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Management Entity Semi-Annual Report
October 1, 1984 - March 31, 1985

Nutrition CRSP - Grant (USAID DAN-1309-G-SS-1070-00)

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CONTENTS

Chronology

- I. Brief Overview
- II. Summary of Events
- III. Two major problems addressed
 1. Egyptian Food Intake: Beaton Report
 2. Missing Data
- IV. Data Management and Analysis Activities
- V. Budgetary revision

APPENDICES

- I. Minutes of September-October 1984 SCB meeting
- II. Informal Minutes of January 1985 PIs meeting (Cairo)
- III. Minutes of February-March 1985 SCB meeting
- IV. Minutes of February-March 1985 IC/Finance Group Meeting
- V. Minutes of the February-March 1985 formative meeting of the Data Analysis Group (DAG)
- VI. Psychological Development ("Cognition") Report

Chronology

- September 26 - October 1, 1984: SCB meeting, concurrent EEP meeting September 26 and 27; Berkeley. (minutes attached.)
- November 3-13, 1984: Visit of Dr. Horan to Mexico project (trip report already furnished.)
- December 4, 1984: Dr. Beaton and Mr. Chafkin appear before the Joint Committee on Agricultural Research (JCARD) of the Board for International Food and Agricultural Development, (BIFAD), Washington, D.C.
- December 11, 1984: Meeting of Dr. Calloway with Dr. Forman and Dr. Kahn, Washington, D.C.
- January 5-10, 1985: Informal meeting of available PIs in Cairo, Egypt to discuss data flow, management, and analysis. (Missing data memo attached.)
- January 4-31, 1985: Visit of Dr. Horan to Cairo meeting of PIs, Egypt project, and Kenya project. (Trip reports already furnished.)
- January 9-12, 1985: Visit of Dr. Beaton, to Cairo meeting of PIs and Egypt project. (Trip report already furnished.)
- February 7-8, 1985: Visit of Dr. Beaton to the Kenya project. (Trip report already furnished.)
- February 25-March 2, 1985: SCB; IC/Finance Group February 28-March 1; formative meetings of Data Analysis/Statistics group February 27-March 2; Berkeley. (Minutes attached.)

I. Brief Overview

The activities of these six months include, first, three major meetings:

- The September-October 1984 SCB meeting, jointly with the EEP, in Berkeley; (see Appendix I.)
- The informal meeting of PIs in Cairo, Egypt, in January 1985; (See Section II, part 2.)
- The February-March 1985 SCB meeting, jointly with the IC/Finance Group, together with the new statistics group to advise and assist in the data analysis phase of the CRSP, in Berkeley. (See Appendix II (SCB) and Appendix III (IC).)

Secondly, the new Program Coordinator, Dr. Horan, made site visits to familiarize himself with the three country projects. Dr. G. Beaton made a collegial visit to Egypt and Kenya, also dealing with the particular problems of food intake in Egypt. (Copies of trip reports have already been furnished.)

Thirdly, a number of administrative changes were made:

- The Program Coordinator's role -- a new person in a new position -- began to take on substance and reality, in general without any of the difficulties anticipated;
- Dr. J. Balderston, former Deputy Program Administrator, continued the development of data analysis and management components of ME under a new position title, as Management Coordinator for Data Systems and Analysis.
- In this regard, Professor S. Fienberg of Carnegie-Mellon Institute, was retained as a Program-wide statistical consultant, and Professor S. Selvin of UCB as the Management Entity's (ME) statistician;
- a simplified and clarified system of budget planning was initiated;
- Dr. George Beaton, ME consultant, became the CRSP's "case officer" for questions of food intake;
- Dr. Lindsay Allen, University of Connecticut, became the CRSP's "case officer" for questions of laboratory quality control;
- Dr. Marian Sigman, UCLA, agreed to write a response to EEP observations on cognition and behavior (copy attached). Dr. Theodore Wachs (Purdue University) agreed to prepare a revision of his paper on the analytical strategies required for psychological measurements. (The term "psychology" is used to include the senses of behavior and cognitive function.)

Additionally, the reorganization process, begun with the May 1984 SCB meeting's requests, continued to move forward.

II. Summary of Events, October 1, 1984 to March 31, 1985

Of the above-mentioned activities, the major meetings deserve more detailed comment.

We begin with the September-October 1984 SCB meeting, which was also the EEP meeting appointed to review the progress of the CRSP. This meeting was dominated by demands for, and discussion of, analytical strategies for the data being collected. The EEP felt keenly that analysis on a preliminary basis should have been begun, and that the absence of clear strategies for future analysis needed remedying, as a first priority. The SCB also felt this, and some strategizing was done. (EEP report and ME response already furnished.)

Subsequently, ME hired the Program statistical consultant mentioned, and then a statistician, at UCB, for ME as such. The PIs planned, then held in Cairo, a workshop on data management and analysis attended by Drs Horan and Beaton. ME and AID continued the work of expediting and implementing recommendations such as reorganization, purchase of micro-computers, and approving outside consultants. The attached minutes show other concerns and interests as well, of course, but the meeting marked the first clear turning from field problems to analytical ones.

The February-March SCB meeting was almost entirely taken up with questions of data analysis, continuing in the directions traced by their previous meetings. The missing data list (see below) received very serious and sustained attention.

The Institutional Council/Finance Group meetings dealt seriously and at length with the projected cost overruns, and finally assigned target cuts to each of the four CRSP components -- the three country projects and ME, as well as giving ME authorization and advice to ensure more fiscal responsibility in budget planning, and in the careful execution of what is planned (see Appendix III).

Management and Program Coordination:

The major thrust of the Berkeley component -- ME and Program Coordination alike -- has been to try to foster a supportive, decentralized, and collegial style of management; to try to simplify, rationalize, and streamline office procedures; and to increase the amount of face-to-face time with the projects.

In this, we have had a good -- although far from complete -- measure of success. What has helped in the success has been the good will, energy, and effort on the part of all concerned. Major barriers to a fuller measure of success have, in our view, been the increasing stringency in two essential resources: time and money. Time constraints put increasing pressure on people, and lead to an inability to do all that is needed -- even if there is complete willingness to collaborate. As projected budgetary overruns exist in two projects (Egypt and Kenya) and no further sources of funding seem at all likely, two processes begin that place a strain on all persons involved:

First, budgetary economies at this stage of a project have painful consequences within a project: (e.g. lay-offs of staff, telling

colleagues that their collaboration will no longer be reimbursed, etc.), and affect morale and productivity adversely.

Second, ME and the Mexico project do not have a projected cost overrun problem, and at least ME has limited reserves against the foreseeable budget short-fall, but not enough to meet all the projected needs of either of the other two projects with an overrun problem, let alone both. This increases a collaborative feeling in the sense that the decisions of one affect the fate of the others. It also creates a competitive reality.

It is clear that humane, equitable and mature participatory decision-making can ease these problems. Nonetheless, even in the best-case scenario, scarcities of money lead to disagreements, and even the best of decisions will hurt at least some persons.

There remains an endemic difficulty in field projects, that field investigators tend to become preoccupied with logistical problems of considerable moment, and management persons tend to become preoccupied with lack of results and information from the field. Both share an uncomfortable dependence on the outcome of processes not really under their effective control.

ME has developed a successfully functioning data management unit (DMU), now turning -- with the projects -- to the process of data analysis. This DMU has been able to offer appreciable, though appropriately limited, support at the request of country projects.

ME's major function is to monitor the quality of the science in the CRSP and the delivery of appropriate documentation. Such a large program, with so many talented investigators, would in time be likely to have results in quantity. ME, naturally, has been concerned with quality of data. In addition, there are specific scientific tasks peculiar to our situation:

First, comparability among the country projects is critical to inter-project analysis, and therefore to ME concerns.

Second, the importance and complexity of the analytical effort by each project is recognized. Program-wide analysis will be even more complex. Planning for the inter-project process has been undertaken by the group of statisticians and data analysts, and the implementation of the first stage of the plan has begun. (See Data Analysis report, Appendix IV.)

This said, we turn now to a consideration of scientific problems addressed, and administrative actions taken.

III. Two major problems addressed

1. Egypt Project Food Intake Data

At the request of the ME and with the agreement of the Egypt PI's, G.H. Beaton was asked to work with project staff to investigate the food intake data and methodology. This request had arisen because of

- a) conflicting interpretation of validation trials that had been conducted;
- b) the appearance that, in the research data sets, energy intakes per kg were usually low in adults, particularly males, and unusually high in toddlers.

With full and complete cooperation of the investigators involved, it has been possible to review in some detail the validation trials, to statistically analyze research data sets, and, in January, to visit the field site and to discuss with Egyptian investigators the apparent issues. The Egypt project has complemented these activities with detailed examination of the records and computation algorithms. The present report provides brief summary of the findings to date.

1. Validation Studies Detailed examination of the previous validation studies revealed that although there was no evidence of bias of one method in relation to the other, there was evidence of wide disagreement between methods. Further discussion of the operation of the validation studies and problems encountered in implementation suggested that there were many possible explanations for the disagreements in data. A further five validation trials conducted under carefully selected conditions exhibited excellent agreement between methods. However, the conditions were so atypical that these too must be faulted as not representative of the ongoing methodology. In essence then, the present conclusion is that previous validation studies must be set aside as essentially uninterpretable. Procedures for a series of new field validation studies were discussed and agreed upon. These are now underway.

B. Research Data Set

As a part of the normal process of examination of data and data quality monitoring, summary statistics and distributional characteristics of the food intake set were examined, first with data collected through April (the first set of data passed to Berkeley) and then again with data collected through July. When these were examined in a bivariate manner, as energy intake in relation to body weight, it was found that energy intake/kg was

low in adults, particularly males, and high in toddlers. Initially there was serious concern that this might have been an artifact of the data collection method -- that in some way communal dishes were being apportioned inappropriately to adults and to toddlers. A number of statistical analyses as well as methodologic reviews were undertaken to see if explanations could be found. In the absence of detection of any flaw in data collection and computation procedures, the conclusion would be that the data are presumed to be valid and indeed that intakes in Egypt are different from other data sets. The investigations are continuing. Some correctable problems have been detected; no methodologic explanation for high toddler intakes/kg have yet been found. The main findings are presented below.

In adults, it was discovered that subjects with incomplete records (one or more meals not captured) had been included in the research data set by accident. All such records carry flags, can be identified in the intermediary data set, and will be deleted from the research data file (not yet done). This effect operates primarily among adult males. It is likely to be the major explanation for low intakes calculated for this group. Examination of the food coding system and computational algorithms, by Egypt Project staff, has disclosed some errors relating to the handling of ingredients in recipes; these have resulted in underestimation of intake for some foods and overestimation for others. The errors are correctable. The net effect of implementing these corrections is not yet known. Correction procedures are now being developed and will be implemented shortly.

For toddler data a number of statistical techniques were used to test various hypotheses that might explain either overestimation of intake in a systematic manner or inflation of the variance of intake between individuals in this age group (account for high upper range estimates of usual intake/kg). The possible explanations included an age effect (because only the young end of the toddler age span was included, intake/kg might be higher than seen in other data sets), household training (because households would have been newly entered in these data sets, the variance of reported data might be inflated), and interviewer training effect (because the first data set examined was at the start-up of the project, it seemed possible that variance was inflated because of inadequate training/standardization of the interviewers). To examine these, the approaches included ANOVA's, regressions of intake on age, cohort studies based on entry time, regressions to examine sequence effects, as well as comparative analyses with the only other available CRSP data set, that of the Mexico project.

No spurious or methodologic explanation for high intakes per kg body weight could be found. It was confirmed that intakes in Egypt are higher than those reported from Mexico (which seem generally in accord with expectation) when both are expressed in relation to body weight.

There is a bias toward low intakes within the Egypt toddler data sets since, at 18 months of age, about half of the toddlers are reported to be breast feeding; it has not yet been possible to examine breast fed and non-breast fed toddlers separately since the Berkeley files did not (but will) carry a code for breast feeding. These low intakes, combined with apparent high intakes/kg in non-breast fed infants (the high intake levels in distribution analyses are assumed to be non-breast fed) increase considerably the interperson variance of the research data set.

At this time, there is no reason to fault the food intake methodology of the Egypt project, given correction of the specific errors that have been detected. All of these errors are correctable.

III. Two Major Problems Addressed

2. Missing Data

It was a happy initiative of the PIs to arrange for January 1985 meeting in Cairo, to discuss data collection, entry, management and analysis. This constructive and profitable meeting revealed, however, a serious set of missing data problems, which were reviewed at length during the subsequent February-March SCB meeting in Berkeley.

In sum, the SCB generated a lengthy table, going variable by variable, project by project, and subject (male, female, toddler, infant) by subject. There are projected missing data problems at the 10% missing data level in nearly two out of five of the cells generated by this discussion, and at the 30% level in nearly one out of six of these same cells. (See Appendix III.) This attached missing data list is, and will continue to be, under revision by the three country projects. Each project will also be reporting to you on their own evaluation and interpretation of their own missing data sets.

It is, of course, apparent that missing perinatal measures are very different in significance from occasionally missing anthropometric data in adults, and the projects will provide more detailed commentary on their own missing data sets. Nonetheless, overall it does render the analytical tasks more difficult. (Some of the analytical implications are presented in Appendix B of the Data Analysis Group's report, showing the problem in more detail for each of a set of research questions.)

In addition, both meetings continued the discussions begun at earlier SCB meetings about the very considerable level of difficulty involved in the morbidity subroutine, especially where infants are concerned. It would appear that all projects are essentially in default in this particular area.

IV. Data Management & Analysis Activities

During the past six months, the ME management and analysis staff has carried out the following activities:

- (1) Received data files in SAS and raw form from the three projects;
- (2) Stored data on tape and disk for use on the Berkeley computer;
- (3) Monitored the quality of data received, computing descriptive statistics by all major variables; files linked by ID across variables and preparation of simple contingency tables;
- (4) Analyzed data on Egyptian food intake in order to resolve specific questions raised at the September 1984 meeting of the EEP;
- (5) Prepared the analytical framework of research hypotheses as background for developing quantitative models;
- (6) Prepared materials for the meeting of the Data Analysis Group in February 1984;
- (7) Developed model tables for use by the three projects in preparation of reports for the April meeting of the EEP;
- (8) Continued communication with project statisticians, data managers, and principal investigators about analytical concerns.

The data management and analysis staff at Berkeley consists of the following people:

Judith Balderston, Management Coordinator for Data Systems and Analyses, oversees Berkeley's data management activities, implementing the data analysis plans developed by ME's statistician, monitoring the ME data management workload and expenditures, and coordinating ME's data management and analyses activities with the three projects.

Steve Selvin, Professor of Biostatistics, is involved on a regular, part-time basis, meeting weekly with the data management and analysis group and contributing significant statistical expertise to Berkeley and the CRSP. He will continue to communicate and meet with statisticians of the three projects in order to assure parallel treatment of data and analysis.

Claudia Waters and Shan-Shan Chen have carried out programming activities with competence, monitoring data received, communicating with project data managers, and implementing data analysis. Unfortunately, Ms. Chen has recently left us to take a job in private industry and we are now seeking a replacement for her who has the requisite skills in programming and statistics.

Two kinds of activities have continued in Berkeley. One is the monitoring of the data flow and data quality. As tapes arrive from the projects, data are scanned and simple summary statistics computed. Files are combined across time and across topics by subject ID. These simple analyses not only yield information about the variables of interest but sometimes also yield unexpected questions about data consistency and quality.

A second set of activities is the investigation of relationships for particular analytical purposes. Arising from discussion at the September 1984 meeting of the EEP and the SCB, a series of issues concerning Egypt project's food intake data were explored. In order to resolve these questions, data analysis in Berkeley was carried out as follows:

- a) Variance of individual food intake data by target individuals;
- b) Computation of univariate descriptive statistics for intake, height, weight, kcals of intake/kg of body weight and kg of body weight per cm of height.
- c) Examination of whether toddlers entered later in the study were significantly different from earlier entrants; measures of food intake and weight were examined in relation to entry time. There did not appear to be obvious bias among groups according to their time of entry.
- d) Examination of the effect of sequence on measurement of food intake; i.e., whether the number of prior measurements of food intake is associated with the value of intake found. It was concluded that there was no such relationship for lead females. For toddlers, the expected increase in intake with age did appear.
- e) Examination of whether food intake before Ramadan appeared to be different from intake during Ramadan and whether participants were less cooperative during Ramadan than during other times. We concluded that there did not appear to be resistance to answering questions during Ramadan and there were no consistent differences in mean levels of intake in Kcals between the month preceding Ramadan and Ramadan itself.
- f) Replacement of earlier versions of food intake with later ones, showing considerable change in newer corrected versions for adults but not for toddlers.

Continuing work on the effect of breast milk intake on toddlers' total intake is now being carried out. Since considerable numbers of Egyptian 18-month olds are breast-fed, it is important to compare intake of all other foods for children still breast-fed with those who have been weaned. We expect to have the results of this analysis shortly.

At a recent meeting of statisticians and other technical staff representing the three projects and management, the CRSP data analysis process, the division of responsibilities, schedules, and methods for preliminary analyses were discussed in detail and formalized. It was agreed that each project would undertake analysis of its own data set and that, at the minimum, this analysis would include parallel activities; comparability of results, requisite to the CRSP, could then be achieved. It was agreed that Berkeley would serve as catalyst for inter-project comparisons, initiating preliminary work and providing help to the projects by serving as resource center and clearing house.

It was the consensus of all project representatives that each project will provide statistical staff consisting of: a senior statistician (professor of statistics or biostatistics) who would be involved at approximately 10% time; a junior statistician (MA or Ph.D. level with competency in computer programming) who would be involved at 100% time; this staff would be added to the data management staff already employed at each of the projects.

A full report by the participating statisticians was prepared. In that report, which includes the plan of preliminary exploratory analyses for the present period, the agreed-upon schedule of activities is as follows:

By the end of March 1985: preliminary univariate analyses to be completed including tables constructed by each project using a three-month set of data for target toddlers. Berkeley prepared the set of "templates" to be used by each project in carrying out these analyses, defining variables, formatting tables, and in some cases offering suggested computer programs. These tables are shown as Appendix A to the DAG report.

By the end of June 1985: additional exploratory analyses for six months of data for target toddlers to be completed employing bivariate techniques discussed in Section VI of the DAG report.

By the end of September 1985: diagnostic and regression analyses to be undertaken using six months of data for target toddlers. These analyses including causal models are discussed in Section VII of the DAG report.

In early fall, 1985: there will be a meeting of statisticians and project representatives to review the progress of the first round of analyses and to develop schedules of work for the following year.

The results of the first round of analyses are presented in Appendix A to the Data Analysis Group report and in the projects' reports. While these results are extremely rough and more work must be done to prepare cleaned data files, the production of comparative tables across the three projects was recognized by all participants as an essential activity at this stage.

It is expected that for the next round of activities being carried out in April through June, 1985, more elaborate bivariate analyses will be carried out. While each statistician and project has specific interests, it was agreed that all projects will do a minimum set of common analyses for purpose of comparisons.

During the period July through September 1985, more elaborate methods of analysis will be undertaken. At the next meeting of statisticians in September 1985, the implications of these analyses will be explored to set the stage for the next round of work.

It is the intent of the group to continue to pass data files to Berkeley for archiving purposes as is required by the USAID contract. In Tables 1-3 we report on the status of data files in Berkeley at the end of March 1985.

Table 1

EGYPT

SAS files received as of March 31, 1985

<u>File</u>	<u># Observations</u>	<u># Subjects</u>	<u># Variables</u>
Food Intake	3,292	470	16
Anthropometry - Target	1,409	470	27
- Non-Target	386	348	27
Morbidity Episodes	936	226	17
Morbidity Weekly Recall	14,915	812	32
Demography	1,400	1,400	13
HH SES	186	186	44
Individual SES	1,400	1,400	21
HH Entry	230	199	54
Hematology	472	472	15
Urine	389	389	16
Reproductive History	66	65	38
Psychology - Father	9	9	36
- Mother	18	18	36
- Class (Schooler)	61	26	46
- Schooler	21	21	37
- Toddler	24	23	35

Note: Additional data have also been received on breast feeding and household sanitation. Corrected versions of food intake files have been received as well.

Table 2

KENYA

Raw data files received as of March 31, 1985

<u>Form #</u>	<u>File Name</u>	<u># of Lines</u>
211	Anthropometry	3,538
612	Demography	4,191
641	Child Care	4,662
341	Physiological Sample	329
412	Pregnancy Survey	965
411	Reproductive History	288
621	Sanitation and Hygiene	253
631	HH SES	285
522	Toddler Interaction	2,443
323	Clinical Exam	78
521	Cognitive Toddler	186
313	Morbidity	295
413	Pregnancy Outcome	19
533	Schooler Playground	146
512	(No documentation)	106
671	(No documentation)	288

Note: A SAS file being used by The Kenya Project, containing anthropometry, morbidity, food intake, and SES data for 111 toddlers has also been received.

Table 3

MEXICO

SAS files received as of March 31, 1985

<u>File</u>	<u># Observations</u>	<u># Subjects</u>	<u># Variables</u>
Anthropometry	627	434	25
Food Intake	4,611	688	18
Demography	2,217	2,210	7

Note: In addition to these files, SES data for Phase I including food prices, migration, and material style of life were received during 1984.

V. Budgetary Revision

1. History & Present Situation:

The February-March 1985 Finance Group and Institutional Council (IC) meeting devoted considerable time and effort to dealing with projected budgetary cost overruns, then projected to run some \$1.2 million.

It will be recalled that the previous IC/Finance Group meeting, in May 1984, had asked each of the three projects, and ME, to live within its projected five-year budget total. This posed no special problems for ME and for the Mexico project; it posed very considerable problems for Egypt and for Kenya. Revised planning budgets submitted in 1984-1985 still projected a total cost overrun of some \$460,000 in these two projects combined, in spite of considerable economies proposed by them to come in within the originally allocated budget.

Accordingly, the 1985 IC recommendations asked the Kenya project to find another \$98,000 in budgetary economies, and Egypt to find another \$102,000 in such economies.

Mexico, which projected a very slight surplus, was asked to find \$100,000 in potential budget cuts.

Management volunteered \$103,000 in budget cuts, and now believes it will be able to meet that commitment, barring additional requests for assistance with projects' data analysis. These funds would be available to projects, based on (a) need and (b) demonstrated ability to use the funds effectively.

All - The country projects and ME -- are now to prepare a new revised planning budget, together with an impact statement. The PIs subsequently agreed that these documents would be circulated among themselves and ME for comment and reaction, before undergoing formal institutional review and approval. At that time, it will be easier to predict the probable degree, and the nature, of any budgetary overrun.

Management plans to require that the revised project budgets, with their impact statements, be available in draft form by May 31st, 1985. This, it is anticipated, should allow ample time for (a) collegial review by the other projects and by management, and (b) revision as needed, prior to final institutional review and approval, all before September 30, 1985, as desired by the IC.

2. What ME feels it can do:

ME, together with the Program Coordinator's office, has substantially reduced and considerably re-organized its budget, in order to assume some expenses formerly borne by the projects, to bear the costs of some new expenses, and to provide a limited, but substantial, amount of money available to the country projects on the "need plus demonstrated effectiveness" basis mentioned above. In more detail:

- a. If a proposed major reorganization of its travel and meetings projections is accepted by USAID, ME will be able to subsume the cost burden of the eight statistical and data analysis meetings newly projected by the SCB in March 1985: travel cost, per diems, and meeting arrangements included.
- b. In addition, ME will bear travel costs of all PIs to a reduced number of projected future SCB meetings.
- c. ME will bear the basic costs for proximate analysis of a limited number of project food samples.
- d. In addition, through staff cuts and some other economies, ME has made substantial cuts in its own planned budget. Its original offer, accepted by the IC, was to cut \$103,000. We have done this but at the expense of diminished ME capability to tackle analytical problems posed by individual projects, and narrower dissemination of final program outcomes.

ME will also continue to try to work on behalf of projects, upon their request, attempting to assist and to 'backstop' whenever possible.

APPENDIX I

(Minutes of the September-October 1984 SCB meeting)

SCB MINUTES

Nutrition CRSP--Berkeley, California, September 26-October 1, 1984
Present: Drs: Allen, Bwibo, Galal, Harrison, Kirksey, Neumann
From Management Entity: Drs. Beaton, Calloway, Balderston, Horan

The agenda for the meeting was discussed in some detail. The following were agreed upon as necessary to consider, and timing was deemed to be best kept flexible.

- Share EEP site visit experiences.
- General update from all projects
- Detailed review of basic/common/project specific variables list
- Role of new CRSP coordinator
- Role of SCB
- Budget
- Data analysis and management; management versus project responsibilities; need for in-country data analysis
- Publications agreement
- Review of timetables for second year of fieldwork
- Time allocation ("activity") protocols
- RMR: implications of missing data
- Immunology
- Intervention: timing, nature, and potential funding

It was agreed that Dr. Harrison will be responsible for generating a draft of the minutes of this meeting; Management Entity will circulate a draft before finalization.

1. Reports on EEP field visits. The Egypt project reported that the field visit of the EEP in mid-July was a very positive experience for local staff and Principal Investigators. Drs. Payne and Keusch took care to learn about the role of the CRSP in relation to other activities within the Nutrition Institute and the Ministry of Health in Egypt. They expressed concern with the perceived inflexibility and remoteness of the Management Entity and with the problems of slow data feedback to the field and data analysis being removed from Egypt. They spent considerable time in discussion with Egyptian senior scientists, and their visit was a major morale builder for the staff.

The Kenya project reported an equally positive experience with the EEP visit, also with the focus on the larger framework. A major criticism by the EEP was the minimal Kenyan scientific input except for Dr. Bwibo, the Co-Principal Investigator, and Davy Koech, immunologist. The EEP visitors spent

considerable time talking to junior scientists, but were not able to connect with senior Kenyan scientists. The current drought and famine in Kenya received substantial attention; efforts to cope with the problems in the area have unexpectedly provided the benefit of more contact with the Kenyan government and with other Kenyan institutions. The EEP recommended extending the core data collection beyond the existing plan's termination date in Kenya in order to document the famine and recovery. This of course would depend upon obtaining additional funding. The CRSP staff have opened a rehabilitation unit and have been able to provide some maize and seed to each family. About 30% of the target families are in trouble with regard to food supply. The CRSP has had no alternative but to get into the relief operation; the project is documenting all activities.

A major problem in the field is that no one has had time to think. It is a constant frustration that logistics take almost all of everyone's time. The project still needs one more physician, preferably a Kenyan, and is also recruiting a new field coordinator to replace Dr. Carter who is leaving in March. The enumerator field staff are excellent, but the opportunities for them after the CRSP has not been solved. The majority of the 140 staff are women and cannot leave their homes in the Embu area to go to other work sites. Some have continued their education, mainly in schools of nursing and the university.

The Mexico project also reported a good experience with the visits of Drs. Yarrow and Thompson to the field. Consistent with their own expertise. These visitors focused on the status of the sample and data collection, field management, and the technical aspects of psychological function. They evaluated the field team's efforts to retain the sample and to minimize attrition, records of tests attempted, field logistics, etc. The Mexico project has changed its morbidity recall methodology and is now utilizing a physician in each field site. Each community now has its own field team. There have been no attempts to take blood samples yet; the suggestion when brought up has not been well received. Metabolic rates were started in June; at the present time the field team has made two measurements on each person. The EEP visitors gave a favorable evaluation of the socioeconomic status methodology and provided a lot of emphasis on psychological function. There was particular concern with mother/infant interaction methods being used. Details of the data management system now in place are in the Mexico project's annual report. The project now has three Apple computers, with data entry in the field taking place on a full-time basis. A major problem has been a large turnover of staff.

2. Psychological Function Measures. Dr. Marion Sigman visited with the SCB and discussed the issue of psychological measures in some detail. It is her opinion that Egypt and Kenya have very similar measures; Mexico's are somewhat different. The Egypt project is doing more than either of the other two projects, but over all, cognitive measures are very similar among all three. The differences are in observational measures. In Egypt and Kenya, observational techniques are naturalistic and based on home observations. The Mexico project currently has with the toddlers more of a teaching situation. Mexico is doing face-to-face observation for infants at three and six months. Dr. Yarrow carried out considerable discussion of Mexico's teaching measure on toddlers while in the field. She questions the utility of this measure. Mexico intends to add toddler observations, the lack of which has been the main difference among the three projects. Dr. Sigman expressed her opinion that artificial measures are not always bad, but that comparability of measures will be improved among the three projects with the addition of toddler observations in Mexico.

She explained to the SCB the opinion of Dr. Yarrow that social and emotional functions may be more sensitive than are cognitive functions to the effects of mild to moderate undernutrition; based on this assumption, Dr. Yarrow wants reassurance that all three projects are measuring social and emotional function with sufficient observational time. The issue of adult measures appropriate for each field situation was discussed. In Kenya there are no Kenya-standardized adult measures which are appropriate to the field situation so the U.S.A. WISC items and Raven's matrices are to be used. Dr. Sigmund assured us that she, Dr. Wachs, and Dr. Field will talk to each other on a continuing basis. Although it may be impossible to put all psychological and cognitive data into one analysis, it will be possible to do interproject analysis on a substantial portion of the data and all projects are measuring in valid ways the same underlying variables.

3. Overview with EEP members. September 27th the SCB met with EEP and representatives of the Management Entity. Dr. Payne gave an account of the meeting of the EEP the previous evening. The EEP was briefed by representatives of AID and asked to provide their informed opinion about the likelihood of successful scientific outcome for the CRSP. After discussion, the EEP concluded that it is impossible to give such an opinion. The implication of this decision is that the EEP must come to the SCB with the task of identifying what is missing in order to render such a decision, how to go about providing the missing information in a reasonable amount of time and with reasonable resources, and consideration of the implications for management at both the project and central levels. The piece of information which is missing which the EEP requires at this point is a set of concrete proposals for the data set which will be used to test the range of hypotheses, analytical plans, models, and statistical protocols, along with trial runs on early data. Lack of this information at the present time is serious. However, the EEP wishes to be constructive in working with the SCB and with Management in order to discuss how to fill in the gaps and how to restructure resources and management to allow the EEP to answer the questions posed by USAID within a reasonable period of time. Dr. Payne suggested that the projects discuss with the EEP in a perfectly open way what they consider to be the problems and potentials of solving the problem voiced by the EEP.

Dr. Allen listed several logistic problems which the Mexico project faces in fulfilling the basic data set. Blood sampling is difficult in this Mexican population; there is doubt that the immunology basic set represents functional measures in any case. Will the core measures really answer the questions, in this and in other areas? The entire CRSP is limited by state of the art methodologies. This is particularly acute in the area of energy expenditure. In any case, field teams are extremely busy at this juncture and the thought of changes in design now is unthinkable. Dr. Payne responded that the EEP has no intention of changing the design at this point in the project.

Dr. Neumann put forth her opinion that the logistics of fielding this complex operation have left no time for investigators and field staff to think. A substantial and important piece which is missing is the "glue" of how people cope, their own perceptions, and how they manage in the face of unforeseen circumstances. We need to add some in-depth interviewing in order to fill this gap. We haven't had adequate time to think about analysis on a project level, probably because we have been too busy collecting data, accounting for everything, and implementing quality control. There will be substantial relevant information missing in reference to energy intake; for example the digestibility

and losses are unaccounted for. Dr. Bwibo stated that he felt it was too late for gross changes in the design. We must do the best with what we have. Sustaining the interests of households is a problem, and the Kenya project additionally has the concerns brought on by the drought and the expectations of households that the field team should be bringing help as well as collecting data. Sustaining the interest of scientists also becomes difficult without immediate feedback of results.

Dr. Galal indicated that we have no protocol within the CRSP for judging success; we probably all have different criteria. We have spent a lot of time trying to improve methodology and quality control; this process could continue forever. The demands of the field's data collection effort have left little time for thinking. There will always be some defects in methodology, but we must evaluate where we are and get on with the task at hand. We need to ask whether the target populations selected for study are appropriate in terms of mild to moderate undernutrition, and are there patterns emerging from the data anywhere? If both of these questions can be answered in the affirmative, we must go forward.

Dr. Kirksey indicated that the Egypt project has uncovered nutritional problems other than energy intake; zinc deficiency, iron deficiency, and pyridoxine deficiency have been documented in our study population. She feels quite comfortable with morbidity and cognitive methodology in place at the present time and confident that good data will be forthcoming in these areas which have been designated as central by the EEP.

A general discussion followed. Dr. Srinavasan indicated that we must achieve a balance between our scientific curiosity and the postponing of analysis. We need a frame work for analysis. We need to think of possible analytic strategies for discovering the underlying signals in a very noisy system. Dr. Keusch reminded us that the central issue is food or energy intake. Second level questions within the research design relate to mechanisms. Dr. Kuesch indicated that he felt that the immunology data may not be extremely valuable in terms of the overall hypotheses to be tested.

Dr. Adams brought up the role of Management Entity in looking at the overriding supraproject issues and their scientific implications. Dr. Beaton addressed the issue of data analysis. For the hypotheses which the CRSP addresses, dummy tables are difficult to construct. Analytical models have not been put forth partly because we haven't yet had the data to reach consensus. There are many possible models and we have not yet had the basis to make decisions among them.

Dr. Beaton reminded us of the history of the CRSP, which first focused on the household unit. At the first EEP meeting, a decision was made to focus on specific outcomes which narrowed the potential from a household focus to a much more individualistic one. This decision necessarily changed the potential for analysis. Dr. Balderston indicated that Management Entity and projects have different missions with regard to data analysis. She offered the opinion that data should not be fed back to data collectors in analyzed form until all data are collected. Dr. Payne disagreed, stating that ongoing data analysis is necessary and should have existed long before now. It would have been ideal from the beginning to have adequate microcomputers and software for analysis and quality control in the field. Inevitably, analytical strategies would have arisen at the project level and now both projects and management would be in a

better position. Dr. Donovan queried whether there are people in each individual project site to do this kind of analysis?

A general discussion of project analytical strategies ensued, and evolved into a discussion of the role of the SCB, the structure of Management, and the role of the new coordinator. Dr. Horan indicated that he intends to provide staff support to all projects as needed and to function in relation to Management as an interpreter in both directions. He hopes to prevent unpleasant surprises and be an honest broker between projects and management. He intends to do whatever he can to facilitate communication among the PI's as well as between PI's and Management.

Discussion of the publications policy followed. Within the existing policy, CRSP scientists have the right to publish data collected prior to the beginning of Phase II (January 1984). All data collected after the beginning of Phase II will not be published until all data have been delivered to Management. Dr. Srinavasan questioned whether a discussion paper series might be an appropriate format for early publication. The publications policy is an SCB decision; the CRSP coordinator and Management should facilitate implementation of the SCB's action in this area.

Discussion of ethical issues and follow-up responsibilities after the current field data collection period is ended followed, with special focus on the Kenyan situation. The Kenya Principal Investigators were shocked to think that the EEP perceived that the community was not adequately informed about the benefits of the study and what their involvement would mean. Innumerable community meetings are being held with the community and local leaders on an ongoing basis. There are larger benefit and information issues involved in all three sites. Dr. Galal indicated that the Nutrition Institute feels an ongoing responsibility to the village of Kalama, and is planning now for an implementation phase following Phase II. The Mexico Project indicated that the INN is planning to keep the Solis Valley as a field research site with an intervention phase as well. Dr. Bwibo discussed the food shortage in Embu and in Kenya. The CRSP can't solve the problems, but must work within the existing government hierarchy. Local chief structures and famine committees are being worked with at the present time. The CRSP is not part of an ongoing institution in Kenya as it is in Egypt and in Mexico; the CRSP has, however, provided useful data to the President's office and to the Ministry of Economic Planning on the changes in prevalence of severe malnutrition with the current crisis. The CRSP is also paying for hospital admissions for severely malnourished subjects and has set up a nutrition rehabilitation unit.

September 28th, SCP met with EEP and representatives of ME. Dr. Payne opened the meeting by reviewing the discussions that the EEP had the previous evening. First, they considered them from USAID. AID wants an informed evaluation of whether the scientific outcomes are likely to be clear at the end of the CRSP. The EEP feels that it cannot make an informed opinion about the likelihood of success at this juncture. The data as collected seem adequate but we don't have the ability to judge outcome at this time. If the EEP were to abandon its evaluative role at this juncture, AID would be forced to set up another evaluative committee with less informed personnel. The decision was made instead to try for something new, based on the reasons that EEP cannot judge the likelihood of successful outcome. The need is for concrete proposals about how the basic data sets will be used in data analysis. Dummy tables, expected outputs, etc., should have been done long ago; on this basis decisions can be made about what

* is missing and what can be done about it in a reasonable way.

In later session of the SCB alone, it was decided that it would be valuable for Principal Investigators and/or senior project scientists to get together for a brainstorming data analysis meeting prior to the next EEP meeting. It was tentatively decided to have such a meeting in Cairo or Nairobi early in January. Discussion of the possibility of Management Entity hiring a skilled new data manager and/or statistician followed.

SCB went through the September 1984 book of variables, reviewing all basic, common, and project specific data sets. The revisions as discussed and decided have since been circulated among all projects.

In the afternoon, SCB met with the EEP, Management Entity and US AID representatives Drs. Forman and Kahn. Dr. Payne opened the meeting by indicating that the EEP has been asked by AID to judge whether the data can be used in a scientific way to achieve the scientific questions asked by the CRSP. The EEP could not formulate an opinion on this, but this situation does not mean that the data collected are defective in any way or that insufficient thought has been given to the project design. The reason the EEP cannot answer the question posed at this juncture is that it needs statistical models, tools, tests of hypotheses, and analytic strategies and these are not yet available. The question of why they are not available has been addressed in various ways; we need these materials soon or the EEP's function will be very limited. Problems which the EEP has identified in its deliberations include the following.

1. The CRSP is missing a flexible, rapid system of checking and summarizing data quality on site. We recognize the resourceful techniques which have been tried at each site, but this area needs substantial improvement.
2. At each project site we face the same problems as we do on an interproject level, that is, no dummy charts, models, etc. Development of these would help the sites in the future and would be an added resource for future research.
3. To rectify these problems, will require a change in the responsibility of the Management Entity with transfer of more responsibility to the SCB especially at the level of scientific analysis. The EEP believes that this potential move is a very positive one. Nevertheless to ensure that the interproject data are analyzed, it is necessary to have an individual accountable. This person is Dr. Calloway. The EEP also suggested that the SCB should form a subcommittee to facilitate the work of the SCB, ensure timely decisions, and to facilitate progress in analysis of the intercountry data set.

The EEP does not accept the assumption that all data must be collected in order to start analysis; analysis should have started long ago. The EEP is enormously encouraged by the discussion with the Principal Investigators over the last few days and during the site visits which showed that the individuals are ready to start now on project analysis and on interproject analyses common to all three projects.

Mr. Chafkin indicated his desire to know whether the Principal Investigators are interested in the interproject analysis. The EEP would like to convene no later than the Spring of 1985. The letter of Dr. Calloway to Dr. Forman (June 19, 1984) is in the right direction for organizational restructuring, although we cannot accept management's original suggestion that ME drop its scientific responsibilities for the results.

Dr. Payne indicated several cross country needs, for example a statistician, data analysis support, etc. One possibility is that an individual employed by the SCB could assist in all three projects and serve as a resource to all three projects to the proposed subcommittee. Dr. Calloway indicated that she hoped the EEP would describe the new management structure in detail. Dr. Neumann voiced the worry that the PIs and the SCB would not have sufficient time and energy to accomplish all this although philosophically she agreed with the proposed restructuring. Dr. Payne agreed with her worry, but indicated that he sees a structure either as having to be built from the bottom up or the top down; Dr. Neumann agreed that the bottom up is better. Dr. Payne indicated that the SCB needs to be thinking hard about this problem and that the management entity should facilitate this thinking.

Dr. Beaton brought up the possibility that the three country analysis might not happen. In this case, individual country conclusions might be enormously limited. Beaton indicated that if the PIs are to be responsible for all CRSP analyses, they will have to make a very large commitment to interproject analysis.

Dr. Allen inquired about how much of the current state of affairs is due to lack of data and how drastic a change is needed in structure. Dr. Payne indicated that he believes a lot of past tensions will be seen in retrospect to have been caused by lack of structure. Dr. Forman asked that the new structure including its operational aspects be clear before this meeting adjourns. AID has a different set of problems in restructuring a CRSP including amendments of contracts etc., and has to operate within program and budget requirements. AID will be agreeable to whatever proposed changes the investigators and Management deem to be constructive as long as the original proposal and contracts are not violated. That is, AID cannot agree to delete three country analysis, and also needs to have clear channels of responsibility.

September 28, 5:00 p.m. SCB and Dr. Horan met. A discussion of the new administrative structure and the mechanisms by which it might operate was held. One or more statisticians is needed; each project needs to have its own, and in addition it would be helpful if management had a statistical consultant or statistician. Several possible individuals were discussed. The structure of an SCB subcommittee in order to facilitate the work of the SCB was discussed and agreed upon. Each project will have one U.S. Principal Investigator as a member of the subcommittee. This will be for the present time Drs. Allen, Jerome, and Neumann. Communications from all Principal Investigators to Management can most simply be made to Dr. Horan. Copies could be sent to Dr. Calloway to, but Dr. Horan will see her weekly and relay any messages. This does not preclude the Principal Investigators from contacting Dr. Calloway directly. The issue of SCB structure and chairmanship was discussed. Dr. Neumann will plan to meet with Dr. Calloway at least every two months. She will continue her chairmanship at least through January, after which she requests that it be rotated to someone else.

A discussion was held with Dr. Beaton on analysis of preliminary food intake data from the Egypt project. A report from Dr. Wafaa Moussa was discussed with regard to results from three methods of food intake estimation. Observation and weighing has been attempted, but few households are actually willing to participate. Out of 71 households screened, 43 were eligible and 34 accepted to participate. Of these only 15 attended a meeting to discuss the project and only three actually participated in observation and weighing. Even individuals known to the households, including relatives, were not able to observe and weigh for any long period of time. The method of short-term recall combined with observation when possible and sample weighing seems to be the best method that is acceptable to households.

September 29. (SCB with Dr. Kahn and Fred Johnson from BIFAD.)

The review of basic, common, and project specific data sets was continued.

Later, the SCB met with Dr. Calloway to discuss management structure. Dr Calloway's understanding is that Berkeley still has financial responsibility and unless she hears differently she assumes that we are still under the institutional council agreement that core data will be delivered on a predetermined time schedule. Management is also responsible to AID relative to the EEP's evaluation and report. Discussion of the need for statistical support ensued, particularly in relation to Management finding and employing a statistical consultant who would be a resource to all.

A discussion of the food intake issues in the Egypt project followed. The Egypt project will continue with 24-hour recall, validated whenever possible with short term recall with observation and sample weighing. It will undertake a validation study with all day observation and weighing on as many households as possible. This will be done on a minimum of ten households. The project reserves the right to make minor changes again based on analysis of the results of comparative studies undertaken so far. The Egypt project will make every effort to have validation substudies available for consideration by the data analysis get together in January. Analysis of the fifty households on whom more than one method is available so far will be completed if possible by the January meeting. Meantime, the 24 hour recall methodology will be continued. If the results look internally valid, it will continue. If not, the design will be reevaluated. The SCB considered and rejected the possibility of stopping food intake within the Egypt project entirely. The SCB also rejected the option of redesigning the intake on the basis of available information. Instead, the Egypt project will continue with existing methodology while undertaking validation substudies and analyzing those data for presentation at the next gathering of investigators.

Consideration of psychological function measures was discussed. Dr. Neumann expressed her opinion that the study psychologists are all competent and in general agreement about the measures being used. The member of the EEP who is professionally expert in this area happens to disagree with them. The Mexico project is adding observational measures as suggested by Dr. Yarrow, which should deal with this particular difference of opinion.

The issue of time allocation and activity patterns was discussed. Kenya will not be able to accomplish these measures until the second year, February 1985. Can these measures be common rather than basic? Dr. Allen raised the question of how to use the data on time allocation. After considerable discus-

The issue of time allocation and activity patterns was discussed. Kenya will not be able to accomplish these measures until the second year, February 1985. Can these measures be common rather than basic? Dr. Allen raised the question of how to use the data on time allocation. After considerable discussion it was decided that time allocation data are basic.

Immunology was discussed. Egypt and Kenya will continue to measure immunoglobulins. Mexico will store serum for later analysis if the assays look useful based on the other projects. In light of the EEP recommendation it was decided that the data on immunoglobulin be analyzed as quickly as possible to see what they look like. Skin testing should be continued.

Discussion of the publications agreement followed. Last May, it was decided that no publication of data collected after the start of Phase II would be allowed at the present time. Dr. Neumann wants to reopen the issue of publication of within-function data. Dr. Beaton expressed the concern that the main issue is making sure that the data released by publication are the "final, clean" data set. It was decided that for after Phase I data, a form would be developed for approval of the SCB for publication of within function data. Dr. Horan will solicit responses and develop a draft form. Dr. Beaton pointed out that this means that the project publication policies will have to be revised. Dr. Calloway indicated that we will need a very clear set of procedures; Dr. Horan questioned whether such a policy was enforceable. It was decided that the above policy covers only within-function data sets and that the linking of food intake or nutritional status with function should not be publishable until completion of all data delivery.

Final decisions. All present agreed that by October 17, all PIs would communicate with each other as to whether the data analysis meeting in January looks possible. By November 1, we should exchange drafts of analytical strategies for within functions data reduction and analysis. Also by November 1, the final list of basic, common, and project specific variables should be circulated. Dr. Harrison will supply her notes to Dr. Horan immediately, he will circulate them then to the SCB subcommittee and an official revised list will be forthcoming by November 1 to all. Responsibility for initial thoughts about data analysis were allocated as follows: Psychology-Dr. Sigmund, RMR activity-Dr. Allen; Pregnancy outcome-Dr. Kirksey, Socioeconomic status-the Drs. Pelto, Morbidity and Anthropometry-Arizona, Dr. Harrison, Food Intake-everyone, immunology-Dr. Neumann, Child care, Household sanitation, scaling of these items - Dr. Jerome.

APPENDIX II

(Informal minutes of the January 1985
Cairo meeting of PIs)



THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

COLLEGE OF MEDICINE
DEPARTMENT OF FAMILY AND COMMUNITY MEDICINE

January 25, 1985

MEMORANDUM

TO: Attendees at recent CRSP meeting in Cairo, plus
Drs. Calloway, Chavez, Jerome, Pelto

FROM: Gail Harrison *gh*

Enclosed is a copy of the notes taken by Nancy Meyer, which summarize the meeting. Nancy is gathering copies of key transparencies, which will follow as an appendix so everyone will have a fairly complete record of the meeting.

Thanks to all for the participation which made it a productive and enjoyable gathering.

enc.

BEST AVAILABLE COPY

28

CRSP INTERPROJECT DATA EVALUATION

AGENDA

Nutrition Institute Cairo

Jan. 5 - 10, 1985

Saturday Jan. 5

- 9 - 11 a.m. . Approval of Agenda
- . Availability of Data (present, late, missing, drop outs,... etc.)
- 11:30-1:30 p.m . Timetable for projects
- . Data entry systems and flow
- 3 - 5 p.m. Group Discussion

Sunday Jan. 6

- 9 - 11A.m. -
- 11:30-1:30 . Description of data
 - Egypt - Discussions
 - Kenya - Discussions
 - Mexico - Discussions
 - General Discussions
- 3 - 5 p.m. . Group Discussion

Monday Jan. 7

- 9 - 1:30 a.m. . Preparation for the analytical presentation
- . Group Meetings

Tuesday Jan. 8

- 9 - 11 a.m. . Activities (strategy for analysis)
cognitive/reproduction/anthropometry/morbidity
- 11:30-1:30 . Activities (strategy for analysis)
haematology/childcare/sanitation/SES
- 3 - 5 p.m. . Group Discussion

Wednesday Jan. 9

- 9 - 11 a.m . Food Intake (Problems and Validity)
- 11:30-1:30 p.m . Exiting households

Thursday Jan. 10

- 9 - 11 a.m . Round-up
- 11:30-1:30 p.m Recommendation for further activities.

CRSP Interproject Data Evaluation Meeting

Egypt, Kenya, Mexico Nutrition CRSP

January 5 - 10, 1985

NUTRITION INSTITUTE, CAIRO, EGYPT.

I. ENROLLMENT SUMMARIES

A. H. H. / Target Entry

Egypt - H.H. entered monthly beginning Oct'83 as Tod/Sch came of age.

Kenya - All H.H. entered in Jan/Feb '84.

Mexico- 80 - 90 hh entered together due to Sch eligibility. Other HH entered as Tod came of age or pregnancy occurred.

B. HH/Target Status

	<u>Kenya (Jan'85)</u>	<u>Egypt (Jan'85)</u>	<u>Mexico (Dec'84)</u>
H.H.	223	284	216(?)
Schooler	137	126	136
Toddler	99	135	96
Infant	62	80	34
Pregnant	42	84	43
Lactating			38

II. COMPLETENESS OF DATA

A. Food Intake

Egypt - 6-12% missing data overall

Approximately 30% L.M incomplete data.

20% missing for schooler.

10% missing for L.F.

Toddler Kcal low from age 18-24 months due to breast feeding .

Kenya - 5% missing overall.
40% missing for L.M.
15% missing for schooler

Mexico - 10-25% missing as of July.
3-5% missing now.
20-40% missing for L.M.

B. Anthropometry

Egypt - Toddlers missing 38% overall
range from 0 - 50%.
Schooler 40% missing during school year
15% missing during vacation.

Kenya - 30% missing for L.M.
20% missing for Schooler.
10% missing for other targets.

Mexico - Missing data due to collection at 3 mo.
intervals on all targets until August.
Now monthly measurement.

C. Morbidity Recall

Egypt - 20% missing due to absences.

Kenya - 5% missing.

Mexico - 5% missing

Subroutines difficult for all countries:
duration generally gotten from next weekly recall,
weights hard to get.

D. Physical Exam.

Egypt - 1% missing

Kenya - L.M. 40% missing
L.F. 30% missing
Sch. 40% missing
Tod. 30% missing

Mexico - 0% missing.

32

E. Cognitive

Egypt - L.M. 60% missing
L.F. 29% missing
Sch. 10% missing
Tod. 38% (19% missed at 18 mo.)

Kenya - 5% missing overall

Mexico - L.M./L.F. 0% missing
Schooler 37% missing as of August.
Toddler 12% of Bayley missing as of August.
38% M-I interaction.
Some 18-mo exams missed, fairly complete at 24 mo.

- Need for adjusting 6-mo test for infants for gestational age?

F. Hematology (initial measure)

Egypt - Tod. missing 17%
Sch. missing 27%
L.M. missing 30%
L.F. missing 25%
L.F. pregnant: time 0 53% missing
mon. 3 85% missing
mon. 5 (est) 15-20% missing

Kenya - Tod. 45% missing
Sch. 50% missing
L.M. 50% missing
L.F 45% missing

Mexico - Subjects refused to give samples
Food iron intake is high (40-80 mg/day)

G. Immunology

Egypt - L.M. 50% missing
L.F. 15-20% missing
Preg. 30% missing
Sch. 80% missing

Kenya	L.M. 50% missing	}	(correct for hematol.&immun.?)
	L.F. 45% missing		
	Sch. 50% missing		
	Tod. 45% missing		
Mexico	Subjects refuse to give		

H. Parasitology

Egypt	One round complete for all members of core HH.		
Kenya	L.M. 40% missing		
	L.F. 30% missing		
	Sch. 40% missing		
	Tod. 30% missing		
Mexico	3 rounds completed		

I. Other Biological Fluids

Kenya	Milk and saliva	no problem
Mexico	Milk and saliva	not collected to date.

J. Reproduction / Infants

Egypt	Birth wt	17% missing	(8% refused for rest of study)
	8th day	4 % missing	
	1st month	4 % missing	
	2nd month	2 % missing	
Kenya	Birth wts	10% missing	
	Dubowitz	35% missing	
	Brazelton	mostly complete .	
Mexico	Birth wts	78% missing	
	Brazelton	78% missing	
	Of those missing - 2/3 were born at home & families don't contact clinic for b.w.		
	1/3 born in Mexico City.		

K. Child Care/Sanitation/Activity

Egypt	Began in March '84, so H.H entering prior have 50% missing data now.		
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Activity began in July, so full 12 mon. of data won't be collected on HH entering prior to July.

Kenya C.C. 20% missing
Sanitation 5% missing

Mexico Activity L.F. 15-20% missing
L.M. 20-40% missing

L. SES

Egypt almost 0% of baseline missing; update done at 8 - 9 mon.

Kenya SES/census 5% missing

Mexico SES/census 0% missing

M. RMR

Egypt

Kenya L.M. 40% missing
L.F. 30% missing
Sch. 40% missing

Mexico For 3 repetitions:
L.M. 30% missing
L.F. 10% missing

Using Max-Plank respirator.

III. MISSING DATA DISCUSSION

- * Even with missing data, may be ways to use data available.
- * Need to look at why data are missing...due to confounders ? (e.g. are all ill missing ? are all missing different in some other way ?)
- * Try reasonably and feasibly to replace data KNOWING that it is a SUBSTITUTION, using:
 - 1) mean value, or
 - 2) predicted value, or
 - 3) maximum likelihood estimation.

* Some approaches:

use only cases with appropriate information

delete all variables with missing data

delete individuals with incomplete data

this data may be comparable, but may not be poolable.

IV. DATA ENTRY

Egypt Until August '84, all raw data to Kansas for entry.
Feedback has been slow.
Beginning Aug in Cairo at Al Ahram Center. Morbid.,
Anthrop., immunol., reproduc.,. Fd Intake there now:
Catch-up w/in 2 months predicted.

Kenya Data from field to DMU to Nairobi for entry 1/wk.
Double entry, rangechecks, printouts returned
1 wk later.
Resolution to Nairobi 1 wk after.
Tape after 1 month to UCLA. (6 wks from collection
date).

Mexico Some entered on 3 Apple computers (FI, anthrop,lab)
& checked against originals.
Others (activity, SES, cognitive) by Public Health
in Mexico city & verified.
Diskettes sent to UCONN
By end of Jan'85 hope to be caught up entirely.
Now current on FI, morbid., activity, anthrop.
Range checks done at UCONN.
Considering IBM-PC in field to do range checks and
convert food to nutrients.

Overview Of Data:

V. FOOD INTAKE

Kenya:	<u>Kcal</u> <u>March '84</u>	<u>Kcal</u> <u>Apr '84</u>	<u>Kcal</u> <u>May '84</u>
LM	2428 ± 1147	2247 ± 1301	2015 ± 947
LF	1918 ± 1017	1764 ± 868	1697 ± 818
S	1612 ± 941	1609 ± 668	1410 ± 572
T	766 ± 390	781 ± 493	807 ± 472
I	10 ± 15	31 ± 67	62 ± 77

Significant differences among communities
Basic diet is mix of maize and beans - boiled
(Supplies 60-70% Kcal)

Mexico: From Jan to July '84, at least 4 recalls:

	<u>KCal</u>	<u>KCal/Kg</u>	<u>KCal/Kg/cm</u>
LM	2800 ± 706	43.2	0.40
LF	2236 ± 505	39.2	0.38
S	1503 ± 462	75.1	0.18
T	907 ± 489	77.1	0.14

Egypt: See Appendix II

Basic diet: tortillas, 45% of diet, beans and pasta 25%.

VI. MORBIDITY/DISEASE

Egypt Nov - Aug '84

Tod. 75% well

30% ill throughout these months

GI incidences higher in summer

Respiratory higher in winter

Sch. 90% well most of the time

Kenya March - July '84

conjunctivities 17% of all illnesses

respiratory 36-49%

fever 6-15%

20-40% of total population reported an illness
each month.

Mexico

Jan - July '84

71% total illness is upper respiratory

9 % is diarrhea

5% infection

2% accidents

2% muscular

11% other

VII. MORBIDITY/LAB

Egypt Parasites

shisto 4-5%

ascaris 6-7%

hook worm 1 case

<20% of pop. had parasite

Anemia:

	Egypt	Kenya
Todd < 11gm	60%	70%
LM < 9gm	7%	8%
LF < 13gm	15%	35%
Sch < 12gm	20%	

VIII. ANTHROPOMETRY

Egypt- LF almost as heavy as LM

Todd. stunted according to WHO standard

Sch not as stunted

Mexico (Egypt)

	<u>Wt</u>	<u>Ht</u>
LM	66.0 (67.7)	165.9 (167.5)
LF	58.4 (63.8)	152.7 (150.4)
T	11.6	83.0
S	21.8	114.8

Kenya- Skin folds

	<u>May '84</u>	<u>Aug '84</u>
LM	25.2mm	25.4mm
LF	25.1mm	25.1mm

Thin population:

Todd had large increase in stunting from March to Nov.'84.

Sch. not much change.

IX. HUGH HORAN - Introduction of self and new job as Coordinator for CRSP. Role is as interpreter between projects and ME.

Data Analysis:

Berkley can offer:

1. Good quality technical advice
2. Cheap (high speed) computer time
3. Arrange for experts to discuss analysis problems
4. Careful scheduling for publications
5. Provide maps, guidelines, modeling for analysis & coordinate some of same done by projects.
6. Reserve some ^{re}sources for emergencies.

ME Fears :

1. Field problems won't be solvable
2. due to lack of money, time or interest big chunks of data won't be analysed.

EEP & AID:

Next EEP report is crucial since at last mtg. EEP said they could not give a report. April is latest month AID will accept EEP report.

New CRSP guidelines from BIFAD:

- 1) Encourage employment of grad. students
- 2) Satisfaction of host country w/ project operations
- 3) Land-grant universities get more int'l experience.

Dec.4 Bifad Mtg: not positive or negative towards CRSP.

EEP & Immunology: In '83 Keusch said blood & Saliva tests would not give significant info from such a short study & still maintains this attitude.

Psychology: CRSP project needs to identify one spokesperson.

Budget : AID is sensitive to purchases of computers, capital equipment, overseas travel.

ME feels it is important ethically to plan a follow-up program to use data gathered for CRSP to aid communities and individuals giving data for the study.

PREGNANCY OUTCOME

Egypt - daily visits to HH when time of expected delivery was near. 80 infants by end of Dec. 17; birth weights missing .

Photocopies of tables and graphs will be distributed.

See Appendix III:

Kenya - 50 - 57 CRSP babies.

4.2% \leq 2.5 kg mean 3.10 kg.
range 2.09 - 4.0 kg

Time of weighing :

w/in 12 hrs 23.8%
w/in 24 hrs 52.4%
w/in 48 hrs 78.6%
w/in 72 hrs 92.9%

Gestation:

By LMP mean = 36 wks range 28 - 42 wks
 \leq 36 wks 48.7%
 \geq 40 wks 7.7%

By Dubowitz \leq 36 wks 14.3%
 \geq 40 wks 22.9%

mean 40 wks range 32 - 42 wks

Discrepancy between these 2 methods.

Lactation:

Kenya 40% Breast fed only
28% Breast fed mostly
32% breast fed and other (mostly cow's milk)
75% feed on demand

XI. IMMUNOLOGY

Egypt- High abnormalities of E-Rosette, transferrin, IgG, IgM indicate repeated infections have occurred.

40

Graphs showed:

- 1) As transferrin increases, morbid. decreases.
- 2) LF immunity correlated w/ todd morbid.
- 3) C₃ of LF correlated w/ todd. morbid.

XII. VALIDITY OF DATA - EGYPT

A. Anthropometry

- 1. 2 physicians each do 2 readings that are recorded monthly in notebooks for checking for outlying values.
- 2. Affected by technicalities of equipment, ie. scales
- 3. Affected by differences in interviewer techniques.

B. Morbidity

- 1. Data collected by 32 jr. physicians.
- 2. Instrument has built-in validity checks.

XIII. APPROACHES TO ANALYSIS OF DATA - EGYPT

A. Morbidity score defined

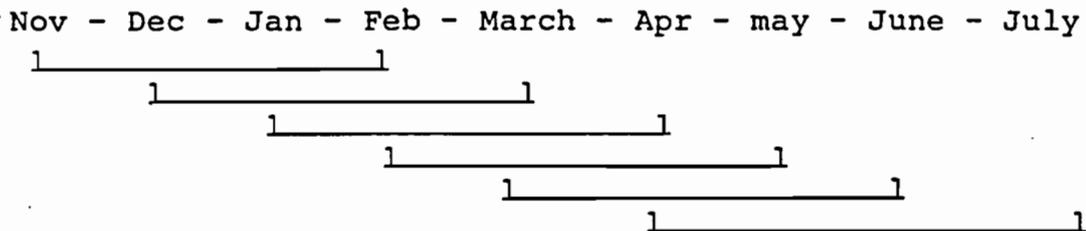
Mild illness = 1

Severe illness = 2

Morbidity score = number of days ill x severity

(See Appendix IV for graphs of correlations of morbidity scores and Anthropometry).

B. Use of moveable time block to create a larger data set.



18 - 21 M. Toddlers

44

Can look at effect of morbidity on monthly, 2-month, 3-month, etc. weight change, wt/ht, ht. change, velocity of growth, absolute wt, etc.

XIV. SUMMARY OF EXITING HOUSEHOLDS - EGYPT

See Appendix v for summary table.

XV. DISCUSSION OF ANALYSIS:

Analysis may need to be done in a time - sequence manner. Important to know the meaning and the reasonableness of factors before committing to a scale for analysis.

The following topics were suggested for discussion with George Beaton:

1. Look at Food Intake methods and discuss how to evaluate the status of the data .
2. Examine Anthropometry over time and see how KCal/Kg relate to this.
3. An analysis procedure if Food Intake were at ideal, and at the real.
4. Consumer Unit.

XVI. INTRODUCTION OF GEORGE BEATON AND FOOD INTAKE DISCUSSION

Food Intake measurement is an estimate to use as a real value. As the independant variable it is the most critical variable in the design. Remove as much of inter-individual variability as possible.

All manipulations have an impact on analysis; i.e. using KCal/Kg or KCal/cm. The strategy depends on the exact question being asked.

4/21

XVII. DESCRIPTION OF FOOD INTAKE DATA

A. Mexico - 3 days/month

1. Weekly food expenditure -

Lead female is asked variety and quantity of food purchased during the past week. This method avoids loss of food information if some item is eaten only once a week.

2. H.H. and Individual food intake -

a. Pilot study was done to compare 24-hour observation and recall method.

b. Because large amounts of tortillas consumed (often 15/meal) caused large error in reporting, a method was devised for individuals to keep track of their own consumption with circles of paper. Now range of error approximately 5 - 15% of KCal.

c. Weighing and recall method used with a schooler usually reporting for the entire HH. Recall taken after main meal to get more complete information.

d. Toddlers and schoolers eat small amount outside HH which is not accounted for. If toddler eats from adult's plate, most is missed.

B. Kenya - 2 days/month on rotating days

1. Data collector at HH from 7:30 am. - 5 pm. Weighs & observes individual intakes, recipes, preparations for meals. Breakfast gotten by recall. HH. marks on plastic bowls to indicate amount of food eaten by individuals.

2. Lead males don't get much weighed data. Most is recall from LM or LF. Schoolers are away 1/2 day so recall food eaten away from HH.
LM alcohol consumption not recorded.

3. Validation trial: 7 continuous days of observation & weighing followed by a different team doing recall. Rejected recall method.

C. Egypt - 2 days/mon. 24 hr recall of food eaten the day before and sample weighing.

1. Dietitians spend 1 - 2 hrs at HH (max. tolerated) for recall. Leftovers from HH food consumption are subtracted. No record of food eaten outside HH and gotten outside HH.
2. LF responds for herself, Toddler, LM (unless present) and schooler (unless present) about meals eaten at home or food taken from home to eat outside.

To determine amount eaten, recipe of mixed dish is gotten, LF reports amount eaten by each person, then grams eaten calculated.

3. Validation:

December '84 validation study for current CRSP method (24 hr recall & sample weighing), observation+weighing, short recall + weighing. Observation done by HH member, short recall by dietitian, 24 hr recall by second dietit.

PLAN: do 5% subsample every month w/ short recall method for validation.

D. Validation Discussion:

1. G. Beaton: This project involves much methodology development which needs validation that can be published to validate our data for other scientists.
2. Since 3 methods will continue, need more validation.

E. Toddler snacking:

Egypt snacking is mostly vegetables, mothers reported sugar and water drinks.

Kenya No problem due to all day observation & isolated location of the houses.

Mexico gets snacks when playing in village and sitting with parents. Kcal gotten by careful questioning when possible.

XVIII. HH FOOD INTAKE

A. Definition

- 1. Egypt - all items of food consumed by HH. members within the HH premises or outside house if taken from HH resources. Food eaten by guests or animals is subtracted.
- 2. Mexico - recipes (corrected for leftovers) + other food eaten by all attendees at meals + foods carried out of HH and eaten - food eaten by visitors.
- 3. Kenya - HH foods consumed by targets and non-targets + snacks and non-HH foods - HH foods consumed by guests.

B. Use of Food Intake Data

See Appendix ^{VI} for summary of use of F.I. data in relation to hypothesis 2A.

XIX. DESCRIPTION OF RMR DATA

A. Kenya - now doing third round of testing :

	<u>Kcal/day</u>	<u>Kcal/kg</u>	<u>Kcal/m²</u>	<u>RQ</u>
LM	1099	20	689	.844
LF	1012	20	689	.845
SM	614	30	758	.845
SF	548	28	688	.872

Values are 70-80% of predicted
10-20% variation on same individual for 2 consecutive days.

B. Egypt

On first 100 subjects tested:

Values are 80-90% of predicted
75% are below predicted + 25% above

XX. USING ANTHROPOMETRY DATA USEFULLY

Relating to hypothesis 2A.

A. See Appendix VII for outline.

B. Summary:

1. Interpolation preferable to extrapolation to replace a point.
2. Should be done at time of analysis.
3. Method used depends on circumstances.
4. Each time used, document procedure.
5. Age of subject is important consideration.

C. Agreement on range of Z-scores for presenting population to the EEP :

Use 0.5 units for T and S.

D. Research goal (outside CRSP):

Day-to-day fluctuation in weight on a random sample of a population same as the study population. This would be an important documentation for the literature.

XXII. USING MORBIDITY DATA

A. See Appendix VIII for outline.

B. For analysis use 1) independent variable, 2) dependent variables (except immunology), 3) intervening variables that appear on food intake, census, anthropometry and morbidity instruments only. This would be minimum analysis for February with more variables added as countries' data will support.

XXIII. LABORATORY QUALITY CONTROL

A. Kenya Daily QC procedures such as: standard curves, internal standards.

4/6

Blood sent to Nairobi weekly
Duplicate E-Rosettes run by external lab.

Egypt Hb : 20% done in duplicate
 Hct : all done in duplicate

 Ferritin : most done in duplicate

XXIV. DISCUSSION OF ANALYSIS OF FOOD SAMPLES

Need to determine number of samples and size of samples needed.

XXV. DISCUSSION OF MORBIDITY SUBROUTINE and request to

M.E. to approve stopping subroutine visit on day 3.

XXVI. SYSTEM FOR FIGURING HH MORBIDITY SCORES:

- A. 1. For each person record severity, incidence, duration by type.
 2. Unit for expressing : average severity/average episode/3 months.
 - a. By illness
 - b. By combining communicable, respiratory, accidents, gastrointestinal, plus other common illnesses.
 3. For HH :
 - a. Add total number of episodes, divide by number in HH.
 - b. Calculate number who were ill/3 months
 - c. Try ratio of number children to number adults in HH.
- B. Also consider:
1. Impact of person's illness on HH.
 2. Toddlers have more illness episodes than adults.

47

XXVII. PURPOSE OF HH FOOD INTAKE

- A. Capture resources available to the HH and how they are distributed within the HH.
- B. Add linkage between our data set and others since others have mainly done HH intake.
- C. Consumer unit will be the lowest common denominator among our projects.

XXVIII. CHILD CARE METHODOLOGY

- A. Egypt Case study done to evaluate methodology.
2 versions done - narrative and frequency until July;
now activity form will cover CC and activity.
Observation time is 10 hrs/3 months
- B. Kenya Mothers give 12 % of time to toddlers
30% of time to infants
Time allotment changes at 18 + 24 months.
- C. Mexico 2 visits / month for LM and LF
Mother/infant interaction is a formal test
Scoring of HH on 30 items by D.C

XXIX. USING PREGNANCY DATA

- A. See Appendix IX for outline.
- B. 1. For analysis need to model a change on a change:
a change of weight for a change of time.
Use reference to see what would be expected.
- 2. Examine how to link a single variable and outcome
when there are multiple variables to affect outcome.
- 3. Analyze: effect of FI on maternal weight gain.
effect of FI on birth wt, gestational age.
- C. Agreement to follow up infants to 6 months past 40 weeks
corrected gestational age... not a rescheduling activities
but extending last measurements to be made at 6 months.

CB

APPENDIX III

(Minutes of the February-March 1985 SCB meeting)

MINUTES
Scientific Coordinating Board
Nutrition CRSP
Berkeley, California
February 25 - March 2, 1985

PRESENT: Drs. Allen, Bwibo, Galal, Harrison, Jerome, Kirksey (Chairman), Neumann, Pelto, Horan (Program Coordinator), Calloway (some sessions only), Beaton (ME), Kahn (USAID), A. Mata (field director, Mexico Project)

February 25th, morning session

The meeting opened with a brief overview by Dr. Horan of the proposed composition of the Data Analysis Group. It is envisioned to consist of the following, for this meeting:

From ME: Drs. Beaton, Selvin, Balderston, Feinberg

From the Mexico Project: Dr. Bert Pelto and Mr. Jeffrey Bachstrand

From the Egypt Project: Dr. Harrison and Dr. Virgil Anderson
(Purdue)

From the Kenya Project: Drs. Coulson and Afifi

For future meetings, the composition of this group will include ME and Project statisticians as well as a PI from each project, and others as needed.

Dr. Steve Feinberg will serve as a statistical consultant to the entire program (projects as well as ME), while Dr. Selvin will work on inter-project analyses (part-time).

A discussion of the agenda for the week was held. The remainder of the morning was devoted to a general update from all projects of project status and activities since the inter-project meeting in Cairo early in January.

Dr. Galal presented an update for the Egypt project. Most of the earlier problems with regard to food intake have been solved, and ongoing validation studies are proceeding. Dr. Beaton is in close touch with the situation. The RMR situation likewise has improved, and there will be few adult targets without at least one measurement. Priority for "catching up" has gone to pregnant women, with other adult targets next. We are just beginning schoolers. Data entry has been moved (as of July 31, 1984) to Al-Ahram Computer Center in Cairo. Data entry is relatively up to date for morbidity, immunology, reproduction, and anthropometry. Food intake and hematology data are now being entered; entry of data on child care has not yet begun.

Initial tapes sent from Al-Ahram to Kansas have proved readable. Data entered in Kansas (data collected until 7/31/84) have all been entered, cleaned and submitted to Berkeley. Dr. Allen inquired about morale of the field staff; Dr. Galal replied that it is good. Data analysis is a new activity, and has shifted the direction of attention. He believes the impact on quality of data still to be collected will be positive, since the interdependence of each area on the others is more clear to all concerned. Kalama is beginning to ask

"What's next?" as some households are exiting.

Drs. Allen and Pelto presented an update from the Mexico project. A recent field reorganization has produced very positive effects. Data collectors (auxiliaries) have been replaced mostly by professionals (nutritionists and others who are post-B.S. level) with auxiliaries as backup. The personal motivation of these professionals is very high, and the community is responding favorably with continuing willingness to participate. The large threatened drop-out which concerned the investigators in December-January has disappeared. Households are feeling better about the attention they are receiving, and are becoming better respondents. Quality control has improved; there has not been time to look at the effect (if any) on the data. Thirteen professionals are now responsible for 20-22 households apiece; they do food intake, sanitary observations, and coordinate all other studies. Auxiliaries now check forms and help with data entry. The missing data situation, especially food intake and anthropometry on schoolers and toddlers, is better than had been previously estimated since most of these children were enrolled in June through September 1984, after many scheduling problems had been resolved. Few households will exit before June 1985. Data entry is still diversified; microcomputers in the field, plus entry at Public Health in Mexico City are continuing. As of right now, data on food intake, morbidity, anthropometry for an entire year are in Connecticut for 50 households. The project anticipates having the data situation relatively up to date and complete for the EEP review. The birthweight situation has also improved, with more than 50% of babies now born in the clinic. The project has data on 100% of infants at 30 days.

Dr. Bwibo summarized the situation in Kenya. There have been major personnel changes in the last six weeks, along with several US visitors and review meetings with senior staff and policy makers in Kenya. Field personnel changes include the field director, the physician, and the anthropologist. The departure of Dr. Carter (the field director) was the occasion for impressive festivities throughout the study area. He was well liked, respected, and great honor was paid to him on his departure. The food shortage situation has eased somewhat, and appreciation of the role of the CRSP in helping to define and alleviate the shortages has resulted in great loyalty to the project. People are now asking "What can we do for the CRSP?" Dropouts are almost zero, and households are asking to be in the study and reluctant to exit after their time is completed. Data flow from the field to Nairobi and UCLA is in good shape, and caught up through December 1984. Review meetings in Kenya have included an assessment of potential uses of the CRSP data by policy-makers. The project has begun a new time-allocation study method, and is validating an agriculture/seed/crop questionnaire with observation. Food aid has stemmed the potential severe malnutrition, has saved lives, and is well documented by the CRSP. Later intervention is now a big issue for discussion. The Department of Community Health in Nairobi is beginning to get involved in data analysis and has a good microcomputer system.

February 25th, afternoon session

The upcoming EEP meeting was discussed at some length. It was scheduled for April 29 - May 4 in Mexico. After discussion, it was decided to move the dates to April 27 - May 2, with a visit to the field site included. ME will pay the expenses for EEP members, ME representatives and one PI per project. Other PI's may attend at project expense. We should in this meeting decide who should attend from the statistics group.

The issue of missing data was reviewed both on a general basis and specifically with regard to each type of data on a project-by-project basis.

Dr. Peltó pointed out that there are several types of "missing" data, each with different implications for analysis. There are missing targets (e.g., Lead Male), missing variables (e.g., Dubowitz exam), and missing observations in a longitudinal series (e.g., food intake, anthropometry). Dr. Harrison stated that it may be useful to examine each variable in terms of the percentage of individuals (by target type) who have too much missing data on a variable to use that variable on that person. Dr. Galal asked whether we can then look at a "slice" of 3 or 4 months of data to see if this approach works.

A discussion of cognitive issues followed. Mexico has added additional mother-child observations in accord with various recommendations, including the EEP's. IT WAS decided that Dr. Neumann should approach Dr. Marion Sigman again about generating a background document for the EEP which would summarize the state of comparability of measurements across projects. (Note: Dr. Sigman agreed). Dr. Horan is to ask Dr. Wachs to generate a clear summary of measures, variables, and analytical strategies for the cognitive measures.

February 26th, morning session

The missing data summary and update continued. A summary table, still in need of more updating and commentary, was completed and circulated. A more detailed version will be included with the documentation sent to the EEP members in advance of their meeting.

Dr. Horan put forth a "rule of thumb" he has used to evaluate missing data, in which less than 5% missing is no problem, less than 10% low, 10-30% serious, 30-50% "grave", and more than 50% "hopeless". Dr. Coulson (who had joined the meeting) agreed in general, but pointed out that these numbers must be viewed in relation to the hypotheses. For example, much of the missing data is in Lead Males, who are not crucial to testing most of the hypotheses of the CRSP. In addition, it is necessary to take into account how much missing data, and in what patterns, can be tolerated for each measure.

Dr. Allen pointed out that it may be valuable to look at total numbers of subjects as well as, or instead of, percentages. A higher percentage of missing data can be tolerated for those targets for which projects have a number of subjects which exceeds that required (e.g., lead males are in excess of 150% of that required).

Dr. Pelto pointed out that projects should distinguish between data which are irretrievably missing and those for which an anticipated "catching up" will occur.

The Egypt project presented plans to enroll some additional pregnant women from households already enrolled because of the presence of a toddler, and to collect on those pregnant women data on weight gain, food intake, RMR, morbidity, and hematology/immunology. In addition, the total number of planned observations on child care will be collected even though they will be more frequent than originally scheduled to make up for a late start in this aspect. The Egypt project will implement a system of evaluating each household at 10 months into data collection to assess the missing data situation and plan for remediation when possible, in order to compress the time needed to complete information. Assessment criteria at 10 months will include % of data collected out of sequence, % missing data that can be estimated, % missing data which are irretrievable; and % of beginning (entry) information missing. These criteria, along with a criterion of acceptable % missing in each area, will be used to decide when to actually discharge a household from study.

Dr. Feinberg joined the group, and the discussion continued on how to devise criteria for tolerable limits of missing data. He mentioned the need to think about future analyses, and to document the criteria and decisions for handling missing data clearly and thoroughly.

February 26th, afternoon session

The SCB met with Drs. Calloway, Beaton, Horan, and Fienberg. Drs. Fienberg and Calloway were briefly updated on the deliberations of the SCB about missing data. Plans for Wednesday's meeting with the Data Analysis Group were reviewed.

Dr. Horan pointed out that the presentations to the DAG can form the basis for a briefing document to the EEP, with supplementary analyses and information. This document should also include a statement about "where each project is" - and needs to be in Berkeley by March 29th. Dr. Feinberg felt that what the EEP wants at the end of April is unrealistic; Dr. Beaton agreed but felt that this should not be overstated. Dr. Feinberg clarified that he meant that immutable models would be a mistake at this juncture; what is needed is a set of rational statements about where we are now, what are current plans for accomplishing analysis, and how the data fit that plan so far. Dr. Feinberg further defined his own role as consultant, as including a) initiating contacts among prospective project statisticians; b) helping at this and other meetings in discussions; and c) can respond to the need for a set of draft models, given some time and information; and d) will be available as help to all projects when possible - feel free to call him directly.

Dr. Calloway reviewed the AID draft response to the proposed reorganization of the CRSP; in general the response was favorable. AID did take exception to the proposal that ME relinquish its role as a voting member of SCB; Dr. Calloway designated Dr. Beaton to represent her in that role in her absence.

A proposed change in the RMR protocol was presented by Dr. Neumann. The proposal has been made by Dr. Gardner, who is serving as consultant in this area to both the Kenya and the Egypt projects. At present projects are reporting data from the last three minutes of each of the 2nd and 3rd of three consecutive 10-minute periods. Dr. Gardner now feels that the first two 10-minute periods are more representative of a steady state than the last minutes of the last period. This change would affect only Egypt and Kenya, since in Mexico the methodology is not comparable to begin with. Dr. Beaton suggested that we examine the data so far to ascertain whether there is consistency in where the lowest values occur. Both Egypt and Kenya will do this in the next few weeks. In the meantime, the previous methodology should be maintained.

The illness subroutine was discussed. The Kenya and Egypt projects are having difficulty carrying it out as agreed. Mexico has been able to complete it, and has roughly 90 subroutines completed. Dr. Neumann indicated that the Kenya project believes the necessity to invoke the subroutine, and the attendant extra work, may be biasing the morbidity recall data in the direction of underestimating the severity of illness. Dr. Harrison indicated that the Egypt project has very incomplete data from the subroutine both because of the logistical problems of scheduling the subroutine and because of the resistance of some families to have such continuing, frequent attention to an ill member. Dr. Beaton pointed out that since much of the toddler data have already been collected, both Kenya and Egypt will have substantial missing data even if the problem could be rectified at this point. Dr. Calloway mentioned that the questions which the morbidity subroutine was designed to answer remain important ones. The question was raised as to whether the Mexican data have been sufficiently analyzed to tell us whether the subroutine will answer those questions; the Mexican PI's indicated that those data are not yet in readily analyzeable form. It was decided that all projects will take a hard look at the underlying questions which the subroutine was designed to answer, and propose how they will attack these questions.

Dr. Jerome brought up the issue of digestibility trials for composite diets from the projects. The Egypt project submitted a protocol for sample collection for this purpose in September, but has not heard from Management as to a decision. Dr. Calloway responded that it was decided that digestibility trials are costly and are not now a budgeted item. (Note: It would be desirable to prepare cocuposites and retain for future consideration as funding permits).

The previous proposal to submit samples of composite diets and specific foods to the Atomic Energy Commission laboratory for trace element analysis was also raised once again. This notion made sense when we were thinking of making composite diets for digestibility trials; it will impose too much of a logistic load if we are not collecting those samples for other purposes.

Dr. Neuman mentioned that the Kenya project still has some problems with food composition analysis. Dr. Calloway offered her assistance in working out the specifics.

Dr. Jerome asked whether the issue of consumer units for calculation of household food intake had been settled or was still open. The "Basic Variables List" gives several possible methods. The matter has been discussed at length in the Cairo meeting in January and projects elected to use RMR calculated from the weight and height for each type of person in the community, using the formulas from the new revision of the FAO/WHO materials as distributed previously by Dr. Beaton in manuscript form and re-distributed (attached) from the printed volume. Equations are still needed for estimating RMR for children under 10 years of age; the last edition of the WHO protein-energy handbook will be used. ME will take responsibility for sending all projects a short memo with relevant information and formulae for children. Dr. Calloway also volunteered to write out a short summary of the protocol for calculating consumer units.

February 26th, afternoon session

The SCB met with Drs. Calloway, Beaton and Horan. The afternoon was devoted to discussions of budgeting for the remainder of the CRSP project.

February 27th, all day

The SCB met with the Data Analysis Group.* Each project described its field site, administrative arrangements and data collection logistics, and methodology relative to food intake, anthropometry and morbidity. Preliminary data were presented by each project on toddler anthropometry, food intake, morbidity, and socioeconomic status/community description, in order to familiarize all of the statistical consultants with the structure, similarities and differences in these data across projects.

February 28th, afternoon

The PI's met once again with the Data Analysis Group, Dr. Feinberg. described the deliberations and conclusions of that group, which had met all morning. They considered the nature of the data set, the magnitude of data management needs, the timetable imposed by the EEP as well as the danger of waiting until the end of the project to analyze data. They concluded that data analysis should be done by each project. Berkeley can serve as a catalyst, in an arrangement involving expansion of statistical activity in each site, an expanded statistical group, with Berkeley serving a coordination role, was agreed upon.

The DAG recommends that each project will require a full-time middle-level statistician, plus at least a month/year time of a senior statistician to oversee analysis, plus commitment for several inter-project meetings/year.

*minutes of the meetings of statisticians will be provided separately.

A "statistical agenda" was agreed upon, to include attention to: 1) data management; 2) data quality; 3) putting forth a "template" for the presentation of explanatory variables; 4) selection of provisional common variables for analysis; 5) development of provisional model equations prior to the EEP meeting; and 6) consideration of a schedule for statistical analysis, and the resources required. These events will take place over roughly six months. By that time, we should have a full set of cross-tabulations, from each project, a selected set of analytical equations, and an agreed-upon common structure for analysis - all circulated and discussed. The process will be interactive among project statisticians and PI's. An inter-project meeting of Statisticians and PI's about the end of September will be required to consider progress, reappraise plans, and flesh out the analysis agenda.

Later in the afternoon the SCB met with Dr. Calloway, and considered specifics of the upcoming EEP meeting. It was decided that the dates will be Saturday, April 27 through Tuesday April 30th. All participants will plan to arrive in Mexico City by Friday evening, 4/26, and can plan to be back in Mexico City by Tuesday evening. Prepare for cold, and rain. A visit to the field site will be arranged if possible, and the meeting will be held in a suitable location near the field site.

Attendants at the EEP meeting will include (besides those members of the EEP who are able to attend), Drs. Calloway, Beaton and Horan from Management, Drs. Feinberg and Afifi from the statistics group, Dr. Kahn and perhaps Dr. Forman from USAID, and at least one PI from each project.

Background documents to be circulated to the EEP ahead of time should include a status report on each project's field situation; an updated and detailed report on the missing data situation; and an update on analysis plans and activities.

March 1st, morning session

The PI's met with the Institutional Council for a general discussion of budget. The budgetary implications of the statistical group's recommendations were discussed. At the direction of the IC, the PI's met separately to discuss the issue of immunology. A detailed discussion of the immunological variables was held, and the following decisions were reached:

The following assays will be kept by all projects, in the order of priority listed.

1. Skin tests
T cells (total lymphocytes; % T lymphocytes)
2. Ferritin
3. Salivary secretory IgA, "ordinary" IgG
Breast milk lysozyme and secretory immunoglobulins
(earlier samples have priority over later ones)
Serum transferrin, C-reactive protein, prealbumin

The following assays will be dropped, unless reagents have already been purchased.

Albumin, C₃, serum IgA, IgM, IgG

It was estimated and communicated to the IC, that the above decisions would result in a savings of approximately \$10,000/project.

Also at the request of the IC, each project reviewed its "non-core" activities. At the present time these are so few and trivial in cost as to represent only a few hundred dollars among all three projects. No action was taken, except to reiterate that all projects should document any non-core (even no-cost) activities.

March 1st, afternoon session

The SCB met once again with the data analysis group. The DAG, meeting in the morning, came to the decision that data management should continue pretty much as it is, with Berkeley continuing to serve a coordinating and archiving function. A future meeting of data managers was proposed. Berkeley was urged to provide a clearing house of items to be shared such as data quality checking procedures, especially protocols for documenting household entry and change of status. The group proposes that a complete data record for each household should go back to the field, while data gathering is still active - near the exit time for each household - for checking and quality control proposes.

SAS will continue to be the main data management system, although projects are free to use other systems for special analyses.

Agreement was reached that analytical exercises for the EEP meeting would use the first six months of data, focusing primarily on toddlers, and a selected set of variables to include:

- I. Morbidity
 - A. Duration (total days ill)
 - B. Average duration (total days) of illness
 - C. Number of illness episodes, and severity

- II. Food Intake
 - A. Kcal/day (3-month average)
 - B. Kcal/kg/day

- III. Anthropometry
 - A. Weight for age (and change in wt/age)
 - B. Height for age (and change in height)
 - C. Weight for height (and change in wt/ht)

All of these variables will be described by each project in terms of mean, median, skewness, and range. Dr. Selvin will send all projects specific instructions for how to prepare these descriptions.

Intervening variables (SES, sanitation, and household morbidity) will be more project-specific. The Mexico project will write out what they have done with SES, and each project will derive its own variables. All will try to capture level of education/literacy in the family, and size

of the household. Household morbidity will include a measure of summation of individual morbidity scores in the household, adjusted for the number of persons in the household.

The statistical group will produce a document summarizing their activities and the plans for the next six months.

An agenda for production of simple analysis of the above variables (histograms, components of variance, seasonal effects, day/week effects, bivariate plots, etc.) was presented by Drs. Afifi and Anderson. Dr. Fienberg presented three analytical models which each project will attempt to produce in parallel analysis. Dr. Selvin will, within the next week or so, generate preliminary analyses in SAS for presentation in the report for the EEP.

Drs. Feinberg and Selvin are available for consultation from project statisticians (Feinberg: 415 321-2052; Selvin: 415 642-4618)

March 2nd, morning session

The SCB met with Drs. Horan, Beaton and Calloway. Drs. Harrison and Allen were elected SCB Chair and Vice-Chair for the next year. They are free to exchange these responsibilities for periods of time due to travel, availability etc. with notice to Management.

Decisions of the IC with regard to budget were discussed. All projects are to submit revised budgets, in accordance with these decisions, along with impact statements, as soon as possible. Projects are reminded that period IV is 12 months, V is 11 months (to August 31, 1986) and VI is 12 months. The budget cut designated to ME will not be allocated until later, based on need within the projects. Informal budgets can be submitted while formal ones are going through signatures, if necessary. Any comments on the ME budget are welcome; send to Dr. Calloway or Dr. Edwards.

Attempts to seek additional (non-USAID) funding were discussed briefly. SCB should review all such attempts.

Preparation for the EEP meeting was discussed. The statistical group will report on the cross-project analyses. Each project must prepare an update on missing data and we need to agree on characterization of all major variables. Drs. Neumann and Pelto will continue to revise a suggested format for missing data presentation, and leave with Dr. Horan who will get it out to all projects this week. Each project should also develop a section on quality control for all procedures.

Dr. Neumann initiated a discussion of the Dubowitz exam timing, in light of new information about its utility after the first two days. It was decided that if the exam is missed in the first two days, it should still be performed up to seven days, but the timing documented.

The issue of school-age children not in school was raised by Dr. Horan. All projects for which this is a problem are providing comparable measures for these children.

Dr. Allen indicated that the Mexico project wants to be on record as worried about potential negative consequences from the budget cuts mandated by the IC. Ultimate outcome cannot be predicted at this time.

ggh
3/85

ATTACHMENT "A"

SCB Minutes, February 25 and 26, 1985

Estimates of missing or incomplete data, with comments, as supplied for each project by its PIs.

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
E	Census	HH	Almost 0	Almost 0	Update at 6-9 months
K	Census	HH	5	5	Done every 3 months
M	Census	HH	0	0	Update every 4 months although on-going process.
E	SES	HH	Almost 0	Almost 0	
K	SES	HH	3-5	2	
M	SES	HH	0 1st round 40 2nd round	0 0	
E	RMR	M and F	100 Jan - Oct 10 Oct - Feb		Started in October, all subjects and are now doing second round. Will have at least one RMR on 90% M in study.
		S	80	?	P and L have priority, 70% at least one measure? RMR on 70% S once in study.
K	RMR	M F S PL	30 20 30-35 ≤20	30 20 30 ≤20	Done each 3-4 months. Needs checking. (Probably missing data is on different persons each time.)
M	RMR	M F S PL	30 10 100 5-10	30 10 10(done once) 5-10	Started in May, 1984. Is BMR. Every 3 months. Max-Plancks. Hope one round for S in June.
E	Fd IN	HH F M S T I	6-12 10 30-40 20 10 10	6-12 10 30-40 20 10 10	Up to 18-24 months a substantial number toddlers still breast-feeding to some extent.

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
K	Fd IN	HH	5	5	May improve. Few T breast-fed at all at 18 months, and probably do not consume too much.
		F	5	5	
		M	30	30	
		T	5	5	
		S	15	15	
		I	5	5	
M	Fd IN	HH	5-10	5-10	HH food intake data will probably be of better quality after August '84 when forms revised. Breast milk intake negligible at 18 months.
		F	5-10	5-10	
		M	30-40	30-40	
		T	5-10	5-10	
		S	5-10	5-10	
		I	5-10	5-10	
E	Anthrop	HH	1	1	For weight For weight Almost all have at least once/3 months; 25% not complete in any month.
		F	5	5	
		M	15	15	
		T	25	25	
E	Anthrop	S	15-30	20	When school is out, (6 mo/yr), 15%, and school is in, (6 mo/yr) 30%
		I	15-20	15-20	
M	Anthrop	HH	100	5	Will be done as HH leave study. Adult M and NPF all done every 3 months. PL, T, S, I weight done every month, all other measures every 3 months.
		M	30	30	
		F	5	5	
		PL	5	5	
		T	5	5	
		S	5	5	
		I	5	5	
K	Anthrop	HH	5-10	5-10	Done monthly Done monthly Done monthly Done monthly Done monthly
		M	30	30	
		F	5-10	5-10	
		T	5-10	5-10	
		I	5-10	5-10	
		S	20	20	
E	Morbidity	HH non-target	<10	<10	Prevalence, not duration.
		M	20	20	
		F	<10	<10	
		T	<10	<10	
		I	<10	<10	
		S	<10	<10	
M	Morbidity	HH	0	0	In the case of absent males, validity of F comments doubtful.
		M	40	40	
		F	8-10	8-10	
		T	8-10	8-10	
		I	8-10	8-10	
		S	8-10	8-10	

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
K	Morbidity	HH non-target	5	5	Just prevalence, not duration.
		M,F,T I,S	5	5	
E	Morbidity Subroutine				"Is almost dropped"
K	Morbidity Subroutine				Sporadic. Intend to do it better for serious illness with intervention, but weighed once/week.
M	Morbidity Subroutine				Discuss Wednesday
E	Physical exam	All targets	0	0	Initial and every 6 months. Chronic disease data - <1% missing on targets at initial exams but is not a separate question.
M	Physical exam	M	30	30	Done every 3 months with RMR. Includes chronic disease update on targets.
		F, T, I, S	5	5	
K	Physical exam	M	30	30	Initial and every 6 months. 5% will have no data. Have chronic disease update every 4 months at HH level.
		F	15	15	
		S	30	30	
		T	15	15	
E	Hearing	M, F	50	0	Once, each adult Once each
		S	50	0	
		T	50	0	
E	Vision	M, F,	50	0	Problem is scheduling at late development of test.
		S	50	0	
		T	90	25	
M	Hearing	M, F S, T	100	0?	Plan to start "almost immediately." Not sure if we have started yet but are prepared.
M	Vision	M,F, S,T	100	0?	

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
K	Hearing	M,	30	30	Most have more than one test.
		F	15	15	
		S	30	30	Toddlers done by cognitive team at 24 and 30 months. Will have 2 measures on toddlers.
		T	5	5	
K	Vision	M	30	30	Most have more than one test.
		F	15	15	
		S	30	30	Done by cognitive team at 24 and 30 months.
		T	5	5	
E	Cognitive	M	61	5	*The "% now" refers to period Jan-Dec, 1984, and represents 110/175 toddlers and at 18 months mostly. There are expected to be far fewer missing at 24 months from now on and the N with complete data at 18 months is in any case sufficient.
		F	29	5	
		T	38	*	
		S	10	*	
		I	Very few	Very few	
M	Cognitive	M	15-20	5	"Missing now" were families entered late. Missing 100% of second round but this is about to start now. Schoolyard observations about 40% missing first round; second round starting. Teacher ratings in process. For exactly 18 months, out of 112 toddlers. Have practically 100% done at 18-21 months. At 24 and 30 months only 5-10% missing.
		F	15-20	5	
		S	5	5	
		T	30-40 at 18 months 5 at 18-24 mos.	20-25	
K	Cognitive	I	5-10	5-10	Essentially finished " " " " " " Finished 18 and 24 months. " " " " "
		M	5	5	
		F	5	5	
		S	5	5	
		T	5	5	
I	5	5			

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
E	Hematology	M	30	30	Out of N = 175; sample quota met.
		F	25	25	
		P	15-20	15-20	
		T	17	17	
		S	27	27	
M	Hematology	M	100	?	Pregnant women started Dec 1984 and done routinely at 5 and 8 months. Hope in March to get one sample in all targets.
		F	100	?	
		P	10	10	
		T	100	?	
		S	100	?	
K	Hematology	M	40	40	These are probably over-estimates (i.e. the situation is better than this). Also people are giving more willingly now.
		F	20	20	
		P	20	20	
		T	35-40	25	
		S	35-40	25	
E	Immunology (blood)	M	50	< 50	M(97) F(82) P(70) S(17) T(3): This is the number of samples taken. Again sample size of 100 will be exceeded for M, F, P groups. Schoolers run away. May be difficult to get a second sample - #s here are once.
		F	15-20	15	
		P	30	20	
		T	?	?	
		S	80	80	
K	Immunology (blood)	M	40	40	Same samples as for hematology, although hematology has priority so % missing might be slightly higher than this for immunology.
		F	20	20	
		P	20	20	
		T	35-40	25	
		S	35-40	25	
M	Immunology (blood)				Plan is to do skin tests with Trichophyton and Candida on all targets in March 1985. At this type a venous sample will be drawn and hopefully all immunology will be done once on all targets.
E	Saliva	Targets	?	?	No estimate of missing data but "all targets give saliva willingly": Samples stored but analyzed since start Phase 2.

65

Country	Variable	HH or Individual Type	Missing Percent Now	% Predicted	Comments
E	Milk	L	15	15	
M	Saliva	M	30*	30	*Started Jan 85, done every 3 months. Plan 3 measures on all targets by end of study.
	Milk	L	?	?	Started Jan 85. Colostrum only if birth is in clinic (50%).
K	Saliva	M	5-10		Started early 1984.
		F	5-10		
		T	5-10		
		S	5-10		
K	Milk	L	Low		"No problem."
E	Parasites	Targets	18	18	Two rounds completed. 18% households refused.
M	Parasites	Targets	5-10?	5-10	Several rounds completed. Done every 3 months.
K	Parasites	M	40	40	Almost everyone has at least one examination.
		F	30	30	
		S	40	40	
		T	30	30	

APPENDIX IV

(Minutes of the February-March 1985 IC/Finance Group meeting)

INSTITUTIONAL COUNCIL MINUTES

The Institutional Council (IC) met for two days, February 28 and March 1, 1985. Morning meetings on both days were joint sessions with country project principal investigators, afternoon sessions were IC only. Attachment I is a list of attendees.

Dr. Calloway joined the group for the first part of the meeting in order to reiterate certain budget considerations that have been of continuing concern in fiscal planning for the CRSP and to receive questions on behalf of Management Entity. She particularly emphasized that AID had consistently stated that it planned no additional funding for the project, that the budget cuts agreed to by the country projects at the May 1984 meeting of the Institutional Council had not been fully met, and that adequate reserves had not been identified in project budgets to cover data analysis costs and certain problem areas of field costs. In response to questions regarding publication costs for final reports, Dr. Calloway stated that country projects should budget for final reports of their projects which would satisfy grant requirements and that ME would budget for production of final monograph.

At the opening session principal investigators were asked to describe their project status with special emphasis on cost items particular to their work and to respond to certain budget cuts proposed by Management and outlined in Dr. Horan's memo of February 25, 1985. (Attachment II).

The Kenya Project reported plans to be out of the field by the end of the year with principal wind down in November and a close down operation of two additional months with 1 or 2 persons remaining in the field during that time. It was estimated that approximately \$98K of proposed cuts could be met and would principally involve cutting down to a skeleton staff in the field and streamlining the exit from the field to coincide as closely as possible to the end of the field study itself.

According to Dr. Neumann, higher than ordinary costs in the Kenya Project were due to a large proportion of UCLA staff filling field positions, the high cost of benefit packages and high salary scale at UCLA. These costs were deemed necessary by the Kenya Project because of institutional policies and unavailability of host country personnel in those staff categories offered under CRSP.

The Egypt Project reported that study households are beginning to be phased out and there will be gradual wind down of field efforts. Items of particular budgetary importance were the reduction of actual field coordinator costs over those planned in May 1984 budget and extensive financial support from the Nutrition Institute in the form of support services, use of vehicles, office space and equipment use. It was stressed that the end of CRSP funding would not be the termination of activities in many areas that would continue as programs under the Institute. It was further noted that the Egypt Project necessarily bears an additional burden in the support of operations at three U.S. institutions compared to one for other CRSP components.

In responding to cuts suggested by M.E., Dr. Harrison stated that cuts could involve a change in research scope. Dr. Jerome agreed that cuts would also change scope at Kansas, but expressed some hope that some data costs can be absorbed by the institution although they must be shown in the budget as AID costs at this time.

It was mentioned, too, that a transfer of data analysis location within Egypt Project might be made and, if so, would involve at least internal budget adjustment. It was not stated whether such a change would likely increase or decrease the overall Egypt budget, although the concern that analysis costs might be seriously underrepresented in the present Egypt budget was raised many times by the Purdue IC representative and he expressed the opinion that the overrun presently shown in the overall Egypt budget was due largely to data management costs.

The Mexico Project reported that it will begin to phase out of the field in July 1985 and that the field study would be largely concluded by the end of the year. It was reported that sizeable budget allocations have been made at the host country institution in order to deemphasize the U.S. presence and to realize certain budgetary advantages. By contrast the U.S. budget has been very tight and strict economies realized from the first. The Mexico Project strongly urged recognition that any present savings were due to forward planning and early budget cutbacks in order to prepare for the necessary expenses in future budget periods.

Proposed cuts in the M.E. budget as stated in Attachment II were acknowledged as feasible by the Program Coordinator and a broad ranking of budget areas where M.E. could make cuts was identified as follows: 1) personnel, 2) computer costs, 3) travel costs.

Questions concerning the adequacy of budget levels for analysis costs were repeatedly introduced into the discussion. There was great uncertainty expressed about present abilities to estimate adequately what these statistical costs would be. In this regard, Dr. Thomas emphasized that decisions being made concurrently in the Data Advisory Group (DAG) would most certainly have significant budget implications. He estimated that following on the meetings in Berkeley, Purdue could provide a revised budget estimate for analysis costs within a couple of weeks and that decisions taken before then would be premature.

The Mexico Project reported that rebudgeting from other categories had resulted in an additional \$90K for analysis costs since their last budget submission.

An informal report of requirements already identified by the DAG were as follows: each project to have one senior-level statistician whose services would be available for at least one month and a more junior-level statistical associate who would be available for 100% time; Management Entity to provide consultation as required with staffing at present level; final decisions regarding analysis structure to be implemented by June 1985.

Dr. Calloway stated that if there were to be a change in Berkeley's obligation to make an interproject comparative analysis, it could only be made with AID concurrence.

Although the IC recognized that current developments regarding data analysis, and decisions to be made about them, could have made budgetary impact the IC felt, nevertheless, that its charter required that it develop budgetary recommendations even though they might have to be reconsidered later.

All country projects expressed the intention to conclude field operations as promptly as possible in light of limited funds. It was noted that a quick pull out of field staff would greatly increase the administrative burden and workload for the staff with a concomitant loss of time for debriefing the workers before teams are disbanded. One P.I. thought that at least two projects would welcome an extension of field time to fill in gaps in the data. It was her opinion that field costs would not necessarily be significantly higher than costs for the follow-on period and were not therefore such a serious budget question in some projects as they might be in others.

Attachment III is a summary of the budgets submitted by the projects and M.E. The budgets reflect an overrun of \$460,575. The IC wrestled with several alternatives in dealing with the overrun. Two of these alternatives which were rejected were to recommend that AID be asked for more money or to make no recommendation until the impact of data analysis decisions was known.

Several of the IC members expressed frustration because they felt that they had not been provided with enough hard information and analysis to enable them to evaluate the details of the budgets presented and to make specific recommendations based on such an evaluation of the contents of the budgets. Instead the IC had to develop general recommendations based upon impressions received during discussions with the P.I.'s, M.E. recommendations (Attachment II) and comments of the program coordinator. In the case of the Mexico project the amount of the reduction recommended was set to be in parity with cuts recommended in the other budgets and the belief that the devaluation of the Peso was not sufficiently reflected in the Mexico budget. In addition the group noted that \$120,000 was budgeted for per diem for Mexican field workers during the period October 1, 1984 - August 31, 1986. This large amount seemed questionable (unfortunately this was not noted until late Friday afternoon and there was no opportunity to question the P.I. about it.)

The IC finally decided upon the following recommendations:

1. That revised budgets be submitted by the CRSP combined with the following reductions from the budgets presented to the IC for review:

Egypt	\$102,000
Kenya	\$ 98,000
Mexico	\$100,000
Management Entity -	\$103,000

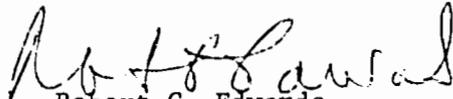
Until these revised budgets (periods IV - VI) are received it is further recommended that Management Entity reduce budetary allocations for period IV up to these amounts at its discretion.

2. That P.I.'s should be asked to prepare impact statements at a result of these budget cuts.

3. That AID approval be sought to transfer funds from the Management Entity to project budgets.

4. That AID be requested to drop the requirements for a final overseas audit and a final EEP evaluation.

Dr. Hudson and Dr. Mare were not present to vote on the recommendations and Dr. Thomas voted against the first recommendation. He was requested to submit a minority opinion for the record which has been received and a copy is appended hereto as Attachment IV.


Robert C. Edwards
Assistant Manager

ATTACHMENT I

Attendees were as follows:

Robert Edwards, IC Chair (UC Berkeley)
Philip Costic, IC representative - Kenya Project (UCLA)
Billie Hudson, IC representative - Egypt Project (Kansas)
C. John Mare, IC representative - Egypt Project (Arizona)
D. Woods Thomas, IC representative - Egypt Project (Purdue)
Alexandra Van Gelder, IC representative - Mexico Project (Univ. of Conn)
Lindsay Allen, Principal Investigator - Mexico Project (Univ. of Conn)
Nimrod Bwibo, Principal Investigator - Kenya Project (Univ. of Nairobi)
Osman Galal, Principal Investigator - Egypt Project (Ministry of Health, Cairo)
Gail Harrison, Principal Investigator - Egypt Project (Arizona)
Norge Jerome, Principal Investigator - Egypt Project (Kansas)
Avanelle Kirksey, Principal Investigator - Egypt Project (Purdue)
Charlotte Neumann, Principal Investigator - Kenya Project (UCLA)
Cretel Pelto, Principal Investigator - Mexico Project (Univ. of Conn)
Dorris Calloway, Program Administrator - Management Entity
Hugh Horan, Program Coordinator, Berkeley
Samuel Kahn, Program Officer, USAID
Katherine Condon, Business Manager, Berkeley

APPENDIX V

(Minutes of the February-March 1985 formative meeting
of the "D.A.G." - Data Analysis Group)

Minutes of the Meetings of the Data Analysis Group
Nutrition CRSP
February 27 through March 1, 1985, Berkeley

Meetings of project statisticians, data managers, and other specialists were held in Berkeley, running concurrently with meetings of the SCB. Some sessions were held jointly with the SCB. The purpose of the meetings was to develop plans formalizing the analytical process for the CRSP and to schedule analytical activities for the remainder of the program. Participating in meetings of the Data Analysis Group were the following specialists:

- Egypt Project: Dr. Virgil Anderson, Professor of Statistics,
Purdue University
- Kenya Project: Dr. A. Afifi, Professor of Biostatistics, UCLA
Anne Coulson, Kenya Project, UCLA
- Mexico Project: Jeffrey Backstrand, Data Manager, University of
Connecticut/Mexico Project
Dr. Pertti Pelto/University of Connecticut
Dr. Alfonso Mata, Field Director, Mexico
- Management Entity: Dr. Steve Selvin, Professor Biostatistics,
UC Berkeley
Dr. Judith Balderston, UCB/CRSP
Dr. George Beaton, University of Toronto,
Consultant/ME
- Consultant: Dr. Stephen Fienberg, Professor of Statistics,
Carnegie-Mellon University and Visiting Fellow
Center for Research in the Behavioral Sciences,
Stanford University, who served as Chair.

February 27, All day

The Data Analysis Group met with the SCB. This meeting was chaired by George Beaton.

During the morning, each of the projects presented its report in a "quasi-rehearsal mode" to prepare for the meeting with the EEP and to provide background on the history and current status for the group of statisticians.

Each project's principal investigators presented a status report on the organization of work in the field, logistics of data capture and data flow, and preliminary data on toddler anthropometry, food intake, morbidity, and socio-economic background.

24

February 28 - A.M.

Meeting alone in the morning under the chairmanship of Stephen Fienberg, the group of statisticians and data analysts discussed the process of analytical planning and statistical advising that would be most effective for the CRSP.

Each project has a Senior Statistician: Kenya project's statistician is A. Afifi of UCLA; Egypt project's statisticians are Virgil Anderson and George McCabe of Purdue; Mexico project's statistician will likely be Alan Gelfand of the University of Connecticut. ME's statistician is Steve Selvin. Stephen Fienberg, and later James Ware, will be involved on an intermittent basis as needed.

It was agreed that individual projects could do more data cleaning, processing, and control. Berkeley would look across data sets, doing independent verification and analysis. The need to "beef up" the analytical capabilities below the level of master statisticians was also recognized. It was agreed that a junior level statistician with competency in programming should be added to each staff. This person would undertake the time consuming preliminary analyses and would carry out final analyses under the supervision of the senior statistician.

It was the consensus of the group that the proper role for Berkeley would be as resource center, coordinator, and clearing house for good statistical ideas. Berkeley should not duplicate what is being done by the projects.

It was agreed that meetings of the PI's and statisticians should occur frequently along with special technical meetings of statisticians alone.

For immediate needs, it was agreed that a "template" should be developed for descriptive statistics, singling out variables from batteries and formulating tables for parallel work across projects. Equations will also need to be developed for estimation by all projects.

Dr. Fienberg suggested that at the conclusion of the CRSP, in addition to each project's special reports and publications, there will need to be a technical report describing the common core of results to be submitted with set of data tapes and documentation. To develop this common core of analysis and results requires resources and careful planning.

An agenda for the meeting was presented by Dr. Fienberg and accepted by the group. It included the following topics:

15

1. Data management
2. Data quality
3. Template for explanatory variables
4. Selection of provisional common variables for analysis
5. Model equations for the EEP meeting in April
6. Schedule for statistical analysis and resources required

This session concluded with establishing the process for short-run analytical activities. The three projects' parallel analyses would take place with input from project statisticians, and Berkeley as communication center. In preparing for the April meeting of the EEP, missing data reports, marginals and some tables based on each project's system of data management and analysis, should be created. Additionally, using a common format and common data system, a set of common tables would be produced by each of the projects. More elaborate tables and reports would also be prepared between April and June for circulation among projects. More careful versions of tables and other analysis would be carried out for the end of September, at which time more serious and complete analytical plans would be made for the remainder of the project.

February 28, P.M.

This meeting was held with principal investigators and statisticians. Dr. Fienberg summarized the morning's discussion and presented the plan for analytical activities. He described the resources needed, emphasizing that data are going to be flowing for a long time and that if the group is not careful, the end of the contract period could be reached without the completion of any analysis. The process for undertaking required analyses should begin immediately. Communications across projects, permitting feedback to the field, serving each project's needs, must rely on an expanded statistical enterprise for each project. Besides, the organization of a statistical group is needed to interface common analyses across projects with each project's own analysis. In order for inter-project analyses to be successful, there will need to be a lot of cooperation in formatting, choice of variables, agreement on models, and agreement on the timing of results. If not, cooperative analysis will not work.

The group of statisticians agreed that each project should have full-time junior statistician and a part-time senior statistician working closely with their PI's. Berkeley will do coordination, ask questions, and help in the preparation of internal memoranda.

For preparation for the EEP meeting, a simple template of tables was proposed. By the end of June a refined template will be prepared for further tables including some cross tabulations. The plan would be to start simply and become more complicated as exploratory

analyses are carried out. Simple preliminary analyses would then become precursors for later analyses.

Each project will be responsible for a common set of cross-tabulations and a set of analytical variables. Each project's statistician would also develop other analyses. All of these results will be circulated by the end of September. If the process is working, and projects have the right kind of analytical support, with sharing among projects taking place, the detailed analytical plan could then be made at a Fall 1985 meeting of statisticians and PI's representing each project. We would need to assess at that point whether the process is working; six months later a reassessment would be needed. If the process is effective, Berkeley will continue to play a coordinating role; if not, Berkeley would have to carry out the analyses.

It was agreed by all project representatives, that for the first set of coordinated analytical work, each project should use toddler data for food intake, anthropometry, morbidity. Socio-economic data should be chosen as appropriate to that project. When scales are computed, raw data should be provided as well as the algorithm or method by which scales are computed.

The afternoon session was concluded with a meeting of the Data Analysis Group alone. Each participant took an assignment to write up a section of the agenda which would be discussed at the meeting and written up for submission to the Data Analysis report for the EEP.

March 1, A.M.

Meeting alone, the group discussed each of the following topics: data management and quality, provisional common variables, the template for preliminary work, exploratory data analyses, and model equations for the presentation to the EEP.

It was agreed that, in order to carry out parallel analyses, the same data management system should be employed by all projects. In principle, SAS will be the data management system and also the default system for data analyses. Special analyses will also be done using other programming methods. Discussion about what data should be sent to the ME in Berkeley and it was agreed that for the CRSP archive required by contract, the basic set of data should be prepared and sent with full, clear documentation. Common analyses would have the same format. Whenever "scales" are used, the raw data should be submitted as well as the algorithm for computing the scale.

Judith Balderston led the discussion on data management and data quality control; Bert Peltó the discussion of proposed variables; A. Afifi presented techniques for exploratory analyses; Steve Selvin the preparation of prototypical examples for tables to be prepared for April and June which will be refined as we proceed; Virgil Anderson presented diagnostic models; Stephen Fienberg equations for "first cut" analyses. Each of the discussants was to prepare a written report based on his/her oral comments. To avoid duplicating the contents of these reports, we refer the reader to sections I to VII of the April 1985 "Report of the Data Analysis Group."

March 1, P.M.

A final session with the members of the SCB was held. Each of the participants in the Data Analysis meeting presented the topic which he/she had discussed in the morning session. Particularly lively discussion with scientists centered on the standardization of anthropometric measurements and whether "cut-off points" could be established as thresholds for food intake. These topics will continue to be of interest as the first set of analyses begin.

It was agreed by statisticians and principal investigators that the schedule of analytical activities would be as follows:

- By the end of March 1985, a set of tables will be produced by each project according to guidelines described in the Data Analysis Report of April 1985.
- By the end of June 1985, exploratory analyses will have been implemented using data for toddlers as described in the Data Analysis Report of April 1985.
- By the end of September 1985, diagnostic and regression analyses will have been carried out using data for toddlers as described in Data Analysis Report.

At the Fall 1985 meeting, implementation of these plans will be reviewed and schedules of statistical activities will be developed for the following year.

18

APPENDIX VI

(Psychological Development - "Cognition" - Report)

REPORT ON THE ASSESSMENTS OF
PSYCHOLOGICAL FUNCTIONS IN THE CRSP

This brief report is written to serve two purposes: (1) to discuss the issues raised in the EEP reports of January 1983, August 1984, and September 1984 and (2) to review our current research status and suggest directions for data analysis and interpretation. Examples will be drawn from the Kenya Project because of my familiarity with that project.

The EEP reports raises several issues regarding choice of measures, ages of study, and sites for assessment. In the following sections, I will discuss the issues in that order. Before proceeding, it is necessary to consider the criteria used in selection of measures, ages for assessment, and locations for testing. There were a number of criteria that guided choices in this study, not all of which were always explicit. Of course, the primary criterion was the theoretical and empirical basis for the research. A second consideration was that the variables selected be meaningful for the culture. This criterion is very important in psychological research and quite difficult to satisfy in a study of this kind. A third criterion in this particular study stemmed from the requirement that similar constructs be measured in all three sites. Thus, the research design had to satisfy not only the requirement for relevance in each culture but also the requirement for generality across cultures. Finally, the psychological assessments are but one part of the investigation and had to be integrated within the time frame, personnel expertise and availability, and demands on the subjects of all parts of the study.



Choice Of Measures

The selection of measurements in this study depended on all the criteria discussed above. The most critical criterion was that a theoretical and/or empirical basis existed to justify the expectation of important relationships. The EEP has had a powerful, beneficial influence on this study by consistently reminding us that mild to moderate malnutrition may have its major impact on the individual's capacity to attend, to regulate behavior, and to learn from the environment. The effects of mild to moderate malnutrition on intellectual abilities, as opposed to the capacity to use these abilities, may be less profound. For this reason, the EEP has encouraged the selection of assessments which tap a broader range than simply sensorimotor or intellectual functions. The criticism that there is a "tendency to administer available standard tests with little consideration of relevant dimensions of cognition measured by these tests and their links to nutrition" is in line with this argument.

Because of the research literature, the psychologists in this project have endeavored to broaden the scope of assessments. For example, in all projects, the Bayley Behavior Record, a rating of such qualities as attentiveness, persistence, and affect, is used at six months and following the toddler assessments at 18, 24, and 30 months of age. In addition, each project includes observational data on the infants' and toddlers' social responsiveness. For example, during the activity observations carried out every two months in Kenya, the frequency of vocalizing, smiling, crying, and social interactions, is observed and coded throughout the first six months and throughout the toddler period. In Egypt, similar observations are made on a monthly basis. In Mexico, the observations are carried out in separate structured situations. While the observational techniques vary from one site

to another, each project attempts to assess the infants' and toddlers' capacities to attend, self-regulate and interact socially. At school age, all projects are employing nearly identical social and attention measures. The attentiveness of the school age child in the classroom is observed in all projects. Social behavior in the playground is measured with an abbreviated version of the observational scale recommended originally by the EEP. While this scale is used in a different observational framework than in its original design, we have found the observations to be reliable measures of individual differences in the degree of social relatedness, the predominant affect, and the activity level of Kenyan school children. In other words, all projects have attempted to go beyond the assessments of cognitive function to measure expression of affect, attentiveness, and social relatedness at different ages.

Within the sensorimotor and cognitive domains, individual assessments have been selected to survey a range of cognitive abilities that we expect to vary in their relationship to nutritional status. In the infant period, assessments of motor skills on the Bayley are combined with investigations of visual recognition memory. Based on the research literature, visual recognition memory should be more closely tied to nutritional status than Bayley Motor score. Of course, this hypothesis depends on the range of nutritional intake at each site. In the event that malnutrition becomes severe, even the infant's motor abilities will be compromised.

During the school age period, we expect nutritional status to be more strongly related to Digit Span score than to vocabulary score since fluid intelligence is likely to be more severely affected by mild to moderate malnutrition than crystallized intelligence. At each age, we have selected cognitive assessments with expectations that certain abilities will be more vulnerable to chronic malnutrition than others.

To summarize the previous paragraphs, selection of measures was carried out based on the research findings regarding the effects of mild to moderate malnutrition. In addition, the three other criterion discussed at the start of this report also had to be satisfied. In some cases, measures were modified or deleted because they simply were not possible to administer or proved meaningless in the culture. For example, I am particularly interested in the development of symbolic play and had convinced the psychologists in this project to measure play behaviors even before I joined the project. However, it was impossible to observe play in a structured situation in Kenya because the toddlers were much too shy in a stranger's presence to play with any spontaneity. We have had to simplify the play measures and carry them out during the activity observation rather than to assess play skills during 18 and 24 month testing in the Kenyan project.

The third criterion, that the measures be applicable across cultures, has been very difficult to satisfy. In some cases, the interpretation of this requirement has been too literal. While we can usually measure similar constructs in different cultures, identical assessment techniques are generally invalid. For example, all projects are measuring verbal abilities in school age children but the particular assessments of word knowledge necessarily vary from one country to another. At times, the requirement for similar measurements has forced us to use assessments that may not be totally appropriate, although they may still reveal meaningful individual differences. In my experience, this has mostly occurred when no appropriate measure was available as a substitute. For example, the Block Design subtest of the WAIS is used to measure perceptual-motor conceptualizations in adults. Kenyan adults find this task rather difficult, although there does seem to be a tendency for the score on this subtest to relate to scores on the other WAIS

83

subtests. We will assess the validity of the individual scores on this subtest by hypothesizing certain relationships. For example, we will test whether more highly educated Kenyan adults perform better on this subtest. If the relations fulfill our expectations, we will use the Block Design subtest scores with more confidence in the validity of the Block Design, despite possible limitations in its sensitivity due to floor effects. In this case, the choice of measures was restricted because there are no standardized Kenyan measures of adult intelligence or perceptual-motor abilities that I could find. Furthermore, the hypotheses about adult abilities were limited so the choice seemed rather less important than those concerning the measurement of children's abilities.

The last criterion for choice of measures was that the measurements needed to be made by a small number of people, with particular strengths and limitations, and in a restricted number of visits. Each psychologist in this project found his or her collaborators to have different levels of expertise or skills. In Kenya, the cognitive assessment group was composed of four women with remarkable capacities to form relationships with children and adults. The task of understanding and administering the measures was much more foreign to them. Furthermore, for some of them, filling in computer forms was quite difficult, although others were more comfortable in this regard. The measurements used in Kenya were modified to ensure that the assessments could be understood and administered appropriately by this group of dedicated, but largely untrained testers. There was a different situation in Egypt where the cognitive group was composed of psychologists with doctorates. Thus, the range of cognitive assessments is broader in Egypt than in Kenya.

84

To summarize, the selection of measures was based on theoretically and empirically generated knowledge about the effects of malnutrition, applicability to the cultures, generalizability across the three cultures, and practicality. Finally, one other consideration entered into the selection process. It was not clear at the beginning of this study what the actual range of nutrition would be in the study area. While regions were selected to locate populations suffering mild chronic malnutrition, more serious malnutrition might have occurred and, in fact, did occur, at least in Kenya. Therefore, restriction of the measures to social and attentional factors might have overlooked consequences for cognitive development due to more significant chronic malnutrition than was anticipated. In light of the uncertainty of the nutritional status of the samples, selection of measures covered a broad range of cognitive, social and affective measures.

Selection Of Ages & Sites For Assessment

Selection of the ages of subjects was based on the same considerations. It was important to find groups of children who would be expected to have variable levels of food intake and this was one of the critical reasons for choosing toddlers and school age children. We agree with the EEP report that it would be worthwhile to study adolescents since more subtle cognitive and attention deficits may only be measurable at this age. However, their nutritional status is less likely to be compromised at the time of testing than is that of younger children so significant inferences might have to be made about previous levels of food intake. There is another important consequence of focusing on younger children. Psychological measures become more specific to particular cultures as individuals mature. The difficulties outlined with the Block Design subtest for adults exemplify this fact. In



order to find cognitive, social, and attentional measures applicable to each culture but generalizable across cultures, it is helpful to study young individuals whose development has been slightly less influenced by the culture. Measurements of adolescents and young adults would have necessitated the design of new assessment procedures in each country which would have had to be integrated across countries. Because of the limited number of measures standardized in the particular countries, we could not have begun the research without a long pilot period.

The choice of locations for testing has rarely been an issue once the measures and ages of assessment were selected. At least in Kenya, cognitive assessments had to be done in the home in the infancy and toddler period. There was no way in which a mother and 7 or 8 children could be asked to come to another site. Obviously, observations of social and play activities had to be carried out in the home. Cognitive testing of the school age children might have been administered at school but this offered few advantages. There was no reason to disrupt the school day when school age children could be more easily assessed at home with more privacy and less noise. Observations of attentiveness were done in the classroom because this is the most focused environment for the children. While it would have been interesting to set up small groups of children to study social interaction, this was not feasible, given the size of the sample and the distances to be covered. I did try to observe social behavior at home for the school age children but this proved impossible as they wandered around the neighborhood forming groups of different size and composition.

Current Status

At this point, a great deal of the data collection has been carried out. In Kenya, the activity observations from birth to 6 months are almost complete and the 6 month testing should be done by the fall. The toddler assessments at 18 and 24 months are finished as are the school age tests; I believe that most of the adult measurements are also finished. In looking at the data, it is clear that we will have to use two different approaches. First, we will need to identify those factors that are identical from one study to another. Second, we will have to restructure the data to facilitate analyses useful for our particular sites. As an example, I will discuss the Bayley data from Kenyan 18 month olds. Because of the shyness of these children and their reluctance to handle the testing materials we were able only to use the verbal scales. It is clear that the infants in Kenya do not find the same items difficult as do American infants. In other words, the Bayley verbal items do not follow the linear pattern shown in the U.S. For this reason, we will probably generate two forms of data. First, we will derive a score for the total number of items passed on all the verbal items administered at 18 months. All projects should have this data. Second, we will reorder the Bayley verbal items so that we can determine the highest items passed by an individual infant. These data will only be useful for Kenyan analyses. However, similar reorderings can be carried out in Mexico and Egypt if this proves necessary. We can then run parallel analyses of measures of verbal abilities with other factors. In this way, some replication will be done with identical measures and some with conceptually equivalent measures. In other instances, we may have to use measures that seem quite dissimilar on the surface but tap similar procedures across countries.

9/1

To summarize this report, in my opinion, the CRSP has gathered a unique body of information concerning the food intake, home experience, medical complications and cognitive and social development of a larger number of young children. Despite some limitation in the data gathered and cultural biases in some of the measures, the body of data is remarkable in its extensiveness and completeness. I hope that this report sheds some light on the considerations that guided the selection of measures, subjects, and testing locations and the implications of these choices for the understanding and interpretation of these data.

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