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Collaborative Research Support Program (CRSP)
Nutrition Intake and Function

REVISED RESEARCH DESIGN - PHASE II

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Preface

This report presents the agreed-upon design resulting from the meeting in May 1983 of representatives of the three collaborating projects of the Nutrition CRSP with the Management Entity.

Those portions of this report which describe hypotheses, research methods, and case studies, were drafted by Principal Investigators representing the several disciplines encompassed by the CRSP. These were Lindsay Allen, Robin Gorsky, Gail Harrison, Norge Jerome, Avanelle Kirksey, Charlotte Neumann, and Gretel Pelto. Portions describing sampling design, data management and analysis were written by members of the Management Entity: Doris Calloway, Judith Balderston, and consultant George Beaton. We are especially grateful to members of the Berkeley faculty who have given generously of their time, including Professor Leo Breiman and Dr. Juliet Shaffer.

A separate report will include details of procedures, questionnaires, and other survey materials to be used during the Phase II data collection.

Proposals for non-core research by the three projects will be forwarded separately.

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I. Introduction

A. Purpose

The origins and purpose of the Nutrition CRSP are to be found in a series of reports and working papers extending back to 1975. A report of a National Academy of Sciences panel assigned the highest priority to the functional significance of nutritional status, i.e., "... the degree to which a given intake maintains, enhances, or inhibits an individual's functional performance (activity, growth, resistence to disease, and so forth)... (National Academy of Sciences, 1977).

Study Team Nine recommended that "Determining energy needs and the effects of substandard intakes of energy should receive priority. On a worldwide basis, inadequate intake of energy because of inadequate intake of food appears to rank ahead of all other types of malnutrition." Noting that "... the number of people who suffer from moderate malnutrition... is immensely larger than the number of people visibly affected," the Team emphasized a "... need to know the implications of the lesser grades of undernutrition and overnutrition."

At the request of the U.S. Agency for International Development (USAID), the Committee on International Nutrition Programs of the Food and Nutrition Board, National Research Council, convened a workshop in 1977 to consider research that might lead to a functional definition of nutritional status. The participants concluded that such research was important (in agreement with the top priority assigned in the World Food and Nutrition Study) and was feasible. They identified five major areas of function to be investigated: disease response, reproductive competence, work output, cognitive function and social and behavioral function. (Food and Nutrition Board, 1978).

Under a USAID Planning contract, a series of workshop were convened further to explore and define issues and research approaches in each of these domains. In a final workshop, senior investigators from developing countries were invited to review the reports of earlier workshops and to consider the relevance, the importance, the feasibility, and the acceptability of the research for implementation in developing countries. Their Precis made several important points: 1) the unit of study should be the household; 2) the mother-child dyad was the logical focal point; 3) food intake should be represented by energy intake encompassing a range of habitual mildly-to moderately restricted intakes; 4) data produced should be generalizable to nutrition problems in LDC's, not country specific, and therefore relying on replication across countries; 5) certain core research determinants would have to be common to all projects; 6) food intake would be the major independent variable; 7) nutritional status measurement would be seen as an explanatory intermediate variable; 8) selected study communities should be stable with low migration rates; 9) specific research topics should have potential policy and program implication; 10) U.S. standards for human research should be maintained, including informed consent; and 11) beneficial services provided during the course of the projects should be maintained upon conclusion of the projects. It was this report also that took a very strong stand on the position that both for scientific and ethical reasons a "naturalistic" rather than " "intervention" design would be the preferred approach to the questions being addressed.

It was against this background and concept of purposes that the collaborating institutions developed the specific proposals submitted to the University of California, Berkeley in 1979. After peer review,

prioritization by a group of scientific advisors, and other external reviews, an integrated collaborative research support program plan was approved by USAID in May, 1980. The funding decision was effective in September 1981.

During this long period of discussion and development, the importance of the research has never been questioned. Rather, during this period, and perhaps in part because of the process of very wide involvement of the scientific community, awareness of the importance of the questions being asked has increased immensely. There is hardly an international document or report of an international conference dealing with nutrition that does not now direct attention to the need to understand the functional significance of the marginal undernutrition that is believed to characterize a large proportion of the world's population. There is now a great awareness that conventional anthropometric indices of nutritional status are insufficient measures of satiation of human nutritional needs. There is recognition that energy requirements must take into account human social function as well as work. Above all, there is recognition that the underlying questions have yet to be answered and that until they are answered there will be great uncertainty about national and international policies and actions intended to ameliorate the perceived situation.

The scope of the underlying question is well illustrated by the summary of a recent review: "Human factors likely to be related to dietary intake and regarded as important across cultures and time are disease response, reproductive competence, cognitive function, work output, and social and behavioral habits. Functional failure in these domains is seen as having profound effects on health and demography.

Most investigators who have examined issues of food intake and human function have accepted some indicator of an individual's body size as a measure for malnutrition.... Evidence from human studies also shows that food deprivation affects ability to produce healthy babies, physical performance, mental attitude, and disease experience, irrespective of body size. Communities that have evolved under conditions of recurrent scarcity will have developed and accepted what are seen to be the lowest-risk strategies for coping with the immediate and longer-range problems of survival. Because the cost of failure is perceived to be high, there will be pressure against innovation. This tendency to avoid risk-taking, in turn, may be among the grave affects of chronic food deprivation, even when the deprivation is not severe." The author notes also, "To address these societal concerns effectively requires a new type of conceptualization of the problems of nutrition ....virtually nothing that the scientific community has discovered about nutrition in this century has altered the prevalence or severity of the dominant forms of malnutrition. We know a great deal about protein-energy malnutrition, almost everything in fact, except what causes it, how to prevent it, and what it costs society not do do so." (Calloway, 1982). Perhaps the greatest contribution that the Nutrition CRSP can make in the area of nutrition policy is to describe the real human cost of not preventing moderate undernutrition--the cost expressed in terms of impaired human function, impaired household and community function, and impaired development of the human population. If, in addition, it contributes insight into ways of ameliorating the situation, that will be an additional bonus, and one which we hope to achieve.

B. Evaluation of Design

The original aspiration of the Nutrition CRSP was to take a holistic

approach in which all functions and their interactions were examined concurrently. This was expressed in the December, 1982 report to the External Evaluation Panel (EEP) in the following words:

"This growing awareness has generated a number of studies addressing the relationship between moderate undernutrition and individual aspects of human functional capacity and expression. However, the Nutrition CRSP continues to stand alone in rising to the important challenge of addressing the group of functional areas concurrently--by addressing the issue of the interaction of the functions within the setting of the household. This was the goal that was perceived from the outset and was reinforced with the evolution of the collaborating proposal."

The advice received from the EEP was that there should be a sharper focus on priority areas, at the expense of the multiple dimensions of the holistic approach.

The Nutrition CRSP has been under discussion and development for almost a decade during which time there has been a progressive evolution of conceptualizations. With this there have been a series of proposed designs none of which are fully competent to capture all dimensions of interest and importance. The final design, presented in this report is no exception. By "optimizing" the design (sampling, data collection) to improve the likelihood of answering some of the most important questions, the design has excluded the possibility of addressing other significant issues.

In recognition of the fact that the approach that includes every important relationship a truly holistic approach is not feasible, provision has been made for the possible introduction of additional research protocols

in year 2.

An important element of the present design, then, is a decision to implement studies that can be undertaken with existing methodologies and feasible sampling strategies while at the same time collecting additional information toward the design of additional studies for year 2. The initial studies, while sacrificing much of the original holistic view have continued to place emphasis on the person-to-person functional interactions within a household setting, while at the same time more narrowly defining the scope of outcomes to be addressed. The second year studies, it is hoped, will provide an opportunity to address either other functional outcomes or other paths of interactional effects. In particular, there is very high interest in a further examination of physical activity as a variable in the accommodation of low energy intake and in the functional significance of such an accommodation. It can be expected that the design of appropriate studies to address this central issue will have high priority.

C. Changes in Design

This report presents the final design for the core studies, to be done across all projects, for the Nutrition CRSP. By prior agreement, all projects are bound to this design unless specific authorization is given for modification. If a particular project requests a modification, Management may approve the modification for unilateral implementation, may refer the modification to the Scientific Coordination Board for approval of a core design change affecting all projects, or may refuse the design change on scientific grounds. In the last instance, the proposing project may request a review by the Scientific Coordination Board. The Scientific Coordination Board shall be kept advised of all design changes, unilateral or multiproject, that have been approved and of all requests for such changes not given approval by Management.

To the extent that the present design provides discretion to the individual project for choice in design or instrument decisions, these decisions shall be reported back to Management and to the Scientific Coordination Board in the form of reports on the operational design of the Egypt, Kenya and Mexico projects.

The projects may add country-specific research components with the provision that these must be judged to have scientific merit, must be feasible of implementation without interference with or compromise of the core studies (including interference with or discouragement of participation of households included in the core studies), and must fall within established budget guidelines (i.e. not more than 15% of total budget). If the scientific merit or interference with core

design are challenged, by prior agreement Management is empowered to draw upon the assessments of outside advisors. All supplementary, country-specific research components require approval by Management before implementation; the Scientific Coordination Board shall be kept adviced of such research.

II. Summary

This report presents the design decisions taken by the Nutrition CRSP at the conclusion of Phase I preliminary data collection. At an earlier meeting, in January 1983, a more ambitious proposal was presented to the External Evaluation Panel for consideration and advice. The Panel recommended that there be a sharper focus during the first year of Phase II and that some other features of the original, larger design be investigated as case studies during Year 1 with possible incorporation during Year 2. This advice is followed in the research design.

We propose here to concentrate on the following set of principal hypotheses:

(1) Maternal intake during pregnancy and lactation influences endowment at birth and during the infant's first six months of breast feeding. Also, maternal intake affects maternal activities for sanitation and child care. Thus, infant behavior and morbidity are affected by maternal food intake;

(2) Food intake of the child between 18 and 30 months affects his/her morbidity, body weight, and psychological development while maternal intake affects her child care and sanitary practice. Thus, behavior and morbidity of the young child are affected by the child's and mother's food intake;

(3) Food intake of the child between 7 and 9 years affects the child's morbidity and behavior while parent's intake affects their behavior toward the child;

(4) Food intake of adults affects their morbidity, responsiveness and performance of usual responsibilities and that this, in turn, affects

the morbidity and performance of other household members;

(5) For adults, a reduction of resting metabolic rate provides a major path of adaptation to restore energy equilibrium;

(6) Household food intake affects household morbidity.

For each of the hypotheses proposed, there will be a minimum of 100 households in which the appropriate set of individuals will be found. Where there are several target individuals present in the same household, data collection for multiple hypotheses may overlap. Data will be collected during 12 months of continuous study of the target subjects. To find the required number of pregnancies, and to allow for attrition during the study, there will be at least 300 households enlisted during the first year. Additional households will be entered to provide the required number of children of 18 to 30 months and 7 to 9 years. For each core household, the target child and parents will be subjects of interest. Data will be collected for them on food intake, morbidity, and specific functions. Other members of the same households will be monitored for some specific purposes.

Data will be collected at each of the field sites, entered on computer files at host country institutions, documented, duplicated, and sent to the U.S. collaborating institution and to the Management Entity central data bank in Berkeley. Statisticians will continue to provide important methodoligical advice in Berkeley and at each of the projects.

III. Research Plan

For purposes of design of sampling and data collection, a series of primary hypotheses have been formulated. These are presented below. It will be recognized that a number of other hypotheses can be examined with the same data sets and do not impose additional design requirements.

Hypothesis 1

A. Maternal food intake during pregnancy and lactation influences the infant's endowment at birth and development during the first six months of breast feeding.

B. Maternal intake during pregnancy and lactation influences maternal child care and sanitation practices in relation to the infant.

By both of these routes, infant behavior and morbidity are affected by maternal food intake.

There is considerable evidence to suggest that severe undernutrition during pregnancy, particularly the later stages of pregnancy, results in a depression of birth weight. There is evidence also that low birth weight conveys an increased risk of early death to the infant. Studies in developed countries suggest that birth weight increases with increasing maternal weight gain and presumably increasingly positive energy balance (Hytten, F.E. & I. Leitch, 1971). Recently, several studies have suggested that women presumably accustomed to chronic low intakes of food have babies of only moderately lower birth weight than seen in developed countries and indeed suggest that the lower birth weight may be in keeping with the smaller maternal body size (UNO report 1981). There has been much speculation about how such accommodation is achieved (by metabolic adjustments, by behavioral adjustments, by some combination),

about whether or not the primary data on food intake are reliable, and about the functional implications, if any, of these accommodations. Data from one of these studies, in the Gambia, suggest that there are compensations among intakes and weight gains during pregnancy and lactation that must be considered conjointly in any analysis of the processes (Prentice, 1983). Very recent, unpublished information from that study suggests that weight gain during pregnancy has a predictive relationship to morbidity and weight in infants to 6 months of age (Whitehead, 1983). Insofar as morbidity is influenced by the biological linkages of pregnancy and lactation and exposure (an environment that may be influenced by maternal actions or non-actions), the duality of hypothesized routes of effects of maternal intake is important.

Maternal intake will be recorded two days each month, beginning not later than the second trimester of pregnancy and continuing for six months postpartum. The interpretation of a given maternal intake in relation to reproductive outcome requires consideration of the woman's body size and tissue reserves and her energy demand for maintenance, for growth of the fetus and maternal tissues and/or lactation, and for physical activity. These factors will be assessed by repeated anthropometric measures, measurement of resting metabolic rate (RMR) during and after pregnancy, infant birth weight and gain, and sanitation- and childcare-focussed activity scales. We judge it to be neither feasible nor necessary to construct a complete energy balance to test the stated hypotheses, but it will be possible to rank subjects according to energy available for non-maintenance uses (intake-RMR).

Weekly illness history (by maternal recall) will define the infant's disease resistance, and duration and clinical course of each episode will establish disease response. Morbidity recorded for all members of the household and scaling of hygienic attributes of the environment provide information on the exposure variable.

Ongoing monthly anthropometric measurement of the infant will help to settle the important unresolved issue of the timing of growth failure in relation to disease: does faltering growth precede disease (i.e. are the presumably poorly nourished more susceptible to disease) or follow from it?

Measurement of immune factors in maternal blood during pregnancy (5th and 8th month) and in colostrum (day 1-3) and breast milk (1, 3 and 6 months) will determine the extent to which maternal immune status could have contributed to infant disease resistance by placental transfer in utero and by lactation. Evaluation of infant humoral immune status will be done only at six months of age using a heel-prick sample taken in conjunction with usual pediatric public health procedures, as blood drawing from this age group is culturally unacceptable.

The amount of maternal time spent in child-caring activities is expected to vary with the adequacy of food intake. Child-care activities will also vary cross-culturally depending upon maternal role expectations, household size and composition, mother's occupation and a host of other factors. Child-care activities may be direct when performed to or for a specific person, such as feeding or bathing the infant; they may also be non-direct, such as washing the family's dirty clothes which includes clothes of the infant.

In addition to gathering information on maternal hygienic practices, needed for environmental assessment, collecting data on child-care

activities will allow us to rank mothers on a "child care proficiency scale" to be entered as a variable in the analysis of the relationship between level of food intake and activity pattern; in this case, child-care activities. Performance levels can be derived from proficiency scores scaled according to (a) frequency of performing an activity--number of times per day, week, month, or year; and b) appropriateness of an activity, using indices of adequacy, inadequacy, or excess. It should be particularly useful to know which categories of child care are reduced or eliminated as levels of food energy are reduced.

The postulated relationship between low energy intake of the mother and the infant's psycholological functioning in social-emotional and cognitive dimensions depends on a series of linkages involving biological and behavioral processes. At any one point in his or her development, the infant's ability to respond (in a testing situation or during an observational period) is a function of multiple factors, including the state of CNS development, motor capabilities, state of physical health, and, progressively with age, previous interactional experience with persons and objects. Thus, maternal intake can be hypothesized to affect infant performance through effects in utero on CNS development and musculoskeletal development, and postnatally through feeding and maternal behavior toward her infant.

While there is considerable evidence from both human and animal research to demonstrate that severe energy deficit affects CNS development, cognitive capacity and emotional reactivity, the effect of moderate maternal deficit on early infancy is far less clear. First of all, there is a serious paucity of data on the subject. Secondly, most of the human studies have used an experimental (intervention) design and the interpre-

tation of results is clouded by methodological issues concerning level of supplementation, effect of supplementation on intake and related issues. Thirdly, the identification of a clear trend in currently available data is hampered by a lack of comparability in the outcome parameters selected for study.

The latter problem is particularly significant in view of the growing evidence that malnutrition impacts differentially on specific behavioral and cognitive processes in young children. Among the processes that seem particularly susceptible to malnutrition are: short term memory (Klein et al., 1975); attention and distractability (Richardson, 1973); responsiveness to stimulation (Lester, 1975); abstract categorization skills (Brockman and Ricciuti, 1971); and social passivity (Barrett, et al., 1982). (Some of these effects would not be clearly discernible in early infancy.)

From the work that has been done, two generalizations emerge strongly:

1) From birth, and increasingly as infancy progresses, the infant's performance reflects both physical conditions and environmental influences.

2) While global measures provide some general picture of performance, the effects of low energy intake on performance are more likely to be discernible in specific components of psychological functioning and may even be masked in more global assessment measures.

The components of psychological functioning in the infant that have been selected for study reflect our postulation that both cognitive and social-emotional functioning are affected by low (maternal) food intake and that both motor and emotional components are involved. We have selected the BNAS, the Bayley Motor Scale, and observation in a semi-

structured situation as the means of assessing a series of specific parameters (see above) because they appear to meet the criteria of sensitivity, feasibility, and comparability outlined in the methods section. A gross measure of physical activity (by actometer) will allow general ranking of infant passivity/activity in relation to social/emotional and cognitive development.

Subhypotheses

The design for the principal pregnancy-infancy hypothesis assumes that in the study settings, a very high proportion of infants will receive almost all of their energy intake in the form of breast milk (to age 5-9 months) and thus that infant intake and maternal output are directly linked even though not measured. Women with low food intake during pregnancy may produce small infants that are not strong enough to establish lactation. Furthermore, during lactation these women may have low energy intakes, which in conjunction with reduced energy reserves and/or illness, fail to sustain lactation. Illness of the infant may affect appetite directly as well as decrease sucking vigor, both of which have negative effects on breast emptying and milk production. In a similar way, early introduction of supplementary foods to infants may have negative effects on lactation. This is dependent upon the type and amount of the supplementary food as well as the timing in relation to breastfeeding. Growth faltering in exclusively breastfed infants occurs when their nutritional needs for growth are not met. This effect can be intensified when energy reserves of the infant are low and when needs are altered by illness or disease.

Early introduction of complementary feeding to infants in less developed countries carries considerable risk of infection, particularly

weaning diarrhea. On the other hand, exclusive breastfeeding for a prolonged time can lead to malnutrition. For most infants, complementary feeding is needed by or before 6 months of age to prevent growth faltering. The implication is that growth faltering and reduced energy reserves due to delayed complementation are associated with increased morbidity and disease.

In this study, the influence of supplementary feeding on growth and morbidity of infants will be evaluated in relation to the age of introduction of the supplement. Monthly questionnaire will be used to obtain information about breastfeeding and the timing, type and quantity of supplementary foods.

To the extent that significant supplementary feeding takes place, such infant-mother pairs will constitute a group in which a subhypothesis can be examined, namely that: Early introduction of solid foods has a detrimental effect on infant morbidity, on infant weight at 6 months, and on infant cognitive status at 6 months. Of course, the opposite hypothesis can be examined as well: Introduction of solid foods by x months has a beneficial effect.

Relevant Variables

A number of variables known to be related to reproductive outcome will be part of the overall data base. These variables are: maternal age; parity; contraceptive practices; breastfeeding patterns (number of breastfeedings per 24 hours and their distribution); and interval since last delivery. Some of these variables have a significant correlation with outcome due to their covariance. (For example, to the extent that age and parity covary, the apparent effect of each will be quite large in simple correlations with reproductive outcome measures.) Each of

these variables is discussed below in terms of its independent effect on reproductive outcome.

Maternal age and parity exert major independent effects on obstetrical outcome. According to U.S. data, age probably does not need to be treated as a continuous variable, but rather is one criterion by which women can be grouped (e.g. $<$18 years, $<$18-30, 30-39, +40) with obstetrical risk lowest in the 18-30 year group. Parity will be handled in a similar manner. U.S. data suggest the following categories: primipara, 2-5, $>$6. Risk is lowest in the middle group.

Hormonal contraceptives may affect lactation and timing of onset of menses and women will need to be categorized as using or not using hormonal contraceptives. Other forms of contraception would affect interbirth intervals but little else.

It has been estimated that at least seven breastfeedings per day are required to maintain adequate maternal prolactin levels for full lactation. It is presumed (but needs to be confirmed) that most mothers in the three field sites will maintain this level of nursing for at least the first four to five months postpartum. Some women may breast-feed 20-30 times per day, but many of these feeds will reflect solace rather than nutrient transfer. Variation in breastfeeding/day will probably be used to group mothers ($>$7, $\leq$ 7) rather than being used as a continuous variable.

In a U.S. study of nursing infants (Quandt, 1981), food introduced prior to three months of age was likely to subsitute for breast milk, whereas that introduced later was more likely to be supplementary. It is possible for us to address the question of whether food given to infants is a supplement or a substitute, only to the extent of its

impact on breast feeding frequency. To date, we have not identified a reliable, noninvasive method of measuring breastmilk output that would allow the frequency of measurement required to establish either maternal output or infant intake. (Projects will continue to seek such methodology for potential introduction in year 2.)

The interval since last delivery may act as a dummy variable representing degree of maternal depletion. However, it has an independent effect in terms of controlling the age at weaning of the previous infant, and as the interval declines there are conflicting demands for sibling-infant nurturance and attention which may directly affect infant psychological function, morbidity, and other parameters.

Hypothesis 2

A. Food intake of the toddler during the period from 18 months through 29.99 months affects the toddler's morbidity, body weight and psychological development.

B. Maternal intake during this period affects maternal child care and sanitation practices in relation to the toddler.

The post-weaning period is recognized as a period when the infant is highly vulnerable to external influences (food intake, sanitary environment including care, psychological environment). It is widely recognized that major inadequacies in this period lead to morbidity, and to deficits in body size and in psychological measures which may persist, at least in environments that do not themselves show major improvements. Much less is known about the effect of less severe challenges and about the effects of intermittent or cyclical changes in conditions (such as those associated with recurrent morbidity) on development of the child during this period.

The hypotheses of this design are that the food intake of the child influences his/her resistance or response to the environment and that the intake of the mother contributes to a variable component of the environment of the target child. These influences are then expressed in terms of morbidity, psychological status and body size and composition of the child. The hypothesis recognizes, and the design takes account of the influences flowing in the opposite directions (i.e. that morbidity influences food intake through effects on appetite).

In the weaning process, the infant moves from total dependence on breast milk to increasing intake of other foods. This process is typically accompanied by increased morbidity and changes in child care. It may also represent a time of increasing diversity or variability between households in the nature of mother-child interactions, as the child's behavior becomes more complex. Because it is a time of stress, vulnerability and rapid change, it is a period in which the impact of low energy intake on behavioral development may be particularly apparent.

Among the main dimensions of development to be examined and that are hypothesized to be affected by intake are: in the social category--exploratory behavior, reactivity to persons in the environment, fearfulness, goal directedness, and emotional expressiveness, and in the cognitive category--memory, attention, persistence, and verbal skills. Physical examination will include measures of visual and auditory capacities.

Physical activity, using gross physical movement as an index, is seen as a component of behavioral output which may both condition and be conditioned by social-emotional and cognitive development.

The same methods will be used to follow growth and morbidity of toddlers as for infants (see above), and the same assessments will be made of the hygienic environment, household morbidity and maternal sanitation- and care-giving activities. Immune status of toddlers will be evaluated at 6-month intervals in conjunction with periodic physical examinations.

A sub-hypothesis of these major hypotheses concerns the process of recovery from illness as an important influence on the overall pattern of infant development. Some researchers have reported that increased morbidity in children is associated with deficiencies in social and cognitive development; they postulate that, because of illness and/or reduced food intake, there is reduction in social interaction and interaction with the environment. To test this, we specify a subsidiary hypothesis: The pattern of infant recovery after illness, measured as weight change during the symptom-free period, is influenced by maternal care (measured as special attention to feeding, treatment, care-taking) which in turn is influenced by maternal intake. This will be examined as a part of a special "illness" subroutine.

Variables of importance that will be recorded include: cognitive endowment and achievement of parents, presence and quality of alternate caregivers and other household composition characteristics. Of particular relevance is the presence of a newborn infant.

Hypothesis 3

A. Food intake of the 7-9 year old child affects his/her morbidity and behavior, including such behaviors as school performance.

B. Food intake of the mother and father influences their behavior toward the child and hence morbidity and behavior of the child.

Hypotheses 1 and 2 emphasized that growth and development as well as morbidity are outcomes of intake. The present hypothesis continues to recognize morbidity as an outcome of current intake (as well as being influenced by unmeasured past history) but places increased emphasis on the relationship between intake and functional expressions of behavior in the child.

Currently available research data suggest that the social-emotional dimension of psychological development is more affected by chronically low energy intake than is cognition. While severe malnutrition in infancy appears to have prolonged effects on cognitive processes (Monckeberg, 1968, MacLaren, et. al. 1973), relationship of mild/moderate malnutrition to cognitive dysfunction has not been demonstrated (Pollitt & Thomson, 1977; Barrett, Radke-Yarrow and Klein, 1982). On the other hand, there are both theoretical formulations and empirical evidence to support the hypothesis that aspects of social-emotional functioning are affected, during childhood, by low energy intake (Barrett, et. al. 1982; Sameroff & McDonough, 1983). Thus, in this research, the focus on the school-age child will be heavily on behavioral aspects. However, more traditional cognitive measures will also be included in the study, both for comparative purposes (with previous research) and to allow us to examine the degree to which the two aspects (cognitive and social-emotional) are related.

The outcome measures or parameters to be studied in the 7 to 9 year olds are:

<u>Social-Emotional</u>

1. Social Interaction: Based on the classic work of the Whitings' (Whiting and Whiting, 1973), target children will be observed for specific behaviors.

2. Cognitive Mediators: attention and goal directedness will be measured by observations of children's behavior in classroom subactivities and by teacher ratings of children for these dimensions.

   Persistence will be measured by the amount of time the child remains involved in attempting to solve a puzzle.

   Cognitive function will be measured by sub-scales of standardized tests which tap dimensions of memory (digit span) and symbolic capacity and reasoning (mazes, block designs).

   School performance will be measured using: observation in the classroom, teacher ratings, and test scores. Observations will also be made of children not attending school.

Anthropometric and disease-related measures for this age group are as stipulated for infants and toddlers. Culture-specific maternal and paternal child-care proficiency scales relating to this age group will be utilized.

Hypothesis 4

A. Food intake of adults influences their morbidity, their social-emotional responsiveness and their performance of usual responsibilities.

B. These impact upon other members of the household (as stipulated in previous hypotheses).

The vulnerability of infants and children to the effects of malnutrition has long been recognized, as reflected in the concept of "at risk groups." The increased demands imposed by pregnancy and lactation lead to the inclusion of women in these physiologic states in the vulnerable category. In many rural communities in developing countries, repeated cycles of pregnancy and lactation are the norm so that women of reproductive age can be regarded as members of a class that are "at risk" of low energy intake. For adult males and many women in poor rural communities, cycles of agricultural labor typically impose varying energy demands over the course of the year. At points during the cycle, increased energy requirements place men, too, in the groups (potentially) "at risk." Thus, for adult women and men in developing countries, low food intake may result in functional restrictions.

The theoretical structure linking adult intake to morbidity involves both physiological and behavioral linkages. Behaviorally, reduced food intake is hypothesized to affect activity level, including activities and behaviors that affect exposure to pathogens (hygienic practices, conditions of the household environment, amount of activity outside the household). Physiologically, low intake is hypothesized to affect immune system functioning and hence the frequency and/or course of illness. In this model, the two main explanatory variables are "exposure to pathogenic agents" and "immune system."

The effect of low energy intake on psychological functioning in the adults is primarily identifiable in components of social-emotional functioning. The relationship of low energy intake to concurrent cognitive functioning is tenuous, except in the extreme situation of starvation. However, it should be noted that low intake in infancy, when

it produces permanent deficit, will be reflected in adult performance. Thus, in the adult couple, an association of intake and function may appear when the community contains adults who were both seriously malnourished as infants and currently are experiencing low intake.

Low energy intake may be associated with tiredness and lethargy, which in turn, can be hypothesized to lead to less willingness to engage in social interaction or greater passivity, less responsiveness and lower emotional affect. As suggested in the portrayal of Hypothesis 3, this may influence the socio-emotional behavior of others. Lethargy and inattention might also contribute to a higher risk of accident and injury in the chronically underfed.

Although cognitive functioning per se, is not hypothesized to be related to current intake, it will be important to measure cognitive performance in target adults as general descriptors of the household and as background for the assessment of social-emotional functioning.

An important sub-hypothesis for the adult is that the extent of adipose tissue reserves established during periods that positive energy balance can be established, exerts a major influence on the extent of functional impairment during periods of negative energy balance (or less positive balance for pregnant or lactating women).

In the design, the lead male and female will be studied in every household chosen for the study.

Hypothesis 5

In adults, a reduction of resting metabolic rates provides a major path of adaptation to restore energy equilibrium.

This is a sub-hypothesis in the sense that it does not impose an

additional design requirement. Conversely, it is currently a major issue in international discussions of energy requirement (e.g. FAO/WHO/UNU report in press, 1983; Sukhatme and Margen, 1981). The proposed design, by including repeated measures of RMR in adults across time and across periods of anticipated positive and negative energy balance (judged by weight changes), provides an opportunity to address the issue. In essence, the question of interest is whether in "marginally undernourished" individuals the RMR is lower in relation to lean body mass than would be expected. The question may be addressed most readily in adult males (without complications imposed by pregnancy, lactation or growth) but will be examined in others.

Hypothesis 6

Household food intake affects household morbidity.

A summary hypothesis is that household experience as a totality is affected by the level of food intake of the household members. This hypothesis is seen as including the epidemiologic concept that proximity and frequency of contact (as in a household including sick individuals) increase the probability of infection. Thus, many factors concerning the household environment and likely proximity of individuals will be considered. It is recognized that both household resources and household income could affect household food expenditures (and thus intake) and household morbidity, and indeed that the latter might affect income. Time lag analyses will be used to disentangle these relationships using also extra-household variables associated with climatic morbidity cycles and agricultural work cycles.

The additional demand imposed upon the design by this hypothesis is the need for household food intake information. With this information, each of the preceding hypotheses can be linked to the total household measure most commonly available in international data sets, household food use.

Acquisition of data on household food intake (and household demographic structure) allows examinations of a set of sub-hypotheses concerning the partitioning of food resources within the household. These might be stated in the form:

> In the face of low household food supply, the toddler/school child/woman is given a disproportionately low share with effects as examined in other hypotheses.

It is possible also to examine another important hypothesis that has major practical implication for policy makers:

> Growth failure in infants and children is attributed in large measure to failure to "catch up growth" between periods of illness and this is attributed to shortage of food in the house.

The obverse hypothesis, of course, is that mothers allocate an increased share of the household food resource to the young child when he or she is in the period of biological need during recovery.

General Design Implication for Hypothesis Testing

The design adopted is such that, for each of the hypotheses proposed above, there will be approximately at the minimum 100 households, in which the appropriate sets of individuals will be studied. To the degree that there are several target individuals present in the same

households, data collection for multiple hypotheses may overlap. It is not intended, however, to collect data on all households throughout the entire period. Data collection relevant to each hypothesis will require approximately 12 months of continuous study in the household. Depending upon the concurrence of target individuals, particular households may be involved for as little as 12-15 months or as much as 24 months. Section V on Sampling Design will discuss the timing in greater detail.

Figures 1 to 4 portray the paths by which intake is hypothesized to influence function.

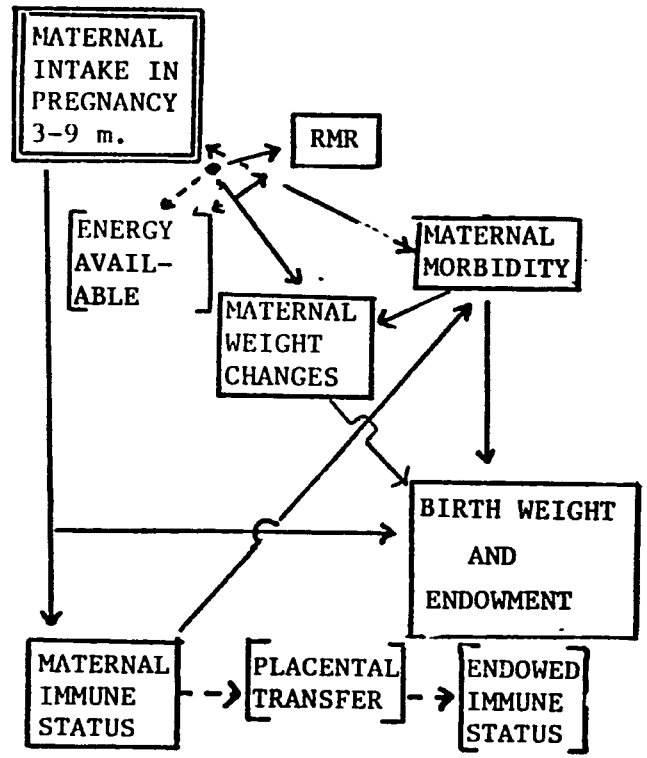

Figure 1a. Paths through which maternal intake influences infant birth weight and endowment at birth.

——— Planned measurements for all projects

--{ }-- Hypothesized paths not measured in core of research design Some of these may be examined in non-core, country project supplementary research designs

Cohort Required: 12 consecutive months beginning at 3.0 months of pregnancy and continuing through 5.99 months of lactation/infancy.

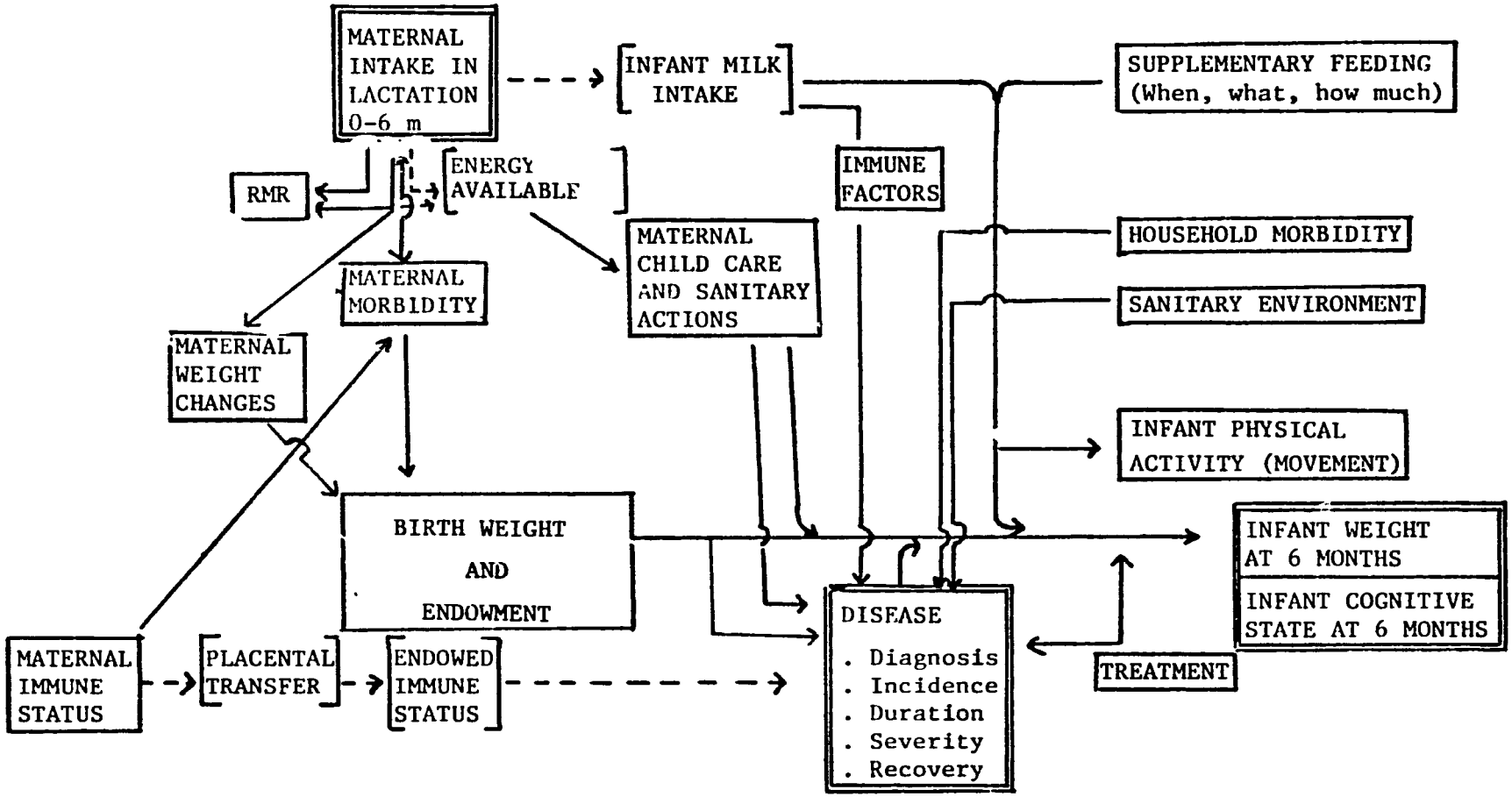

Figure 1b. Paths through which maternal intake influences infant morbidity and cognitive status. .

Planned measurements for all projects

Hypothesized paths not measured in core of research design
Some of these may be examined in non-core, country project supplementary research designs

Cohort Required: 12 consecutive months beginning at 3.0 months of pregnancy and continuing through 5.99 months of lactation/infancy.

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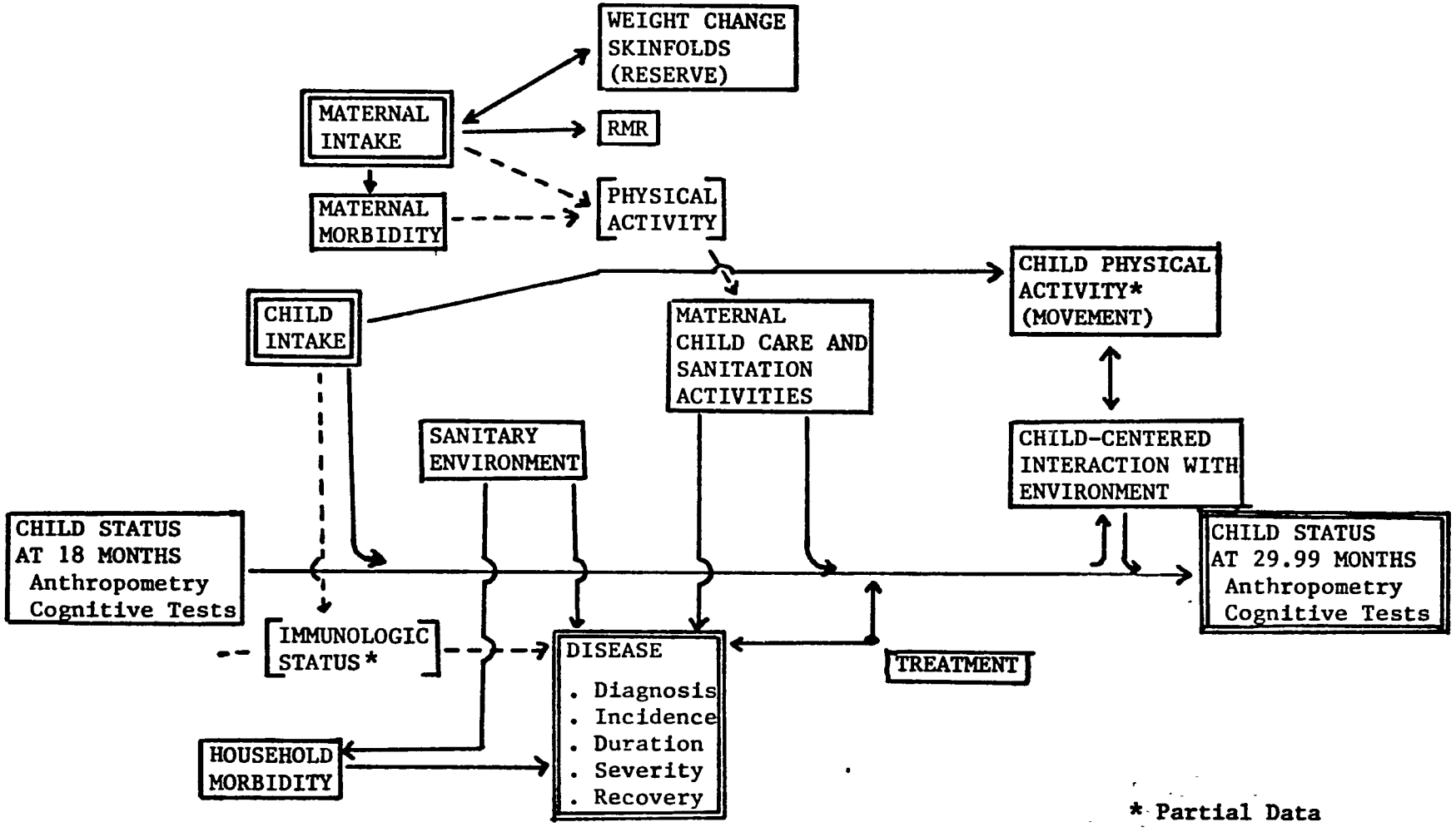

Fig. 2 Paths through which child and maternal intakes influence child morbidity and cognitive status

Measurements planned for all projects

Hypothesized paths not directly measured in core design

Cohort Required: 12 consecutive months beginning at 18.0 months through 29.99 months and parents.

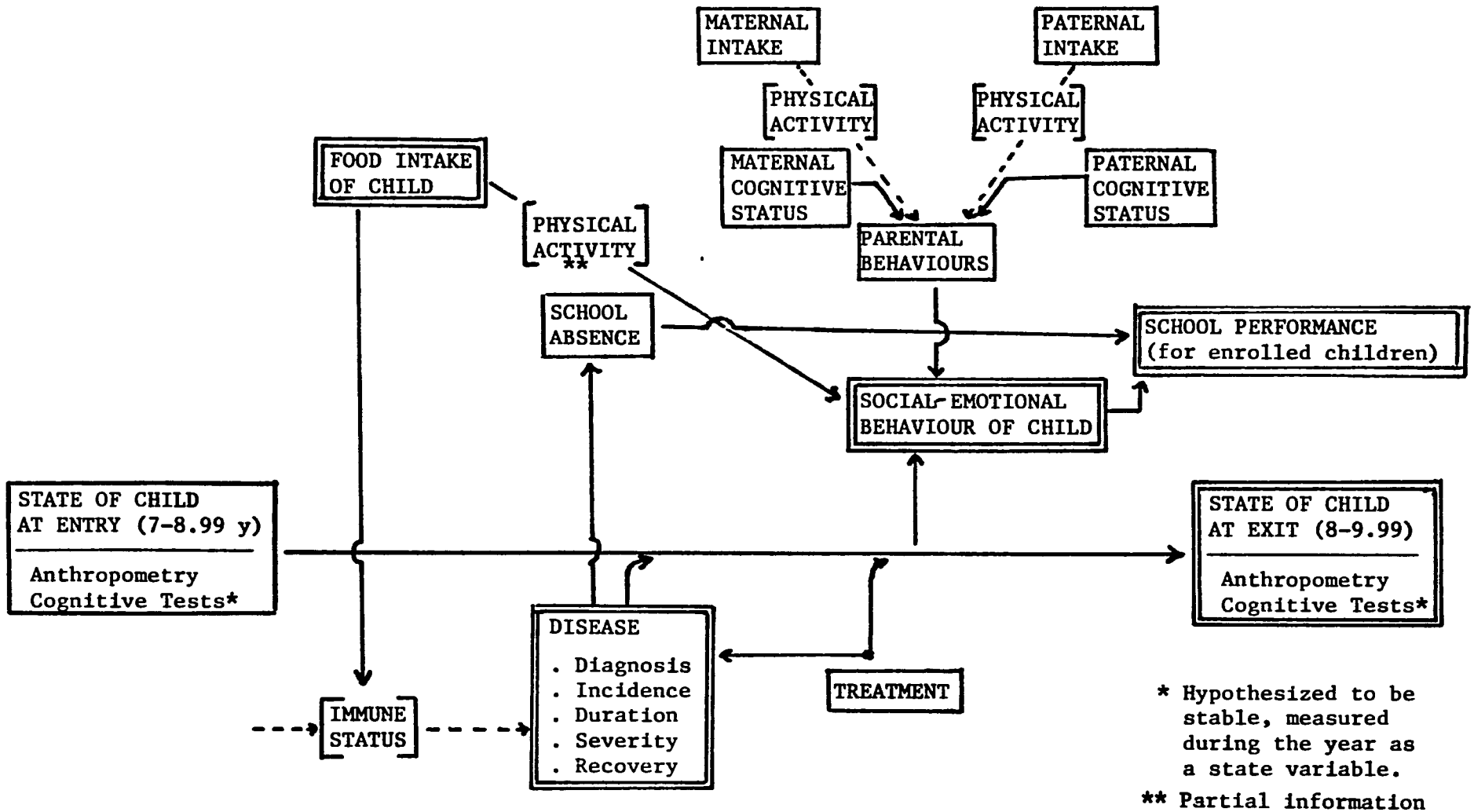

Fig. 3. Paths through which the child's intake affects its morbidity, social-emotional behaviour and school performance, indicating also paths by which parental intake may influence this process

Planned measurements for all projects

Hypothesized paths not measured in core of research design

Cohort Required: 12 consecutive months beginning at an age between 7.0 and 8.99 years, together with parents

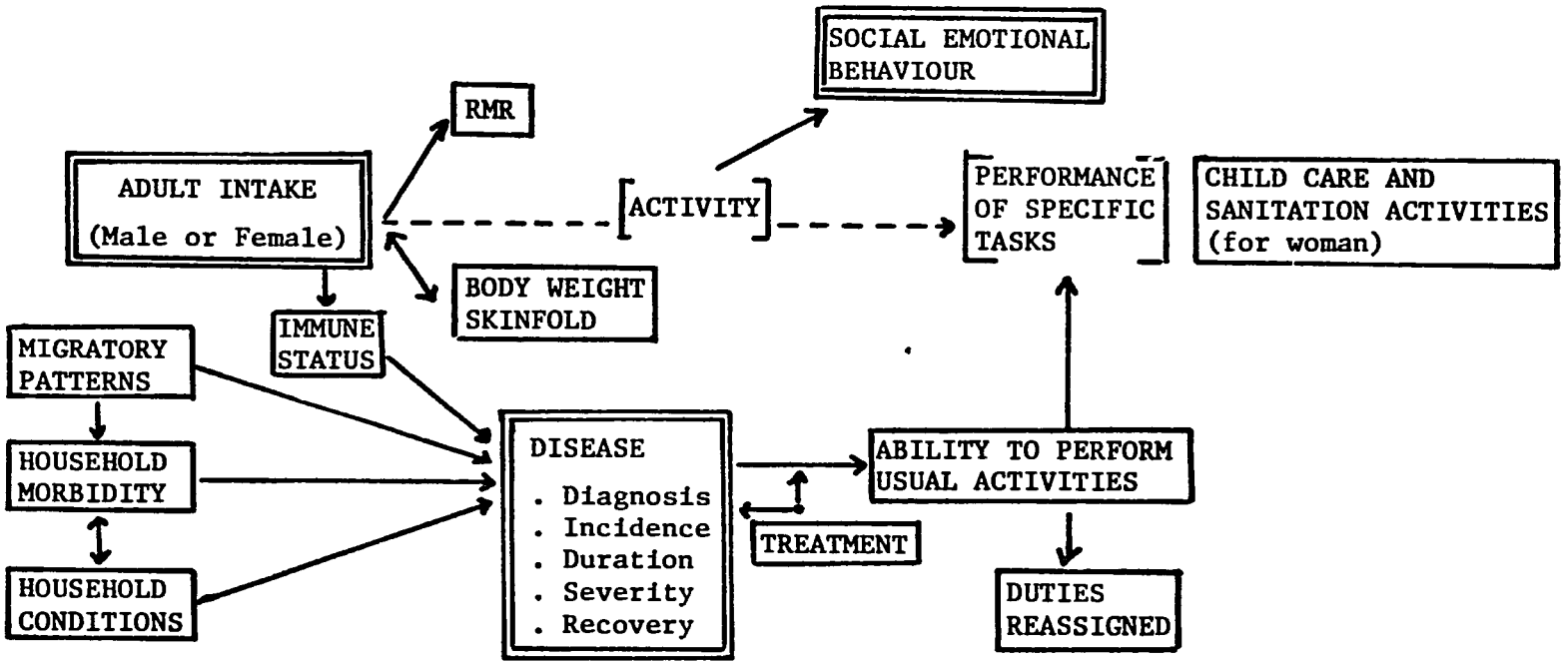

Fig. 4 Some paths through which the intake of adults affects their morbidity and social emotional behaviour. The schematic suggests also the linkage of adult performance with other individuals in the household. For further development of this aspect, see Figures 1-3.

Cohort Required: Collection of data concerning the lead male and lead female is included as a part of all clusters of individuals implied in previous hypotheses

—[ ]— Planned measurements for all projects

--[ ]-- Hypothesized paths not measured in core research design

IV. Methods

A. Food Intake: The Independent Variable

Food intake is the major independent variable to be measured. Therefore, a great deal of care has been taken in planning to ensure that the core food intake design a) will be feasible in all three project settings; b) will yield data which can be compared across projects with confidence; and c) will be adequate to characterize the food intake of key individuals, the food used by households, and the partitioning of food resources among individuals in households. The focus in design decisions relative to the food intake core is on meeting the above criteria for energy intake. Some details of data collection methodology will differ somewhat among country projects due to variation in local dietary practices and the conditions of data collection in the study communities. However, the data collection will meet the three requirements listed above. Pilot studies have been carried out in Phase I to estimate the range and variance in energy intakes and to determine feasibility of methods.

All projects will collect quantitative data which will represent the total food use of the household and the food intake of "target" individuals.

1. Household Food Intake. In all three research sites, household food intake will be measured on the same two days/month as the target woman's food intake through estimation (by a combination of recall and weighing) of the total amount of food prepared for the family for the 24-hour period, adjusted by subtracting food not consumed by family members and adding food obtained away from home.

2. Individual Food Intake. All projects will collect a minimum of two days' quantitative food intake data per month on the target woman, target toddler, and the target school-age child. Quantitative data will also be collected on the target adult male when he is available to be interviewed personally. (The three projects estimate that some adult males, from very few to about 30 percent may be unavailable for complete food intake data.) When the target male adult is present in the household but not available for interview, his within-household food intake will be ascertained by interviewing the target woman. This information is needed to determine if intake of other target subjects is affected by the man's presence or absence from the household.

The methods used will combine short-term recall and weighing, with the exact proportion of each and the number of hours to be recalled varying somewhat according to specific project needs and constraints. It is expected that adults and children 7 years and older will provide their own oral report. Mothers will report the food intakes of children 18-30 months of age.

The number of observations proposed (2 days per month) will yield data for six days per three-month period; this is judged to be an adequate number to yield a reliable measure of usual energy intake based on the intra-individual variation in energy intake in the pilot studies. (Coefficient of variation of the estimate of average intake of an individual over a three-month period is expected to be 10 to 15 percent.)

The food intake of all target individuals will be studied on the same two days, in order to be able to begin to address the issue of intra-household food distribution.

3. Infant to age six months. The newborn infant is included in the core design through the first six months of life as a potential outcome with respect to maternal food intake. It is not possible to determine with accuracy the energy intake of the infant. All three projects have concluded on the basis of pilot studies that the standard test-weighing methodology for estimating breast milk intake cannot be done on all study infants over enough 24-hour periods to yield adequate data. Other methods have been explored. Repeated use of heavy isotope tracers has been rejected on ethical and feasibility grounds. Some pilot data have been collected on interval weighing, corrected for changes in clothing, to estimate intake; preliminary results indicate that this method or a modification thereof may be useful in ranking the intake of infants, but the accuracy and feasibility of repeated observation need further testing. In any case, it is not feasible to accomplish 24-hour weighing in any study community except perhaps on a sub-sample of infants. Therefore, the design of the core has been constructed on the assumption that we cannot know the energy intake of the breast-fed infants. Until age six months, we think that the infant's morbidity and development can legitimately be viewed as outcomes of maternal intake. Supplemental feeding other than breast milk may occur prior to six months in all study communities for some infants and will be recorded as part of a continuing monthly lactation questionnaire.

4. Special Considerations. Some specialized times relating to recurring cultural events present special problems which are unique to each project. In Mexico, it may not be possible to use the same methodology on Sundays as on weekdays. The Sunday methodology will be

validated against other methods, such as observation and weighing. In the Egyptian situation, the month of Ramadan with its significant changes in food consumption and fasting patterns poses a special problem. During the current preliminary year, in-depth interviews with the lead female and other household members are being conducted during Ramadan. A protocol to capture dietary data with more precision during Ramadan in the second year will be developed, based on experience in the first year.

During and after an illness episode in a target subject, there will be an alternate-day interviewing routine, until the subject is symptom-free on two consecutive days. This interview will include questions about food and liquids given and withheld. The information elicited can only be semiquantitative or descriptive, given the tolerance to intrusion in the study households. It is a key component of the maternal care-giving proficiency assessment, and additional days of post-illness interviewing may be added based on local project experience.

5. Personnel. Food intake data will be collected in all three projects by observers trained specifically in the protocols for this study. These data collectors will vary among projects with respect to their prior background and training due to local personnel considerations. In Egypt, university-trained dietitians on the staff of the Nutrition Institute will be employed. In Mexico and Kenya, food intake data collectors will be individuals with secondary school education recruited from nearby communities and trained and supervised by professional nutritionists. The approximate personnel requirement for this task is fifteen full-time data collectors and supervisors for the core

observations. The personnel in Egypt, because of their prior training and experience in dietetics, will undergo training in how to avoid providing systematic nutrition education to households.

6. Validation and Quality Control. Prior to initiation of data collection, all projects will validate their food intake methods against weighed intakes for a full day on a small number of households. This validation will be repeated at least twice in the two-year study.

Quality control of food intake data will be achieved in three major ways: 1) rotation of interviewers and ongoing analysis of interviewer reliability within each project; 2) ongoing analysis of means and variances of energy intakes for all projects. Unexplained changes in either will prompt re-training of interviewers; and 3) whenever possible, tape recording of interviews will be done and data compared against the taped record for completeness and accuracy.

7. Food Composition Data Bases. To meet the needs of the CRSP, it is essential to have available for each project a food composition data base which includes all foods which are major sources of food energy in the study communities. Minimally, data are required for these foods on water, fiber, nitrogen, total fat, utilizable carbohydrate, and other nutrients which may be of importance in interpreting the data on energy relationships. There are some gaps to be filled for all three projects, with the work to be done ranging from a minor amount in Mexico to a very great amount in Kenya, with the Egyptian situation intermediate. The Mexico project will utilize food composition data available from the Instituto Nacional de Nutricion supplemented with information from the Central American data base available through INCAP. A few foods of

importance, however, require analysis. In Egypt, existing data bases consist of the tables published by the American University of Beirut in the early 1970s for Middle Eastern foods, plus some limited local analyses. In Kenya, there are very few data available appropriate for local foods, although some use of African food tables can be made with some significant assumptions.

The best solution would be for a well-equipped laboratory with experience in food analysis to undertake the necessary analyses for all projects. Consideration is being given to obtaining the services of a U.S. government laboratory. Several composition samples of entire days' intakes from each project could be subjected to an extensive analysis including trace minerals and vitamins, and the major foods of importance could be analyzed in several replicates for the essential components. If a central laboratory is not possible, the following will be done: Mexico project will conduct the necessary analyses at the INN in Mexico City; Egypt project will undertake some analyses in Egypt and may send samples to the University of Arizona and/or Purdue University for some analyses; and Kenya project analyses will be done at the University of California at Berkeley. Management Entity will supply check samples for quality control analyses.

8. Handling and Transfer of Food Intake Data. Core data on food intake will be stored in each country project with the following minimum information: person ID code, date, food code, total amount (in grams) for 24 hours. Additional data stored (such as time of day consumed) will be optional and country-specific.

Food intake data will be converted to nutrients by country projects and the following core information transmitted regularly to ME: person

ID, date, total nutrient intake/24 hours for food energy, protein, and all other nutrients calculated. Copies of the food composition data tapes used will be supplied to ME, and protocols will be developed for informing ME of all changes made in these data bases over time in country projects.

Table 1

Summary of Food Intake Protocol

Target Subject	Frequency	Method
Male Adult	2d/month	Self-reporting of total intake by interview or reporting by target female adult of within-household consumption.
Female Adult (includes pregnant 4th - 9th month, lactating 0-6 month, and all other women selected)	2d/month	Self-reporting supplemented by weighing and observation
School-Age Child (7-9 years)	2d/month	Self-reporting by interview
Toddler (18-30 months)	2d/month	Reporting by mother or alternate care-giver
Infant (0-6 months)	1/month	Reporting of supplementary feeding, by mother or alternate care-giver.* Breast-feeding frequency and duration by interview and observation.
All subjects during illness + 2 days recovery	every other day	Interview of self or care-giver as to food and liquids given, taken and withheld*
Household	2d/month to coincide with target woman's data collection	Weighing and/or measuring of all food prepared and served to family and food not eaten. Record of food eaten away from home by target individuals and of food eaten by visitors within household.

*Semiquantitative; all others are quantitative, 24-hour totals.

B. Body Size and Composition

Documentation of change in body size, proportion, and composition is crucial to the design in several areas. Although these changes are not seen as functional outcomes of intake (since functional significance of differences in these variables is largely unknown), they are critical in interpreting the relationships between food intake and function (Table 2). Food intake may affect functional outcomes on a causal path through nutritional status as reflected in anthropometric variables, or it may operate through separate pathways to affect growth or change in body size and a function of interest. These relationships may or may not be competitive.

In most instances, the rate of change in one or more anthropometric characteristics is the variable of interest. This approach does not require the relating of anthropometric values to any standard of "normality" or "reference data." Preliminary anthropometric surveys in the study communities have documented a range of "normal" through "moderately malnourished" status in relation to international reference data; for Phase II the variables of interest will be longitudinal rather than cross-sectional.

In longitudinal analysis, the magnitude of the error term is much more important than in cross-sectional use of anthropometric data. Therefore, all projects will adopt rigorous methods to minimize measurement error, and to document reliability of measurement; in addition, measurement of target individuals is scheduled to be repeated at intervals frequent enough to obtain reliable estimates of rate of change.

The measurements selected are the minimal ones needed to ascertain

Table 2 Rationale for Scheduled Anthropometry

Target Individual	Design Purpose for Anthropometric Measurements
Pregnant Woman 4th - 9th months	Change in weight and body composition (and pattern of change) in pregnancy is necessary to interpret the relationships between maternal food intake and activity, morbidity, pregnancy outcome (birthweight), and infant morbidity.
Lactating Woman 0 - 6 months	Necessary to interpret relation between maternal food intake and infant growth, morbidity, and cognitive development.
Infant to age 6 months	- Birthweight (for gestational age) an outcome variable adequacy of maternal food intake in pregnancy. - Change in status (and pattern of change) necessary to interpret relationship maternal food intake and infant morbidity, infant cognitive development. - Growth rate of infant an outcome variable for maternal food intake in lactation.
Child 18 - 30 months and 7 - 9 years	Change in weight and body composition necessary to interpret relation between adequacy of food intake to cognitive and morbidity outcomes across seasons.
Adult Male	Changes in body weight and composition needed to interpret relative adequacy of food intake to morbidity across seasons and in relation to work demand.
Adult Female	Changes in body weight and composition needed to establish base-line for pregnancies beginning during the study period, and to examine questions of maternal depletion with repeated pregnancies and lactations in relation to food intake.

change in body size and energy reserves: height (length--for infants), weight, mid-arm circumferences, skinfolds at three sites (triceps, biceps, and subscapular) and for infants only, head circumference. Except for height in adults (age $\geq$18 years), which need be measured only once, all measurements will be taken monthly on all target individuals. Additional measurements will be scheduled in connection with the special illness routine, as an index of recovery.

Quality control measures include agreement on: equipment; documentation of inter- and intra-observer variability; permissible levels of variation; and pre-scheduling of examination dates so that minor variations in timing of data collection do not accumulate during the course of the study. A core methodologic manual has been prepared and will be utilized (supplemented with pictures) to enhance training utility. Permissible error limits have been adopted from those in current use in the Fels Longitudinal Growth Study. Reliability checks are pre-scheduled and built into the recording form.

Skinfold measurements will be utilized as estimates of subcutaneous fat. In addition, cross-sectional fat and nonfat area of the upper arm will be calculated as estimates of fat and muscle reserves according to the formula of Gurney and Jelliffe. Data analysis will utilize analysis of growth <u>patterns</u> in children and patterns of change in adults (especially pregnant women) as well as absolute rate of change in variables.

A variety of techniques are available for reduction and analysis of longitudinal anthropometric data. Since these have been developed largely on data collected over much longer time periods and at less

frequent intervals, ongoing work will take place in adapting these methods to the relatively more sensitive changes which will be seen in this data base.

Table 3 Summary of Anthropometry Protocol

Target Subject[a]	Frequency	Measures			Circumference	
		Height (or length)	Weight	Skinfold Thickness	Arm	Head
Infant, 0 - 6 months	At birth[b]		x			
	At 8 days	x	x	x	x	x
	Monthly for 6 mos.	x	x	x	x	x
Toddler, 18-30 mos.	Monthly for 12 mos.	x	x	x	x	
	1st, 6th and 12th mos.					x[d]
School-age child, 7-9 yr.	Monthly for 12 mos.	x	x	x	x	
	1st, 6th mos.					x[d]
Female Adult (including target pregnant, lactating and NPNL)	1st and 6th month	x[d]				x[d]
	Monthly		x	x	x	
	8th day postpartum		x	x		
Male Adult	1st and 6th month	x[d]				x[d]
	Monthly		x	x	x	
Previously ill	2nd sympton-free day[c]		x	x	x	

[a]Other household members will have height and weight recorded once as a household descriptor.

[b]Within 24 to 36 hours of birth. Dubowitz score to be determined within 72 hours at birth.

[c]Infants and toddlers will be weighed every other day of illness if the local conditions and nature of the disease allow it. Weekly follow-up weight of toddlers and infants will be added if consistent with local acceptance and resources.

[d]State measure, repeated for validation only.

C. Periodic Physical Examination and Health Evaluation

1. Health Status. A medical history and physical examination (for clinical signs of nutritional deficiency and the examination for presence of disease combined) will be administered once a year to all members of study households and at six-month intervals to target children below age 10 years.

The physical examination in addition to physical signs will include: blood pressure of individuals three years old or older; vision acuity assessment by standard eye chart on children of three and over; hearing evaluation (audiometer), and anthropometric measures as described in part B above.

Chronic morbidity such as hypertension, diabetes, and renal disease, will be detected by physical examination and by simple laboratory studies, e.g. urinanalysis and blood pressure measurement.

Intestinal parasites will be detected by stool examinations for ova and parasites. Stool specimens will be obtained using rectal swabs or on specimens brought for examination at the time of physical examination. Semi-quantitative methods will be used.

Blood smears will be examined for malaria in Kenya. Evidence of schistosomiasis will be sought in urine samples in Egypt.

2. Anemia. All projects will carry out studies for anemia and iron deficiency by measuring:

hematocrit (microhematocrit),

hemoglobin(cyano hemoglobin method) and

serum ferritin (ELISA technique or radioimmunoassay). In addition to the annual (adult) or bi-annual (children) physical examina-

tion, these tests will be performed on all pregnant women at the 5th and 8th month of pregnancy.

3. Reproductive History. On the first visit, all women will be queried about number of pregnancies, live births and living children; menstrual history; and lactational history. Men will be asked the number of their live-born and living children.

Women who are pregnant will be followed according to usual community practice. Those included in the target population will be seen monthly for anthropometry. They will have blood samples taken for anemia and immune factor status at the 5th and 8th month; routine urine analysis will be made at that same time.

Table 4 Summary of Physical Examination and Medical History Protocols

Subject	Frequency	Physical Exam & History	Blood Samples (finger or heel prick)	Urine Sample	Stool Sample
All members of study households	1/year	x	x	x	x
Target Infants	At Birth	x[a]			
	At 6 mo.	x	x	x	
Target Toddlers	2/year	x including vision & hearing	x		x
Target School-age	2/year	x including vision & hearing	x	(Egypt only)	x
Target Pregnant Woman	initial, 5th and 8th mo.	x[a]	x	x	x
	At delivery	x[a]			
Target Lactating Woman	6th month	x	x	x	x

[a]Special protocols for birth and delivery examinations are intended and available.

D. Sanitary Aspects of Environment

The household environment is an important determinant of morbidity. The main purpose of collecting data on the household environment is to rank households on an "environmental hygienic adequacy" scale. The score of households on this scale will be entered as a variable in the analysis of the relationship between maternal food intake and infant morbidity, and between morbidity and own intake of toddlers, schoolers and target adults. Other scales for each household will also be derived under the main scale sub-headings of "contamination," "hygienic practices," and "illness care."

It is assumed that the presence of pathogens in the infant's environment may be ubiquitous. Therefore, core measurement of pathogens will be limited to screening for the presence of E. coli in the family water supply for the house, and for drinking,as an indicator of fecal contamination.*

Descriptive data that will be used to construct the hygienic adequacy scale include: number and type of animals and birds entering the house and adjacent to it; character of yard (cleanliness, drainage, etc.); number of flies, mosquitos, cockroaches and rodents in the house; disposal of fecal matter in and near the house; wearing of foot protection;

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* Projects with the capacity to measure the presence of E. coli, Shigella, and Salmonella in other household locations may make additional measurements in locations such as: specified utensils, specified areas of the house, and specified foods. Descriptive information of the presence of these pathogens is expected to show marked seasonal variation, and may explain part of the seasonal morbidity and weight loss of family members which might occur in these populations. These would be included in none-core research activities.

cleanliness of utensils, their storage and food protection; cleanliness of places infants and toddlers play and sleep; cleanliness of clothing. The last two items will be observed monthly and the others four times a year. Each item will be scored and the aggregate will constitute the hygienic environment variable, applicable to all members of the household.

E. Morbidity

It is well documented that the severity, duration, and number of infections are increased in severe protein-energy malnutrition. Also to be considered are accidents and injuries which may have some association with nutritional status and sense of well-being and psychological problems. We wish to determine if the above is also true for less severe food deprivation.

The approach is to define common disease entities clearly in locally used terms and descriptions and then to make the diagnoses from recognizable components which will be reported by field staff on the basis of structured interviews.

1. Defining Morbidity

Pilot studies will be needed to define illness in terms of locally recognizable entities and terms, signs and symptoms.

Definitions of disease (incidence, severity and duration) will be based on objective criteria. The basic instrument for deriving incidence data will be a weekly recall of illness. Therefore, it is necessary carefully to investigate factors which will affect the identification of signs and reporting of symptoms in the three settings. These factors relate to perceived illness rather than disease. Our efforts will focus on diarheal and upper respiratory disease since these are by far the most prevalent conditions. However, the same principles can be applied for any illness found to be significantly prevalent in target individuals.

A focused ethnographic investigation will take place in all three study communities to identify:

a. perceptions of usual or normal status with regard to the variables in question (e.g., number of stools/day; nasal discharge);

b. perceptions of types of diarrheal and upper respiratory illness and usual labeling terminology;

c. criteria for identification of the illness described in b;

d. potential accuracy of reporting the variables of interest (e.g., number of stools/day); and

e. usual methods of treatment and criteria employed to decide on the need for treatment since variation in these may affect reporting.

The methodology will consist of a systematic interview/observation pilot study focused on target-age individuals in the study communities to take place prior to finalization of morbidity recall forms. At least six lead females from each sociodemographic household type will be interviewed in each study community (more if variability on response so indicates).

Observation of the target individual, when the subject is an infant or small child, will be used to establish the validity of reporting of the major variables of interest (number and character of stools; frequency and character of nasal discharge).

The information derived will be used to adapt the morbidity recall instrument to facilitate accurate reporting on each community, and to define for analytic purposes the criteria for identification of disease. In all cases the community in which the feasible valid identification of the disease is the <u>least sensitive</u> will determine the definition for purposes of cross-project data analysis.

Variables to be explored for each target-age individual include:

What is the usual number of stools per day when not sick?

What is the perceived usual number of stools/day when not sick?

What are clothing, cleaning and disposal processes and how do these affect potential recall?

What criteria are used to define "diarrhea" (number of stools, color, odor, consistency, associated symptons, other)?

What types of diarrheal illness are perceived to exist (by symptom, emology, treatment)?

What criteria define perceived severity and/or need for intervention?

What interventions are utilized under what circumstances?

What is the prevalence of nasal discharge/stuffy nose?

What is presumed to be normal with regard to nasal discharge? stuffy nose?

What are hygenic/disposal practices and how do they affect accuracy of recall?

What criteria are used to define upper respiratory illnesses?

What types of upper respiratory illnesses are locally identified?

What criteria determine perceived severity and/or need for intervention?

What interventions are utilized and under what circumstances?

The ethnographic aspects of the major classes of morbidity will be a subject of continuing investigation in Phase II, using an abbreviated version of the interviews described above initially and at least once later in Phase II, to identify variability and change over time in these factors which may affect the validity of morbidity recall data.

2. Illness History Recall

On day 1 of the weekly household visit the field workers will administer a structured questionnaire to obtain a history of illness and trauma during the preceding week for all household members. If the respondent (mother or other knowledgeable adult) says there is no illness -- this will be recorded but there will follow a systematic probe to be certain that no illnesses were present.

If an affirmative response is obtained in a target individual then an in-depth questionnaire with selected pre-coded signs and symptoms for the day of interview and the six preceding days will be conducted. Information on symptoms, signs, date of onset, duration will be elicited; dietary modifications, medical or other treatment, source and type of treatment obtained and change in usual or customary activity. If a person was seen at a medical care facility, the medical record will be checked to record the diagnosis if at all possible.

For non-target household members only initial probing questions will be asked.

3. Illness Categories and Definitions

General

Fever - $\geq$ 100° using a disposable skin thermometer or oral thermometer

Record DPT or other immunizations given within 48 hours

Edema - swelling of face or extremities

Skin

Bacterial

Cellulitis - diffuse, warm, erythematous areas

Impetigo - superficial oozing and crusted lesions

Pyoderma - boils, abcess, deep infections

Fungal

Ringworm - dry round patches

Scabies

Papules around wrists, fingers, body creases, intense itching

Lower Respiratory

Cough with breathing difficulty

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* To be measured on all morbidity visits in children.

Wheezing

Pneumonia - usually febrile, rapid respirations > 30 minutes, labored respirations, grunting, breathing with nostrils flaring, retractions (sucking in of chest wall between ribs)

Gastrointestinal

Diarrhea and/or vomiting

Stools change in usual quantity and consistency*

> four watery stools/24 hours or blood and mucous mixed in stool

Severe - dehydration present (sunken eyes and fontanelle; ten stools per 24 hours)

Mouth

Sore or red tongue

Stomatitis - blisters, ulcers on gums, lips, tongue, roof of mouth, inside cheeks

Communicable Diseases

Measles - fever, cough, red sore eyes, persistent cough, photophobia, sore mouth, synmetrical confluent rash

Pertussis - eye hemmorhages, paroxyms of coughing followed by whoops or vomiting, thick, sticky mucous

Jaundice - yellow eyes, dark urine, large liver (hepatitis or malaria)

Tuberculosis - persistent, productive cough plus positive skin test

Viral Exantham

Rash with fever

Other

Insect bites,allergies, etc.

Ulcers - punched out areas of skin

Seborrhea

Other

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* Breastfed infant may have loose stools 3-4 times per day.

Eyes

Conjunctivitis: diffuse redness and/or eye discharge

Eyelid infection of rim of eyelid

stye - absess of eyelid

Respiratory

Upper Respiratory

Common cold - nasal discharge (yellowish or white mucous non-watery), cough with no respiratory distress, sneezing, little or no fever

Group - hoarseness, noisy crowlike sound on inspiration, suprasternal retractions (sucking in at supersternal notch)

Tonsillo-pharyngitis - red pharynx and/or tonsils ± exudate, fever, enlarged cervical nodes

Otitis

external - pain, boddy, scaly external ear (pinna, lobe)

media - (middle ear)

mastoid - pain, redness, ear pain, discharge, usually fever swelling behind ear

Accidents

Trauma

Burns

Other (describe)

Mental Illness

Depression

Agitation

Hysteria

Violent behavior

4. Current Illness

If the respondent indicates that an illness that started during the preceding week continues on the day of the household visit or starts within 24 hours of the household visit, a current illness observation form, one per person, is completed. Minor respiratory infection (common cold -

except in infants less than one year), minor skin conditions and minor trauma or conjunctivitis will not invoke the subroutine.

Household visits on alternate days will be made to individuals with current illnesses. Body weight (if feasible), arm circumference and skinfold thickness are to be obtained on all febrile individuals (fever 102°F or more) and those with gastroenteritis, pneumonia, measles, pertussis, or other potentially serious illnesses, at onset of illness if not done within the previous week, and weekly throughout and at end of illness (i.e., 2nd symptom-free day). Additional weight records will be kept during symptom-free periods for target infants and toddlers if the households are willing, in order to follow catchup growth.

5. Illness Verification

Certain illnesses which are considered "conditioning infections" for malnutrition must be verified by the project physician or nurse. These include suspected cases of pneumonia, dehydration, measles, pertussis, fever $\geq$ 103°F, rash, diarrhea greater or equal to 10 stools/day and vomiting in infants under one year of age, or whenever there is a question about a potentially serious illness or puzzling finding. These conditions may be the same ones which intervention would be sought (see below). The verification visit should be made on the same day. Suspected kwashiorkor, edema, marasmus, should also be verified.

Condition on day of observation or within past 24 hours, to be verified by physician or Public Health Nurse:

pneumonia

diarrhea $\geq$ 10 stools/day

dehydration

measles

pertussis

fever $\geq$ 103°F (101°F under 1 year)

rash with fever

fever, vomiting - infant (0-2 yrs.)

potentially serious or puzzling illness

kwashiorkor

marasmus

convulsions

paralysis

death

6. Diagnostic Coding

The project physician will review each morbidity record within two days and make a diagnosis or diagnoses based on clusters of reported signs, symptoms and observations and using the operational definitions which will be precoded. To count the same illness as a new episode seven symptom-free days must elapse.

Recovery is defined as two symptom-free days with resumption of usual activities, appetite and in the case of an infant, smiling and normal responsiveness to the environment (see Summary Diagnostic Categories).

There will be three levels of diagnoses:

1. by recall information only;
2. by illness observed by field worker as well as recall;
3. a. by illness verified by project physician or nurse as well as 1 or 2; and
   b. by illness verified by non-project medical care provider as well as 1 or 2.

Type and severity of illness will be considered according to the following criteria:

	Mild	Severe
Diarrheal disease	3-5 stools per 24 hours above usual number or of abnormal consistency (WHO definition) no vomiting normal or usual intake of food and fluids normal hydration	Dehydration or more than five stools above usual number of stools or vomiting, or more than ten stools per 24 hours
Respiratory disease	Upper respiratory disease Common cold, sore throat or tonsillitis but fever of 100°F or less No respiratory distress	Common cold in a child under one year Bronchitis Bronchiolitis Strep. pharyngo-tonsillitis Pneumonia
Skin	Impetigo - localized Insect bites Ringworm Scabies, limited Other superficial lesions	Generalized infected scabies Abcess, single or multiple Cellulitis Ulcer
Ear	Pain No fever External	Perulent discharge Feder Mastoiditis
Febrile illness	Fever 101°F or less No localizing or specific signs	Any fever in child 0-2 years 101°F or higher Others 103°F or higher
Communicable Infectious	Mumps Chickenpox Rubella Rash with fever less than 101°F	Measles Malaria Pertussis Tuberculosis Sepsis Meningitis Urine infected or hemmorhagic Chickenpox
Trauma	Small cuts 1° burns Small abrasions Sprains, bruises	Burns 2°, 3° Extensive area Fracture, long bones, skull, pelvis, spinal column Head injury

7. Specific Conditions Requiring Intervention

Fever - any patient with a temperature of 103°F

PEM - any child with severe PEM (Marasmus or Kwashiorkor)

Dehydration - any patient with moderate/severe dehydration due to diarrhea or vomiting or any other cause

Respiratory Infection - any respiratory infection presenting with a severe form of respiratory distress, e.g., pneumonia, croup, bronchitis, tuberculosis

Convulsions - any patient with convulsions with or without fever

Unconsciousness - any unconscious patient or a patient with recent loss of consciousness

Trauma/Accidents - any patient with severe trauma, e.g., fractures, severe wounds, burns, severe bleeding

Pregnancy and Labor - any patient with complicated pregnancy and prolonged/obstructed labor

Miscellaneous - any patient the field research staff is concerned about or is in doubt about

Hemoglobin 8gm/dl or below

Immediate First Aid will be given to hemmorhage, severe trauma, loss of consciousness, convulsions, severe dehydration, cardiac arrest, cessation or breathing or airway obstruction and phylaxis or any other immediate life-threatening situation

8. Quality Control - Morbidity Data

a. Local terminology and disease concepts must be determined by the ethnographic survey. The signs and symptoms and names of diseases must be translated into the local language and retranslated into English to check the accuracy of translation.

b. Field workers - data collection needs to be standardized and the field staff will be rotated periodically to offset interviewer bias. Interview/reinterview bi-weekly by supervisory staff plus validation of illness by the nurse or M.D. of serious illness and regular spot checking of the field worker and by the supervisor will be carried out.

c. Concepts of disease, analysis of common diseases prevalent in a given study area, will be discussed in training sessions. Abundant visual aids will be used. The staff will be shown repeatedly examples of all signs and symptoms they will need to recognize -- from patients in clinics, hospital wards, households. Training will be ongoing with monthly educational meetings. Role playing will be used in training and standardization of interviewing. Initial training should take about one month.

d. Specificity and sensitivity testing should be carried out. For example, a check can be made of one worker's results versus the recall obtained by another worker on alternate days. The supervisor can obtain independent measurements for the same time periods.

e. It is important to assess the ability of parents and field workers to identify certain physical signs as they compare to physical examination by the M.D., nurse of clinical officer.*

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* A technique in the area of diarrheal disease, for example, is to request the mother to save all stools on a given day on a young child and then have stools examined daily by a field worker and health personnel and compare findings to mother's description of stools as to normality. This could be done on a subsample.

f. Weekly meetings to discuss data collection problems plus monthly educational sessions are essential. Feedback to the population about the findings will help in reliability reporting.

9. Mortality

If a death is reported the circumstances or terminal event prior to death must be inquired into (e.g., convulsions, etc.). If medical care was sought or if death occurred in a medical facility, the facility should be consulted for further information. The morbidity questionnaire should also be administered for the deceased individual in the hope of identifying the terminal illness.

Table 5 Summary of Disease/Morbidity Protocol[a]

Subjects	Variable/Procedure	Frequency
All members of study households	Diagnostic categories/by recall of lead female, by structured questionnaire	1/wk
All target subjects, with any current illness or injury	Onset/history of symptoms; confirmation of selected illness by professional	Each occurrence
	Severity/scaling of symptons	
	Deviation/observation	
	Limitation of activity/ observation and report	
All target subjects with illness mild	Therapeutic regimen followed[b]	Alternate days

[a]Alse see Physical Examination and Health Evaluation section above

[b]Also see food intake anthropometry and care-giving special routines

F. Immunocompetence

Cell-mediated immunity, humoral immunity and secretory immunity will be examined. There is universal agreement by the three projects and it is well documented in the literature that cell-mediated immune function is most affected by nutritional deficiency, particularly protein and energy malnutrition. Secretory immunity and humoral immunity are probably affected to a lesser extent in mild-moderate malnutrition. The tests included are minimally invasive, require relatively small amounts of blood, saliva, or breast milk and the tests can be done in laboratories in each of the host countries.

The tests selected will indicate overall immunocompetence including contributions of the B- and T-cell systems and presence of chronic infection.

1. Cell-mediated Immunity (CMI)

In selecting specific tests an important preliminary step is to determine which immunizations and which naturally occurring diseases are present in the study population so that skin tests for testing cellular immunity can be structured to have greater specificity.

Basically for the core measurements examination of tonsillar size, total lymphocyte counts and percent and number of T-lymphocytes will be relied upon.

a. Tonsillar Size. Grading of size by physical inspection will be done. In protein energy malnutrition it has been observed by several workers that tonsillar size in preschool children is reduced proportionately to the degree of severity of protein energy malnutrition. Tonsillar

size can be graded on clinical examination. The grading of tonsillar size is as follows:

0 Trace or no tonsillar tissue seen.

1+ Tonsils clearly visible but do not extend beyond faucial arch.

2+ Tonsils enlarged beyond the arch but not beyond the midpoint between the arch and the uvula.

3+ Tonsils extend beyond the midline between the arch and uvula.

Normally tonsillar tissue should be seen in children of all ages. The majority of children ages 2-6 have been scored 2+ and 3+ tonsillar tissue visible.

b. Total Lymphocyte Count. This can most easily be done by obtaining total white cell count either by standard white cell count procedures manually or by Coulter counter, if available. A differential count is then done on a Wright stained blood smear and percent lymphocytes enumerated. Lymphopenia is 2000 lymphocytes per mm^3 or less.

c. Percent and Number of T-lymphocytes (T-cell). This is determined by the ability of T-cells to form rosettes with sheep erythrocytes (E-rosettes). Blood sample requirements are 3 ml of whole blood drawn into heparinized tubes.

Lymphocyte separation will have to be carried out in an immunology laboratory at a center. For example, in Mexico City, University of Nairobi, and the Nutrition Institute at Cairo. The blood must be kept cool or room temperature (not frozen) but not stored longer than 24 hours before lymphocytes are separated. There are methods of freezing samples in the field using liquid nitrogen.

2. Humoral Immunity (B-cell function)

In numerous studies B-cell numbers and functions have been found to be variably or not at all affected even in severe protein energy malnutrition. However, there may be disturbances in immunoglobulin production.

a. Quantitative Immunoglobulins (QIG). IgA, IgM, IgG, will be measured by single radial immunodiffusion, a widely used technique.

IgE may be under T-cell control and high levels have been seen in protein energy malnutrition. Also high IgE levels are indicative of allergy and parasitism and would be useful to study. Because of the great expense of the IgE kits, however, this analysis is not included in the core, year 1.

b. C-Reactive Protein (CRP). An acute phase reactant is a good indicator of infection, particularly bacterial. This requires 0.2 ml. serum using a rapid plate method or radial immunodiffusion, and hence can only be done on adults.

c. Complement Components. Complement C_3 and factor B levels are extremely sensitive to protein energy malnutrition. These are easily measured along with the QIG's by single radial immunodiffusion.

d. Serum Proteins. Transferrin, albumin and pre-albumin are good indices of protein nutrition and will also be measured by single radial immunodiffusion along with C_3, Factor B and QIG.

3. Secretory Antibody Production

Several studies have documented decreased secretory antibody levels in mild moderate PEM. Saliva and breastmilk are readily available biologic substances and obtained in a non-invasive way. Single radial

diffusion or enzyme-linked immunosorbent assay (ELISA) may be used to measure levels. Methods must be strictly standardized.

a. Saliva. The subject is requested to spit into a sterile tube containing sodium oxide as a decontaminant of the saliva which is heavily contaminated with bacteria. Secretory IgA and IgB and lysozyme are to be measured.

b. Breastmilk. Breastmilk to be measured will be secretory igA and IgG and lysozime. PMN and macrophages (cells per min^3) will be counted. For all tests 3ml of colostrum and 30 ml samples of breastmilk will be collected and 2 ml aliquots taken for secretory immunoglobulin measurements. The remainder will be frozen for future optional studies as determined by each project.

For purposes of immunologic studies it would be best to collect the milk at the beginning, midway, and at the end of the feeding. Colostrum should be obtained at 72 hours, if possible, and breast milk at 1, 3, and 6 months.

4. Frequency of Immunologic Studies

Studies for CMI, humoral immunity and secretory immunoglobulins will be done starting with six-month old infants. Studies requiring more blood than can be obtained from a heel or finger prick* will be done only in adults. The studies will be done twice per year (every 6 months) in children and once per year in adults, except that humoral immunity will be tested in women during the 5th and 8th months of pregnancy.

*Since consent of parents will be required for children, for some subjects, blood samples may not be available.

5. Quality Control

Common standards will be used by all collaborating laboratories.

Common antisera batches will be used.

Samples will be exchanged among the different laboratories of the country projects; e.g., between the host country and the counterpart in the United States and all the three country projects and with a reference laboratory in the United States (e.g., of the US institutions).

Table 6 Summary of Immunology Protocol

Classification	Infant* @ 6 months	Target toddlers* & school-age child	Target adults
Cell-mediated Immunity			
Tonsillar size	once	2/yr	
Lymphocyte count	once	2/yr	1/yr
T-cell count			
Humoral Immunity			
Serum IgA, IgG, IgM; complement components, and proteins	once	2/yr	1/yr & pregnant @ 5th & 8th month
Serum C-reactive protein			1/yr
Secretory Antibody Production			
Salivary lysozyme, secretory IgA, IgG		2/yr	1/yr & pregnant @ 5th & 8th mo. lactating @ 1st, 3rd, 6th month
Colostrum/breast-milk			day 1-3, 1st,
lysozyme, secretory IgA, IgG			3rd and 6th month

*Since consent of parents will be required for young children, for some subjects, blood samples may not be available.

G. Metabolic Adaptation

Few data are available to demonstrate whether basal metabolic rate (BMR) or resting metabolic rate (RMR) are altered during marginal malnutrition (beyond the effects that may be associated with altered body composition). There is some evidence that BMR is reduced in experimental food deprivation of adults but population data are lacking. It has been suggested that a reduction in BMR or RMR may occur as an "adaptation" during malnutrition, thereby lowering energy requirements. Since the conditions required for measurement of BMR are difficult to meet in the field (e.g., 12-15 hours postprandial, complete rest, etc.), RMR will be evaluated instead of BMR in the present study.

The purpose of measuring RMR here is to:

1. determine whether energy requirements for resting metabolism are reduced in the marginally malnourished individual;
2. account more precisely for a considerable proportion of total daily energy expenditure (RMR is approximately 1600 kcal/day for a 65 kg male and 1300 kcal/day for a 55 kg. female); and
3. since energy intake will be known, the difference between intake and RMR will provide us with an estimate of the quantity of energy theoretically available for physical activity.

RMR will be measured in all adult male and female target subjects in the households once (in duplicate) each three months for at least one year. RMR of pregnant women is to be measured during the fifth and eighth month of gestation, and one, three, and six months postpartum.

a. General Protocol

Subjects should be at least two hours postprandial and have not smoked for at least one hour. Initially they will rest in a supine position for a period of 30 minutes, in a comfortable environment. After allowing for accustomization to the noseclip and mouthpiece, expired air will be collected for ten minutes. After ten minutes of rest the collection procedure is to be repeated. Volume, oxygen and carbon dioxide content will be measured and corrected to standard temperature and pressure.

b. Quality Control and Training of Personnel

Procedures which should be followed to establish the validity and repeatability of the measurements are:

i. Duplicate measurements. Duplicate measurements of RMR, in terms of oxygen consumption for one minute should vary by not more than 5%. Duplicate measures of oxygen and carbon dioxide content should agree within 2%.

ii. Test -- Retest. A homogeneous and representative group (6-10) of nonpregnant subjects should be tested on three occasions about a week apart to establish intra-individual and inter-individual variance. Intra-individual variance in excess of 10% and inter-individual variance in excess of 15% requires further training of staff.

H. Psychological Function

For the purpose of examining relationships of intake to behavioral development, observational and test data will be collected at the three ages of infancy and childhood that are of specific interest in this study. Particular dimensions of behavior have been chosen for this study because of their significance for child development and because prior work has indicated relationships to nutritional factors. In addition to measures of the infant or child's behavior, data will also be collected on the observed behavior of parents with their children. Additional, selected components of standard cognitive tests will be given to adults to provide background descriptors of parental cognitive level.

A set of criteria was established for selection of "outcome parameters" of psychological functioning in the infant and the young child. These criteria are:

1) The outcomes must be sensitive to energy deficit (inferred from previously demonstrated effect in conditions of more severe deficit).

2) The outcomes must be sensitive to the effect of interactional deprivation (inferred from previously demonstrated effects in various conditions of environmental deprivation).

3) The outcomes must be measurable with methods that can be used without major revisions in the true research setting. Although modifications of instrumentation and data collection procedures may be necessary in each location, the parameters selected must be available for study in comparable fashion across the three sites.

4) Primary data collection must be feasible in the field, with equipment that can be brought to the field setting.

5) To the extent that identified outcome measures first meet the criteria above, efforts should be made to utilize measures that have been used in previous research on malnutrition-psychological development interactions.

Infancy: Birth to Six Months

Based on these criteria, the following components of cognitive and social-emotional functioning of the infant (birth to six months) were selected:

1. Motor status and coordination
2. Activity level (measured by a behavior profile)
3. Capacity to interact socially
4. Affective expressiveness
5. Capacity to modulate state (neonate)
6. Attention
7. Capacity to respond to stress
8. Vocalization

The instruments or techniques that will be utilized for collecting these data are:

1) The Brazelton Neonatal Assessment Scale (BNAS)

2) The Bayley Motor Scale

3) Behavioral Observation in a semi-structured situation ("face to face play" with the mother and in toy play--the latter at six months only).

4) Actometers

Procedures

Schedule

The BNAS will be administered to all infants between 1 and 7 days of age. This time span is sufficient to allow the research team some flexibility in scheduling while maintaining a sufficiently narrow time range that comparability across projects is not compromised.

The Bayley Motor Scale will be assessed at six months. At the same time, the behavioral observation in "face to face play" will take place, as well as an observation of the infant with a toy.

Personnel; Training and Data Quality Control

Effective administration of the BNAS requires a highly-skilled and well-trained individual. In each site, professionals (in medicine, nursing or psychology) have been identified and are currently receiving (or will shortly begin) training in administering the BNAS.

Data quality control for the BNAS will follow the standard procedures developed by Dr. Brazelton, including successful completion of the initial certification examination.

Behavioral observation and administration of the Bayley will be carried out by research assistants who will also be trained to do classroom and playground observations and administer cognitive tests to other "target" or "key" individuals in the study. (see below) In each site, efforts will be made to recruit personnel with some post-high school education. Written training manuals and, in at least one site, video tapes, will be used in training these research assistants. Examination of inter-rater reliability will be a major feature of training, and a

schedule for checking inter-rater reliability during Phase II will be built into the data collection schedule.

Administration

The BNAS will have to be administered in the home (where this is the place of birth) unless parents are willing to bring the newborn to the clinic-research site. When birth takes place in the clinic, the BNAS should be administered before the mother returns home.

The observation of infant-mother interaction in semi-structured play should, whenever possible, take place in the clinic so that extreme interuptions are kept to a minimum and environmental conditions are kept constant. When it is not possible to use a setting outside the home, care must be taken to avoid distractions from other people.

Measures and Scoring Procedures

1. The BNAS will be scored for all standard dimensions.
2. Bayley Motor (at 6 months) will be total scores on 12 items.
3. Observation of mother-infant (at 6 months) in "face to face play" will be scored for the following behaviors in the infant:

   a. looking at mother
   b. smiling
   c. cooing
   d. laughing
   e. yawning
   f. frowning
   g. fussing
   h. "bicycling" of limbs
   i. squirming

4. Actometers (activity "watches") should be placed on two limbs for the duration of the measuring period. Initially, a full 24-hour period should be obtained.

Toddler: 18 to 30 months

Among the main dimensions of cognitive and social-emotional development that are hypothesized to be affected by intake during the second and third years are:

A. Social - Emotional

1. Exploratory Behavior
2. Reactivity to Persons in the Environment
3. Fearfulness
4. Good Directedness
5. Emotional Expressiveness

B. Cognitive

1. Memory
2. Attention
3. Persistence
4. Verbal Skills

C. Activity

The instruments and data collection tools that will be used to obtain this information are:

1. Uzgiris-Hunt Infant Development Scales
2. Bayley Mental Scales of Infant Development
3. Observation in semi-structured situation: toy play; play with mother
4. Actometer

Procedures

Schedule

Psychological measurement with structured instruments (Uzgiris-Hunt, Bayley) and behavioral observation (toy play; play with mother) will be carried out at 18, 24 and 30 months of age.

Personnel, Training & Quality Control

Training and quality control will follow the procedures discussed in the infant section.

Administration

Administration of tests and observations will be carried out at home or in a semi-structured situation (as described in the infant section)

Scoring Measurement

Attention	-	Observation of toy play; mean duration of play time; Bayley IBR Attention Span Score
Persistence	-	Uzgiris-Hunt Development of Means, highest ordinal level score; IBR Endurance Score
Memory	-	Uzgiris-Hunt sub-scales of object permanence
Goal Directedness	-	Bayley IBR goal Directedness Score
Exploration	-	Codes developed from Uzgiris-Hunt for observation of toy play
Language	-	Bayley clusters; Bayley mental scale items involving verbal production or comprehension; Uzgiris-Hunt verbal imitation
Social Reactivity	-	Bayley IBR, Codes
Social Responsiveness	-	derived from reviews of infant observation scales (Wachs & Gruen; Field)

School-Age Child: 7 to 9 years

The instruments and data-gathering techniques that will be used to collect information on children of school-age are:

1. Playground and/or home observation
2. Schoolroom Observation
3. Teacher Ratings
4. Revised Wechster
5. Ravens Matrices
6. Continuous Performance Task
7. Actometer

Procedures

Schedule

The cognitive measures that use structured instruments (Wechsler, Ravens matrices, continuous performance task) will be assessed twice during the school year - once in the first half of the term, once near the end of the year. Teachers will also be asked to make their ratings twice.

Observation in the classroom and in the school yard uses a procedure in which all target children in the room or yard who are present are observed sequentially for 10 second blocks. To assure a more representative behavior sample, each child should be observed over several days of a month during the early part of the school year and a second period during the latter part of the year. Observations should continue until there is a 40 minute record, per child, for each setting (play yard and classroom) for each time period. The number of classrooms to be visited or play yard scenes to be observed will vary from one research site to another since it depends on the "distribution" of target children into classroom and playground scenes. (Note: when a substantial portion of children 7-9 are not in school on a regular basis, alternative play observation settings will be utilized.)

Personnel: Training & Data Quality Control

See infant section for description of personnel and traning.

Administration

As with younger children, it is important to do the cognitive testing in an environment that is not distracting. At the same time, it is important to avoid a testing situation that will be threatening to the

child and thus depress his or her response. Appropriate settings are currently being determined in each site.

Observations, as noted above under Schedule, be carried out in classroom, play ground, and, as necessary, other play settings. A manual with coding sheets has been prepared; observers will be specially trained for group observations.

Scoring Procedures

The social interaction observation will be coded with categories derived from Barrett, Radke-Yarrow & Klein, as follows:

1. Interaction with Peers

    1. Friendly interaction
    2. Helps, shares, comforts
    3. Physical aggression
    4. Verbal agression
    5. Rough and tumble play
    6. Intrudes, interferes
    7. Dominates, asserts self
    8. Seeks help
    9. Submissive
    10. Defends self
    11. Positive response to bid
    12. Negative response to bid
    13. No interaction

2. Contact with Adults

    1. Seeks attention
    2. Seeks physical contact
    3. No interaction with adult

3. Behavior with Environment

    1. Involved in group activity
    2. Plays with materials
    3. Destructive with materials
    4. Wanders
    5. Physical play alone
    6. Imaginative play
    7. Distracted by outside events
    8. Only watching
    9. Inactive

4. Level of Activity

   1. Very Low
   2. Moderate
   3. High
   4. Very high, frenetic

5. Emotion

   1. Happy, laughs, smiles
   2. Anxious
   3. Angry, hostile, irritable
   4. Sad
   5. Loses control, cries
   6. No emotion shown

Classroom observation will utilize codes derived from Wachs, as follows:

1. Talk (non-permitted vocalizations with other children)
2. Play (manipulation of objects)
3. Off-task (not doing work or attending)

Other coding categories for classroom observation are also being developed.

For structured cognitive tests, standard scoring procedures will be utilized. (Eg. Wechsler Digit Span for memory will be scored as scaled recall score on digits.)

Scoring categories for teacher ratings are also currently being developed.

E. Social-Emotional & Cognitive Functioning of the Adult Woman

Psychological functioning in the adult women of reproductive age has been seriously ignored in previous research, in spite of the growing realization that she may be a significant component in the development of the infant and child. While her cognitive functioning probably affects all aspects of her household management, her social-emotional

interactions are more likely to be significantly affected by low food intake.

Extrapolating from research on nutritionally stressed children, the following dimensions of psychological functioning have been selected for study in the adult woman:

I. Social-Emotional

1. Positive - Negative Affect
2. Verbal Responsiveness
3. Contingent Responsiveness
4. Animation

II. Cognitive Functioning

1. Fluid Intelligence
2. Crystalized intelligence
3. Attention
4. Reaction

The data collection procedures and instruments to be used in obtaining this information are:

1. Behavioral Observation in a semi-structured situation
   a) with her infant
   b) with her toddler

(Note: when neither an infant or toddler are in the household, an alternative "other" will have to be utilized.)

2. Adult WAIS*
3. Porteus Maze
4. Continuous Performance Test

*Selected components: block design; colored progressive matrices; arithmetic (modified for local currency and market prices); similarities (modified) for local conditions); digits ~~for word~~ forward and ~~background~~ backward.

5. Picture Span

6. Story recall and recall of childhood event

Procedures

Schedule

Behavioral observation of the mother is concurrent with observation of the infant and/or toddler. For the woman who has both a toddler and a newborn during the course of the study, there will be five observational periods (toddler at 18, 24 and 30 months; newborn at 3 and 6 months). For a woman with a toddler only, the values will be obtained as an average from three observations. For a woman with a newborn only, the rating will be based on the average from two observation sessions.

The structured tests will be administered once during the first year of the study.

Personnel: Training & Data Quality Control

(see above)

Administration (see above)

Scoring Procedures

The cognitive tests will be scored in the standardized way, for those test items that are not modified. Modified tests (e.g. story recall, picture span) will be scored in a manner that parallels scoring procedures in the standardized tests that the modifications are surrogates for. For example, a picture of digit span, will be scored for number of recalled items.

The behavioral observations in interaction with infant and/or toddler will be scored for:

1. Eye to eye contact
2. Initiation of vocalization
3. Vocalization in response to infant/toddler initiated vocalization
4. Smiling/laughing
5. Exaggerated facial expression
6. Imitation
7. Touching/Fondling
8. Moving infant's limbs
9. Playing "infant games"

F. Psychological Functioning of the Adult Male

Low energy intake in the adult man may be expected to have parallel effects on psychological functioning to that of the adult woman, including effects on social-emotional responsiveness. However, at this time we do not plan to carry out observational studies in semi-structured conditions of men's social-emotional development. The same battery of cognitive tests scheduled for the adult woman will be administered to the "target" male in the household and will be regarded as a "descriptor" if the household in which the social-emotional development of other "target" members is being assessed.

Procedures - See description of adult women

Table 7
SUMMARY OF PSYCHOLOGICAL FUNCTION PROTOCOL

Target Subject	Method	Frequency
Infant, 0 to 6 months	Brazelton Neo-natal Activity Scale (BNAS)	First week
	Bayley Motor Scale, 12 items	At 3 and 6 months
	Observations of mothers and infants with specific behaviors to be noted	
	Actometer (activity watch) placed on 2 limbs for 24 hours	At 6 months
Toddler, 18 to 30 months	IBR Endurance Score	At 18, 24, 30 months
	Uzgiris-Hunt sub-scales: object permanence, observation of toy play	
	Uzgiris-Hunt verbal imitation (during second year only)	
	Bayley IBR Attentiveness span	
	Bayley Clusters	
	Bayley mental scale items for verbal production and comprehension	
	Bayley IBR codes for social reactivity	
	Scales of social responsiveness for observations developed by Wachs, Gruen, and Field	
	Actometers	
School-Age Child, 7 to 9 years	Observations of social interactions based on Barrett, Yarrow	Twice during school year
	Ravens Matrices	Beginning and end of year
	Continuous Performance Task	
	Wechsler scales: digit span, story recall, block design	
	Teacher Ratings	
	Actometers	

Target Subject	Method	Frequency
Mother	Adult WAIS Porteus Maze Continuous Performance Test Behavioral observations in a semi-structured situation with infant or child Picture span Story recall	Structured tests, once Observations with target child as shown
Father	Adult WAIS Porteus Maze Continuous Performance Test	Once

I. Care-giving and Hygienic Activities

We refer to the specific activities performed by a mother in behalf of the infant (0-6 months of age) and toddler (18-30 months) and by both parents in relation to the school-age child (7-9 years) to enhance their well-being and personal development. A list of direct and indirect child care activities follows. As noted above, child care activities are expected to vary cross-culturally depending upon parental role expectations, household size and composition, mother's occupation, and other factors.

Parental food energy intake and "child care proficiency" are viewed as being causally related. We hypothesize that parents' intakes are likely to affect their behaviors with respect to the child through energy available for parental physical activity. We will observe parents and children in the natural setting for the purpose of rating care-giving activities. Ratings will account for the frequency and quality of activities. The "child care proficiency scale" will also be entered as a variable in the analysis of the relationship between childrens' level of food intake and measured outcomes.

Evaluating Child Care Proficiency

Proficiency scales will be derived from performance scores indicating a) frequency of performing an activity -- e.g., number of times per day, week, month, or year, and b) appropriateness of an activity -- e.g., indices of adequacy, inadequacy or excess. These lists and scores must be developed on the basis of local conditions, but an indicative (not exhaustive) series of topics is as follows:

A. Nutritional Activities

food preparation

food distribution/feeding

food hygiene
-- preparation
-- storage
-- service

B. Hygienic Practices

frequency of washing, mother (body parts)

frequency of hair-washing, mother

frequency of bathing, mother (whole body)

frequency of washing, infant (body parts)

frequency of bathing, infant (whole body)

use of soap for hand-washing, mother

use of soap for bathing, mother

use of soap for washing, infant

use of soap for bathing, infant

use of disinfectants in house

frequency of dish-washing

boiling of water for drinking by infant

boiling of water for drinking, other family

use of diapers (yes, no)

adequacy of diaper washing

disposal of fecal matter in house (frequency, method)

disposal of fecal matter in yard (frequency, method)

removal of house/yard garbage (frequency, method)

wearing of foot protection (for hookworm risk)

C. Illness Care of Infant

appropriateness, adequacy of care

illness prevention score

adequacy of changing diapers/underwear

frequency of bathing

D. Clothing Care

washing
boiling
ironing
protection from insects
mending

E. Supervision and Safety

hazards in the house
attention to location
awareness of sibling conflicts

J. Socio-economic Information on Households and Communities

Information on household socio-economic conditions will be collected for the purpose of classifying households and supplying socio-economic data for analysis and interpretation of intake - function relationships.

For the classification of households, there will be different culturally appropriate measures used in each community for assigning socio-economic status to the household. In Egypt, for example, occupation and formal education of the lead male has been proposed to be the single most important determinant for ascribing status to the household. In Mexico, the bundle of assets termed the "material style of life" appears to be a valuable descriptor of status and assets. In Kenya, since most families are farmers, the house type and materials used in the house appear to indicate family status. Once measures of SES are fixed, a ranking system for each locale will be determined, with distance between ranks to be roughly similar across projects.

Household socio-economic information on households will be needed for statistical control purposes. This information will include family physical assets, such as housing, land-holding, vehicles, animals, tools; and human capital of household members such as educational levels, leteracy, occupation, and employment

Information on the details of the household environment which influence family morbidity were described in Section D above.

Case studies will permit the collection of more complete information on household expenditures and sources of income which may serve as

the basis for aditional data collections during year 2. This information would include detail on agricultural activities, on migration patterns, and on household income, financial assets, and expenditures.

Survey instruments will utilize pilot work done in Phase I, and will also rely on questionnaires used successfully by the World Bank, the Kenyan Statistical Bureau, and preliminary instruments used by the collaborating projects. Surveyors will pay each household an initial visit at the beginning of the study and will update changes in household composition, employment, and assets, during routine household visits on a quarterly basis.

Data on household socio-economic status will be collected on the following measures:

Characteristics of the house: Structure, types of materials used for walls, roof, floor; and condition of repair, number of rooms, water source, type of sanitary, facilities, cooking source, appliances.

Land by location, quality, and quantity.

Other physical assets: vehicles, tools, animals.

Financial assets if possible: savings, mortgages, loans, occupations of lead male, female, and other adult members of household.

Education of household members.

Occupation and employment of household members.

Migration patterns of lead male and female.

Community-level Data

In addition to household-level data, a great deal of information has already been amassed by each of the projects during earlier phases

of work -- in choosing the community for the study, in carrying out household censuses, and in investigating the variability and feasibility of collecting data. These data will provide a wealth of detail on the following characteristics of the community: geographical and physical features, retrospective mortality rates, health patterns, access, communication, facilities, services, commercial activities, social organization, community events. This information will become valuabel for interpretation of research results; it will also provide an important detailed description of each community.

On a continuing basis, information will be collected at the community level on: local prices of commonly-purchased goods, typical wages for commonly-held jobs, market prices of foods grown by farmers.

Because of the special significance of climate in affecting the agricultural cycle, and for purposes of explaining seasonal change in work and in food availability, local weather conditions will be recorded daily on: temperature, humidity, rainfall, and barometric pressure (which will be needed for recording metabolic rate).

V. Sampling and Scheduling

A. Sampling Design

In order to test the principal hypotheses discussed above, it is proposed to collect data for the core study on clusters of individuals in households which contain the following target subjects: (a) a woman in the first trimester of pregnancy, or a woman likely to become pregnant, whose infant will be at least six months old before the end of the second year of the study; (b) a child who will be 18 months old during the first year of the study; and/or (c) a child who will be between 7 and 9 years during the first year of the study. Once the household is selected, the mated pair who are parents of the target child will also become key subjects for the study. For some types of measures, data on additional members of the same households will also be collected as well as information on the household as a whole. In Section VI, we shall discuss measurement schedules to be followed. In this section, we shall describe how subjects and households will be selected in each of the study communities.

It is intended that the data collection will be completed within a period of approximately two years. Thus, the strategy for selecting households must yield the required number of twelve-month cohorts within that period. Preliminary considerations suggest that recruitment of the pregnancy-infancy pairs may pose the most difficult sampling problems for the study.

The study is designed to yield, at the minimum, 100 subjects of each target type on whom data will be collected over a twelve-month period. These subjects are:

A. Pregnant woman and their infants: from 6 months before birth to

6 months after birth.

Observations on a minimum of 100 mother-infant pairs are desired with pregnant mothers to be observed for six months before birth and six months postpartum. Thus, at the beginning of the study, all those women in their first three months of pregnancy, plus those who are likely to become pregnant during the following nine months, are candidates for satisfying this criterion. The first births eligible for the study would, therefore, be those occurring during the sixth month of the first year; the last births to be accepted into the study would be at the eighteenth month.

B. Toddler: 18 to 30 months old

One year of observations on at least 100 children from 18 to 30 months are required. Thus, at the first month of the study, all children between 6 and 18 months are candidates. Children will be included as they reach 18 months but no subjects can be less than 18 months by the beginning of the second year.

C. School-Age Child between 7 and 9 years

Observations on at least 100 children between 7 and 9 years of age are to be collected for a one-year period. Thus, to be eligible for the study, a child must be at least 6 years at the beginning of the study and not older than 9 at the beginning of the second year.

While subjects for the 18 to 30 months old and 7 to 9 years old categories are readily identifiable for the study, mother-infant pair are uncertain. The strategy for selecting potentially pregnant women can be approached theoretically as follows:

Given the time frame of the study, we propose to select women who are either less than four months pregnant at the beginning of the study or are likely to conceive within the first nine months of the study. The last acceptable birth, occurring at the eighteenth month of the study, would permit sixth months of observations of infancy before the end of the study.

To obtain an expected number of valid case (6 months of prenatal and 6 months of postpartum observation), the following variables and assumptions will be taken into account:

	Assumptions
(1) The number of women 0 to 3 months pregnant at the start of the study.	nil
(2) The number of women who are contracepting, and an estimate of the contraceptive failure.	nil
(3) The distribution of women at risk of conception. (Defined as below)	nil
(4) The probability that a woman at risk will actually conceive in a 9 month period.	$\sum_{n=0}^{8}(.8)^n(.2) = 0.855$
(5) The probability of intrauterine mortality, including spontaneous abortion and still-births.	0.20
(6) The infant survival rate up to 6 months.	0.95
(7) The drop out rate from the study.	0.33

Source: Assumptions (4) and (5) are based on Bongaarts (1983), and (6) based on World Bank estimates for the rural areas in these three countries. Assumption for (7) is by study design.

Unfortunately, nothing is known about (1),(2), and (3) and thus it must be assumed that women "at risk", i.e., fecund women living with a spouse and not contracepting can be identified. The number of women, N,

to be followed during the first nine months of the study, who are expected to produce 100 births would therefore be found as follows:

$$N\ (.855)\ (.80)\ (.95)\ (.33) = 100$$
$$N = 214$$

Since infant deaths in the first six months are also of interest to the study, these calculations which assume that all infants will survive for at least six months slightly overestimate the required number.

If we can also identify the number of women who are within the first three months of pregnancy at the beginning of the study, the number of women to be included can be reduced accordingly.

In one of the field sites (Egypt), it will be possible to inquire whether women are contracepting. In the other communities to be studied, it is not known whether these women can actually be identified.

From this set of theoretical computations, we propose the following general rules of selection:

(1) Women should be recruited into the study who are within the first trimester of pregnancy, i.e., not more than three months pregnant at the beginning of the study.

(2) Women living with their 6 to 18 month old or 6 to 9 year old children should be included. Currently, non-pregnant women whose last child is close to, but not older than 18 months, would provide observations for toddlers and are high probability candidates of providing observations for new infants.

(3) To increase the chance of having enough observations in category A, newlyweds should be taken into account since they are at high risk of pregnancy.

(4) About 150 children aged 6 to 18 months and 150 children aged 6 to 9 years would be followed, allowing for a 1/3 dropout rate from the study.

(5) The actual selection of households and subjects will have to be determined by each project and will depend on total population size, costs, and the need to capture variability of food intake. If, for purposes of minimizing costs, infants, toddlers, and schoolers are chosen from the same mothers, households of similar structure would be likely to be chosen. In such households, the mothers would probably be in the late thirties and the 6 to 9 year old children would likely be of earlier birth order. If we believe that nutritional intake of children correlates highly with place in the family and the size of the household, and if this variability is of interest to researchers, then efforts should be made to select the infants, toddlers, and schoolers from different household structures, birth order, and age of mother.

IV. Recommendations

Each study site has its own characteristics and limitations. Specific recommendations made here take into account the demographic picture of each community.

(1) Egypt

There are 1121 monogamous married women between 15 and 45 in the community who were defined as "lead females." For them, 252 births were reported in the twelve month period between June 1981 and June 1982. The mean birth interval in the last fourteen years in this community is 2.798 years. There are 139 women with children aged 6 to 18 months old and 6 to 9 years old.

The general rules of selection outlined above should be followed. The size of this community allows a certain degree of selectivity and sampling design. The selection and design will have to be decided by the researchers.

(2) Kenya

A preliminary study of the area was conducted in March, 1983. Data are based on a sample of 471 households. These are households with a married couple in residence, and also satisfying one of the following:

(1) a pregnant mother

(2) have a child between 0 to 2 years old

(3) have a child between 6 to 10 years old

(4) have a female under 35 years old

The number of 0 to 12 months old reported in March, 1983 is 200. The mean birth interval is 25.43 months. Number of children in the 6 to 9 years age range is 485.

Fertility is very high in this region and the community is fairly large. The general rules of selection should be followed. The actual selection of households should, again, depend on the desired variability.

(3) Mexico

There is a total of 594 women in the fertile age range as of June 1982. Among these 594 women, 323 are identified to be living with their husbands, 90 live births were reported during the 12 month period between June 1981 to June 1982. There are 59 women who have a 6 to 18 month old and 6 to 9 years old children living in the same household.

Considering the study design and the size of the community, there is little room for selection. Efforts must be made to ensure continued participation in the study; the size of this community simply cannot afford a drop out rate of 58%. A screening of all 594 women should be conducted at the beginning of the study. Pregnant women in their first four months and "women at risk" should be identified and recruited. It is likely that the community will not give enough subjects required by the current calculation. In that case, all women at risk should be followed to maximize observations, and the study may have to be extended to nearby communities.

Table 8

Demographic Information of the Communities

	Egypt(1)	Kenya(2)	Mexico(3)
No. of females 15 - 44 living with husband	1121	471	594
No. of 0 - 12 months old	252	200	90
No. of 6 - 18 months old	209	184	85
No. of 6 - 9 years old	439	485	183
No. of 6 - 18 months old and 6 - 9 years old	139	N.A.	59

(1) Data based on the preliminary community census as of April, 1983 for lead females between 15 and 45 years.

(2) Data based on 471 households satisfying specific criteria (see text for detail). Information as of March, 1983. This number is approximately half of the households actually available for study.

(3) Data based on community census as of June, 1982.

B. Schedule of Data Acquisition, Core Studies*

The Nutrition CRSP design calls for a cycle of most measurements repeated monthly or over regular three month periods. Within this cyclic pattern of data collection, there is a need to schedule concurrent data collections for those parameters requiring simultaneous analysis (i.e., linking at a single point in time). Some data (such as individual food intake or individual activity profiles) may be averaged for the individual across three-month periods to obtain reliable estimates. Other data, measured only once in three months, will be collected at some point during the same three-month period for all individuals or households, and thus not be truly concurrent in time with other measures. In general, measures collected less frequently are those which are expected to be more stable; but, if they show significant changes within three-month periods, then it will be necessary to approximate time-related measures by interpolation.

For logistical reasons it is to be expected that projects will establish, for each household, a routine schedule of monthly visits and, within that schedule, to arrange for phasing of additional measures that are to be done on every third or sixth visit. An implication of this method is that, in general, data collection will not fall at the precise age of young children but within a short period of time near the "intended age." For monthly data, the allowable interval around intended age will be ± 1 week; for data collected quarterly, ± 3 weeks. Where age is critical (as in the newborn) a separate schedule is needed--and presumably

*Not included in this discussion of schedules are the protocols for the supplementary country-specific studies. These may or may not draw upon the core households and hence may or may not need to be integrated into the presented time schedules.

a separate field team to implement that schedule.

Some measurements will be conducted in central locations (e.g., physical examinations, RMR determinations, and many of the psychological tests). It is quite possible that the scheduling of these measures will not coincide with household data acquisition schedules; however, it is agreed that the collection of those data with related time values will be measured within a share interval of the required age of the subject.

In the field a major consideration in scheduling will be convenience to households and individuals. Since the CRSP must collect data through monthly visits to households, it is essential that imposition on households is kept as low as possible, consistent with research needs.

Guidelines for measurement schedules will be provided by Berkeley, based on design needs. Operationally, each project will develop its own protocol for the scheduling of data collection, taking into account logistical considerations and needs of the particular community. Schedules will recognize the sequences of data gathering when necessary. Country-specific protocols will be submitted for review before implementation of the core studies.

We present here the general framework of scheduling which shows frequency of measurements rather then the actual schedule of dates. Table 9 refers to the measurements that will be made for all core individuals and households for as long as they are a target of data collection. Not included in this tabulation is the collection of graphic and other information about the community and region; this will

be an ongoing activity that does not directly involve the study households.

In these tables, adult "lead" or "target" male and "lead" female refer to a mated pair who are the parents of the study children. The toddler will be an infant aged 18 months studied for 12 consecutive months. If there is more than one 7.0 to 8.99 years old child in the household, the child nearest 7 will be studied. These individuals, once entered into the study, will be followed for at least 12 months and some adults as long as 24 months, if involved in more than one study. It is possible that a single household will have up to 5 persons under study at one time, though this will not be the norm.

It was agreed that every effort will be made to retain households in the study once recruited and that no household will continue beyond the period required for data collection on target individuals for target periods. For many households, this will mean less than 15 months; for a few, as long as 24 months. All data collection in the communities will be completed within 27 months of entry into the first household. If any project(s) wishes to extend data collection beyond this time frame, review and approval by the Scientific Coordination Board and identification of sources of additional funding will be required.

In addition to measurements described in Table 9, a questionnaire will be administered if and when a household (or an individual in a household) withdraws from the study.

Table 9

Schedule of Proposed Measurements on Target Subjects for Core Study

Class of Measurement	Frequency				
	Monthly	Every 3 months	Every 6 months	Yearly	Once
Food Intake Household Individual	2 days Minimum, 2 days/month				
Anthropometry	All measures (except height and head circumference for adults)				Adult height & head circumference
General Physical Exam and Illness History	Pregnant Women		Infants at birth and 6 months Children (18-30 mos.) (7 to 9 yrs.)	Adults (except pregnant women)	Special birth & death subroutine
Menstrual Status	All females 15 to 45				
Morbidity One Week History Illness Subroutine	Weekly questionnaire to all members of household Alternate days when ill				
Immunology	Subroutine for colostrum and breast milk (1 to 3 days; 1, 3, 6 months)		Infants at 6 months Other children every 6 months	Adults	Once during pregnancy and lactation
RMR		7 to 9 year olds Adults Pregnant women at 5th & 8th month			
Specific Child Care Activities	Home Observations of mother and father with child				
Psychological Function	See separate schedules				
Socio-economic Information Household Community	Daily temperature barometric pressure rainfall	Updates			Initial questionnaire

VI. Data Management and Analysis

A. Data Management

Data management has been of central importance to the Nutrition CRSP. Recognizing the necessity for careful monotoring of the data collection, contractual responsibility for assuring quality and consistency of data on a continuing basis was placed in the office of the Program Director. According to inter-university agreements, each project's data management methods are to be consistent with inter-project agreements to insure quality and comparability of data and of subsequent analysis.

The report in January 1981 of the Technical Advisory Group (TAG) on Statistical Design and Data Management has provided important guidelines during organizational phases for the planning of data management activities. Recognizing the need to complete three highly comparable investigations in three different country settings, the TAG report stressed continuing inter-project collaboration to develop comparable protocols, coding procedures, quality control, and data management. The TAG urged that there be continuing concern for data quality at all levels, that variables and documentation be standardized across projects and that the data management system provide adequate monitoring of both collection and transfer of data from field to collaborating institutions. Further, they recommended that Berkeley serve as the center of data management activities, coordinating work of the three projects.

Continuing responsibility for the CRSP data management system has been placed with the Deputy Program Director, who works closely with the Berkeley data manager and an experienced programming staff. The Berkeley

office monitors and consults with Principal Investigators of U.S. and overseas projects and their specialized data management staffs to insure the consistent quality of data collections at the field level and at every level where data are coded, converted, and transferred to computer files.

1. Preparation of Variable Lists, Protocols, and the Data Manual

In the broadest sense, all CRSP research activities involve data management and all design decisions have data management implications. With scientific decisions on subjects, methods, and measures complete, a comprehensive list of variables is being drawn up to serve as the basis for the manual being assembled which includes all data capture instruments. Preparation of data capture instruments is being carried out by investigators, in consultation with their data managers, to insure that forms are appropriate for coding or direct data entry. Once data capture instruments have been developed, the Berkeley data management staff will create a "data book" which will focus on the core data. This manual will provide documentation and information on variables which are similar between projects. It will include information on variables, data capture instruments, and instructions for data collection. In some cases, such as anthropometry, instruments, measurements, and methods of data collection will be almost identical. In other areas, while variables will be expected to be the same, methods of collection will differ between projects. Where possible, one-way tabulations from each project will become part of the data book.

2. Data Flow

In a narrower sense, CRSP data management begins as data flow from field collection operations to collaborating institutions in the host

countries and the U.S. These data flow activities are shown in Figure 5 which portrays Phase II procedures according to place and sequence of activities to be carried out. In preparation for receiving data from the field, data management activities for the transfer, cleaning, editing, documentation, and simple analysis are already in place and have been in operation during Phase I collection and processing of preliminary data.

During the period of Phase I activities, data management staffs have had the opportunity to gain experience in transferring tapes between far-flung institutions, and in reading computer files across a variety of computer installations. The experience so gained will be valuable indeed; it has provided a "dress rehearsal" for Phase II activities, has created a communications network of those involved in data management operations, and has underscored the need for precision in documentation, verification, and editing procedures.

3. Data Base Management

Since the ultimate goal of the data management system is to facilitate comprehensive inter- and intra-project analyses, a data base management system employing SAS, Statistical Analysis System, has been selected for use by all collaborating projects. This management system will permit all three projects to share in development maintenance, and use with the advantages of:

--Standardization of data definition and document action

--Improvement in physical access to data items

--Reduction of data redundancy

--Simplification of writing application programs

--Reduction in the need for program maintenance

--Consolidation of updating, retrieval, reporting, and utility functions

Data will exist in the most basic and simplest of forms, i.e., the images of the raw data collected. This will constitute the computer readable (magnetic tape storage) "raw data files." When the data are transferred to the management system, this basic form will be preserved. For analysis, access of the entire database will not be necessary but instead, the data management language of SAS will enable the production of specific files for specific analytical purposes. Thus, it will not be necessary at the outset to predict all types of analyses which may be required later; the sophisticated computer system will permit conversion of basic data to complex analysis files at any later time.

4. Editing and Error Detection

With respect to editing and error detection, since important variability may be contained in uncleaned data (including real, though inconsistent, responses to questions and genuinely mistaken observations), it is especially important that all raw information is retained. It should be possible, for example, to reconstruct any record as it existed at any stage of its data-processing history. With computerization of the data base, and particularly with the use of a sophisticated management system, it is possible to use markers to indicate both the original erroneous data and the clean replacement.

Data validation requires both manual and machine processing. In the case of large datasets, such as in the Nutrition CRSP, it is important

that manual processing be minimized and computer processing should be maximized. Extreme care should be taken when planning data editing procedures to assure that errors will be detected, and that additional ones will not be introduced when the original errors are corrected. Editing has three parts: error detection, error resolution, and error correction.

Quality control of large datasets requires the careful organization of error detection. Casual editing procedures often applied to small datasets, such as visually scanning for missing records or for records that are off by one column, are inappropriate. Error detection needs to account for both key fields and data fields, employing both univariate and multivariate tests of inconsistencies. Key fields are those which contain basic identification information for each case. Undetected key field errors are very costly, leading to mistakes in matching variables by identifiers.

Error resolution must also be formalized when dealing with large datasets. Data cannot be altered without carefully documenting all changes in forms, which identify the error, the correction, and the person who made the decision. Error correction, consists of record deletions, record additions, and data item value changes which can be entered with explicit codes directly on the files or by creating special transaction files, which document all changes to be made, and are maintained as part of the study database.

5. Data Transfer for Archiving and Analysis

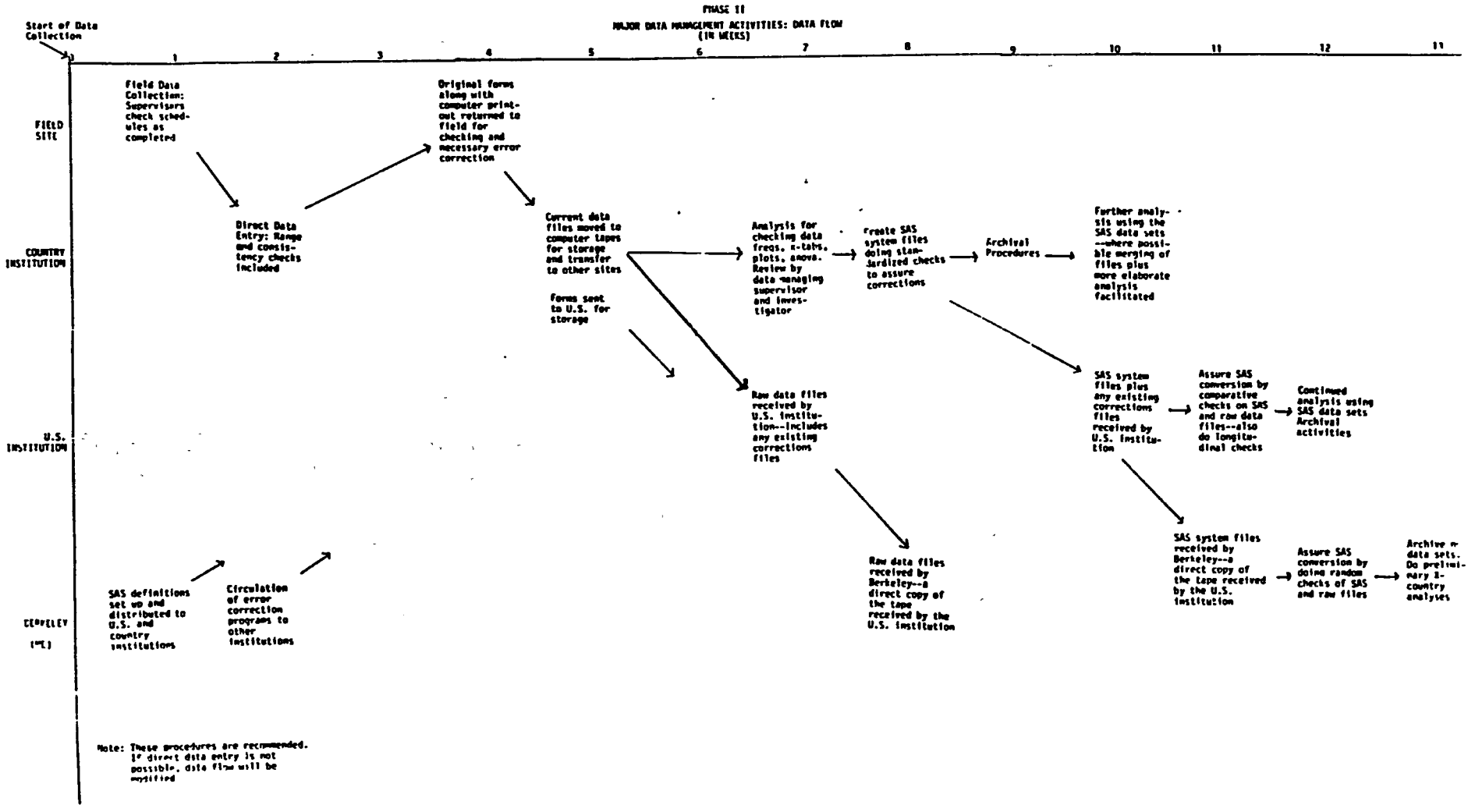
Data will be held in each collaborating institution for analytical uses by co-investigators. Since some analytical activities will

take place within projects while others will involve sharing between projects, official sets of completely documented data will need to be available to researchers at every collaborating institution.

At each of the sets of collaborating institutions, the data management staff, consisting of a consulting statistician, a data manager, and programming staff as needed, will have the expertise to carry out independent analysis. Collaborative work across projects will be advised and monitored by the Berkeley statistical and data management staff. With the interest and continuing involvement of faculty members of the Berkeley Statistics Department, considerable power will be added to Management's analytical capabilities.

Throughout the Phase II data collection, the data management teams and project statisticians will carry out analyses for the projects. These analyses will be important throughout the work of the CRSP in determining whether data being collected are appropriate for testing research hypotheses. At the completion of Phase II data collection, during Phase III analyses, data management activities will continue under the supervision of statisticians and project investigators. At the conclusion of the grant, data will be accessible to all users in the scientific community.

Figure 5



Best Available Document

VI. B. Statistical Analysis

Analysis will be carried out using data collected on target subjects in core households during Phase II. Statistical analysis will consist of the testing of statistical hypotheses and the estimation of quantitative relationships linking intake and the functions of interest. Hypothesized relationships, proposed by the multidisciplinary team of investigators, were depicted in Figures 1 to 4. From these complex networks of large sets of potential influences, analytical models will be constructed.

1. Methods of Analysis

Multivariate regression analysis, including autoregression, will be used to develop descriptive and/or predictive equations when dependent variable(s) are continuous, or if discrete, are assumed to take on a large range of ordered values. If the dependent variable is categorical, then logistic regression, discriminant analysis, or tree-structured discriminant methods* will be employed. Since the data will consist of sample units observed repeatedly over time, methods for pooling cross-sectional and time series data will be used in model development.

2. Considerations in Performing Analyses

a. Quantity of data. For certain variables of interest, acquiring a large body of data will not be feasible, especially for measurements relating to infants. When data are scarce, building highly complex models (those involving many parameters) from the data may be undesirable. While it is not possible to state an omnibus rule by which estimated models are

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* Recent work by Breiman and Stone will be especially helpful. (Cf. Leo Breiman and Charles Stone, unpublished paper, 1981.)

judged "too complex" for the data available, judgment and practical sense should guide the data analysts. Using cross-validation techniques may also help in developing sound data-derived models.

Another problem that may arise when data are scarce, concerns using data to search over a wide range of candidate explanatory variables (such as using best subsets or stepwise selection techniques) and evaluating model fit on the same data. Such "data dredging" can give a misleading impression of a good model fit.

b. Missing Values. Consideration will be given to the possibility that some variable measurements will not be made as planned. If missing data occur in ways that may suggest a relationship with the values that the data would assume if they could be acquired, serious problems may arise. In the less problematic case of data "missing at random," replacement techniques or case deletion can be used.

c. Recursive or Looping Relationships. An autoregressive estimating method may be usable, interpreting the recursion as an effect noticed at a later point in time. Given the relatively short time span of the study, the effectiveness of this technique will greatly depend on the ability to control measurement error.

d. Transforming Variables to Meet Model Assumptions. This is a routine, but important, aspect of model building. When using regressions, achieving near linearity and homoscedasticity are primary objectives when selecting variable transformations. Prior knowledge of the phenomena will be helpful in developing an accurate and sensible model.

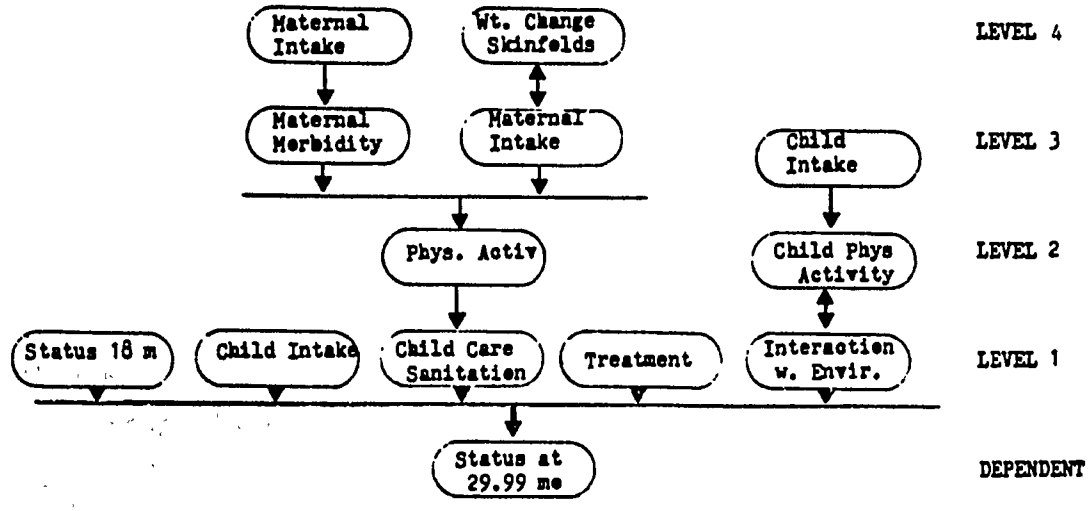
e. Creating a Test Set. If it is feasible, it may be desirable to set aside a part of the data with which to develop error estimates of

the models created with the non-test portion of the data. This may not be desirable if the amount of independent data is not large.

3. Procedure

a. Model Specification. The nature of the modeled relationship between a dependent variable and explanatory variables depends on the choice of explanatory variables to be included in the model building process, and the chosen functional form of the relationship of these with the dependent variable. Because path diagrams, such as the ones shown earlier in Section III summarize "prior knowledge" of the interrelationships of variables of interest, they are a natural starting point in specifying which explanatory variables to use in modeling a dependent variable. This spares the analysts the need for excessive "data dredging" in specifying these models. However, searching for explanatory variables whose relationships to the dependent variable are not indicated in the path diagram may be advisable if the antecedent variables alone cannot explain the dependent variable in a satisfactory manner.

In modeling the relationship of a dependent variable with other variables in a path diagram, it seems prudent to rely on measured path variables most antecedent to the dependent variable. For example, a scheme for estimating Child Status at 29.99 months can be described in the following diagram:



Using variables of antecedence level greater than 1 may be advantageous in model specification under several circumstances: 1) the path diagram should have placed certain of these variables at antecedent level 1, giving them direct explaining power for the dependent variable; 2) the higher level variables can be measured with much less measurement error and/or bias than lower level variables following in the path diagram; 3) missing values frequently occur in lower level variables. Antecedent variables may be used to estimate the missing values, although it should be stated that non-antecedent variables may also be used for this purpose.

In selecting variables to be used in building the explanatory model, classes of variables can be entered into models in an ascending level of antecedence; initially, fit all Level 1 variables, and use backward elimination to eliminate weak predictors. At this point, higher level variables may be entered if they improve the fit of the model substantially, or can be substituted for Level 1 variables with less error or bias. Similarly, higher level variables may be searched until a satisfactory model is

obtained. It should be stressed that this is not an algorithmic or mechanical method for variable selection, but rather one which uses the natural hierarchy suggested by the path diagram, supplemented by professional knowledge and judgmental considerations, to develop explanatory models which fit the data reasonably well with minimal use of data dredging.

b. Pooling Cross-Sectional and Time Series Data. As noted above, the data collected in the study will consist of a fixed number of independent, or cross-sectional, entities observed at specified time intervals in the time frame of the study. Since a given cross-sectional unit (i.e., an infant at the Kenya site) will produce data which are autocorrelated (i.e., the infant's weight at a given age), techniques taking this effect into account need to be utilized. An appealing and tractable formulation of this would assume that only the first order autocorrelations are significant; this would imply that an observed phenomenon at a given point in time has its dependence on previous measurement contained in the immediately preceding measurement (a Markovian model of dependence).

c. Modeling Measurement Error. While measurement error occurs in all studies, it presents special problems in non-experimental ones. In the present study we will be especially sensitive to the well-known biasing effect of measurement error and will build into the study repeated measurements with rotated observers.

When observers are assigned randomly, so that observer error, and especially systematic bias, can be assumed to be independent of other sources of error, it is possible to account for errors of measurement in the models. Identified models can be constructed using repeated observations,

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c. Modeling Measurement Error. While measurement error occurs in all studies, it presents special problems in non-experimental ones. In the present study we will be especially sensitive to the well-known biasing effect of measurement error and will build into the study repeated measurements with periodic cross-checking and rotated observers, if possible.

When observers are assigned randomly, so that observer error, and especially systematic bias, can be assumed to be independent of other sources of error, it is possible to account for errors of measurement in the models. Identified models can be constructed using repeated observations,

taken by different observers, on the same subject over time. Using models which account for both latent ("true") variables and variables observed with errors, the computer program, LISREL, based on the work of Jöreskog and Sörbom, will permit the utilization of repeated measurement to correct for bias.

d. Simultaneous Analysis of Multiple Independent Samples. When the same model accounts for relations among the same sets of latent variables in multiple independent samples, for example, across field sites, there may be advantages to simultaneous analysis of data sets if any of the unknown parameters can be assumed to be equal across samples from prior information. This could be the case, for example, in the relationships among biological variables -- e.g., effect of kcals per day on weight gain when allowing for metabolism and morbidity at a given age and sex.

The gain in information can take two forms: 1) using the augmented, pooled, sample size increase precision of estimate of selected common parameters, or 2) identifying otherwise underidentified parameters. LISREL IV and V provide for the analysis of covariance structures in simultaneous independent samples and permit accounting for constraints on parameters across samples.

VII. Case Studies

General Purpose

In the core design of the Nutrition CRSP a series of at least twenty case studies in each project is intended to serve two related but distinct purposes.

The first of these is that usually accepted for case studies: to increase our understanding of the processes that allow households to accommodate to the degree of deprivation of food and other resources that we believe *a priori* to exist in these communities. Accomplishment of the above will help to place other findings of the core research in some perspective. That the households have accommodated to deprivation and are at crude equilibrium with their environment is not at question. The issues at hand are how they have done this and what is the human cost associated with it. The first objective of the case studies may be expected to address the "how" in qualitative terms and perhaps give hints toward the "cost."

The second objective derives directly from the first. To the extent that the case studies can contribute to hypotheses about mechanisms and impacts, particularly related to those influenced by food intake of the household unit or of classes of individuals within households, they will contribute to the development of specific designs for year 2 research. Within this framework there is particular interest in activity as a variable. In the psychological sense, adjustment of the duration and/or intensity of activity is the mechanism by which energy balance is probably established in the face of constrained intake. There are strong hints from other studies that this is so. However, knowing how duration and/or

intensity of activity changes yields little information on the functional outcomes of activity change. For this purpose it is important to know the "content" of the activity in order to translate activity patterns into functional outcomes.

Pilot studies already completed in the study communities have provided some information concerning time allocated to major tasks and aggregate energy expenditure in activity. Both appear to vary across households. Neither appears to answer the functional question.

We look to the case studies for information on those activities which are more important to household function or individual development. From this information we expect to be able to hypothesize how intake affects specific activities; specific research protocols and research instruments will be designed to examine these hypotheses and to investigate relationships during year 2. These second year studies will therefore enable us to complete the original major objectives of the Nutrition CRSP. In the following pages are described the approach to design and implementation of case studies to meet these purposes.

Approach

The case study approach which integrates quantitative and qualitative data on specific topics has particular application to the multidisciplinary research design of the Nutrition CRSP. The approach requires intensive study of specific behaviors and other phenomena on a small but representative sample* of households during two periods or seasons when food intake,

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* Representative of the households to be studied in the core and of the range of conditions in these households rather than of the community *per se*.

morbidity and activity patterns are likely to vary. Through this approach we will be able to document how individuals in specific types of households in the three cultures adapt to these changes, and to identify tradeoffs and compromises that are either maladaptive or potentially maladaptive to individuals and groups in each research site. Moreover, through this highly focused approach we could conduct intensive, comprehensive studies on time use and time allocation patterns of individuals in households.

For example, pilot studies in one research site (Egypt) indicate that mothers receive substantial assistance from kin and non-kin in child care and general household care. The case studies will more clearly depict how household duties, child and family care, and other work are distributed among household members -- adults and children -- and to what extent relatives, servants, adopted children, adopted kin and other helpers recruited from neighboring and distant communities reduce the work burden of target families.

Information on work- and responsibility-distributed patterns in households from case studies will begin to address such complex issues in a preliminary way and guide the development of research strategies, instruments, and measures for more definitive answers in the larger core study during year 2. Essentially, from these studies, we should be able to determine which individuals, in what types of households, in which cultures, make what kinds of adjustments and tradeoffs to accommodate changes (e.g., fall in income, illness) in household conditions. These adjustments can be both subtle and complex and require special research strategies and tools for their investigation.

Specific purposes of the case studies are:

1. to describe the dynamics of daily life in households representing a range of household types, food intake patterns, and socioeconomic situations in the study communities;
2. to depict time use and time allocation patterns of all household members and workers, paid and unpaid;
3. to determine and compare role adjustments made by individuals, and adaptive strategies of households to changes in household living conditions in the three cultural settings;
4. to demonstrate linkages between household living conditions, time allocation and activity patterns, and food intake;
5. to predict which aspects of human behavior and activity are both important to household function and likely to be affected by differences in food intake levels, and to define the parameters of these behaviors and activities in specific terms; and
6. to determine research strategies and approaches that can be applied in the ongoing study on food intake and function during year 2.

Methodology

From census data and sociodemographic survey, each project will identify and select a minimum of 20 households representing a range of SES and of the major household structural types included within the core study sample (see Section V).* For example, if the three major household types in the community are nuclear, stem (extended Type I), and joint (extended Type II) these three household types will be represented in the sample as follows:

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* The ~~core~~ case study households will not be drawn from the core but they should be analogous in representing the range of (a) food energy intake patterns, (b) household types, and (c) socioeconomic situation.

High SES with 3 household types nuclear, stem, joint	6 households
Intermediate SES with 3 household types nuclear, stem, joint	8 households
Low SES with 3 household types nuclear, stem, joint	6 households

Each project will attempt to ensure that a range of food energy intakes (based on data from pilot studies) is included in each of the three groups.

At each research site, during two seasons over a 6-8 month period, data on food intake and on time use and activity patterns will be obtained on each individual in the 20 representative households. Similar data will also be obtained on every person associated with each household such as employees, visiting relative and other transients.

Dietary data will be obtained in a manner analogous to the Nutrition CRSP protocol for that country project. Sociodemographic data will be obtained on household members and on all others associated with each household, using descriptors discussed in Section IV-J.

Additional quantitative and qualitative data for describing household living conditions and the dynamics of daily life will be obtained using the field research method, participant-observation, to be supplemented with structured and unstructured interviews. Information to be obtained from households and individuals, using these methods is shown below:

- patterns of social interaction within the household
- patterns of communicating with the local and distant communities
- patterns of food production, acquisition, processing, exchange, distribution, storage, consumption and waste disposal

- patterns of eating away from home
- acquisition and use of water
- patterns of illness care (and individuals involved in rendering care and substituting functional roles)
- sanitation practices
- health maintenance practices
- illness prevention practices
- infant and child feeding patterns
- child rearing practices
- role expectations and styles of role performance
- strategies used in protecting children and adults from danger
- decision-making styles
- household management styles and styles of priority-setting
- leisure and recreational styles
- significant life events and crisis intervention styles

Time use and activity patterns will be obtained according to an Activity protocol. The frequency of collection will be determined in accord with seasonality and apparent day-to-day variability in the households.

As we have hypothesized above, there is a likelihood that particular categories of tasks, such as child-care, personal hygiene, and sanitation may change with different levels of energy intake deficits. However, there may be no change in these tasks with respect to level of deficit. If no change is seen in these task categories, this relationship may be explained by the content,duration, frequency, and/or body position in other categories. This will be explored in the case studies by some combination of activity recall and observation, specific to each project. Questions asked during recall will be:

(1) General

- What did you do in the last $\underline{t}$ hours (minutes)?

- How many times did you do this task?
- What body position did you use each time?
- Who helped you do it each time?
- How long did it take each time?

(2) Specific

- Did you do task x specically?
- How many times?
- What body position?
- Who helped?
- How long did it take?

If observations are used to validate the recalls, the same information needs to be gathered.

Background information also needs to be gathered on the usual tasks performed in the community, each task's purpose and importance to the community lifestyle, the usual method used to perform the task, and the person expected to perform it. Information on approximate energy cost can be collected from published values. From the case study, local standards of performance and other activities important to the community will be determined, to be considered in year 2.

Criteria for selection of activities to be surveyed are:

- Activities requiring high energy expenditure (e.g., heavy load and/or large muscle group movement).
- Activities which might be expected to show greatest variation in frequency of performance over a stated period of time.
- Activities essential for household viability (e.g., activities productive in the sense of economic, administrative, self-regenerational, or social).

Using these criteria and data already available from the field and/or to be collected in the next 2 months, a list of activities will be generated for the survey instrument, to be applied to each lead female and male (if present) in the case study households.

The survey instrument will include a checklist of specific tasks as generated above. The subject will answer for a previous time period, the length of this recall to be determined by each project. At the end of each "day", if some of the specific tasks on the list have not been accomplished, an additional question will be asked as to whether that task had been completed in the last week and, if so, the frequency, body position, duration, and who helped with the task.

For sufficient precision to capture seasonal differences, this information on (1) and (2) is likely to need to be collected over 6 different days for each 3-month period, the 6 days to be determined by each project.

Data will be analyzed by:

- calculating the energy cost of each specific task, using published values, and aggregating these costs into a crude energy cost per week per subject;
- calculating the number of times per week each task is performed;
- calculating the total time per week spent in each specific task;
- calculating the total time spent per week in high-energy, mid-energy, and low-energy tasks (to be project-defined); and
- calculating the total time spent per week in each body position (lying, sitting, standing, moving).

This analysis could provide information on adaptation to levels of energy deficit if there is no difference in body position or in RMR, or in activities included in the core design. We will refine our survey instrument if case-study questioning and analysis reveal no significant

differences in rank proportion of time by level of energy deficit. Suggested improvements would be to:

- more clearly define the content of specific tasks,
- subdivide specific tasks,
- measure intensity of performance,
- measure output of tasks, and
- include tasks found, through the case study, to be important.

Results will be shared among the 3 projects to refine and set the year 2 instrument for more detailed examination of activity.

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