks pregnant will be enrolled later. Also, women who do enroll that early in pregnancy may be nonrepresentative of the total population in one of two ways: (1) an unusually high number may have other health problems which necessitate clinic attendance and thus their overall health status may be worse than that of the general clinic population, and (2) an unusually high number may have more motivation and more knowledge of the benefits of good diet and preventive health care and thus their general health status, without the addition of supplemental foods, may be

better than that of the general clinic population, and in some cases they may not be in need of supplemental foods.

Precision estimates discussed in the protocol will not be accurate if the total sample size is greatly overestimated, or if the term and health condition distributions of the sample are not representative of the target populations.

Suggested alternatives

1. Accept pregnant women into the study past the 16th week of pregnancy, in both the "control" group and the group enrolled in later months.

2. Increase the number of projects to get larger sample. However, this may not be an acceptable alternative unless quality control is substantially increased as discussed on page 11.

3. Develop programs to decrease the anticipated 50 percent attrition rate.

4. Measure one cross-sectional sample several times rather than measuring different samples each time as is now proposed. More sensitive data could be obtained from both dietary studies and biochemical determinations if this approach were used.

CONTROL DATA

Consultants' comments

As discussed earlier there is no provision for control groups in this study and this limits the types of conclusions that can be drawn from the study. Although the use of cross-sectional data as described in the proposal is logical, the lack of sufficient

description of local clinic procedures and practices will further limit conclusions.

There is also a possibility that problems will arise in collection of baseline data. Because the sample size may be overstated, the number of persons on which baseline data is available may not in actuality be sufficient to provide adequate baseline data. Also, the study is designed in such a way that the evaluator will not receive data until well into the 2nd month of evaluation. Thus it will not be known if major problems in data collection are occurring until this time. If major problems do exist and are not corrected much earlier the major portion of the baseline data could be invalidated, since the great majority of participants are expected to be enrolled during the first 2 months of operation.

Suggested alternative

Have the first month's data reported daily or weekly to the evaluator so that any problems found in data collection and summarization can be detected and corrected promptly.

TRAINING AND QUALITY CONTROL

Consultants' comments

The initial training as described in the proposal appears adequate. However, for proper training in such a research study care must be taken to insure that in all cases the person who will actually be doing the measurements or taking the data is the one trained by the evaluator's team. Provision must also be made to train new people as they are brought into the program. If these procedures are not followed, the validity of the data will be highly questionable.

This training, however, will not be sufficient to insure standarized measurements. Unless some systematic method of quality control is instituted--including on-site visits from representatives of the evaluator--all data collected will be questionable. Also, there is no provision in the proposal for attempting to standardize measures taken at hospitals. This data is particularly significant because it is the basic data being collected on outcome of pregnancy.

Because of lack of any direct training or controls over collection, the data to be obtained from the other projects to be operated (not in full medical evaluation) will be of little or no value for evaluation purposes.

The quality control procedures outlined for the laboratory tests appear adequate, but sometimes are very difficult to implement and therefore should be monitored closely.

Suggested alternatives

1. Institute some procedures for quality control at the clinic sites, such as having some measurements taken twice, either by the same person or by a different person.

2. Institute a system of frequent on-site monitoring. This could be done by the evaluator's personnel, by USDA personnel trained by the evaluator, or by some other organization under subcontract.

3. If the total quality control effort can not be increased, increase controls on a few of the larger projects, thereby increasing

the probability that reasonably accurate data will be obtained from them. This may be an acceptable alternative even though it will result in a smaller sample.

MEASUREMENTS AND TESTS PRESCRIBED

Consultants' comments

The anthropometric and biochemical measures prescribed are generally adequate, although there are additional tests such as urinary protein determinations which in some circumstances might be valuable. However, the numerical determinations will be of little significance unless accompanied by some more descriptive health assessment. (Is a 25 pound weight gain during pregnancy too much, too little, or adequate? Is it composed of fat, fluid or fetal maternal tissue?) Also, the proposal states that mortality and morbidity data will be recorded whenever possible. It would appear impossible to determine the medical and health benefits of the supplements, especially on the women, in the absence of such data for all patients.

The proposal is not precise about what information will be collected on infants born to program mothers, but it appears that the only information to be obtained from the hospitals is birthweight. More information on new-borns is necessary; birthweight alone is not significant. For example, one would not know if a child were obese, undernourished, "small for date" or premature, or even if it were healthy if only birthweight is obtained.

Some more specific potential problems which may be encountered in collecting the data prescribed include:

1. Vitamin A determinations are being done on only a small sample of adults in one area of the country (Southwest). There are apparently two reasons for this: (a) venous blood is necessary to do such determinations and venous blood is being taken only from adults, and (b) results of the Ten-State Nutrition Survey indicate that deficient Vitamin A levels are more often found in the Southwest. It must be noted that even in the most undernourished populations Vitamin A has only been found to be deficient in children and futhermore the results of the Ten-State Nutrition Survey are not universally accepted and perhaps should not be a basis for limiting this study. It is extremely doubtful that Vitamin A determinations on a small, localized sample of adults will provide useable data for this study.

2. There is serious doubt that accurate serum iron and transferrin levels can be obtained from finger or heel stick determinations. The experience of the consultants is that most blood from finger or heel stick determinations has at least a small degree of hemolysis (which results from such things as squeezing or "milking" the area from which blood is being taken). This hemolysis invalidates the determinations.

3. The measure of head circumference by itself is no indication of the program's effect on mental development. Furthermore, even under strictest procedures standardized measures are virtually impossible to achieve.

Suggested alternatives

1. Add to information collected some language describing the general health status of participants.

2. Implement a system by which more detailed hospital records for each newborn could be obtained (at least with the major hospitals which will be serving the program participants), and insure that information on the neonatal health status of each infant is obtained. (It is recognized that standardizing measures from various hospitals will be difficult.) Also, current information on previous reproductive history of women should be obtained; it is basic in interpreting the results of the pregnancy under study.

3. Considering the high costs of performing Vitamin A determinations and the little likelihood of obtaining usable data, it may be desirable to drop this measure (as now planned) from the study. However, there might be great value in doing Vitamin A determinations on children. Although there is recognizable risk in drawing venous blood from infants, there is no medical reason why venous blood could not be drawn from children 2 years of age or older (and more than twice from women). Therefore, drawing venous blood from children for this purpose might be considered. It is recognized, however, that taking venous blood may be objectionable to participants and might, therefore, contribute to a higher attrition rate.

4. Prescribe strict procedures (and good controls) for drawing finger and heel stick blood to prevent hemolysis which

would invalidate measures of serum iron and transferrin.

5. Exclude the measure of head circumference from the study. It should be pointed out that because both the number of severly subnourished persons and the degree of subnutrition which can be expected to exist in health clinic populations is small, the amount of change which might be expected is also small and therefore both identification of those individuals most in need and accurate and precise measurements of individuals and groups are of critical importance.

DIETARY STUDIES

Consultants' comments

It is of major importance in measuring the effects of the supplemental foods to determine if the supplements were consumed and, if so, if this represented a change in the participants' consumption patterns. (A strong possibility in programs of this kind is that food supplementation may not change or improve nutritional status since these foods may displace those ordinarily eaten. Thus overall consumption may stay the same.)

Dietary recalls such as described in the proposal are very difficult to interpret, even when administered under the best conditions. For example, there is often a tendency on the part of participants to say what they think is expected of them (e.g., if they are given milk they'll often say they drank it whether they did or not). The attitudes of those taking the recalls (e.g., if they consider the recall an added burden they do not want, or conversely if they are strongly

committed to the program and proving its success) can also bias results, as can the environment in which recalls are taken. Recalls for children are frequently questionable since the mother (or person accompanying the child to the clinic) may not have prepared all the child's food and may not, in reality, be certain of what was consumed.

It is recognized, however, that, in the context of the study as planned, some form of dietary recall is probably the only feasible method to use to determine consumption patterns of participants. However, in addition to the items discussed above, the studies as proposed present other problems.

Although the 3-day training seminar for those taking dietary recalls is a necessary step, as with all other measures to be taken, some on-site quality control procedures must be instituted to allow the factors discussed previously to be controlled as much as possible. (Although it is recognized that trained personnel are necessary to administer the food recalls, it should be noted that if dietary studies are done only at sites where qualified nutritionists are on board, interpretations of results may be difficult since "improved diet" might be attributable to the nutrition education given as well as provision of the food.)

The sample is very small and it appears that the proposal intends that dietary studies will not be taken on the same sample each time; the reason for this is not clear. The proposal also does not state whether or not the contractor has available an operating coding system (converting recipies to nutrients, etc.).

Generally speaking, the dietary studies will be extremely expensive relative to the expected benefits to the evaluation, under the procedures described in the proposal.

Suggested alternatives

1. The contractor intends, according to the proposal, to include in the dietary studies some form of food frequency study in combination with a 24-hour recall. It is possible that placing the emphasis on the "food frequency" studies and substantially increasing sample size may increase the reliability of data - although the precision of the data would be reduced.

2. As with the other measures taken, more sensitive data could be obtained if one sample were followed instead of taking a different cross-sectional sample each time (regardless of what kind of dietary study--24-hour recall or food frequency recall--is done).

3. It would be very valuable to have properly trained and oriented people administer the recalls. This could be done either by the contractor's staff directly/or by local employees trained and paid through USDA or the contractor. If this is not possible it might be valuable to have members of the contractor's staff administer the recalls directly for a subsample of patients at each clinic.

FOOD SUPPLEMENTS

Consultants' Comments

Although the regulations state that iron will be provided to both children (more than 100 percent RDA) and women (60 percent to more than 100 percent RDA), there is some question as to whether this percentage of RDA for pregnant women is provided in even the maximum amounts of supplements allowed in the program. Also, the almost total reliance on cows milk to supplement the diets of people who are predominantly non-white is bound to encounter very significant rejection, either because of real intolerance to the lactose in milk, or because of firmly entrenched eating habits.

As discussed earlier, it is expected that participants will have varying degrees of "nutritional risk" and therefore varying needs in terms of amount of supplementation required. It is questionable whether sufficient food is provided to rehabilitate someone who is severely malnourished, especially in the limited time periods available. Furthermore, if the proposed supplements were passed out unselectively and then actually consumed as supplements in the maximum amounts allowed (not displacing an equivalent number of calories), the supplements are almost certain to be unnecessary for, and may well result in marked obesity in at least a portion of the participants. It should also be noted that the study is not designed to allow any conclusions on the adequacy of the food package itself.

Suggested alternatives

1. Provide some high protein foods as a substitute for milk.

2. Include additional foods high in iron in allowed supplements.

3. Insure that in the analysis obesity is recognized as a problem.

OTHER COMMENTS AND SUGGESTIONS

1. The charges for individual laboratory determinations seemed to be high, although an evaluation of this type can reasonably be expected to cost $800,000 to $1 million. However, the necessity of equiping a laboratory to handle peak loads which will occur only periodically is questionable. Utilization of some existing laboratory under subcontract might have been more economical.

2. Because many of the conclusions reached will be based on the health status of pregnant and lactating women it is advisable that an obstetrician be directly involved in the evaluation at all stages to insure that all necessary data is collected and proper analyses are made.

3. The evaluator has a moral responsibility to advise local clinics of the results of tests performed. Furthermore, the prompt receipt of complete information on the status of patients may provide incentive to local clinic personnel to cooperate in a project which may in some cases be viewed mainly in terms of increased reporting requirements and additional interference from State and Federal governments.

4. Although in its draft of revised regulations USDA has recognized the necessity to obtain the informed consent of program participants included in the evaluation, it is essential that both USDA and the evaluator be aware of proposed regulations involving the protection of pregnant women and children.

Also, consent forms must be carefully worded to avoid unnecessarily frightening potential participants. Steps should be taken to insure that potential participants are not in any way coerced into signing the forms.

5. Because a high attrition rate can be expected, some study of the health status of dropouts and, if possible, the reasons for dropping out should be made to determine what effect, if any, these factors have on analyzed data and conclusions.

6. Although the legislative history indicates that the evaluation should determine the program's effects on mental development of participants, it is not considered feasible for any broad-based study to make such a determination.

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It should be noted that the proposal is based on many assumptions concerning operations at local clinics (capabilities of staffs, frequency of attendance at clinics, etc.). Until it is known whether or not these assumptions are correct, the feasibility of the study as proposed, cannot fully be determined. Also, because the questions to be asked of the data and thus the

analyses to be made have not been delineated, it can not be determined whether or not all necessary research questions will in fact be addressed in the study.