

Cooperative Agreement

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QUARTERLY REPORT

Sept. 16, 1982 - Dec. 15, 1982

International Center for Epidemiologic  
And Preventive Ophthalmology  
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## 1.0. INTRODUCTION

During this first quarter of operations for the 1982-83 annual work plan several, new major initiatives were launched while highly visible landmarks were achieved in several on-going country projects and methodology studies in which ICEPO has made substantial resource investment.

## 2.0. MAJOR NEW INITIATIVES

### 2.1. ICEPO - NRDC (Bogor) Memorandum of Understanding

During November 1982 a five-year 'Memorandum of Understanding between two World Health Organization Collaborating Center for Collaboration in the Control of Xerophthalmia and Vitamin A Deficiency' was formally signed between the directors of ICEPO and the Nutrition Research and Development Center (NRDC) in Bogor, Indonesia. This memorandum provides a basic 'framework for the regular exchange of information and the exploration of areas of mutual interest' to promote collaborative research and training activities that can impact on xerophthalmia in Indonesia and South East Asia. To date the collaborative efforts (previously conducted on the basis of an informal agreement) include investigations into:

- (1) the stability of vitamin A stored for variable lengths of time under ambient conditions in small brown bottles;
- (2) the feasibility and efficacy of fortification of MSG with vitamin A as a preventive strategy to combat vitamin A deficiency;

- (3) the development listing of a nightblindness questionnaire for use by village health workers in screening children for clinical vitamin A deficiency;
- (4) the comparability of common laboratory tests for determining serum vitamin A levels throughout the entire, physiologic range of serum vitamin A concentration; and,
- (5) the usefulness of a new monoclonal antibody test for early detection of conjunctival keratinization.

2.2. Project for the Prevention of Vitamin A Deficiency Blindness in Malawi

ICEPO hosted two meetings during this quarter for representatives of major parties (see Appendix A for list of attendees) involved in blindness prevention activities in Malawi to discuss the International Eye Foundation (IEF)/Helen Keller International (HKI)/ICEPO proposal to investigate the extent of xerophthalmia and alternative strategies to reduce its incidence in Malawi. During October and November, Dr. Sommer met with Dr. Moses Chirambo in Washington to help outline the more quantifiable objectives of this Project, and corresponded regularly with HKI about such developments. Frequent contact between ICEPO (Mr. West) and the IEF have been maintained in order to begin defining specific study procedures and the timetable of events for the Project, which is currently scheduled to begin in August 1983. A further meeting with Drs. Schwartzwood, and Meaders and Mr. West to discuss the nutrition component of the survey is scheduled in January 1983 followed by a joint IEF/ICEPO site visit to Malawi in February 1983.

Dr. Sommer visited Dr. Larry Schwab at the University of West Virginia in December (at no cost to the project) to develop the Malawi Survey procedures further as well as to initiate plans for a series of hospital-based measles/nutritional blindness studies in Malawi, similar in design to those already taking place in Tanzania.

2.3. Ms. Joanne Katz, MA joins ICEPO under the Cooperative Agreement

In August 1982, Ms. Joanne Katz, a 1981 graduate of Princeton University and statistician accepted the position as a statistician for the International Center For Epidemiologic and Preventive Ophthalmology. She brings with her expertise in programming, research analysis, and statistical methods. Ms. Katz together with Mr. Stephen Singer (see Section 3.1.1) will incorporate a new data management package entitled, 'Scientific Information Retrieval System' (SIR), to help maintain the data of the Glaucoma Screening Study and Aceh Study.

2.4. Dr. James Tielsch, Ph.D. joins ICEPO under the Cooperative Agreement

In December 1982 Dr. James Tielsch, an epidemiologist with several years field experience in developing countries, began contributing his epidemiologic, statistical, and programming skills to the vitamin A project on an 'as needed' basis to assist in the management and interpretation of data from round one, and the development and modification of procedures for round two of the Aceh Study.

2.5 Development of a Standardized Xerophthalmia Survey Procedural Package

Initial plans were generated this quarter for the development of a standardized procedural package for conducting a xerophthalmia survey in a developing country. It will be designed to serve as a 'template' which can be readily modified to country-specific interests and capabilities. This package will include a model sampling scheme, modifiable field survey forms, statistical and data entry software for field level, microcomputer entry and tabulation of data, and a detailed manual of operations for basic survey, data entry, and analytic procedures. Given his epidemiologic expertise, Dr. Tielsch is particularly well qualified to develop this survey package, drawing on ICEPO survey experiences in Aceh and Malawi, when the latter project is carried out in the Fall of 1983. An estimated 1 1/2 to 2 year period is projected for the completion of this activity.

2.6. Plans for the Evaluation of a Vitamin A Nutrition Education Strategy

While visiting Indonesia in late September, Dr. Sommer seeded the notion of launching and evaluating a major nutrition education strategy to influence increased consumption of vitamin A rich foods in a region in Java. Various aspects of such an approach were actively discussed among Indonesian, HKI, NRDC, Cicendo, and ICEPO representatives at a full-day meeting. Current plans call for the development of such a proposal during the coming year.

2.7. State-of-the-Art Paper

Mr. West began writing the second ICEPO 'State-of-the-Art' paper on the mass dose periodic vitamin A intervention strategy in terms of

mega-dose efficacy in preventing vitamin A deficiency and xerophthamia, and demonstrated program effectiveness, drawing on available literature about previous and on-going country programs throughout developing regions of the world. This paper is scheduled for completion by early February 1983.

## 2.8. Relocation of ICEPO Offices

In November, all professional and support staff (with the exception of Mrs. Rider in the Biochemistry Reference Laboratory) and Ms. Hawkins were finally consolidated into the Wilmer Institute, and all vitamin A project offices are now located along one corridor on the first floor of the old Wilmer building. The close proximity of the ophthalmologic, statistical, epidemiologic, computer programming, and nutrition sections has resulted in further improvements in communications and work efficiency within the Center.

## 3.0. MAJOR COUNTRY PROJECTS

### 3.1. Indonesia

#### 3.1.1. Aceh Study

Upon completion of field team training in Aceh and data entry personnel training and forms printing in Jakarta during the first three weeks of September, the first round of the field survey phase of the vitamin A capsule distribution evaluation study was launched officially on 22 September 1982 in Kabupaten Aceh Utara, and the following day in Kabupaten Pidie. The Government capsule distribution program in UNIVAC villages began in November on a designated schedule, followed by the

capsule distribution monitoring procedures in these same villages. This initial survey round is scheduled for completion by early September 1983.

The data management and analysis system has been under development in Baltimore by Ms. Hawkins, Ms. Katz and a contracted data systems consultant, Mr. Stephen Singer. The data management package SIR (Scientific Information Retrieval) is being used as the major data management tool. Ms. Katz and Mr. Singer attended an advanced course in the use of this package in December 1982. A major part of the system is expected to be in place by the time Ms. Hawkins and Ms. West go to Indonesia in late February and early March. The data entry procedures have been refined based on experiences with keying forms during the first two months of the project.

Revisions to chapters of the Manual of Operations following start-up are nearing completion with drafts of Chapters 8 (Procedures For Completing Ophthalmologic Examinations) and 16 (Study Policy) currently being circulated to all operation units for comments and modifications. In addition, Chapters 1 and 2 of the Data Processing Manual have been written by Ms. Hawkins and distributed.

Mr. West and Ms. Hawkins have maintained regular communication between ICEPO and colleagues in the Indonesian Study through bi-monthly memoranda to the field teams in Aceh, and monthly telephone conferences with Dr. Tilden in Jakarta and Dr. Djunaedi in Banda Aceh.

### 3.1.2. Nutrition Education

Initial ideas and comments were discussed regarding a proposal to

evaluate a multi-faceted nutrition education strategy in Java (See section 2.5).

### 3.2. Tanzania

The xerophthalmia surveillance system, generated from recorded, routine observations of ophthalmologists, and from pediatric ward admissions to local hospitals throughout the country, is now in place and ongoing, although in its early stages. Draft forms for the measles/nutritional blindness interaction study are currently undergoing revisions. This multicenter collaborative study began in November 1982 and will run for approximately one to three years.

### 3.3. Malawi

Much preliminary activity has taken place to move the Malawi Study into its planning stages. The field survey is anticipated to begin in September 1983 (See section 2.2.).

### 3.4. Zambia

While definitive action on possible studies in Zambia addressing nutritional and measles-interactive blindness in the Lua Pula Valley has not been taken during this quarter, plans have been made for Dr. Taylor and Mr. West to conduct a site visit to Zambia in July 1983 in order to investigate more completely the potential for ICEPO collaboration with the Zambian Government in its control of nutritional blindness program.

### 3.5. Brazil

A request has been received at ICEPO for providing technical

assistance to the Government of Brazil in planning a strategy to define the geographic distribution, extent, and severity of xerophthalmia, and to assist the Government in the selection and evaluation of an appropriate intervention strategy. ICEPO awaits additional technical information, evidence of commitment for action on the part of the GOB, and response to suggested funding mechanisms.

### 3.6. Haiti

Surveillance for xerophthamia continues in Haiti as an ongoing program. We now have data for 15 months from four centers--two hospitals where ophthalmologists routinely examine all pediatric admissions and two health centers where pediatricians screen all children for evidence of xerophthalmia. The number of children examined each month varies from approximately 60 in Cap-Haitien to 300 in Port-au-Prince; whereas, the two health centers each examine 200 to 300 children per month. In Port-au-Prince, one or two cases of xerophthalmia are seen each month. At the other three, one case is seen every two to three months. The full impact of a surveillance system must wait until sufficient data has been accumulated to allow the establishment of an expected baseline. So far, the system seems to be working well. A separate program of assessment of the presence of night blindness in pregnant women and infants has been operating for one year. Medical assistants interview each person they examine and, to date, 8% of women and 25% of children are identified as complaining of night blindness. This is higher than would be expected, and suggestions for investigating this further have been forwarded to Haiti. This screening has been conducted in four dispensaries and is continuing.

3.7. Mexico

The scope of the xerophthalmia and trachoma study in Mexico has been greatly curtailed following the eruption of the volcano El Chichonel. However, examination of two communities has been completed. Approximately 970 people in 165 families have been examined. All children were specifically examined for signs of xerophthalmia, and for all children under the age of six, a history of night blindness was sought. The data from these examinations is now in Baltimore ready for computer entry and preliminary analysis. Data regarding the prevalence of xerophthalmia in these Mexican villages have been collected and are currently being analysed (at no cost to the project).

#### 4.0. BIOCHEMISTRY REFERENCE LABORATORY (Mrs. Agatha Rider)

##### 4.1. Comparability of Vitamin A Assay Techniques

Experiments designed to evaluate serum vitamin A determination methodologies were completed. These final experiments included determining the recovery of added vitamin A, the effect of saponification on the observed vitamin A levels in sera containing large amounts of lipids, and estimating the degree of reproducibility associated with each method for vitamin A determination and others.

##### 4.2. Serum Vitamin A Determination Methodologies Preliminary Report

A Preliminary Report describing the procedures of the HPLC, Trifluoroacetic Acid, and Spectrophotometric-Ultraviolet destructive irradiation methods for determining serum vitamin A levels, and the comparative results from these studies, was prepared and forwarded to USAID in December.

##### 4.3. Effects of Simulated Adverse Field Conditions on Vitamin A levels in Sera

In an attempt to quantify the effects of adverse conditions such as prolonged exposure of collected serum samples to hot ambient temperatures, delayed centrifugation or other potentially disturbing factors which could invalidate a serum vitamin A determination under field conditions, a series of studies are being carried out to investigate these factors on the stability of serum vitamin A using the three above methodologies mentioned in Section 4.2. Serum samples have been collected from the (vitamin A replete) Wilmer Institute staff to

provide a resevoir of sera required for these studies.

#### 4.4. Protocol for Blood Collection for Tanzanian Study

A protocol for the collection, storage and processing of serum samples in the Tanzanian multi-center nutritional blindness/mealses- interaction study was prepared and forwarded, with necessary equipment, to Dr. Allen Foster at the Mvumi Mission Hospital in Dodoma.

#### 4.5. Carotenoid Determinations in Green Leafy Vegetables

Preparations have begun for determining various carotenoid levels in dried samples of selected sun dried dark green leafy vegetables shipped from Tanzania.

#### 5.0. TRIPS AND MEETINGS

##### Dr. Sommer

September: Conducted site visit to Aceh; also visited Jakarta and Bogor, Indonesia.

October : Attended International Congress of Ophthalmology, delivered multiple lectures on xerophthalmia.

Attended second General Assembly of the International Agency for the Prevention of Blindness, Washington, DC - delivered multiple lectures on xerophthalmia.

December : Formally presented a description of ICEPOs mission and technical assistance activities at the Annual Meeting for Federally Sponsored Research Programs in Human Nutrition, Washington, DC.

Dr. Taylor

October: Scientific Meeting Group on Filariasis, WHO, Geneva. Met with Drs. de Maeyer and Keller of nutrition and Dr. Thylefors of PBL to discuss ongoing activities. (no cost to program)

November: International Agency for Prevention of Blindness, Washington, D.C. (no cost to program)

International Congress of Ophthalmology, San Francisco.

Lectured on prevention of blindness and xerophthalmia. (no cost to program)

Ms. Hawkins

October : Returned from Jakarta, Indonesia after having reviewed forms, and field procedures, trained data entry personnel, and set up the data entry system for the Aceh Study.

Served as a member of the faculty at a Conference on Changing Concepts in Bioavailability and Clinical Trials, sponsored by the University of Maryland School of Pharmacy.

Met with Drs. Tarwotjo and Tilden in Baltimore following IAPB meeting to evaluate progress of Aceh Study and to review field procedures.

Participated in two telephone conferences with Dr. John Mason and colleagues at Cornell to exchange information concerning the use of microcomputers in data collection and management in developing countries.

Ms. Hawkins will go to Indonesia to review field activities and data handling procedures; to implement procedures for forwarding corrections to data already sent to ICEPO for storage; to discuss the status of data collection and the implications of preliminary data; to participate in the development of forms and procedures for the follow-up round of the Aceh Study.

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APPENDIX A

MALAWI VITAMIN A INTERVENTION

COORDINATING MEETINGS

(10/23/82; 11/10/82)

APPENDIX A

MALAWI VITAMIN A INTERVENTION COORDINATION MEETINGS

(10/23/82; 11/10/82)

10/23/82

ATTENDEES: Helen Keller International: Susan Leone

ICEPO, Johns Hopkins: Alfred Sommer  
Hugh Taylor  
Joanne Katz  
Agatha Rider  
Jim Tielsch  
Barbara Hawkins

International Eye Foundation: Robert Meaders  
Randy Whitfield  
Teferra Tizazu  
Jack Swartwood

USAID John McKigney

Christoffel Blindenmission Joe Taylor

Observer Prof. Fred Hollow

11/10/82

ATTENDEES: ICEPO: Alfred Sommer, M.D.  
Hugh R. Taylor  
Keith West

IEF: Robert Meaders  
Larry Schwab  
Teferra Tizazu  
Jack Swartwood  
Randy Whitfield