

Semi-Annual Report

October 1, 1983 to March 31, 1984

Collaborative Research Support

Program on Intake and Function

Functional Implications of Malnutrition

(CRSP) 931-1309

**Management Entity
University of California,
Berkeley**

Semi-Annual Report - Nutrition CRSP
October 1, 1983 to March 31, 1984

Summary of Activities

This period has marked the beginning of Phase II, the collection of data in the three field projects of the Nutrition CRSP. With the External Evaluation Panel's approval of the Phase II research design and with USAID's concurrence in September 1983, the Nutrition CRSP's core data collection was to begin in each of the three field sites on October 1.

Due to delays in the initiation of field activities, the Egypt project began its data collection in early November, while Kenya and Mexico did not enter their first Phase II core households until the beginning of January. The three project's reports which are attached provide details of field activities. In order to begin the Phase II data collection, each project organized its field office operations, selected and trained staff, chose target subjects, assigned enumerators to households, and began data collection on core study households and subjects. While some of these functions were begun during Phase I, not all staff had been hired and trained until late in 1983, nor were all instruments nor methods of collection available at the expected time. Because of these delays, the entry of study subjects and measures did not begin according to earlier, agreed-upon schedules.

Each project's Phase I activities provided experience for the development of Phase II methods. Each project prepared instruments appropriate for its own field site which would capture core data specified by the research design.

Meanwhile, the Management Entity assembled lists of core variables from the research design and, in conjunction with materials provided by the projects, Management created the Data Management Manual which contained core variable lists, schedules of measurements, and data flow and quality control procedures. Projects were directed to complete the construction of their instruments in conformity with this list. The manual also directed projects to furnish Management with documentation on the mapping of core variables from data capture instruments.

Because of delays in beginning data collections, the first quarter of Phase II data was not ready to be forwarded to Berkeley according to the original schedule of January 31, 1984. One set of files (from the Egypt project) was received during the period of this report. Case studies which were to have begun in July and concluded in March, were also delayed because of difficulties in staffing and establishing procedures. The data management staff completed preparations for the receipt of data.

Representatives of the Management Entity, Program Administrator Doris Calloway and Deputy Program Administrator Judith Balderston, visited all three field projects during this period. Specific recommendations on procedures, organization, and data management are

included in these trip reports which are attached here.

The Deputy Program Administrator also met with administrative officers at Connecticut and Purdue Universities to facilitate management operations of these two projects. These discussions included Principal Investigators and other staff responsible for business, accounting, and contracts at each of these universities. She also met with USAID representatives in Washington and attended a CRSP Director's Meeting in October.

Research Design and Modifications

The Revised Research Design which was formulated by the group of U.S. Principal Investigators and Management in May 1983, approved by the External Evaluation Panel in August, and USAID in September, became the accepted protocol for the Phase II of the CRSP. According to the method adopted for modifying this protocol, any proposed changes in design were to be submitted for approval by all projects and by Management. One set of such changes was proposed and adopted after agreement by all projects and by Management. It was agreed that these changes would not alter the objectives of the research design nor would they detract from the analytical capabilities of the core data collection. Other proposed protocol changes were circulated but were not ratified by the group and decisions were deferred until the May meeting of the SCB. In the absence of formally approved changes, it was agreed that the core research design was to be followed by all projects as originally intended.

Manuals describing detailed routines being used by each project, along with data capture instruments, were to be furnished to Management by each project for Management's review. These materials will become part of the permanent CRSP archive.

Data Management Activities

CRSP methods for handling data flow were derived from early plans set out by the "Technical Advisory Group on Statistical Design and Data Management." Detailed procedures implementing these plans had been developed by the group of project data managers and by the Berkeley data management group. Procedures were designed to assure the quality of data, the accessibility of data for analysis across the three projects, and for archiving the data for later release to the community of scholars. During the six months of this report period, detailed data management procedures were completed by the staff of computer programmers and statisticians who serve as research assistants to the Management Entity, under the direction of the Deputy Program Administrator. Variable lists and schedules of measurements were assembled from the agreed-upon research design. Instructions for coding and entering data, for creating files, mapping variables from survey instruments to the core SAS data set, documentation, quality control, error detection and reporting, treatment of missing data, and procedures for transfer of data files were all included in this manual. (A complete manual is attached to the comprehensive semi-annual report.)

As households are entered into the study, a record is prepared on the computer showing the status of the household for the study--presence of the target schooler, toddler, or potentially pregnant woman. Similarly information is kept for household exit or for the change of status of the household during the course of the study. With this information, it is possible to monitor which households have been entered, and the flow of data on target subjects and households. Tables reporting the presence of data are constructed from these household entry forms.

Projects have been directed to report the set of information on core variables according to a standard list of SAS variables provided in the manual. Since all projects have agreed upon the set of measures to be taken, analysis of data at the conclusion of Phase II will be facilitated by standard naming and documenting data across all projects. While it is expected that projects will find it convenient to do their own analysis using SAS, it will not be required for all projects to use this data management system for their own internal activities. However, it is expected that central data management monitoring and archiving activities will require parallel methods for documenting and arranging files in equivalent form for cross-project comparisons.

Quality control procedures have been developed so that measurement error, recording error, instrument and human error, are all minimized. All sources of error will be monitored as an ongoing activity of all levels of the CRSP. For each class of measurements, appropriate methods for checking, replicating measures, and reporting errors are to be followed by the projects and by Management. In order to guarantee that all official sets of data are consistent in error correction, all changes will be reported on standard error correction forms provided by Management.

In addition to these data management procedures which are described in detail in the Data Management Manual, the statistical group has begun to develop analytical frameworks for later analysis. This is an important on-going function of Management to assure the sufficiency and quality of analytical results. Several working papers have served as the basis for group discussions and are included in the comprehensive copy of this report. Since data in the early stages of collection will continue to be sparse, while important design alterations may be needed, efforts to treat preliminary sparse data analytically have been discussed.

The Egypt project's first data set was received in mid-February. It consisted of files reporting demography, household and individual socio-economic characteristics, anthropometry, reproductive history, and household entry and change. Table 1 summarizes the data received from Egypt. Data from Kenya and Mexico were not received by Berkeley during this period. Some data collected in the field during this period and entered in the computer were received during April and will be discussed during the next period's report.

Table 1
Files Received by Management
As of 3/31/84

	<u>Egypt</u>		
	Date Received	# of Subjects	# Variables per subject
Demography	2/20/84	212	16
HH SES	2/20/84	27	44
Individual SES	2/20/84	212	20
Target Anthropometry	2/20/84	29	21
Non-target Anthropometry	2/20/84	30	21
Reproductive History	2/20/84	4	37
HH Entry-Change-Exit	2/20/84	28 (27HH)	54

Management Entity Administrative Activities

In addition to the administrative research activities outlined above, other activities carried out by the Management Entity related to its organizational and fiscal responsibilities. These included:

1. **Budgets:** Management Entity solicited and received budget projections from the three projects through the completion of work until 8/31/87. These formed the basis for budgetary discussions which were to take place at the Institutional Council and Finance Group meetings in May in Berkeley and for identifying possible areas of cost savings.
2. **Expenditures:** As before Management continued to receive and review the quarterly reports of expenditures by all projects.
3. **Fund Advances:** Management arranged for fund advances to the University of Connecticut and Purdue University during this period. UCLA continued to receive its funding within the University of California system.
4. **Grant Amendments:** Management Entity received grant amendments from USAID with modifications of the clause relating to equipment approvals. Because the language of this amendment was found to be ambiguous it was referred back to USAID with suggested changes.
5. **Audits:** Management Entity received the overseas audit report from Deloitte, Haskins, and Sells for the period 9/1/81 to 3/31/83 and advised institutions to prepare for the next round of audits for the year beginning 4/1/83.

Audit of the Kenya project and the Newfoundland component of the Mexico project were not covered in the first round of audits. The second round of audits for those projects will cover transactions of these components in all prior periods.

6. Management Entity continued to review project's proposals for equipment purchases. Management monitored these purchases with care, approving them when they related to the core research design needs of the CRSP.
7. Management continued to review overseas travel of all projects before granting approval and forwarding to USAID for travel clearances. Criteria for approval of travel included relevance and importance of the trips in relation to the core design and adequacy of the length of stay in the field.

The method of approval was established along more formal guidelines than before to assure that Management Entity's approval preceded AID's clearances.

8. The search for a full-time Program Director was concluded during December. One eminently qualified candidate was selected but he was unable to accept the position. Other candidates for the positions were not deemed to be adequately prepared by the faculty committee. The search was discontinued.

APPENDICES

- A. Trip Reports of Doris Calloway and Judith Balderston
- B. Protocol Changes Adopted
- C. CRSP Data Management Procedures
- *D. Data Management Manual

*Included only in comprehensive report.

Appendix A

TRIP REPORTS:

Doris H. Calloway, Program Administrator
Judith B. Balderston, Deputy Program Administrator
to Mexico, Kenya, Egypt during period December 1983
through March 1984.

Trip Report: Doris Howes Calloway, Program Administrator, Nutrition CRSP
December 5-7, 1983

Judith B. Balderston, Deputy Program Administrator, CRSP
December 5-9, 1983

Objectives The purposes of this trip were:

- (1) To observe and evaluate the operation of the Mexican component of the CRSP;
- (2) To meet with staff in the field and observe interview techniques;
- (3) To meet with data management personnel and to visit the Institute of Nutrition.

Persons Consulted

Dr. Adolfo Chavez, Director, Community Nutrition, Institute of Nutrition,
and Co-Principal Investigator, CRSP, Mexico

Dr. Lindsay Allen, University of Connecticut, Co-Principal Investigator,
CRSP, Mexico Project

Dr. Alfonso Mata, Field Director, CRSP Mexico

Dr. Homero Martinez, Chief Morbidity and Health

Leticia Serrano, Chief, Food Intake

Eulalia Martinez, Chief, Cognition

Luzma Meneses, Chief, Socio-economics

Julia Beatriz Castillo, Chief, BMR and Activity

Ramon Lira Colorado, Data Manager

Mr. Samuel Taylor, USAID Field Representative, U.S. Embassy, Mexico

Engineer Sergio Ahumada, Director of Systems, Mexican Department of
Public Health

Engineer Francisco Martinez Palomo, General Director of Information and
Systems, Department of Public Health

Angeles Rufrancos, Chief of Data Capture Office, Department of Public
Health

itinerary

D. Calloway and J. Balderston departed San Francisco, 12/5/83, arriving Mexico City at 3 p.m. Were met by Dr. Adolfo Chavez and transported to Solis, arriving early evening. Evening meeting with Drs. Chavez, Mata, Martinez to review project. Shown facilities at Solis.

12/6/83 A.M. visited one community to observe general living conditions and to accompany surveyors who were collecting intake data. D. Calloway also accompanied an interviewer to a household for an activity recall trial. J. Balderston observed two interviews - one for information on productivity and one for household socio-economic information.

12/6/83 P.M. Met with Chavez, Mata, Martinez, Allen, and chiefs of each of the areas included in the study. Discussion of problems in the field. Returned to Mexico City in evening.

12/7/83 Met all day at INNSZ with Drs. Chavez, Mata, Martinez, Allen to discuss organization of the Mexico CRSP and the carrying out of field work. Late afternoon meeting with Samuel Taylor, AID Representative, Mexico to describe work of CRSP.

12/7/83-Evening D. Calloway left for CYMMYT Board Meeting.

12/8/83 and 12/9/83 J. Balderston met with members of the data management group at INNSZ and at the Department of Public Health. Also met on 12/9/83 again with Drs. Mata, Martinez, and Chavez.

Observations by D.H. Calloway on Site Visit to Mexico

Interviews about food intake by sample families were conducted at one site. The first addressed 24-hour recalled intake by all target subjects, including recipes used in preparing food. Portions were quantified by weighing and volumetric measurement of household implements and serving dishes. The interview and procedures were time-consuming, and the woman being interviewed evidently felt it an imposition but was friendly and cooperative. Conditions in this house were abysmal; the woman owned almost no crockery or utensils, cooked over a floor-laid fire in a corner of the single room, and had to transport water from a remote location. She kept fresh and reusable water in separate containers and the house reflected great effort to maintain order and cleanliness under the most poverty-stricken conditions. In response to questions about illness, the woman rated all family members as "not sick"; the infant had a deep cough and several children had running noses. The project staff recognize a need to address definitional issues in morbidity data.

The second food intake interview concerned weekly purchases and food usage of the household level. This method is to substitute for conventional food inventory. The interview took place in a well-organized separate kitchen room. The woman interviewed was alert and friendly. She had no reluctance about responding, nor difficulty in listing amounts and costs of foods purchased at the weekly market, and remembered the amount of sugar loaned to a neighbor. This method seems satisfactory provided there is some method of verifying that a weight purchased is a weight delivered, or at least that weighing errors are random. It will also provide valuable economic information.

The field staff arranged a special interview with a worker's wife, to illustrate the use of the recall activity method. The method has promise but will require highly skilled and perceptive interviewers. It could provide a valuable, detailed description of time allocation patterns but not a quantitative assessment of energy expenditure as presently structured. This interview method is not included in the core, but may provide useful background for development of the health-care activities test schedule, for which there is not now a field-ready method.

Equipment for measuring energy metabolism has not yet been delivered, so the protocols have not yet been adjusted for local conditions. The clinical laboratory is under construction. It is unlikely that related studies can be carried out within the first quarter of data collection.

Other methods still under development are those for evaluation of parent-schooler interaction. The proposal to test school-age children at school needs to be reviewed, given that many children in outlying areas fail to attend school regularly.

Observations by J. B. Balderston on Site Visit to Mexico

At Solis, in order to illustrate the technique for collecting productivity and socio-economic information, two special interviews were conducted by the members of the SES survey team at houses directly adjacent to the Hacienda. In both cases the interviewers appeared to be well-trained and bright. The persons questioned were cooperative and willing to provide answers on work, land ownership, and details of the house. The productivity interview was conducted rapidly because of the fact that the man appeared to have little land and no small business. (I am concerned, however, that for farmers with several parcels of land, that the productivity questionnaire might be lengthy and intrusive.)

The interview concerning house and possessions proceeded smoothly, with little hesitation on the part of the subject in answering questions. The woman chosen for this mock interview has been involved with the work of the local clinic and is therefore especially cooperative. The interview did not include questions about the presence of running water and sanitation in the house. It is clear that these questions need to be asked at the time of the first household survey, with questions about sanitary practice to be asked during other interviews.

Our meeting with the "Area Chiefs" at Solis was informative. Each supervisor spoke of the problems in her area of responsibility. For the area of diet data: the problem of counting tortillas and tacos has been partially resolved with the use of small colorful stickers. The intake collection takes three visits per month -- the first as preparation, the second and third for data collection. The problem of the child sitting on the parent's knee and eating from the same plate has not yet been resolved. The observation of the 18 to 30 month old is difficult because children wander and mothers cannot recall what the children eat. Rotation of observers and the migration of male heads of households was also discussed. There will be trial observation of toddlers in December.

For the morbidity area, the clinical history of males is different because they are frequently out. Since the clinical history is so lengthy, there will be pilot testing to see what information can be omitted. The algorithm for common illness diagnosis has been worked on and will be circulated soon. Problems in using the Brazelton for the newborn were also mentioned.

In the SES area, there was a discussion of validation and cross-checking. It is simple however to collect what is in the house. It was pointed out that there must be sanitation and water included in this survey.

For the psychological tests, adults will have to be taken to the health center but there is difficulty in arranging transportation. There are problems when testing is done at home because of the interference of visitors, radios, and sometimes testing must be terminated prematurely. Problems of child-mother interaction were also discussed. Since the mother is not always the caretaker, there may need to be some adjustment in the observations of child and usual caretaker. Some problems have arisen with cognitive tests that require solution of mazes by adults

unfamiliar with paper-and-pencil testing. Some modifications of psychological test protocols are being proposed by the Mexico project to Management and will be considered by the other projects for approval or disapproval.

Activity recall was discussed. There appear to be problems in conducting lengthy interviews (45-60 minutes) and methods are being piloted for reducing the intrusiveness of this part of the survey.

Considerable discussion of the readiness of the Mexico project to begin data collection took place both at Solis and during the following day in Mexico City. It appears that the Mexico project is not completely organized and ready to begin full-scale data collection until January and that even then there will be some parts of the core that will be delayed for the completion of design and piloting. Although all households have been selected, and a considerable amount of data collected on them (175 households in the four villages while others in the "preliminary test villages" may also be included) investigators of the Mexico project are still concerned about their readiness to bring the project up to full strength. One component of the problem is the recent termination of four experienced food intake interviewers who will need to be replaced and trained.

My meetings with Ramon Lira and his staff at INNSZ and with the members of the Department of Public Health were very informative. I was impressed by the high degree of cooperation of Public Health with the CRSP. Since they are providing free computer entry, experienced staff, facilities, and interest and support, the Mexico project appears to be fortunate in having very efficient data entry. Although I did not have the opportunity to visit the IBM installation, I understand that it also has excellent facilities and interested professionals. Ramon Lira and Pesaj Goldfeder (currently on leave) appear to have organized the data management of the Mexico project efficiently and carefully. The attached schedule of data management activities shows the method of data transfers being used, indicating that a month's time is needed between data collection and availability of data for shipment to the University of Connecticut.

During my meeting with the Department of Public Health's chiefs of Information, it was clear that there is great interest in what we are doing and great concern that we share the analytical expertise and results with them and with other Mexican colleagues. The Mexican government is interested in health and nutritional surveys and in how to handle large data bases; obviously by providing facilities to the CRSP they are also interested in sharing in the knowledge gained. When workshops are organized at the completion of the work, we should be aware of their interest and invite their participation.

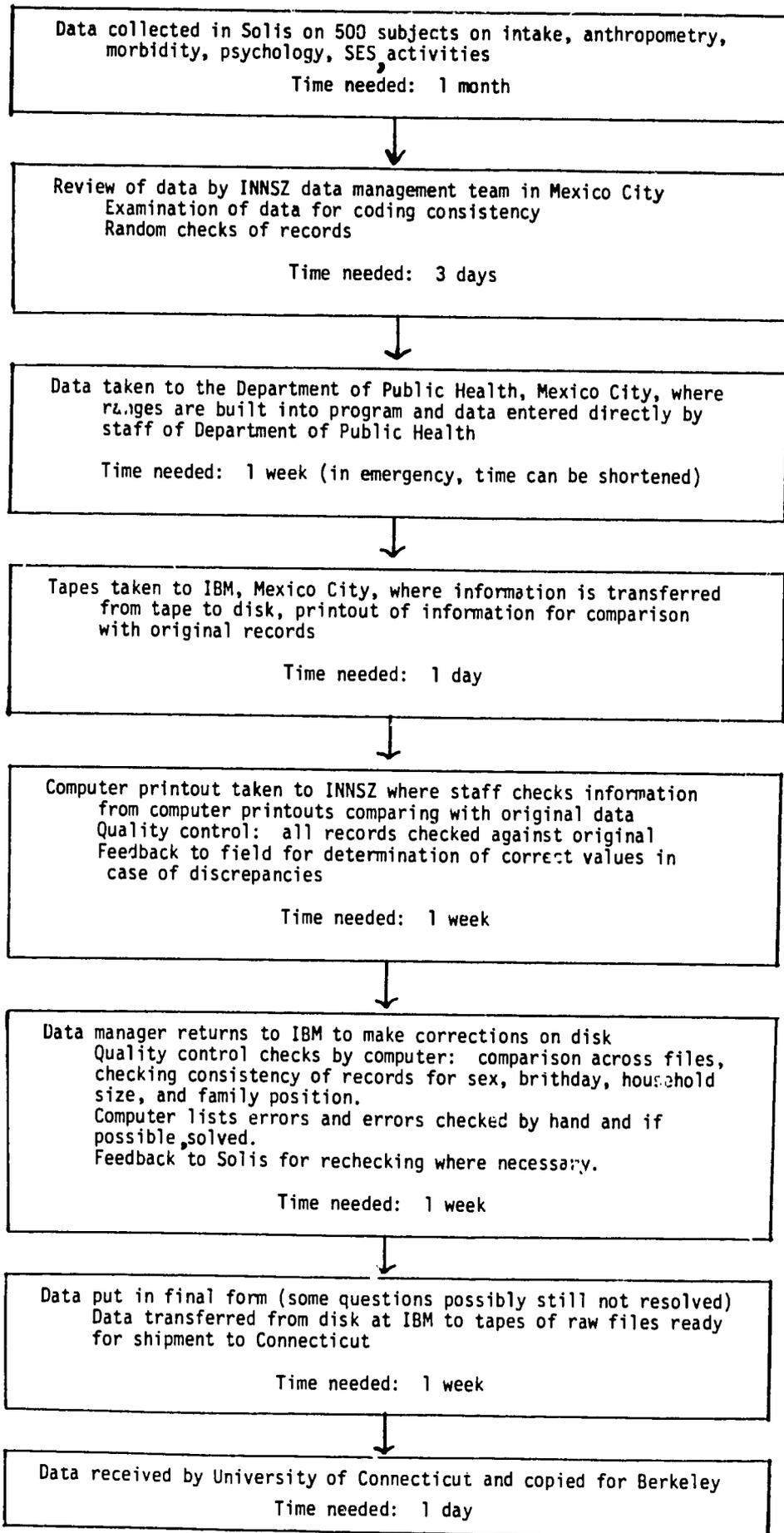
Our meeting with Samuel Taylor at the Embassy was brief. He inquired about the nature of the CRSP and the present activities. He did not appear to be eager to participate with us but should be kept well-informed of progress.

Other administrative topics of discussion during our meetings with Dr. Chavez included the transportation problem, namely the provision of vehicles for the use of the project. It is now impossible for the CRSP funds to be used for purpose of vans since USAID rules prohibit purchase of non-U.S. source vehicles, and Mexican rules prohibit importing of American cars. It has been suggested that the vans which have been purchased by INNSZ and are being used by the CRSP should be leased to the CRSP. INNSZ and the University of Connecticut will arrange for such an agreement.

Recommendations: As results of visits to Solis and the Institute of Nutrition in Mexico City, observation of field methods, and meetings with two of the Principal Investigators, the field director, and the supervisors, we recommend that:

- (1) More administrative guidance is needed in the field. It is critically important that one or both of the U.S. Principal Investigators should be present in the field during the first part of the data collection to insure that all procedures are properly prepared and carefully carried out. While there is a high degree of involvement and concern by Dr. Chavez as Co-Principal Investigator, by the field director, and by each of the area chiefs, there is absent the unified direction, continuity, and firmness that a resident Principal Investigator can provide.
- (2) Communication between the Mexican field operation, the Mexican data management staff, and the University of Connecticut should be improved. We observed that the flow of information and materials between components of the project has not been as smooth as it should be.
- (3) Transfer of data will be carried out as soon as possible to test the "pipeline" between Mexico, Connecticut, and Berkeley. It was agreed that the newest pilot data (Phase I) will be sent in January as soon as possible. The first month of Phase II data collected in January will be sent no later than March 1 to the University of Connecticut and then copied for immediate shipment to Berkeley. Similarly, February data will be sent to Connecticut on April 1 and March data on May 1. This will enable us to examine the system of transferring data as well as the information itself.

DATA MANAGEMENT SCHEME - MEXICO PROJECT



Total time elapsed: approximately 1 month.

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Trip Report: Judith Balderston, Deputy Program Administrator,
Nutrition CRSP

January 10 to February 3, 1984 - Visits to Kenya and
Egypt Projects

Objectives:

- (1) To assess Phase II operation of the Kenya and Egypt projects;
- (2) to assist projects in implementation of the core design with special attention to the data flow and data management aspects of project activities;
- (3) to become acquainted with field operations and community environments;
- (4) to understand specific organizational problems;
- (5) to meet with host country principal investigators and their colleagues.

In order to carry out these objectives, I spent more than one week at each project, in group meetings with project staff, in discussions with individual team members, and in household visits. Accompanying surveyors in their work, I observed how core design had been translated into specific, culturally-appropriate instruments, and how these instruments were being used by surveyors in their interviews. In both projects, I concentrated on the implementation of data management activities, to ascertain whether prescribed quality control procedures were being followed and to offer suggestions on how to improve the system of data flow.

KENYA PROJECT

During the period from January 10 to January 23, I visited the University of Nairobi, met with Professors Nimrod Bwibo, James Kagia, their colleagues in the School of Medicine, and with University Vice Chancellor Joseph Mungai.

At USAID-Nairobi I met with Dr. Rose Britanek, Health and Nutrition Officer and with Deputy Director Barry Riley. Spending several days at Embu and at the field cluster sites, I met with all of the scientists and administrators in the field as well as with numerous supervisors and enumerators.

Persons Consulted

Professor Nimrod Bwibo
 Dr. Thairu
 Dr. Julius Meme
 Dr. Bowry
 Dr. Eric Carter
 Mr. William Martin
 Dr. Dorothy Cattle
 Ms. Susan Weinberg
 Professor Charlotte Neumann
 Professor Gerald Gardner
 Dr. Rose Britanek - USAID Nairobi Health Office
 Mr. Barry Riley - USAID Deputy Director
 Mr. Anthony Vodraska
 Mr. Dragon - Legal Officer, Nairobi USAID
 Dr. Judith Geist - presently assigned to Kenyan Ministry of Planning, Nairobi, and formerly of UC, Berkeley
 Dr. Joseph M. Mungai - Vice-Chancellor, University of Nairobi

Chronology

January 10	Arrived Nairobi and met informally with Professor Bwibo
January 11	Met with Professors James Kagia and Gerald Gardner of UCLA. Drove from Nairobi to Embu. Met in evening in Embu with Field Director Eric Carter and Project Administrator William Martin.
January 12	Visits to study households with enumerators. Accompanied census, socio-economic, and food intake enumerators in their rounds. Met in afternoon and evening with field staff members Carter, Cattle,

- Weinberg, and Martin to discuss project progress.
- January 13-15 Personal Touring
- January 16 Returned to Nairobi and made arrangements for remainder of week's schedule
- January 17 Meeting with Vice-Chancellor Joseph Mungai of the University of Nairobi, and Professor Bwibo.
- Discussion of the CRSP, especially assurances of equal collaboration with Kenyan participants. Also met with Dr. Judith Geist, formerly of UC Berkeley, and presently attached to the Kenyan Ministry of Planning.
- January 18 Met with Charlotte Neumann on her arrival in Kenya. Eric Carter, Dr. Neumann and I met in the morning with USAID-Nairobi staff, Dr. Rose Britanek, Mr. Barry Riley (Deputy AID Director), Anthony Ladroska, and Mr. Dragon, legal officer. Meeting in afternoon with University of Nairobi Medical School professors, Bwibo, Kagia, Thairu, Meme, and Bowry. Informed during meeting of work stoppage in Embu. Spent rest of meeting planning response.
- January 19 Early morning trip from Nairobi to Embu. Meeting with professors and Field Director Carter, and Charlotte Neumann. Drs. Bwibo, Carter, Neumann, and I met with 100 or more enumerators and supervisors at Kyeni School grounds with meetings continuing all day. Resoluton of issues by afternoon.
- January 20 Visited field operations in all four clusters in morning. Accompanied enumerators to households where mother-child interactions were observed.
- January 21 Household visits with teams doing Census Updates and Reproductive Surveys. Meetings with Dorothy Cattle and her Kenyan collaborators, Duncan Igara and Benjamin Nyaga to discuss SES surveys and case studies. Decisions on simplification of activities. Afternoon meetings with William Martin on data flow procedures and on budgetary implications of structural wage adjustments.
- January 22 Meetings with UC senior staff members to discuss workload, budgetary issues, plans for implementation of policy results, and management problems.
- January 23 Departed early morning for Cairo.

Report of Observations, Discussions, and Accomplishments

The Kenya CRSP is located outside of Embu in a far-flung set of communities, scattered over a 60 square kilometer area. In order to carry out the intended research design, the project has employed more than one hundred enumerators plus supervisors organized into four clusters. Enumerators and supervisors must cover large areas on foot. To provide organization for scheduling and collection of completed instruments, there are four cluster offices, each with an office manager who coordinates scheduling, assuring that conflicts between enumeration teams are avoided, checking completed survey instruments, and transmitting them to the field office in Embu on a daily basis. The field operation appears to be very well organized and will assure that data are flowing through the system on a well-regulated basis.

During three of the days spent in the study communities, I accompanied enumerators who were collecting demographic, psychological, socio-economic and food intake information. For most of these activities, enumerators were experienced, forms were clear, and the data collection appeared to be smooth. For those portions of the work in which there were still some unresolved problems, such as in the case of observations of mother-child interactions, more refinement of protocols was clearly needed.

My general impression of the Kenya CRSP organization was favorable. The training of enumerators appears to have been thorough, stressing both quality control and the importance of

motivating subjects to cooperate with the study. Clearly CRSP's training of surveyors and supervisors has already made a contribution to the Embu area of Kenya; when the project is completed, there will be a corps of experienced workers for other types of health surveys and censuses.

Meetings with junior Kenyan and U.S. staff also gave evidence of competence and energy. Young men and women, recent graduates of Kenyan universities, work closely and collaboratively with the American field staff. This collaboration will continue to be of great importance in the implementation of the data collection and analysis of the results.

Meetings were held with Professors Bwibo, Kagia and their colleagues of University of Nairobi, Professors Thairu, Meme, and Bowry. It is obvious that there must be added senior scientists for immunology and for psychology without delay. During the course of my visit, a work stoppage occurred that called attention to the need for the participation of faculty members from the University of Nairobi (and most particularly, Professor Bwibo) on a more regular basis. Since Dr. Bwibo has recently been appointed Head of the University of Nairobi Department of Health Sciences, there are extremely heavy demands on his time and energy. Nevertheless, he has enormous interest in and dedication to the project and has shown his willingness to leave his other duties when his presence is urgently needed by the CRSP.

There are problems resulting from the sheer size of the Kenya project; nevertheless, due to the apparent organization, and competence, of the field staff, this project has been able to

complete the necessary stages of preliminary work. The Field Director, Dr. Eric Carter is an exceptionally organized and able scientist as well as administrator. With the dedicated work of Dr. Dorothy Cattle, Susan Weinberg, and the recent additions of William Martin, the Field Administrator, the U.S. field staff functions well. The Principal Investigator, Charlotte Neumann, has also spent extended periods in the field. Several young Kenyans serve as junior scientists, providing the knowledge of the local environment needed for developing instruments, and helping to train and supervise the large group of unseasoned workers. Procedures of data collection and quality control appear to conform to requirements of the CRSP core design. There are, inevitably, some portions of the core that may be difficult to implement in Kenya because of the large area that surveyors must cover on foot. Eric Carter has offered preliminary suggestions on modifications of design and, at the time of the next Scientific Coordination Board meeting in May, there will be full discussion of concerns from each of the projects. Meanwhile however, the Kenya project appears to be carrying out the intent and procedures prescribed by the May 1983 design with great attention to detail and to quality control.

The work stoppage of enumerators and supervisors that occurred on January 18 and 19 called attention to some problems which have developed in the field project due to its size and complexity. While there may be organizers who could profit from disrupting the project, there are, indeed, some real concerns: among these are inequities of pay (sweepers have been paid as much as enumerators); problems of transportation over the wide area, particularly for

those who must carry heavy equipment; and some instances of poor inter-personal relationships between some senior staff members and enumerators and supervisors. It was clear that more frequent visits and interest of the Nairobi professors, (especially of Dr. Bwibo) and regular, frequent meetings of staff, need to take place.

In accompanying enumerators to households I noted the following:

(a) Experienced enumerators are quite familiar with the terrain and were able to locate remote households without difficulty. Project maps are very helpful although some less experienced surveyors appeared to have difficulty in using them. These problems will likely be resolved over time.

(b) Surveyors are equipped with badges, knapsacks, and clipboards which lend a professional manner to the CRSP field work. Forms appear to be well-worked out with carbon copy duplicates.

(c) The interview process was delayed while enumerators entered information that possibly could be filled out just prior to the household visit or immediately at the close of the visit. The length of the stay in the household and the intrusiveness on household activities could be reduced if this were done.

(d) Additional checks on subject's ages are needed when there are no official records. Since a child's age is especially important, when there are no records, there is the risk of losing subjects who might otherwise be included.

(f) In studying mother-child interactions, there has been considerable effort to create instruments that reflect the intent of the core but some ambiguities still remain. During my visit,

preliminary forms were being used to record levels of activities among several household members. It was difficult for the observer to focus on the mother-child interactions when so many interpersonal activities are taking place simultaneously. Discussions with Dorothy Cattle and Charlotte Neumann concluded that activities can be further clarified, combined, and simplified.

(g) I was pleased to see that forms were assembled and logged in rapidly after collection. This method minimizes any altering of information after collection. This is essential for the preservation of data quality.

I spent considerable time examining the data transfer and data management procedures in the field. The attached Figure 1 shows the flow of data from collection in the field to computer entry and transmittal. Because data quality and quantity are central concerns to the CRSP, the success of all of the projects rests on their ability to collect and transfer data for later analysis. I was impressed with the process and the safeguards that the Kenya project employs for scheduling data collection, for recording, checking, and transferring the data to the computer. At the time of this writing, the first month's data have not reached Berkeley, so I am unable to report yet on the outcome of this collection.

Recommendations

While I was generally favorably impressed with the operation of the Kenya project in the field, I have the following specific recommendations:

(1) All instruments must be completed in final form immediately so that the data are collected in a comparable and standard manner for the entire Phase II.

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(2) Inter-personal relationships among senior and junior staff members will need continuing attention. Under Eric Carter's direction, the regular presence of Dr. Bwibo, and the frequent scheduling of staff meetings, it is unlikely that there would be recurrence of the January work stoppage.

(3) Senior Kenyan scientists must be found for immunology and psychology activities as soon as possible.

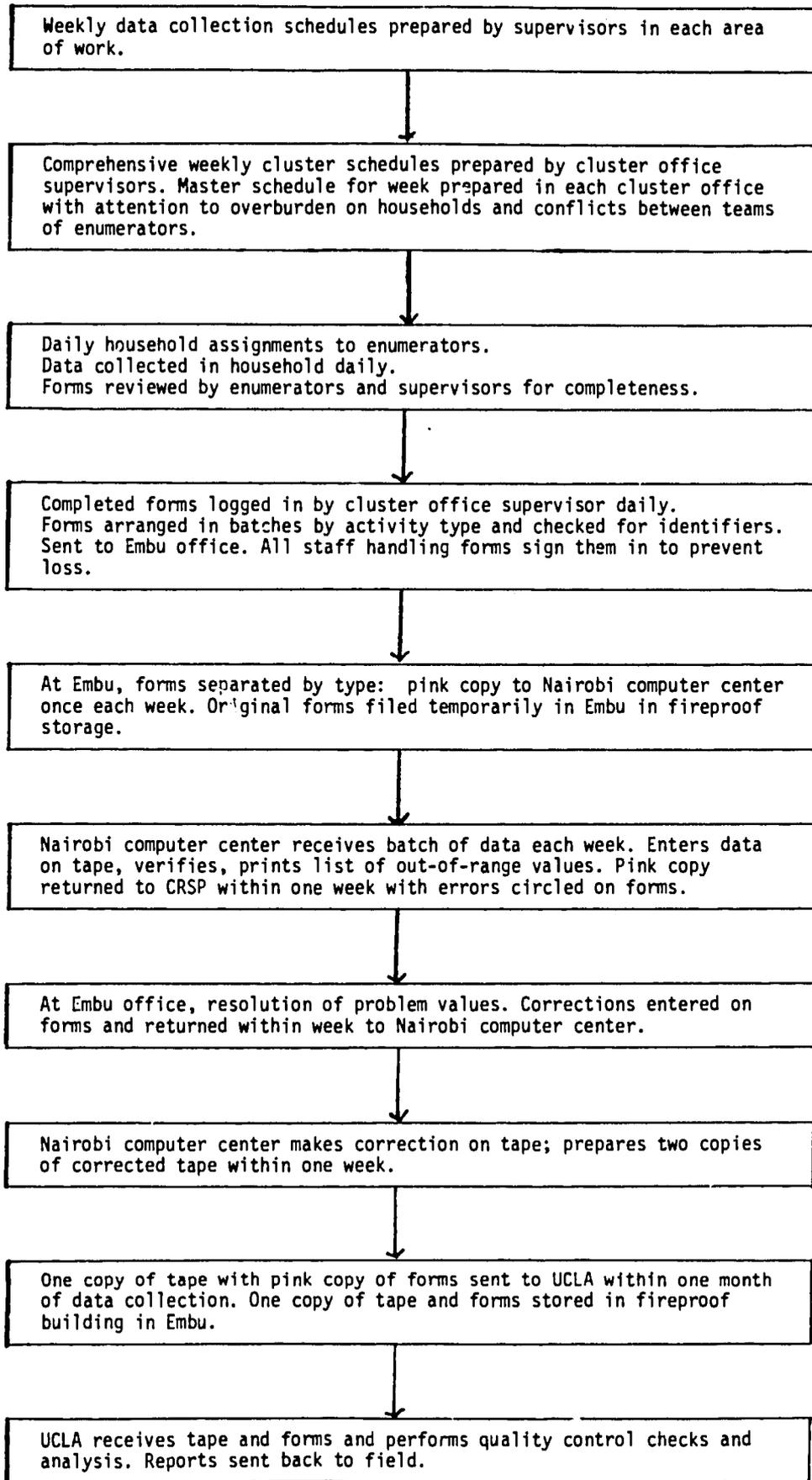
(4) Activities need to be combined to eliminate unnecessary intrusion on households. Also some portions of forms could be recorded just before or after household visits to shorten the length of interviews.

(5) If possible, transportation for those enumerators who need to carry heavy equipment such as scales, should be provided.

(6) A Kenyan deputy for Eric Carter should be trained. This person would assist Dr. Carter, substitute for him when he is away, and replace him during a later stage of the work if necessary.

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Figure 1
DATA FLOW PROCESS - KENYA PROJECT



Total time elapsed: approximately one month from collection to transmission of completed tapes.

EGYPT PROJECT

During the period from January 23 to February 2, I visited the Nutrition Institute in Cairo and the field site in Kalama, devoting the time to meetings with Principal Investigators, Senior Staff members and to observations of data collectors during their interviews with study subjects. These meetings and observations permitted me the opportunity to assess progress in the field with particular attention to problems of scheduling, quality control, data flow, and data entry. I also met with Dr. William Oldham and John Wiles at the Cairo USAID Mission to discuss the progress of the project in Egypt.

Persons Contacted

In Cairo I met with the following people:

Dr. Osman Galal, (Director, Nutrition Institute and Principal Investigator, Egypt CRSP).
 The following Senior Scientists at the Nutrition Institute:
 Dr. Wafaa Moussa (Food Intake)
 Dr. Farouk Shaheen (Morbidity)
 Dr. Amin Kamel Said (Reproduction)
 Dr. Daisy Fleita (Immunology)
 Dr. Zeinab Bishry (Cognition) Dr. Faisal A. Yunis (Cognition)
 Dr. Ahmad M. Dakroury (Biological Fluids)
 Dr. Mohammad El Bhorab (Biological Fluids)
 Dr. Hekmat El-Sayed Aly (Member, Executive Committee, formerly Director of Institute)
 Dr. Saneya Abdul Azim Wahba (Data Manager)
 Dr. Adel Fahmy (Statistician at National Research Center, to be assigned duties for data analysis at Nutrition Institute for CRSP)
 Ms. Nancy Meyer (Field Coordinator)
 Dr. Ahmed Nagati (Director, Strengthening Rural Health Project, located in Nutrition Institute, Cairo)
 Dr. Thomas Engler (Senior Technical Advisor, Strengthening Rural Health Project)
 Bafik Farrada (IBM Systems Engineer)
 Dr. William Oldham (USAID, Health Officer)
 Mr. John Wiles (USAID, Nutrition Officer)
 U.S. Principal Investigators: Gail Harrison, Norge Jerome, Avanelle Kirksey
 Dr. Theodore Wachs (Purdue Psychologist)

Chronology:

- January 23: Arrived Cairo late morning. Went directly to Nutrition Institute to attend meeting with Principal Investigators on scheduling problems. Reviewed status of project.
- January 24: Meeting with data manager Dr. Saneya on data management procedures and plans. Meeting with four Principal Investigators Galal, Kirksey, Jerome, and Harrison.
- January 25: Visit to field project in Kalama with Dr. Shaheen and US PI's Kirksey and Jerome. Meeting with Statistician Dr. Fahmy and Drs. Jerome and Galal to discuss data entry plans.
- January 26: Meeting with all Egyptian Senior Scientists and Principal Investigators to discuss progress of work and ability of group to meet goals of core project.
- January 27: Day of worship in Egypt.
- January 28: Meeting with group of all Senior Scientists and PI's to discuss scheduling to meet core research goals.
- January 29: Meeting with Data Manager Saneya and Field Coordinator Nancy Meyer to reformulate scheduling data management plans to insure that core research needs are achieved.
- January 30: Meetings with USAID staff Oldham and Wiles. Meeting at IBM on costs of data entry and feasibility of various plans for data handling. Budget meeting with four PI'S.
- January 31: Visit to field project in Kalama all day. Visited households with data collectors. Meeting with Doris Calloway on her arrival in Cairo.
- February 1: Meeting with all Egyptian Senior Scientists, PI's, and Calloway to discuss objectives and plans. Full discussion of data flow scheme. Meetings with US PI's for remainder of day.
- February 2: Returned to U.S.

Report of Observations, Discussions and Accomplishments

Meetings were held with the entire senior staff of the Nutrition Institute who are involved in the CRSP, the four Principal Investigators, and other associated participants. Several full staff meetings and group discussions centered around specific problems of scheduling and data management questions, giving me ample opportunity to assess the current status of the project and to advise participants on methods for improving the project's data flow and data management. Two days of field site visits also permitted observation of study subjects during interviews by data collectors. Discussions with the Egyptian statistician, Dr. Fahmy, and other computer scientists facilitated planning for the system of data entry and data management in the Egypt project. A meeting with USAID representatives was productive, offering us an opportunity for a general review of the current status of the CRSP with Dr. Oldham and Mr. Wiles who are very supportive of the project. Dr. Oldham was especially helpful in suggesting alternatives for data entry in Cairo.

Spending parts of two days in the village of Kalama, I visited the health center and surrounding buildings including the physician's residence, walked around the village extensively, and visited five or six households where data were being gathered on mother-child interactions, food intake, morbidity recall, and socio-economic status. I also observed anthropometric and physical examinations taking place at the Kalama Health Center. Staff physicians under Dr. Shaheen's direction undertake several activities--anthropometry, physical examinations, and morbidity inter-

views and examinations. Dietitians under Dr. Wafaa were collecting food intake data on a carefully established monthly schedule. Dr. Faisal's staff was performing standardized cognitive testing.

My visits to households were not sufficiently long to see many interviews. Since I do not know Arabic, I could not interpret the questions and answers. However, I do have two comments about what I observed.

First, during a household visit with Dr. Wachs to observe the recording of mother-child interactions, it was evident that the preparation of dietitians to do these observations is not appropriate. It is evident that the recruitment and training of additional, specifically trained personnel will be needed for these measurements.

Second, protocols for collecting anthropometric data require two observers yet only one person was carrying out the work when I visited. For quality control purposes, it will be necessary to obtain a second set of measurements from another observer.

Although the Egypt project has made progress in surveying the study community, in collecting preliminary data, and in pilot-testing some of the instruments, a great deal of work remains to be done before the project is brought to full strength for Phase II. The level of staffing and lack of integration of schedules were matters of special concern.

Because of the fact that schedules for household visits were each being made by separate teams, frequently, more than one team was appearing at a household on a given day. Moreover, sequencing of visits was being done haphazardly rather than systematically.

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During the discussions with the Field Coordinator, Data Manager, and PI's, a method of integrating schedules was developed and it was hoped that problems could be solved through this method. Details for reorganization were subsequently presented at the full staff meeting by the Data Manager.

During our discussions, it became evident that, at the current rate of household entry, the Egypt project would not be able to complete successfully the research plan in the allotted time. Because households are being entered at the rate of 25 per month, the total study sample would not be brought in until the second year of the data collection, too late for a full year of data. An even greater problem is the fact that pregnant women may not be included early enough in the first year to guarantee that sufficient numbers of pregnant women are followed during their second and third trimesters to satisfy research requirements.

It was also evident that data flow was too slow to keep up with the pace required by the core design. Enumerators were not submitting their completed data capture instruments in a timely manner. Sometimes several weeks elapsed between data collection and submission to the Data Manager. It is obvious that this problem will have to be resolved before the full level CRSP activity is attained. From both data quantity and data quality considerations, it is essential that data instruments are never altered for anything but minor transcription errors. No other reasons for changing data once the survey instruments completed can be allowed. In order to assure that data quality is preserved and that data are ready for analysis, there cannot be delays in submitting data for computer entry and data cannot be changed.

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Two factors make the Egypt project different from those in Mexico and Kenya. First, regarding the level of training and experience of the data collectors: if Egyptian staff members are compared with those in the other two projects, it is clear that the Egyptian staff is more highly trained and more experienced than counterparts in the other projects. For example, data collectors of food intake information are experienced graduate dietitians who worked in the Nutrition Institute staff for many years; data collectors for morbidity, anthropometry, and clinical examinations are recent medical school graduates currently fulfilling their field work requirements. Of course, it is beneficial to the project to have such highly educated staff members, but it is also evident that staff members with advanced training are likely to have independent and strong opinions on how to conduct interviews. This is the case in Egypt where enumerators' opinions do not coincide with prescribed CRSP methods. If the Egypt project is to maintain comparability with the other two projects, however, it will have to guarantee that its data collection conforms to CRSP standards and protocols.

Second, the Egyptian work schedule is different from the schedules followed in the two other countries of the CRSP. As is customary in Egypt, each member of the staff of the Institute organizes activities in one of two time intervals -- morning or afternoon. As a result, the number of hours worked by the data collector typically is half of the number of hours worked under Mexican or Kenyan work schedules. Therefore, by necessity, there must be roughly twice as many surveyors as in the other two

projects. This however is not the case. At the time of my visit, there were approximately fifty data collectors working on a part-time basis. This number will need to be expanded rapidly to accomplish all of the tasks required in Phase II.

Dr. Galal, the Senior Scientists of the Nutrition Institute, and the other participating scientists from nearby Cairo universities are an impressive group in terms of academic credentials. However, this group lacks the strong direction and coordination necessary to carrying out the CRSP research plan successfully. The Principal Investigator, Dr. Galal has heavy responsibilities as Director of the Institute. Each of the Senior Scientists has specific responsibilities within each of the research areas. Similarly, the U.S. Principal Investigators and their colleagues have each undertaken their own separate investigations. What the Egypt project has lacked is the coordination and cohesiveness essential to the success of this complex multi-disciplinary effort. If the project is to succeed, all four Principal Investigators will need to be informed of progress in order to assure data quality and conformance to schedules and protocols.

The Data Manager, Dr. Saneya, has been in charge of continuing data management activities. The Field Coordinator, Ms. Meyer, has been assisting in the coordination of schedules and the administration of the CRSP business activities and research. Both of them are very competent and energetic staff members. During my visit, I worked with Dr. Saneya and Ms. Meyer to create the method for scheduling data collection and data flow more efficiently and

rigorously. The proposed method is shown in Figure 2. Whether this process works will become the responsibility of the Cairo staff and the U.S. Principal Investigators.

I am troubled that, because of the heavy responsibilities of the Egyptian PI and because of the separated responsibilities of the U.S. PI's that the diffusion of authority will continue to be a serious problem unless there is a change in the structure of the Egypt CRSP. In my recommendations below I shall offer some comments on restructuring. Meetings with members of the Egypt project did not convince me that success of the core CRSP project is assured under current organization of the project.

Meetings with the statistician, Dr. Fahmy, were constructive. Dr. Jerome, Dr. Fahmy, Dr. Saneya, Ms. Meyer and I discussed extensively the method by which data could be handled in Egypt. After exploring several options, including private computer companies, it was decided to pursue a data entry method using computer facilities already existing for the Strengthening Rural Health Project. The latter project is located in the Nutrition Institute Building, although not part of the Institute itself. This solution was recommended by Dr. William Oldham of USAID who has worked with the Rural Health Project. After a meeting with the staff of that project, it was apparent that with some additional pieces of equipment which could be added to the present installation, the CRSP would be able to carry out data entry in an appropriate manner. With such supplementary equipment, the Nutrition Institute's capacity to handle data would be improved and this could have long-term benefits for the Institute. By having

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equipment and staff trained to handle the data, the CRSP would be making a lasting contribution to the Nutrition Institute.

Dr. Jerome and Dr. Fahmy continued to explore means of handling data entry after my departure from Cairo. With the interest and enthusiasm of Dr. Galal, it was hoped that progress would be made on resolving data management problems.

Much of my time at the Institute was spent in working with the Data Manager, the Field Coordinator, and the Principal Investigators to improve and accelerate the data flow process. By the last day of my visit, a procedure had been developed to guarantee data collection quality and quantity. (See Figure 2 which presents the agreed-upon procedure.)

Recommendations

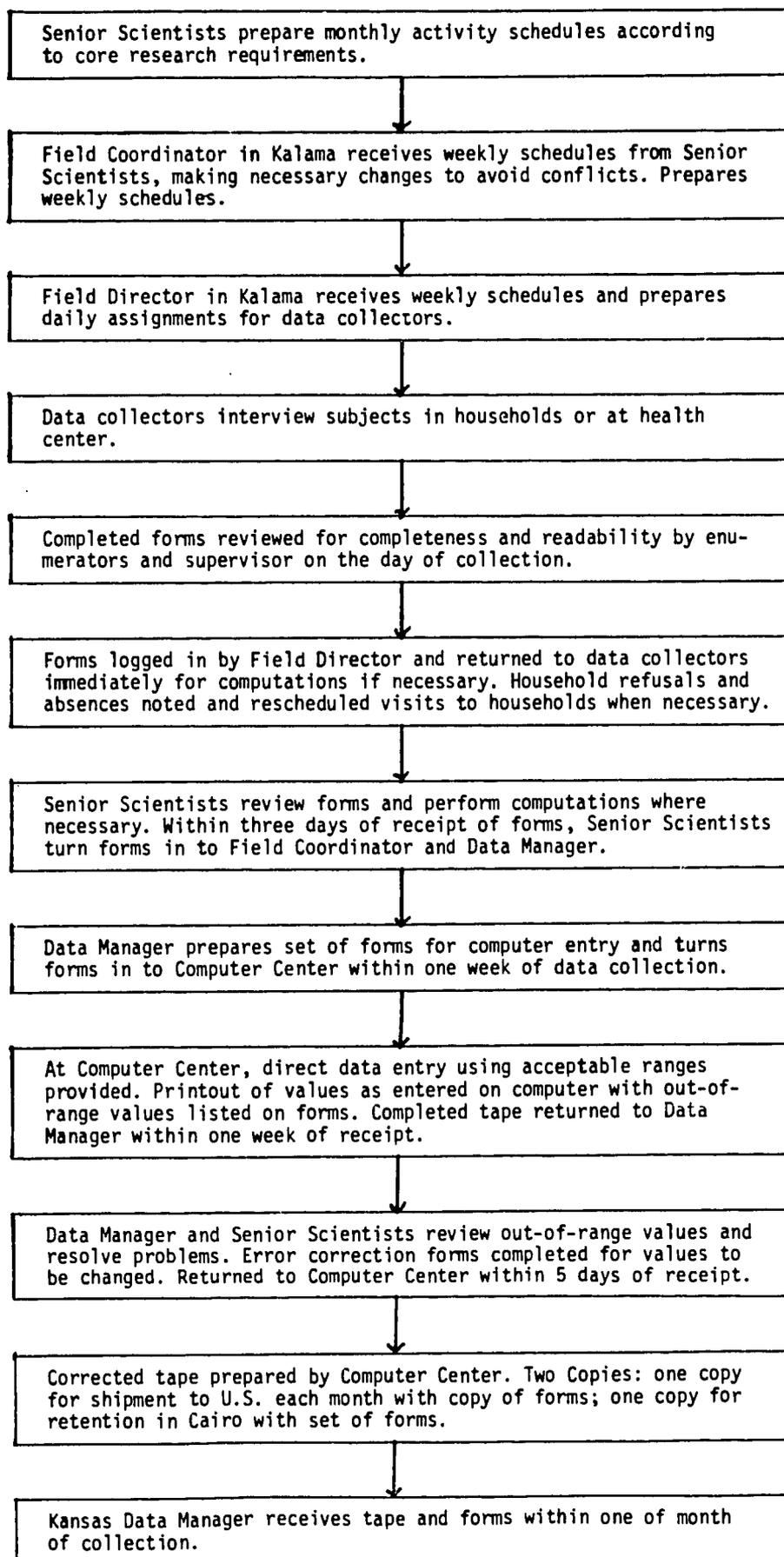
In order to accomplish the research activities of the CRSP in the two-years of Phase II, it is essential that the Egypt project reorganizes its work. I recommend the following measures are taken as soon as possible:

1. Because of Dr. Galal's heavy administrative responsibilities as Director of the Nutrition Institute, there is no one with power in Egypt to see that the research plan is being properly implemented. While the Field Coordinator and the Data Manager are both very competent, they do not have the authority to see that decisions are carried out. Therefore it is important that a person, deputed to act for Dr. Galal, has responsibility for administration and implementation of the research plan.

2. Due to the diffuseness of responsibility among the three U.S. Principal Investigators, there is no one person among the group who is aware of all aspects of the project's progress at any time. Communication among the PI's is uneven and the project suffers from lack of continuity and coordination of leadership among the three collaborating universities in the U.S. There needs to be a more formal structure with regular monthly progress reports on program status. The three Principal Investigators must agree and speak with one voice or the ambiguities of leadership will continue. One of the Principal Investigators must be in Egypt at all times.
3. More field personnel must be hired and trained to bring the project to full strength as soon as possible. It is essential that the Principal Investigators project personnel requirements of the core design and set in motion the plan for adding workers to the project. This must be done immediately as the project's current level of staffing is obviously inadequate to carry out core requirements.
4. Since it is essential for the success of the study that household intrusion is minimized, there must be better integration of schedules. Better scheduling will also increase the efficiency of the surveyors' work at the field site by minimizing conflicts between teams.
5. Once collected, data may not be held by enumerators or Senior Scientists. Data must be reviewed immediately after collection and submitted within three days to the Data Manager for computer entry or for shipment to the University of Kansas Computer Center.

6. Because malnutrition in Kalama is not obvious to the casual observer, the first three months of data will need to be analyzed to see if there is present a sufficient range of intake. Additional households may need to be entered to provide the needed variation. It is therefore very important to present to Berkeley as soon as possible the intake for the first months of data collection.

Figure 2
 PLAN FOR DATA FLOW - EGYPT PROJECT



CRSP Data Management Procedures

Figure 3 portrays the process by which the three CRSP projects are undertaking Phase II data management activities. Beginning with the preparation of the core variable list created by Berkeley from the June 1983 design, the schedule of measurements was formulated and completed by September 1983. Each of the projects prepared survey instruments during the Summer and Fall of 1983, and completed their work in time to begin the Phase II data collection by year's end.

This figure shows the continuing process by which each field project prepares monthly, weekly, and daily assignments for data collectors, checks and reviews completed forms, and submits completed forms to their managers. After checking forms for completeness, the paper forms are copied and one set submitted to the computer center for data entry. Once entered, printouts are reviewed for errors and frequencies prepared to flag out-of-range values. Problem values are identified and resolved when possible; whenever errors are corrected, special forms are prepared. Problems that cannot be resolved are set aside for later review. When no resolution is possible, these values will later be declared missing.

Each month a copy of the data tapes are to be sent to the U.S. project data management center with another copy retained in the host country. At the U.S. data management center, quality control checks are performed, including comparisons of a sample of the data on tape with the original forms. Frequencies, ranges, and simple analyses will be created as the data arrive. When errors

are flagged, error correction forms will be prepared and all users of the files will receive the reports.

SAS files will be created from the raw data files for shipment to Berkeley. These files will be submitted to Berkeley within 8 weeks of data collection in the field.

The Mexico and Kenya projects are presently using this scheme. The Egypt project plans to use these procedures once data entry equipment is obtained in Cairo. Meanwhile the Egypt project's data are being sent on paper to Kansas for computer entry.

**Trip Report: Doris Howes Calloway, Co-Administrator, Nutrition CRSP
January 31 - February 7, 1984 - Visit to Egypt**

**Objectives: To evaluate progress on implementation of Phase II CRSP
research, USAID contract #DAN-1309-G-SS-1070-00**

Persons Contacted

Dr. Hekmat El-Sayed Aly, Nutrition Institute

**Professor Seinab Bishry, Department of Psychiatry, Ein-Shams, University
of Cairo**

**Dr. Ahmad M. Dakroury, Head, Department of Nutritional Biochemistry and
Metabolism, Nutrition Institute**

**Dr. Mohammad El-Ghorab, Department of Nutritional Biochemistry and
Metabolism, Nutrition Institute**

Dr. Abdul Wahab El-Nagger, Hadayk El-Kouba, Cairo

Dr. Farouk Abd El-Wahab, Director, National Sport Research Center

Professor Daisy Fleita, American University, Cairo

Professor Mamdouh Gabr, Faculty of Medicine, University of Cairo

**Dr. Osman Galal, Director Nutrition Institute, Ministry of Health, Cairo
(CRSP-PI)**

**Dr. Wafaa Antonius Moussa, Department of Surveys, Surveillance &
Programs, Nutrition Institute**

**Dr. Amin Kamel Said, Department of Clinical Nutrition, Nutrition
Institute**

**Dr. Farouk Shaheen, Department of Surveys, Surveillance & Programs,
Nutrition Institute**

Dr. Saneya Abdel Azim Wahba, Data Management, National Research Center,
seconded to Nutrition Institute

Professor Feisal A. Unis, Department of Psychology, University of Cairo

Professor Gail Harrison, University of Arizona (CRSP-P.I.)

Professor Avanelle Kirksey, Purdue University (CRSP-PI)

Profesor Norge Jerome, University of Kansas (CRSP-PI)

Professor Ted Wachs, Senior Investigator, Purdue University

Ms. Nancy Meyer, Administrative Assistant (Purdue Univ.) Nutrition
Institute, Cairo

Ms. Mary Mudd, Graduate Student, University of Arizona

Dr. William Oldham, USAID, Director, Office of Health & Population,
Cairo

Mr. John Wiles, USAID, Nutrition Officer, Office of Health & Population,
Cairo

Dr. Seham Faid, National Research Center, Dokki, Cairo

The site visit began with a meeting of all principal investigators and senior scientists involved in the CRSP, at the Nutrition Institute, Director Osman Galal presiding. Dr. Galal stressed the importance of the CRSP project in guiding development of the next Egyptian national 5-year plan. The present plan (1982-7) is focused principally on productivity and lacks a nutrition component. The intention is to incorporate primary health care and nutrition objectives in the 1987-92 plan, based on findings of the research now in progress. The Nutrition Institute is, therefore, committed to conduct CRSP-type research as an obligation to the Egyptian government, as well as to Purdue University and USAID.

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The technical discussion centered on problems of scheduling and data management. The complexity of the research and distributed authority for component portions of the project has led to overlapping interview schedules for individual households and to delay and lack of coordination in submission of completed forms and other data. Responsibility for these functions has now been centralized with Dr. Saneya Wahba in charge. The need for an orderly flow of field data was emphasized and after further discussion, senior scientists agreed to submit forms within 48 hours of completion, the time lag being allowed for quality control checks by the scientists in charge of the components. (Subsequent discussion with Dr. Wafaa Moussa indicated that the dietitians could not comply with this schedule because of the manner in which they record information. See below.) Second level data management, from forms to computer, had not yet been arranged and several alternatives were discussed. Acting on a suggestion made by Dr. Oldham to Dr. Balderston, the possibility of shared use of the computer facility of the Rural Health project group was investigated and later proved to be the least costly option available. The equipment is not currently used after 3 pm and the proposal is for the CRSP project to use it from 3 to 11 pm. The CRSP will have to purchase equipment to interface between the existing PDP 11 and US IBM equipment, at a cost of about \$10,000; this will also enhance the analytical capability of the Rural Health group.

I then met privately with collaborating non-Nutrition Institute Egyptian scientists to determine if collaborative arrangements (financial and other) are satisfactory to them. All those present concurred that present arrangements are appropriate.

Plans for measurement of metabolic rate were discussed with Drs. El Naggat and Farouk Abdel Wahab, who have local responsibility for this component. The Beckman equipment (selected by all CRSP physiologists) has arrived but training in its use has not been completed, awaiting arrival of a Beckman technician from Europe. There is not now a protocol for this testing and the question of BMR versus RMR was raised. The tentative plan is to measure BMR because of expected difficulty in standardizing meals and meal-times. It was stated, however, that pilot testing produced some high RQ's indicating that subjects were not in basal, fasting state. We discussed the units in which data are to be reported, in view of the fact the results of pilot tests were presented in a form that does not meet CRSP requirements. Protocols must be developed according to CRSP agreement and it was suggested that documents should be obtained through Dr. Gardner, UCLA. He might also visit the project, if he travels to Kenya, for further interproject standardization. Investigators (and, later, USPI's) were reminded that work performance measures, for which there is local enthusiasm, are not part of the core design and are not to be initiated pending review of all non-core research.

The day ended with a tour of Nutrition Institute facilities. Extensive renovation is in progress and several upgraded laboratories in which CRSP samples are to be analyzed are already in use and others are nearing completion. The data management group occupies a small laboratory space which it will soon outgrow as there is insufficient filing capacity for the volume of paper that will be generated when the full sample population is enrolled and all tests are in place. The CRSP

project has two administrative offices assigned for its exclusive use and has a generous time-share of Institute meeting and conference rooms. Because of the volume and type of analyses required for the CRSP, equipment has needed to be augmented from CRSP funds.

The next four days were occupied with visits to the project village Kalama, conferences with individual senior scientists and examination of all existing forms, protocols and instruction manuals.

The rendezvous point for CRSP workers in Kalama is the health clinic, where we were greeted warmly by the resident physician, dentist and nurses. The clinic principally provides outpatient services but there are a few emergency beds. The CRSP has renovated for its use a small house adjacent to the clinic where BMR measurements and biological procedures are to be carried out. I was told that the clinic physician has requested that this house be returned for his occupancy. Dr. Galal has received assurances that project use will continue unless a second, larger, unused clinic facility can be renovated at a cost, to the project, of about \$5,000. A potential problem will be avoided if, as Dr. Galal suggests, additional renovation is at fixed cost and the responsibility of the government, however that can be arranged.

Visits made to study households with project field physicians indicate a need for further training. One gave packets of cookies and candy to children; apart from the prohibition of food donation in a study focusing on food deprivation, household conditions were such that it would have been virtually impossible to determine how much was eaten by a target toddler or schooler. There were several deviations from written protocols for simple medical procedures and failure to use

printed forms properly. For example, skin-testing had been done on a 13-month-old infant (non-target) and he was brought by a brother to the clinic for anthropometric measurement and measured under conditions clearly and unnecessarily frightening to him. In one household, the lead male and female were wrongly identified, grandparents being targetted instead of parents. Over half of physicians field time was occupied in attending to medical complaints of non-study households. This service does build good will but at a high cost to the project. It was, however, evident that the doctors were welcomed by and enjoyed good relations with study families. Deficiencies encountered were subsequently reported to Drs. Farouk Shaheen and Gail Harrison. Dr. Shaheen had already instituted weekly meetings with the young doctors as a group and assured us that deficiencies can and will be corrected. To make more efficient use of physicians' time, it was recommended: that doctors be assisted by a paramedical person to serve as recorder (This requires that all medical forms be printed in Arabic as well as English.); and that one project doctor attend at the clinic each day project physicians are in the field, to take all referrals for medical service to nonproject households (This assignment should be rotated.).

Dr. Wafaa Moussa, who with Dr. Norge Jerome is in charge of food intake measurement, described the present operating procedure. This is not as described in the field manual. Dietitians first record the total amount of food prepared for the household and then determine the amount eaten by each target subject. Amounts prepared are determined by recall of raw ingredients used in mixed dishes (the main components of most meals); the volume or weight of these ingredients (or proxy substitutes)

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is measured, using a spring scale of 500 gram capacity. Portions served to target S's are recalled in common measures. Because recipes must be calculated to derive nutrient values of the total prepared before the content of portions can be assigned, dietitians record information in notebooks and transcribe the data onto forms later. Entries are then checked by two reviewers for accuracy. This process entails about a 5-to 7-day delay in submission of records. Intake is being recorded 2 or 3 days each month, to accumulate 7 days of intake information for each household each three months. Food eaten by lead males away from home is not being recorded. Nine dietitians are assigned to the project and because of prevailing working conditions, each can interview two households per day. Dietitians are also assigned the tasks of monitoring mother-child interaction. Assuming that each dietitian works 22 days per month, 396 household visits can be scheduled, which would be insufficient for coverage of required household enrollment at project midpoint. It was noted that only 6 days of food intake need be recorded each 3 months, which will reduce workload by 1/7th, and that dietitians could be relieved of the interaction assignment. Since there were said to be no other dietitians that can be released to the project, another suggestion made is to employ diet aides as interviewers; these could be trained and supervised by the dietitians.

Dr. Wafaa raised several important questions about a modified sampling frame, food coding, quality control, food analysis, and assumptions about preparation losses of nutrients. (Please see attachment #1.) The statistical basis of the present design was explained. It was suggested that quality control for food entries

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should be computed from records in hand (pilot and current) of average portions eaten by each target age/sex group; values outside two standard deviations should be rejected unless accuracy has been verified by dietitians' annotation of the original record. Dr. Wafaa asked about the necessity of recording and coding noncaloric additives to food; these substances contribute little to the weight of mixed dishes. Since blood pressure is being recorded and there is little information about Egyptian sodium intake, Dr. Wafaa was encouraged to follow up her interest in gathering this information. It was agreed that all items eaten or drunk should be recorded, irrespective of energy content.

There is no easy answer to the problem created by recording the weight of raw food prepared but not the finished product, and yet estimating portion sizes of cooked food served and eaten. Some foods increase in volume when cooked (e.g. rice) and others are reduced (e.g. leafy greens). Dr. Wafaa has recorded recipes and values for some typical dishes but it is difficult to judge without more information if the variation from cook-to-cook and at different times is so large that 'standard' factors for yield cannot be accepted. (I agreed to and did, later, explore the question with FAO, but there seems to be no alternative to measurement of weight of cooked dishes, or their moisture content by analysis, or both. FAO does not propose any standard factors for preparatory losses.) Energy and protein content of raw foods can be computed using the FAO table of food composition because most of the analyses for the Middle East region were supplied by the Egyptian Nutrition Institute (confirmed by FAO). These tables are, however, incomplete as regards some vitamins and minerals. Protocols are yet to

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be developed by the SCB for total diet analysis and will be discussed at the May meeting.

The food intake subroutine during illness has yet to be developed by project personnel and should be presented for review by the SCB in May, or earlier.

Visits made to households with the dietitians and separately reveal that the food intake methodology needs to be redesigned. The equipment and recording system currently in use are likely to fall short of accomplishing what is intended (i.e. household food consumption and within-home food consumption by target subjects) and, in any case, different information is required to meet CRSP objectives. In particular, I saw large amounts of sugar being given to children by women and other children in a manner that would defy accurate recording; target infants and toddlers were fed by more than one adult and it was not evident that a second feeder was contributing information; it was reported that children were given sugar-water to drink ad lib. during the night; and some food disappeared to foraging domestic animals unobserved by recorders. To obtain accurate records, more intensive participation of lead women will be required and there will need to be one-on-one observation of target toddlers and infants during most of their waking hours. If total intake by lead males cannot be recorded accurately, (and culturally this maybe impossible) then hypotheses linking their intake and function cannot be tested.

Forms and protocols for reproduction studies, prepared by Drs. Amin Said and Avanelle Kirksey are all in hand and need only minor revision. Voluntary pregnancy testing is being arranged to aid in

final selection of the sample population. Project staff were reminded that the entire sample of pregnant women (and all others) must be entered by October, 1984. As noted in the project annual report, Dr. Kirksey has made a serendipitous observation that indicates a potentially serious problem of vitamin B-6 nutriture among lactating women and their infants. Anecdotal information from Dr. Amin suggests that sugar water is commonly given to infants in early life, which would further dilute the nutritional quality of the diet. If there is a serious essential nutrient problem in the population, as seems likely, additional non-core research to define it must be given high priority.

Dr. Wachs was in the field to provide additional training on schooler cognitive measures. He and Dr. Seinab Bishry were satisfied that the in-school observation instrument and its application are satisfactory. I did not see other cognitive measures being made, but the forms and instructions are complete and Dr. Faisal Unis is well-trained and appears to have field arrangements in hand. We discussed introduction of a new low-cost core measure suitable to the very young. The matter was referred for interproject reconciliation by the project psychologists, for resolution at the May SCB meeting.

Socioeconomic information, care-giving activity measures and case studies are the responsibility of Dr. Jerome and Dr. Hekmat Aly. Forms and manuals retranslated from Arabic, were reviewed but I did not observe their use. This component differs from the others in that a few village residents have been hired as observers/recorders in order to cover the requisite hours of the day. Completed case studies are due in April.

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The immunology laboratory, established by Drs. Daisy Fleita, Ronald Watson, and Otto Sieber, is ready to process blood samples, pending receipt of one additional standard. Obtaining blood samples has not proved to be the problem anticipated and laboratory manuals are in good order.

The biological laboratory, supervised by Drs. Dakroury and El Ghorab, is now assaying hemoglobin, hemotocrit and ferritin in project blood samples, and checking urines for glucose, protein and ketones by the qualitative Combistix procedure. Given the prevalence of bladder stones in Egypt, it seems advisable to use an expanded Combistix paper to measure urine pH and concentration, and it was so recommended. The PI's might also wish to consider measurement of blood urea nitrogen if a hypothesis of essential nutrient deficiency is advanced. Dr. El Ghorab is quite interested in vitamin A nutrition and I encouraged him to seek independent grant support for additional analyses of project samples. Methods are not in place for assessment of parasite loads; the possibility of enlisting the assistance of the Tropical Disease Research Institute in this activity is being explored. Potential requirements for preparation of total diet composites were discussed and suggestions solicited. We agreed that the process of labeling, subdividing and storage and distribution of biological samples should be centralized.

I met twice with Dr. Gabr, who has continued a friendly interest in the project dating from his sponsorship of the proposal in the Ministry of Health. We discussed particularly the importance of coordination within the project and of quality control measures at all stages of data gathering and analysis.

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I called on Dr. Oldham and Mr. Wiles at the USAID office to provide a brief report on the condition of the project and to thank them for their assistance in the computer problem. I reported on discussion I had with Dr. Seham Faid about the general availability of analytical laboratories in Cairo. I was advised that it is unlikely that equipment from previous projects in other institutions could be released to this CRSP. Dr. Oldham appreciates the difficulties presented in our type of collaborative research and is supportive of its multiple goals.

At the exit interview with the PI's, the following specific recommendations were made:

1. The project lacks internal coordination and direction. This may be a result of poor performance of the previous field work coordinator but also is ascribable to partitioning of responsibility and authority for project components, lack of inter-PI communication and sustained presence in the field. Barring agreement on a solid alternative plan, it seems necessary that a USPI must be in residence at all times, each for extended periods of time, with sufficient overlapping time during rotation. The USPI should relieve Dr. Galal of some of his day-to-day involvement with the CRSP, which is too demanding in view of his larger responsibilities. The USPI must be empowered to make on-site decisions, as is necessary for the smooth operation of the CRSP, on behalf of all PI's not in residence.

2. All forms used to gather project data must be reviewed and revised by U.S. and Egyptian principals to eliminate duplication of information requested of respondents. Forms should bear English and Arabic equivalents where that is feasible. Forms should be given

identifying numbers and date of original/revised versions. An archival copy of each form in both languages should be sent to UCB.

3. Training manuals and protocols must be reviewed and revised by U.S. and Egyptian principals. Where this has not already been done, they must be translated into Arabic and retranslated into English for verification. Documents must be submitted for all data-gathering analytical procedures. Documents are missing for: resting metabolic rate; immunological assays; parasitologic assays; sampling methods for saliva, tears, breast milk, urine, and feces; morbidity sub-routine; medical intervention lists and protocols. Archival copies of each should be filed in the NI and UCB.

4. A centralized control system for issuance of data forms and labels must be developed.

5. Protocol(s) for preparation of diets for analysis is requested.

6. Involvement of households is demanding and may result in high drop-out rate. Procedures should be reviewed for feasibility of merging some observational components.

7. Highly-trained, scarce staff must be used more efficiently to accommodate the full sample of households. The possibility of using dietary aides under the direction of dietitians, and nurses to assist doctors should be explored.

8. Additional methods should be explored for gathering information on non-household food consumed by adult men and schoolers. It will be necessary to verify toddler's food intakes by the child-following method. Intake of sugar in all forms is a central issue for infants and toddlers.

9. The complete sample of pregnant women (and all others) must be enrolled by October 1, 1984, and performance of all tests and measures must have reached 100% of core requirement.

10. In selecting additional households for enrollment, the eligible households should be stratified to guarantee adequate representation of low-intake families/target S's.

11. Emphasis on training/retraining and quality control must be continued.

12. Incentives may be required to sustain household participation. All projects staff should give thought to what these might be. Food and income are not allowable.

13. If an essential nutrient deficiency hypothesis is developed, proposals for noncore research to test it should be submitted for early review.

14. Cost-reducing strategies must be explored. Travel, particularly short-term, is a principal target for savings. This may mean restriction of travel by U.S. senior investigators whose principal interests are no longer reflected in the core design.

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Trip Report: Doris Howes Calloway, Mexico, March 20-22, 1984

Purpose: To evaluate progress on implementation of Phase II CRSP research, USAID contract #DAN-1309-G-SS-1070-00

Persons Contacted:

Dr. Adolfo Chavez, Director, NIN (CRSP-PI)

Professor Gretel Pelto, University of Connecticut (CRSP-PI)

Professor P. Pelto, University of Connecticut (CRSP-Sr. I)

Dr. Alfonso Mata, Field Director

Dr. Homero Martinez, Clinic and Field Physician

Ms. Elsa Molina Rivera, Chief Field Nutritionist

Ms. Julia Castillo, Chief Field Physiologist

Ms. Marguerite Mata, Laboratory Chief

Ms. Luzma Meneses, Chief Field Social Worker

Ms. Leticia Serrano, Chief Field Dietary Intake

Ms. Eulalia Martinez, Chief Cognitive Studies

Mr. Ramon Lira, Principal Data Management

Dr. Robert Tripp, Nutritional Anthropologist, CIMMYT

The evening of March 20th, I met with Dr. Chavez and the Peltos for a general discussion of the status of the project. The Peltos are spending a one-year sabbatical leave in Mexico (except for summer travel to Finland) and are in residence in Mexico City. Dr. P. Pelto has begun analysis of project socioeconomic data using locally developed microcomputer programs, and provided as examples two preliminary analyses. (Please see attachments.)

The next two days were spent in Solis with Drs. Chavez and G. Pelto, and field staff. At my invitation, Dr. Robert Tripp joined us on

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the first day. His expert area is on-farm agricultural research and his comments on the productivity questionnaire were sought. (The Mexico project inquiry in this area is much more extensive than other projects and might be regarded as non-core.) He also participated in a discussion of food consumption methodology and observed a food intake interview in a sample household. I observed a newly-introduced toddler food intake method and visited the laboratory, clinic and offices, and the teams measuring resting metabolism of schoolers and conducting playground observation.

There have been several changes in project management since our last visit (December, 1983). A new chief field nutritionist has been hired (replacing Ms. Serano lost by matrimony in December); she has had some advance nutrition training at the INN and seems a real asset to the project. Rooms have been rented in four locations, in a minimodel of the Kenya project structure. The field staff now numbers about 40. There are also outreach health facilities staffed by young physicians. Since December, 130 households have been enrolled in the study, of which only 7 have dropped out. The project laboratory is still under construction; work has been temporarily stopped until an electrical problem can be resolved. The circuit available has wide swings in voltage and cannot be adequately controlled to instrument needs. Alternatives are to bring a new line from Temascalcingo, tap into the hospital line, or buy very expensive voltage regulators. Meanwhile, laboratory space is being donated in the hospital and routine laboratory work is underway. Pregnancy testing has revealed that 35% of women sampled are pregnant, which is good news for the project, if somewhat

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disheartening to the birth control program. Stool parasites are being examined and routine hematologic procedures are in place. The Matas are exploring the possibility of using a Combistix bacteriologic test to assess water quality. If this procedure is successful, it opens up many new possibilities for assessing sanitation at very low cost. Immunologic tests are not yet being made; Dr. Chavez and I discussed the desirability of having expert advice and training available locally. He will follow up with the PI's.

The project appears to have most of its forms in good order for tests currently in progress. If written instruction for methods and administration of forms exist, they were not available for examination. Training emphasizes "hands-on" aspects but, while this is unquestionably needed, it was strongly emphasized that written materials are crucial for continuity, uniformity and quality control. Copies of all forms and manuals were again requested for ME.

Dr. Gretel Pelto reported that a decision had been taken to measure toddler food intake by direct observation (with food weighing) over an entire daily feeding cycle. This is an expensive method as it involves one-on-one observation, but the PI's believe there is no reliable alternative method; I agree. The nutritionist I observed clearly understood the procedure and had elicited the necessary cooperation of the mother. Notes were being taken in ink using a spiral notebook; if this method is to be used routinely, suitable forms will need to be designed to facilitate coding. In the late afternoon a second interviewer came to the house to begin the routine food intake measurement (household food preparation and individual intake of target

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S's). It would seem more efficient to have the nutritionist-observer already present do the additional recording required, and/or conduct other appropriately structured observations/inquiries. The PI's were already considering consolidation of some field work to minimize the number of workers, dealing with a given household.

A room for RMR measurement of schoolers has been made available at the school. Cots have been placed in it but several windows are broken and there is no insulation. On the day of my visit, it was uncomfortably cold and hence, unsuitable for test purposes. The team is making creative use of makeshift equipment (a Kofranyi for measurement of volume, with expired air sampled in large plastic syringes) as the new Beckman apparatus is still delayed in customs. There is no barometer available as yet but Dr. Allen is procuring this essential instrument. In the case of adults, the plan is to measure BMR in their homes early in the morning (teams begin work about 0500 hours). This will provide an ideal opportunity for recording body weight as well. According to Dr. Mata, it will not be possible to measure skinfold thickness of adults due to objection by male heads of household. This development will have to be discussed by the SCB but the project staff should be encouraged to try for upper arm measures, at least.

Playground observation seemed to be under control but we did not linger as our presence was a deterrent to usual behavior. Cognitive tests have been completed on nearly all adults in the present sample population. Cognitive measures of infants and toddlers are not yet in place; the principal field worker was away, receiving training in the methodology, in the United States. Dr. Gretel Pelto and I discussed the problems this poses, i.e. that the method may need adjustment for local

conditions, and that toddlers now enrolled are passing the ages designated for measurement. Staff were reminded of previous advice, to enroll toddlers at 15 months of age in order to be ready for the 18-month measures.

Morbidity questionnaires are being administered weekly, using a simplified reporting system, as was agreed by the project physicians at their last meeting. Principal data are presence or absence of illness and grade of incapacitation (1-3). A system for differential diagnosis and specification of intervention has been developed, using the Apple computer. This program is used particularly for training new staff (physicians and auxiliaries). Data presently stored locally include the complete community census (project and other), and vaccination and other health records. Programs have been developed locally to retrieve selected information. According to Drs. Martinez and Mata, the Apple is used only on Fridays for non-project health studies, that being the day that project staff meetings and weekly case reviews occur. Collection of non-project data will allow determination of the degree to which the project population is representative of the health conditions of the community, but the PI's should be aware that this is not necessary to the research design and costs (time and resources) invested in this manner must be carefully weighed against other non-core research priorities.

Food intake measurement remains a serious and unresolved problem. Dr. Tripp and I received mixed messages about the reliability of reported food purchase and other food transactions as a measure of household food consumption; the PI's should now validate this method by

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other measures of a representative sample of households, and also assure that the variance in a purchased weight or measure is known reliably. The most distressing discovery, however, is one made by the new chief field nutritionist. She states that accurate recording of tortilla consumption remains a great difficulty; she believes that of the 123 households currently enrolled, data are fully trustworthy for only 49 and marginally so for another 50. I asked that codes for these households be identified with the data tapes, and that the 24 unreliable sets be eliminated. Various strategies were discussed; the most promising appeared to be allocation of tortillas by count in plastic bags with color coding of target S's.

The difficulty of conversion from raw weight of food to portions as eaten was again raised by Dr. Pelto. Cooked yield of recipes is being recorded in the case-study families and examination of these data should aid decision-making about the need for laboratory analysis, individual household factors and the like. Questions about diet composites were held for the May SCB meeting.

All present were reminded of the requirement that all target subjects be enrolled by October, 1984 and that all outcome variables must be appropriately linked to food intake over 12 months for each subject or mother-infant pair. Decisions as to whether or not the population provides the variability needed to test hypotheses will be made on the basis of data available May 1, 1984.

Dr. Gretel Pelto was taken quite ill and Dr. Chavez left the city on business the following day, so I did not have an opportunity to discuss Dr. Tripp's comments (reported to me 3/25) with them. Dr. Tripp

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thinks that there is some opportunity for simplification of the productivity questionnaire and that simplification is highly desirable. He will discuss this with Dr. Pelto personally.

The project has come a long distance since December but serious problems remain.

Recommendations:

1. The PI's need to give close, consistent and sustained attention to field work. Dr. Chavez cannot be expected to carry more of this major burden than he already does, given his other responsibilities, so it is fortunate that Dr. Pelto has leave to do so.
2. Solution of food intake measurement problems must be highest priority.
3. Performance of core research components must reach 100% (quantity and quality) by October, 1984. Hard work and more staff will be required to reach this goal.
4. Training manuals, protocols and forms must be prepared or revised as required. Forms should be given identifying numbers and data of original/revised versions. An archival copy of each form, in Spanish and in English, should be sent to UCB.

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Trip Report: Doris Howes Calloway, Kenya, February 7-12 and 22-26, 1984

Purpose: To evaluate progress on implementation of Phase II CRSP research, USAID contract #DAN-1309-G-SS-1070-00

Persons Contacted:

Professor James Mungai, Vice Chancellor, University of Nairobi

Professor Nimrod Bwibo, Principal Faculty of the Health Sciences,
University of Nairobi (CRSP, Co-PI)

Professor Miriam Were, Head, Department Community Medicine, University
of Nairobi

Professor K. Thairu, Director, Kenya Medical Research Institute, Nairobi
(CRSP Sr. Investigator)

Professor S.N. Kinoti, Director, Medical Research Center, KEMRI (CRSP
Co-PI)

Professor A.A. Jansen, Department Community Medicine, University of
Nairobi (CRSP Sr. Investigator)

Dr. Kaviti, Director, Public Health Laboratory, Ministry of Health,
(Food & Water Analysis)

Dr. J. Kanani, Senior Deputy Director, Medical Services, Kenya

Professor C. Neumann, UCLA (CRSP PI)

Professor M. Sigman, UCLA (CRSP Sr. Investigator)

Dr. E. Carter, Field Director

Dr. D. Cattle, Senior Field Scientist

Ms. Susan Weinberg, Field Nutritionist

Dr. A. Khelghati, Field Physician

Dr. Wafsa, Field Physician

Mr. W. Martin, Project Administrator

Mr. Meke, Graduate Student, University of Nairobi

Other Project Field Staff

Dr. Rose Britanek, USAID, Health and Nutrition Officer

Mr. Charles Mantione, USAID, Health and Nutrition

Dr. Dwight Walker, USAID, Agriculture Officer

Professor A. Kielman, Head, Applied Nutrition Unit, Department of Food Science & Technology, University of Nairobi

Most of my first day in Kenya was spent in Nairobi, calling on senior colleagues at the University of Nairobi and Kenyan government officials, accompanied by Drs. Neumann and Carter. We were cordially received by Dr. Kanani who had been instrumental in early arrangements for establishment of the CRSP project and continues to keep an eye on it as he endorses the flow of research materials through customs. With Dr. Kaviti at the Ministry of Health laboratory we explored the availability of analytical data on Kenyan food and water supplies which is a responsibility of this unit; it was explained to us that data are incomplete due to lack of adequate sampling. We offered to supply whatever samples the laboratory would wish from our project area and expressed particular interest in water quality assessment; response was friendly but noncommittal.

Professors Bwibo and Thairu spoke enthusiastically about the excellent progress of CRSP research, in which both play an active part, and we had a preliminary discussion about interinstitutional working relationships. (Most of our senior Kenyan colleagues hold positions at the University of Nairobi and also with the Kenya Medical Research Institute (KEMRI), Ministry of Health.) Professor Marian Were is now

Head of the Department of Community Medicine, having replaced Professor James Kagia in that position. She is aware of the CRSP project as two members of the Department (Kagia and Jansen) are importantly involved in it. She expressed a wish to be kept more fully informed about the project and Dr. Neumann agreed to send copies of reports to her personally. We attempted, unsuccessfully, to contact Professors Bowry and Meme who have counterpart responsibilities for immunologic and cognitive studies, respectively. Dr. Kagia was away, supervising medical students' field work in Machakos.

Dr. Rose Britanek welcomed us warmly at USAID. She has an excellent up-to-date, working knowledge of the components of the project and of the personnel involved, both U.S. and Kenyan. Her perspective on administrative concerns is informed by experience and she is enlightened and helpful in all appropriate ways. We agreed to meet again after my visit to the field.

The next three days were spent at Embu, the field location. The project field organization and management are well-described in travel reports filed previously by Drs. Martin Forman (August, 1983) and Judith Balderston (1/10-23, 1984). I concur in their judgment that the research is efficiently organized and managed. It seems, however, that the field managers are stretched very thin and prompt buttressing is in order. A very heavy burden falls on field staff because US principal investigators cannot, of necessity, spend extended periods of time in Kenya, and because senior Kenyan colleagues have other major responsibilities and limited supporting nutrition research infrastructure. His experience with the CRSP led Dr. Carter to reassess

his career goals and he has now been accepted to medical school. He is fully dedicated to successful completion of the project and has deferred his admission for one year. This means, however, that a deputy field director must be hired very soon, so that she/he will be fully prepared to assume Dr. Carter's duties in June, 1985. There is no Kenyan counterpart to Dr. Dorothy Cattle, and there are neither U.S. nor senior Kenyan field staff carrying day-to-day responsibility for cognitive and immunologic measurements.

Food intake measurement is supervised by Ms. Susan Weinberg. She has well-trained district supervisors in each of the four outposts who see that schedules are followed, make spot-checks of observations in progress, and collate forms. One interviewer/observer is assigned to a household for obtaining a 2-day intake record that is recalled in part, but includes complete weighing of food prepared (raw ingredients and cooked product) during an entire day. Households are issued colored plastic bowls into which food to be consumed by target S's at non-observed meals is placed and the fill-level is marked with a wax pencil. The interviewer also records all food consumed by a target toddler during the observation period. Large-scale equipment is needed for these measurements and this must be carried for long distances (of the order of 3 miles). The methodology is undoubtedly the best that can be devised for local circumstances and attention to detail and verification is exemplary. Two potential problems exist that might be forestalled. Firstly, observers have long periods of inactivity that may result in boredom and inattentiveness (reading, knitting, etc.), and families will be tempted to ask the observer to aid in small tasks,

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modifying normal activity patterns. Project staff might explore the possibility of assigning additional duties to the observer (e.g. timed, frequent observations of activity of target S's). A second concern is that transportation may be a critical need during the rainy season. Something to protect the persons, equipment and records from rain would seem a sound and minimum investment.

Unfortunately, there is no Kenyan table of food composition. Dr. S. Kinoti has agreed to tackle the analytical work at the MRC (KEMRI) but the volume of work required is formidable and it has not been an ongoing activity of the center. (See below.) It was agreed that energy and protein content of diets should be calculated using values tabulated for Africa generally, recognizing that these values may need to be revised later. It is unlikely that use of general tables will introduce bias so we will be able adequately to assess range and variability of intakes. Final decision on food analysis was deferred to the May SCB meeting.

Dr. Thairu and his graduate student, Mr. Meke, are making good progress in setting up the RMR testing. The Beckman metabolic cart is operating well (only a small part, needed to suspend the mask and hose assembly comfortably and correctly, is missing), using power from a specially installed generator. A technician is being trained, as well as Mr. Meke, so there is adequate back-up for this procedure. A room has been set aside for the RMR work in the clinic. The plan is to bring S's to the clinic for physical examination, blood sampling, anthropometry and RMR at one appointment. Technical problems yet to be solved are standardization of the Beckman apparatus (reference gas has

not yet arrived) and recording of barometric pressure. Temperature in the room must be kept in the comfort zone, requiring installation of an air-conditioner and a room heater. Scheduling of transportation and multiple tests also poses some problems; staff were encouraged to separate blood-letting and RMR measurements as far as possible in time. It may be difficult to persuade S's to give up such a large block of time during seasonal periods of heavy work requirement. Dr. Thairu is keenly interested in heart-rate recording, as a measure of daily activity, and other non-core aspects of work performance; we agreed to exchange references and reprints.

The new field physician, Dr. Khelgati, had just arrived and examining rooms were being outfitted in the clinic. Dr. Neumann, and Dr. Kagia, who joined us for part of the day, gave their attention to standardization and training in the health procedures. There was no actual field measurement to be observed.

Dr. Jansen, who is locally responsible for reproduction and anthropometric measurements, spends about two days a week in the field. Our visits did not overlap, so we did not have an opportunity to discuss methodology and quality control procedures in the field, and we had only a very brief meeting in Nairobi beforehand. Households wherein pregnancies are anticipated have been enrolled but measurements are to begin only with detection of pregnancy. If I have understood the sampling frame correctly, the specific hypothesis will be tested but there may not be sufficient information on non-pregnant, non-lactating women, to answer important subsidiary questions. Forms and protocols for pregnancy/lactation studies were not available for review.

At the field level, availability of vehicles, orderly cash flow, and labor stability are major administrative concerns. The project work depends absolutely on prompt and efficient transport of subjects, field workers, blood samples, equipment and forms; doctors require emergency transport. We endorsed purchase requests already in process and agreed to authorize rental of used vehicles, and purchase of motorcycles if necessary. Funds reach the project from UCLA via the University of Nairobi, a procedure originally required by UCLA over University of Nairobi's objections, but now institutionalized in Kenya. The process is cumbersome and there is concern that University of Nairobi might be closed again and funds impounded. (I followed up later with Dr. Bwibo. He said that he has been given assurance that CRSP funds are fully protected in the event of University of Nairobi closure. Also, University of Nairobi has made accounting arrangements to speed up transactions.) The CRSP project, with about 130 employees, is the principal employer in the Embu district, and has been faced with some traditional labor issues (wages, hours, working conditions). These seem under control with institution of communications and grievance procedures. All students planning to enter University of Nairobi have been summoned to appear for six months of national training, so the project may be faced with need to replace several of its most valued field staff on short notice. There is some redundancy now, in anticipation of turnover, but replacement, training and quality control will always be a concern. This makes the preparation of training aids, to which staff have not yet given their full attention, a more urgent matter.

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Dr. Marian Sigman was in the field for training of local personnel in cognitive measures. The enthusiasm and competency of the two principal field workers were impressive and I share Dr. Sigman's confidence that the work is in good hands. Our presence was clearly disruptive to the testing itself, so we kept field observations to a minimum. The Brazelton test for infants is not yet operational; Dr. Meme came to the U.S. for training and has the necessary forms in Nairobi but he has not been able to make time for training of field staff.

Schooler observation presents serious scheduling and staffing problems, because of the location and timing of recreational periods. Dr. Cattle has looked for alternative settings but there appears to be nothing workable. Dr. Sigman will consult with the interproject group of psychologists on this issue.

Dr. Cattle has excellent field staff working on care-giving activities and socioeconomic and community-environment studies. Final decisions on refinement of these measures await analysis of the case studies, and of activity records obtained by Drs. Gorsky (USPI) and Cattle last fall.

As we visited households, Dr. Neumann and I encountered two children with developmental defects. We are told that five others have been identified (prior to cognitive testing). This is a very high prevalence and suggests that there may be some environmental agent involved. It was suggested that project staff gather information on past and current pesticide use, presence of heavy metals and the like.

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I left the field with a clear sense that the project is in good hands, that remaining problems were already recognized, and that these are soluable or avoidable. More sustained involvement of Kenyan scientists (and perhaps less short-term intervention from the U.S. side) is desirable and would be welcomed.

Professors Bwibo, Kagia, Thairu, Neumann and I convened again in Nairobi, to discuss concerns arising from the field visit, and future actions. Dr. Kagia posed both long-term and current issues for consideration. The project structure has four levels: senior scientists, field director, middle-level technical personnel, and field workers. There is a fair distribution of Kenyan and U.S. staff at the senior and middle levels, and all field enumerators are Kenyan. There is, however, no Kenyan counterpart to the Field Director as there should be. Dr. Kagia believes that at least a 2-year contract will be necessary to attract a well-qualified candidate. This will require redistribution of UCLA funds to the Kenya budget. Dr. Kagia noted that computational and analytical facilities available at the University of Nairobi are not adequate to allow the sophisticated data analysis that the CRSP research demands. We should assist the USPI's in seeking a solution to this problem; key elements are acquisition of equipment and augmentation of biostatistics training.

In the longer-term context, Dr. Kagia presented two issues: follow-up of the CRSP research, and investment in training. Continuation of the CRSP might logically take the form of a planned intervention based on project research findings. I commented (here and again to individuals visited the following week) on the need for Kenyans

to enunciate their nutrition objectives and plans for development of a secure infrastructure wherein persons now being trained could count on career continuity. Kenyan colleagues intend to assign additional graduate students to the project for thesis (M.S. or Ph.D.) research. Dr. Kagia requested that we think now about scholarships (as many as three) for persons now employed by the project to undertake graduate study in the U.S. when the field work is completed. Dr. Neumann is not optimistic that UCLA will be able to support such students but qualified candidates would be welcomed as students if external funds were available. I offered to take up these points with USAID. (See below.)

There followed a general discussion of intraproject administration. It was accepted that increased participation by senior Kenyans would be most desirable, and that there are two chief barriers to it. Firstly, all the senior scientists are heavily burdened with University and Government assignments, and play key roles in the pan-African and international scientific communities as well. A second issue is that principals have primary allegiance to an array of institutions/departments; there is no over-all PI who occupies a position ordinate to all and who might, therefore, be able to negotiate on their behalf. We concluded that Dr. Bwibo could best serve this PI role in as much as all the senior Kenyan investigators hold appointments in the faculties of the health sciences, all of which are in his charge. This change in PI's will be offered to the SCB for ratification. Senior Kenyan scientists will discuss specification of their project roles and Dr. Bwibo will report on this later.

Having noted how disruptive our presence was to the orderly flow of field work, I asked Dr. Neumann and Dr. Carter to assure that visits are strictly limited to those who have a mutually acknowledged, official reason to visit. Short-term visits by U.S. project scientists are also to be discouraged, particularly as UCLA currently projects a budgetary shortfall. Dr. Carter increasingly receives requests from interested outsiders for copies of forms, manuals and the like. We decided that all such requests should be referred to ME. Dr. Neumann left for the U.S. and I completed official visits the next week, following up on items noted above.

I met first with Dr. Bwibo who reported that the Kenyan investigators had already met and that internal planning was proceeding smoothly. He will attend the May SCB meeting. He introduced me to Vice-Chancellor Joseph Mungai and joined me in reporting on the progress of the project. Vice-Chancellor Mungai expressed his full support of the CRSP research both as a project and a model of how binational projects should be conducted. He has, in fact, introduced the same organizational constructs in a number of other projects now in force with other nations. We agreed to, and did, meet some days later to continue this discussion and take up other inter-University matters. Vice-Chancellor Mungai will assist in the identification of candidates for advanced training in nutrition and he plans, official duties permitting, to visit California later this year.

At the project's request, Dr. Britanek looked into the availability of used vehicles from other, terminating projects; there are none but other officers were alerted to the project's need in case

anything turns up. On the matter of training, Dr. Britanek is well aware of the need and suggests that some of the traineeships annually awarded by USAID might serve this purpose. She described the procedure for nomination and this information was relayed to Dr. Bwibo. USAID would welcome an application by Kenyan scientists for research following from the CRSP project findings but Dr. Britanek could not, of course, give any assurance of probable funding at this juncture. Dr. Britanek urged that I contact Dr. A. Kieldman and Mr. Luke Wasanga, both of whom have important involvement in Kenya nutrition activities. She also arranged for me to meet with an agricultural officer at USAID, at my request.

Dr. Lundberg was out of town so I met, instead, with Dr. Dwight L. Walker. My purpose was to identify resource people familiar with agriculture in the Embu region and with pesticide use. There are no other USAID-sponsored projects in that district. A joint meeting was soon to take place between two other CRSP's operating in Kenya; I am sorry that the Nutrition CRSP was not included because the meeting might have provided useful agricultural contacts. Unfortunately, I could not extend my visit on short notice. It was suggested that we contact Dr. Peter Giles, an expert in biocontrol (c/o Provincial Director of Agriculture, Kisumu).

Dr. S. Kinoti is the senior Kenyan scientist involved in CRSP food analysis and food intake measurement. He is currently Director of KEMRI's Medical Research Center and has personal charge of its Nutrition Division as well. He related the history of the Center, from its founding by the Netherland's government, and progress made since its Kenyanization a year ago. The center has five divisions (Nutrition,

Oral Health, Epidemiology and Community Health, Parasitology, Biostatistics and Technical) only two of which are headed by expatriates. Dr. Kinoti received nutrition training at Cornell with a view to strengthening the Nutrition Division. The laboratories of the Division were chiefly engaged in hematologic studies when I visited but there is a modest technical staff who can undertake food analysis. Dr. Kinoti's position at the Center is particularly demanding during this transitional period and he also has other academic and clinical duties. Even so, he is willing to assist the CRSP and is seconding a staff member to the field for this purpose.

The contact with Dr. A. Kielman proved very fruitful. He is Head of the Applied Nutrition Unit of the Department of Food Science, in the Faculty of Agriculture, University of Nairobi. The German government is sponsoring the development of a master's degree program in Applied Nutrition, with a commitment to its Kenyanization over a span of five years. We discussed various ways in which we might help each other's efforts. Dr. Kielman has access to well-equipped laboratories and provides entree to the College of Agriculture. The proposed degree program also involves the faculty of Medicine, and Kenyan colleagues might consider sponsoring students for field work experience with the CRSP project; current project field staff might feed into the degree program when the data-collecting phase ends. Berkeley will also try to assist in meeting training needs of individuals destined for appointment to the unit's faculty.

I was unable to contact Mr. Wasanga, nutrition officer in the Ministry of Economic Planning and finance. In 1979 FAO sponsored a

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Kenyan project on nutrition in rural development planning and creation of Mr. Wasanga's position is one outcome. USPI's are encouraged to pursue the contact.

Drs. Carter, Cattle and I met again to discuss the outcome of these various contacts. We reviewed the need for data in advance of the May SCB meeting and look forward to Dr. Carter's attendance at it.

Recommendations:

1. A carefully-selected, well-qualified person, Kenyan if possible, should be appointed to a post of Deputy Field Director during Dr. Eric Carter's tenure, to be advanced to Field Director when/if Dr. Carter resigns. This suggestion is intended also to enable Dr. Carter to be relieved of some of his day-to-day responsibilities.
2. The field staff has reached the maximum carrying capacity of the managing staff. As some core measurements have yet to be scheduled, it would seem prudent to keep all procedures to frequencies specified for the core and explore ways to reduce observer/interviewer "downtime." There must be absolutely no noncore studies performed (except those that can be derived by analysis from data/information samples that are being collected as part of the core.).
3. Visitors to the field must be strictly limited to those officially sanctioned. Demonstrations required for official purposes should, to the maximum feasible extent, be conducted in non-core households.

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4. Some information that would be extremely helpful in interpretation of CRSP outcomes is not included in the core, particularly characterization of the agriculture and agriculture industry of the region. PI's are encouraged to contact the Ministry of Agriculture and various agricultural teaching institutions, extension agents and the like to find out what information is available.
5. Training manuals, protocols and forms should be prepared and/or revised as necessary to reflect current practices. Forms should be given identifying numbers and date of original/revised versions. An archival copy of each document should be sent to UCB.
6. PI's are reminded that the entire sample and all tests and measures must be in place before October 1, 1984.

Addendum: I discussed the environmental contamination issue with Dr. Stachys N. Muturi, Director of Agriculture, Ministry of Agriculture (a fellow trustee of CIMMYT) in March. He expressed interest in collaborative research on this problem. Drs. Neumann and Bwibo are requested to contact him in Nairobi.

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Amendments to the Nutrition CRSP Research Design, June 1983
As Approved by Project Representatives

By prior agreement, all projects are bound to the Revised Research Design-Phase II, June 1983, unless specific authorization is given for its modification. The set of changes listed below has been adopted by majority vote of project representatives and with approval of Management Entity. Henceforth, all projects will be bound by the June 1983 protocol which has been amended as follows:

- | |
|--|
| <p>1. Interpretation of Case Study Protocol: It is to be understood that the <u>purposes</u> of the case studies and hence the required outcome information shall be as described in the original document. However, it is to be accepted also that the actual procedures for conducting the case studies shall be developed and implemented (with retrospective description) by the individual projects. Thus, much of pp 121-126 shall be interpreted as an example of the type of approach that might yield required information rather than as a fixed protocol for the collection of information. Reports are due by April 1, 1984.</p> |
| <p>2. Last sentence of paragraph 2, page 35 to be modified to read: "Mothers will report the food intakes of children 18-30 months of age and supplement the information on other members of the household. Reports on children 18-30 months may be supplemented by direct observation."</p> |
| <p>3. Mexico will be allowed a different system of interviewer interchange for the quality control of dietary data (page 38). Teams of 2-3 persons would be assigned for each household but the team would not be identical across households. Mexico will provide a proposal for the analytical protocol for quality control measure using this partial interchange of personnel/ households.</p> |
| <p>4. Modify schedule on page 41 as follows: Method for School age child shall be "self reporting by interview + information from mother/care giver" and for Toddler, "Reporting by mother or alternate care-giver + observation"</p> |

<p>5. For information only: Mexico has been authorized to add calf circumference measurement for all instances when arm circumference is being measured.</p>													
<p>6. Table 3, page 46, to be modified to include a footnote to Height for adult females: "Female to be measured in non-pregnant state on two different occasions." (inference: do not measure height when pregnant)</p>													
<p>7. Stool parasite examinations will be restricted to target subjects only (page 47, paragraph 4; Table 4, page 50, delete fecal examination from other household members) The infant at 6 months be included.</p>													
<p>8. To be meaningful, stool parasite examinations must be quantitative (page 47, paragraph 4)</p>													
<p>9. Haematological examinations, including serum ferritin, be restricted to target subjects only (page 47, Anemia: Table 4 delete blood samples from other members of household)</p>													
<p>10. Projects will be given discretion to include a screen for parasites and anemia (excluding ferritin) on non target individuals in household based upon assessment of local conditions and ethical need. (Table 4, page 49)</p>													
<p>11. Changes in schedules shown in Table 4 are as follows (page 49) - in addition to changes noted above: Delete urine sample for non-target members of household and for target infants; add a stool examination for target infants; add a urine examination (Egypt only) for toddler. Schedules of measurements to be noted as follows:</p> <table data-bbox="578 1288 1478 1882"> <tr> <td data-bbox="578 1288 1156 1343">All non-target members of household</td> <td data-bbox="1172 1288 1478 1343">Once</td> </tr> <tr> <td data-bbox="578 1343 826 1397">Target infants*</td> <td data-bbox="1172 1343 1478 1397">At birth At 6 mos.</td> </tr> <tr> <td data-bbox="578 1441 826 1496">Target toddlers*</td> <td data-bbox="1172 1441 1478 1496">At entry and each 6 mos</td> </tr> <tr> <td data-bbox="578 1528 826 1583">Target School Age</td> <td data-bbox="1172 1528 1478 1583">At entry and each 6 mos</td> </tr> <tr> <td data-bbox="578 1627 908 1681">Target Pregnant Woman</td> <td data-bbox="1172 1627 1478 1681">At entry, ^{1st} 9m At delivery</td> </tr> <tr> <td data-bbox="578 1681 1073 1882">Target Men and Nonpregnant, Nonlactating women (for physical exam, blood, urine sample, stool sample)</td> <td data-bbox="1172 1681 1478 1882">At 6 mos lactation At entry and each 6 mos</td> </tr> </table>	All non-target members of household	Once	Target infants*	At birth At 6 mos.	Target toddlers*	At entry and each 6 mos	Target School Age	At entry and each 6 mos	Target Pregnant Woman	At entry, ^{1st} 9m At delivery	Target Men and Nonpregnant, Nonlactating women (for physical exam, blood, urine sample, stool sample)	At 6 mos lactation At entry and each 6 mos	
All non-target members of household	Once												
Target infants*	At birth At 6 mos.												
Target toddlers*	At entry and each 6 mos												
Target School Age	At entry and each 6 mos												
Target Pregnant Woman	At entry, ^{1st} 9m At delivery												
Target Men and Nonpregnant, Nonlactating women (for physical exam, blood, urine sample, stool sample)	At 6 mos lactation At entry and each 6 mos												

*with parental consent.

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11. Cont'd: The Egypt project advises that urine parasite screens in adult males, females pregnant and lactating women should be done every 6 months at the time of the physical exam. (Scheduled urine collection are for other purposes as well as some/all being used for parasite screen.)

11. Cont'd: All projects are asked to advise if urine samples will be examined (e.g. for glucose) in adult men and in non-pregnant, nonlactating women. If not, it is proposed that urine specimen be deleted for this group except for Egypt parasite screen.

11, Cont'd: Management will provide a vision test for target toddlers. Adult vision and hearing to be tested at least once. Projects are asked to advise on test they will employ for hearing at all ages and for vision in school age.

12. Morbidity: Mexico has promised to distribute a field manual of clinical signs and symptoms including colour photographs (and models of normal/abnormal stools?)

13. Page 56, definition of diarrhea to be changed to read:
"Stools - change in usual quantity, i.e. 3 or more above usual number*, or abnormal consistency, i.e. more than 4 watery stools/24 hr or blood and mucous mixed in stool"

Projects must submit a protocol describing how they will establish the normal number/consistency of stools by age group in their community.

14. Page 60. The statement on chicken pox should read on page 60: "Infected or hemorrhagic chicken pox." in the severe category.

15. Page 61, to Miscellaneous, add the following statement:
"Criteria for intervention, appropriate to the local community and subject to interproject concurrence, shall be specified in the project field manual."

16. Table 5, page 64, last entry, delete "mild" so that it will read: "All target subjects with illness"

17. Page 67, C-Reactive Protein, modify to read: "...This requires 0.02 ml serum using a rapid plate or radial immunodiffusion. (This has the effect of allowing measurements on young children previously prohibited because of apparent need for venipuncture)

<p>18. Page 68, Add a new section 4 and renumber 4,5 to 5,6:</p> <p>"4. <u>Cutaneous delayed hypersensitivity</u>: Intradermal skin testing will be carried out with <u>up to three</u> antigens, selected as appropriate to the community, plus control</p> <p><u>Method</u>. The antigens will be injected intradermally with disposable plastic multiantigen applicators designed for this purpose. All subjects will be reexamined 48 hrs after injection (i.e. specially scheduled visit). A test will be classed positive if the induration is greater than 3 mm compared to the control test or equal to or greater than 5 mm response, measuring the maximum diameter at 48 hr.</p> <p><u>Comments</u></p> <ul style="list-style-type: none">i) skin testing is not to be done in <u>acutely</u> ill subjects or in those who have just received measles vaccine within the previous week. Skin tests may be applied at the same time that measles immunization is given.ii) If a child is found not to have received appropriate immunization for age (appropriate to that community), skin tests shall be performed and the child shall be referred for immunization after reading the tests at 48 hrs. Pregnant women, if unimmunized for tetanus shall likewise be immunized.iii) Projects shall advise Management of the exact antigens that are used as well as of the results for testing for each antigen. The antigens used shall not be changed during the duration of the project.
<p>19. Table 6, page 70 to be modified as follows:</p> <p>For infant at 6 mos., add "once" for all measures except colostrum and breast milk measures</p> <p>For target toddlers, replace "2/yr" with "at entry and every 6 mos." Also to be included on this schedule is Serum C-Reactive Protein</p> <p>For target adults, replace "1/yr" with "at entry and at 12 mos." leaving additional specifications for pregnancy and lactation.</p>
<p>20. Table 6, page 70, add</p> <p style="padding-left: 40px;">Skin Testing once for each class of target individual</p>
<p>21. Table 6, page 70, <u>delete</u></p> <p style="padding-left: 40px;">Serum IgA, IgG, IgM for all classes shown (Chandra advises that these will not be useful)</p> <p><u>add</u></p> <p style="padding-left: 40px;">Serum IgG for pregnancy 5th and 8th month only</p>

22. Page 74, 6 lines from bottom, change to read:

"1) The Brazelton Neonatal Assessment Scale (BNAS), modified"

(The proposal is to delete from the test the pin prick and raise-up tests which are objectionable to parents; management has been assured that the measures obtained by these components will be obtained by other components)

23. Page 47 and Table 4, page 49

Determination of serum zinc on same schedule as serum ferritin shall be done by projects if desired.

Revised Table 4. Summary of Physical Examination
and Medical History Protocols

Subject	Frequency	Physical Exam and History	Blood Samples (finger or heel prick)	Urine Sample	Stool Sample
All <u>non-target</u> members of study households	Once	X	a	a	a
Target Infants	At birth at 6 months	X ^c X			X
Target Toddlers	Initial and Each 6 months	X ^b	X	Egypt only	X
Target School Age	Initial and Each 6 months	X ^b	X	Egypt only	X
Target Pregnant Woman	Initial, 5th and 8th month delivery 6th m lactation	X ^b X ^c X ^b	X X	X ^d X ^d	X X
Target Men and Non-pregnant, Non-lactating Women	Initial and Each 6 months	X ^b X	X	X ^e	X

^a Examinations for anaemia (excluding serum ferritin) and for parasites and other endemic conditions to be implemented at discretion of project based on assessment of need.

^b To include vision and hearing tests. In adults, this will be once only.

^c Special protocols will be used at birth and delivery

^d Egypt will perform parasite screen as well as measures for all projects

^e Egypt will perform parasite examination; it is assumed other projects will check for glucosuria, albuminuria, etc.

Revised Table 6. Summary of Immunology Protocol

Classification	Infant*at 6 months	Target Toddlers* & School Age Child	Target Adults
<u>Cell Mediated Immunity</u>			
Tonsillar Size	once	Entry and every 6 m	
Lymphocyte count	once	Entry and every 6 m	Entry and 12 m
T-cell count			Entry and 12 m
<u>Humoral Immunity</u>			
Serum IgA, IGG, IgM	once	Entry and every 6 m	once per year Pregnant at 5,8 m
Serum Complement Components and Proteins	once	Entry and every 6 m	Entry and 12 m Pregnant 5,8 m
Serum C-Reactive Protein	once	Entry and every 6 m	Entry and 12 m Pregnant 5,8 m
<u>Secretory Antibody Levels</u>			
Salivary Lysozyme, and Secretory IgA, IgG	once	Entry and every 6 m	Entry and 12 m Pregnant 5,8 m Lactating 1,3,6 m
Colostrum and breast Milk Lysozyme, Secretory IgA, IgG			Lactation Day 1-3 and Month 1,3,6
<u>Skin Testing (up to 3 Antigens)</u>	once	once	once

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

Appendix C

CRSP Data Management Procedures

Figure I portrays the process by which the three CRSP projects are undertaking Phase II data management activities. Beginning with the preparation of the core variable list created by Berkeley from the June 1983 design, the schedule of measurements was formulated and completed by September 1983. Each of the projects prepared survey instruments during the Summer and Fall of 1983, and completed their work in time to begin the Phase II data collection by year's end.

This figure shows the continuing process by which each field project prepares monthly, weekly, and daily assignments for data collectors, checks and reviews completed forms, and submits completed forms to their managers. After checking forms for completeness, the paper forms are copied and one set submitted to the computer center for data entry. Once entered, printouts are reviewed for errors and frequencies prepared to flag out-of-range values. Problem values are identified and resolved when possible; whenever errors are corrected, special forms are prepared. Problems that cannot be resolved are set aside for later review. When no resolution is possible, these values will later be declared missing.

Each month a copy of the data tapes are to be sent to the U.S. project data management center with another copy retained in the host country. At the U.S. data management center, quality control checks are performed, including comparisons of a sample of the data on tape with the original forms. Frequencies, ranges, and simple analyses will be created as the data arrive. When errors

are flagged, error correction forms will be prepared and all users of the files will receive the reports.

SAS files will be created from the raw data files for shipment to Berkeley. These files will be submitted to Berkeley within 8 weeks of data collection in the field.

The Mexico and Kenya projects are presently using this scheme. The Egypt project plans to use these procedures once data entry equipment is obtained in Cairo. Meanwhile the Egypt project's data are being sent on paper to Kansas for computer entry.

Figure 1

