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DEPARTMENT OF STATE
AGENCY FOR INTERNATIONAL DEVELOPMENT
Washington, D.C. 20523

PROJECT PAPER

INDIA

BIOMEDICAL RESEARCH SUPPORT
(386-0492)

USAID/INDIA

JUNE, 1985

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AGENCY FOR INTERNATIONAL DEVELOPMENT PROJECT DATA SHEET		1. TRANSACTION CODE <input type="checkbox"/> A = Add <input type="checkbox"/> C = Change <input type="checkbox"/> D = Delete Amendment Number _____	DOCUMENT CODE 3
2. COUNTRY/ENTITY INDIA		3. PROJECT NUMBER 386-0492	
4. BUREAU/OFFICE ASIA		5. PROJECT TITLE (maximum 40 characters) Biomedical Research Support	
6. PROJECT ASSISTANCE COMPLETION DATE (PACD) MM DD YY 03 31 92		7. ESTIMATED DATE OF OBLIGATION (Under 'B' below, enter 1, 2, 3, or 4) A. Initial FY 89 B. Quarter 4 C. Final FY 91	

8. COSTS (\$000 OR EQUIVALENT \$1 =)						
A. FUNDING SOURCE	FIRST FY 85			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total			4,400	10,257	2,843	13,100
(Grant)	()	()	(600)	(7,300)	(2,000)	(9,300)
(Loan)	()	()	(3,800)	(2,957)	(843)	(3,800)
Other U.S.	1.					
	2.					
Host Country			-		7,020	7,020
Other Donor(s)						
TOTALS				10,257	9,863	20,120

9. SCHEDULE OF AID FUNDING (\$000)									
A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1) HE	B511	540	540	-	-	600	3,800	9,300	3,800
(2)									
(3)									
(4)									
TOTALS				-	-	600	3,800	9,300	3,800

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)				11. SECONDARY PURPOSE CODE	
550	570	580			520

12. SPECIAL CONCERNS CODES (maximum 7 codes of 3 positions each)					
A. Code	BR	R/H			
B. Amount					

15. PROJECT PURPOSE (maximum 480 characters)

The project is to assist the Indian Government create a functioning program of laboratory-based field epidemiology with its concomitant emphasis on preventive medicine. Activities will be supported in field spidemiology, laboratory support services, clinical epidemiology, establishment of a computer-based information system, and quality control of biologicals.

14. SCHEDULED EVALUATIONS				15. SOURCE/ORIGIN OF GOODS AND SERVICES				
Interim	MM YY	MM YY	Final	MM YY	<input checked="" type="checkbox"/> 000	<input checked="" type="checkbox"/> 941	<input checked="" type="checkbox"/> Local	<input type="checkbox"/> Other (Specify) 935
	03 87	07 87		10 91				

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a _____ page PP Amendment.)

17. APPROVED BY	Signature	18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION		
	Title Richard M. Brown Director (Acting)	Date Signed	MM DD YY	MM DD YY
			06 25 85	

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memorandum

DATE: JUNE 21, 1963
REPLY TO: Rogers Beasley - HN
ATTN OF: *W. H. Beasley*
SUBJECT: Biomedical Research Support (386-0492)
TO: The Director - USAID/India

ACTION:

You are requested to authorize a \$9.3 million Grant and a \$3.8 million Loan of Section 104 funds for the Biomedical Research Support Project.

DISCUSSION:

The present public and private health care system in India is urban directed, clinically based, and curative rather than preventive in nature. As a result, it does not serve adequately the seventy percent of the people living in rural areas and it fails to deal with the major causes of mortality and morbidity, particularly among rural infants and children under five years of age. To improve the development and implementation of more appropriate rural health care policies, it is essential to have a continuous flow of information on the diseases affecting rural populations and the relative efficacy of applied interventions. All of this is the province of epidemiology which involves the application of scientific methods and statistical reasoning to the problems of diseases and health care in populations as small as villages or as large as nations. Despite their fundamental importance, epidemiological services are virtually non-existent in rural India. The few epidemiological units that do exist are involved only in outbreak investigations and play no role in the assessment of health status or morbidity and mortality trends. The quality of health information is such that it is rarely used to determine health policies.

This project is designed to improve rural health care in India by creating an epidemiological network through which relevant information can be gathered and evaluated and appropriate policy decisions can be made. Five critical, mutually reinforcing areas of activity which have been identified for support are briefly described below:

A. FIELD EPIDEMIOLOGY:

This component will develop a self sustaining capability to train substantial numbers of field epidemiologists and will support demonstration of the impact of epidemiology services by creating a fully staffed epidemiological unit in one state. The activity will be executed through the National Institute of Communicable Diseases/India with assistance from the U.S. Centers for Disease Control and the World Health Organization.

B. LABORATORY SUPPORT SERVICES:

The public health laboratory service will be developed, in a top to bottom pyramid fashion. The national level (NICD) will be a highly sophisticated laboratory serving as the reference laboratory to the other public health laboratories throughout India and providing applied research and specialty testing. The state laboratories will provide most of the diagnostic testing required. The district laboratories will provide basic laboratory support. An important part of this process will be introduction of new rapid diagnostic techniques to the public health laboratory system.

C. CLINICAL EPIDEMIOLOGY:

The objective of this component is to establish fully functioning clinical epidemiology cells in three Indian medical colleges as national training centers and thus create a critical mass of trained epidemiologists. The component will be implemented with the advice and assistance of the Rockefeller Foundation's International Clinical Epidemiology Network.

D. MANAGEMENT INFORMATION SYSTEM FOR MALARIA:

This component will demonstrate the application of computer technology for epidemiological surveillance and resource management in disease control. Malaria was chosen for two reasons. First, the program has high visibility due to the high priority the government places on malaria control. Second, because of the substantial investment the government has made in the malaria program, the staff has experience in data collection and analysis unmatched by other disease-specific programs.

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E. QUALITY CONTROL OF BIOLOGICALS:

This component will support the construction, equipping and staffing of a new national quality control laboratory for biologicals, including vaccines, reagents, rapid diagnostic test kits and others. The component will begin with a two month detailed project planning period during which a time phased development blueprint will be drawn up. The cooperation of the U.S. Food and Drug Administration will be sought.

FAA SECTION 612(b):

When the development assistance program in India was re-established, it was determined that project local costs could be dollar funded rather than funded with U.S. owned excess rupees. PPC reaffirmed this policy by memorandum on May 7, 1980, with the understanding that all interested agencies would have an opportunity to express their views on the matter at the annual CDSS and ABS reviews. The ABS submission for FY 1983, which included this project, was reviewed and approved by AID/W without objection.

Therefore, the use of dollars for local costs of this project can be approved. In accordance with past practice, your signature on the attached authorization will provide the basis for certification authorizing the use of dollars as required under this section.

CONGRESSIONAL NOTIFICATION:

A Congressional Notification was forwarded to congress on June 12, 1985.

RECOMMENDATION:

That by signing the attached authorization, you authorize the Biomedical Research Support Project.

Clearance: PRO:KKBablani Bab CDC
CO:DEHickson DEH
CO:PMWarrier PMW
PD:RWNachtrieb RW

PD:RWNachtrieb:sw:06/21/85/1843C

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PROJECT AUTHORIZATION

INDIA

Biomedical Research Support
386-0492

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the Biomedical Research Support project for India (the "Cooperating Country") involving planned obligations of not to exceed Nine Million Three Hundred Thousand Dollars in grant funds and Three Million Eight Hundred Thousand Dollars in loan funds over a five year period from the date of authorization, subject to the availability of funds, in accordance with the A.I.D. OYB/allotment process, to help in financing foreign exchange and local currency costs.
2. The project is intended to assist the Government of India create a functioning program of laboratory-based field epidemiology with its concomitant emphasis on preventive medicine. Activities will be supported in field epidemiology, laboratory support services, clinical epidemiology, a computer based information system, and quality control of biologicals.
3. The Project Agreement, which may be negotiated and executed by the officer to whom such authority is delegated, in accordance with A.I.D. Regulations and Delegations of Authority, shall be subject to the following essential terms, covenants, and major conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

a. Interest Rate and Terms of Repayment

The Cooperating Country shall repay the Loan to A.I.D. in U.S. Dollars within forty (40) years from the date of the first disbursement of the Loan, including a grace period of not to exceed ten (10) years. The Cooperating Country shall pay interest to A.I.D. in U.S. dollars from the date of first disbursement of the Loan at the rate of (a) two percent (2%) per annum during the first ten (10) years, and (b) three percent (3%) per annum thereafter, on the outstanding disbursed balance of the Loan and on any due and unpaid interest accrued thereon.

b. Source and Origin of Goods and Services

Goods and services, except for ocean shipping, financed by A.I.D. under the project shall have their source and origin in the Cooperating Country or the United States in the case of Grant funds and in the Cooperating Country or countries included in A.I.D. Geographic code 941 in the case of Loan funds, except as A.I.D. may otherwise agree in writing. Ocean shipping financed by A.I.D. under the Project shall be financed only on flag vessels of the United States and the Cooperating Country, except as A.I.D. may otherwise agree in writing.

c. Conditions Precedent to Disbursement

(1) Prior to the disbursement of any funds for the field epidemiology component of the project, the Cooperating Country will provide, or cause to be provided, evidence that:

(a) the pilot demonstration state and the primary training state have been selected and an adequate number of positions have been sanctioned for each state epidemiological unit and, in the pilot demonstration state, one position has been sanctioned for each district epidemiological unit;

(b) the principal long term consultant has been approved by the Cooperating Country.

(2) Prior to the disbursement of funds for the field epidemiology component and the national laboratory component, the Cooperating Country will provide, or cause to be provided, evidence that the National Institute for Communicable Diseases has appointed an officer on special duty in tenure for three to five years, an individual responsible for managing the two efforts and for assisting the Director of the National Institute for Communicable Diseases.

(3) Prior to the disbursement of funds for the creation of clinical epidemiology cells, the Cooperating Country will provide, or cause to be provided, evidence that three medical colleges have been selected as project sites in consultation with the Rockefeller Foundation.

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(4) Prior to the disbursement of funds for equipment and supplies for the quality control of biologicals component, the Cooperating Country will provide, or cause to be provided, evidence that the construction of the National Quality Control Laboratory has been sanctioned.



Richard M. Brown
Director (Acting)
USAID/India

25 June 1985
Date

Clearance: PRO:KKBablani Day CDC
CO:DEHickson BT
CO:PMWarrier PMW
PD:RWNachtrieb IL

PD:RWNachtrieb:sw:06/21/85/1843C

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- B. Logical Framework
- C. Statutory Checklist
- D. Cooperating Country Request for Assistance
- E. USAID India's Health Sector Strategy

I. Project Summary, Rationale and Detailed Description

A. Project Summary

1. Project Purpose

The Purpose of this six year project is to support an Indian Government initiative to create a functioning program of field epidemiology with its concomitant emphasis on preventive medicine. To this end the Government will establish a program of training for field epidemiologists; establish a system of state and district epidemiology support systems; strengthen and modernize the necessary public health laboratory support systems; the health information system at the district level and below, and the quality control of biological materials. It will strengthen and upgrade the capacity of the National Institute of Communicable Diseases (NICD) to serve as the apex body for field epidemiology and public health laboratory support services.

2. The Need for an Integrated Approach

Reorienting the Government of India's program from the clinical-curative medical system toward a system where decisions are grounded in epidemiology, and where there is a concomitant emphasis on preventive medicine, will be a long and difficult process. Because it is a process, no single program or project activity can bring about the change. What is needed is a set of interrelated activities that are mutually supportive and mutually reinforcing. Five such critical areas of activity have been identified, which as five separate sub-project activities, constitute this project. The need and rationale for each is discussed below. The five are:

- Field Epidemiology
- Laboratory Support Services
- Clinical Epidemiology
- Health Information Systems
- Quality Control of Biologicals.

3. Project Components

a. Field Epidemiology

This subproject will be executed through NICD with the assistance of the U.S. Centers for Disease Control (CDC) in Atlanta, and the World Health Organization.

This subproject has two main objectives:

- to develop a self sustaining capability in NICD to train substantial numbers of field epidemiologists;

- to establish a pilot demonstration of epidemiology services in a state which is fully staffed with trained epidemiologists down to the district level.

D. Laboratory Support Services

The public health laboratory service will be developed in a top to bottom pyramid fashion. The national (NICD) level will be a highly sophisticated laboratory serving as the reference laboratory for the other public health laboratories throughout India and providing applied research and special testing. The state laboratories will provide most of the diagnostic testing required. The district laboratories will provide basic laboratory support, such as water bacteriology. An important part of this process will be the introduction of new rapid diagnostic techniques to the public health laboratory system.

c. Clinical Epidemiology

This subproject activity will be implemented by utilizing the training capabilities of, and establishing a working relationship with, the International Clinical Epidemiology Network (INCLIN), with the advice and assistance of the Rockefeller Foundation.

The objective of this association will be to create fully functioning clinical epidemiology cells in three Indian medical colleges. These cells are intended to create a critical mass in their medical colleges which will result in the incorporation of clinical epidemiology in the curriculum as a basic science. This institution of clinical epidemiology into medical education is, in turn, intended to:

- Train physicians to select interventions within a clinical setting that are both effective and efficient, and
- Encourage, over time, and on a broader scale, a more rational approach to the allocation of resources for medical care in relation to the health status of the population.

d. Management Information System In Malaria

The objective of this subproject is to provide a computerized management information system for malaria control. It will have two outputs: an automated information subsystem established at the national level and another subsystem established in a pilot test state (Gujarat) with microcomputers in each district of the state. The two outputs will be linked together to form an automated vertical

malaria surveillance information system. The purpose is to test the application of computer technology for epidemiological surveillance and resources management in disease control; the feasibility of doing this on a decentralized basis; and the potential for expansion to other health intelligence systems.

e. Quality Control of Biologicals

This subproject will support the construction, equipping and staffing of a new and truly national quality control laboratory for biologicals, including vaccines, reagents, rapid diagnostic test kits and others.

B. Rationale for A.I.D. Support

1. A.I.D.'s Health Sector Strategy

A.I.D.'s approved health sector strategy stems from the continuing high priority and large budget allocations accorded to improved rural health by the Government of India (GOI) and in relationship to other development activities. The Mission's health sector strategy is contained in Annex E.

The A.I.D. Mission's health goal is a significant reduction in fertility and child mortality within two or three Indian states.

The means to achieve this goal, and the subgoals that the Mission is pursuing, are :

- Establishment of proven, high-impact intervention programs to address selected, key fertility and mortality problems;
- Development of an effective epidemiological intelligence and monitoring system, and biomedical support institutions to permit health priority setting and clear evaluation of program impact; and
- Creation of a client-centered health service institution, which incorporates careful analysis of client needs, beliefs and behavior, in creating and meeting demand.

The USAID supported Integrated Rural Health and Population Project, the Integrated Child Development Services Project, the Family Planning Communications and Marketing Project, and the other health, nutrition and population activities are all directed at the first and third of these means to achieve the health goal.

This project is directed at achieving the second means, a group of activities that are vital in the long run to the success of the other two, and hence the achievement of the goal.

2. The Project Premise

Children under five years of age comprise about 15 percent of India's population, but they account for 46 percent of all of the deaths that occur each year. Two-thirds of these are children under age one.

There are proven technologies readily available to deal with the major causes of infant and child morbidity and mortality in India that could be applied now at a cost which the nation can absorb and sustain.

These technologies are not being applied, in part, because of:

- the lack of accurate data necessary to recognize and define the specific principal causes of morbidity and mortality; and
- the lack of a continuous monitoring capability to assess trends and changes over time, particularly in relation to intervention programs.

The present public and private health care system in India is an urban directed, clinically based, curative system which deals with persons after they become ill. Seventy percent of the budget goes for urban people. As a result;

- it ultimately has little impact on mortality;
- it does not well serve the seventy percent of the people who live in rural areas; and
- it fails to deal with the major causes of mortality and morbidity, particularly among rural infants and children under five year of age.

The effect of the lack of accurate data has been clearly demonstrated by the case of measles. Measles is a major cause of child mortality, but the cause and effect relationship is not obvious. The deaths are not direct. They result from the interaction of the complications of measles with diarrheal and respiratory diseases, and the deaths are usually attributed to the latter. Because the relationship is not direct and obvious, and because adequate data is not available to prove the indirect relationship, Indian health policy makers have only recently come to recognize that measles, a vaccine preventable disease, is a major killer of children.

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The imbalances which result from the clinically based health care system raise questions of a fundamental nature regarding resource allocation, efficacy of interventions, and national priorities -- questions which impinge upon the quality and quantity of care for individuals and the health status of the population as a whole.

These problems cannot be addressed by fundamental biomedical investigation, nor can investigations conducted on small samples of hospitalized or clinic patients alone provide sound bases for either clinical or policy decisions. Indeed, the hospital perspective tends to distort the physician's impression of the real burden of illness in terms of numbers, distribution, and extent of physical impairment.

An adequate picture of the distribution of diseases over time and place requires that hospitalized patients be related to the populations from which they come. Further requirements include identification of high risk groups and critical evaluation of those diagnostic treatments and preventive interventions (drugs, vaccines, surgery) which will be most effective for the most important health problems of the entire population.

All this is the province of epidemiology, which means, literally, "the study of that which is upon the people". It involves the application of scientific methods and statistical reasoning to the problems of diseases and health care in populations as small as the villages served by a primary health center, or as large as the nation as a whole. The use of epidemiological concepts and methods is essential for estimating the burden of illness experienced in a community; for identifying environmental, behavioral, and occupational health hazards; for establishing the efficacy of preventive, diagnostic, and therapeutic measures; and for assessing the relative impact and cost effectiveness of different mixes of resources and services in improving the health status of the population.

The expansion of epidemiological thinking and skills is also crucial for the evaluation and application of the fruits of biomedical and behavioral research. Without information about the disease priorities of underserved populations and the relative efficacy of interventions, it is unlikely that research efforts or policies will be directed effectively to meet those priorities.

Despite their fundamental importance, epidemiological services are virtually non-existent in India. Epidemiology, which is a basic science as important as physiology, biochemistry and immunology, is present only as one element of the relatively minor social science and preventive medicine curriculum in India's medical colleges. Several postgraduate schools of public health and veterinary science have full-fledged epidemiology departments, but the training is entirely didactic, and is but one segment of a broad public health course. The few epidemiologists who have been trained are mostly working in research or teaching.

Few states have state epidemiologists, and there are none at the district level. Even in the states where health intelligence bureaus and state epidemiological units exist, there is little if any coordination or exchange of information between them. The epidemiology unit is involved only in outbreak investigations and plays no role in the assessment of health status or morbidity and mortality trends. Health information is rarely used to determine health actions.

3. The Opportunity

In recent years this problem has come to be recognized by the Government of India, and plans are being made to begin to correct it.

The Government's health goals and policies, as delineated in the Statement of National Health Policy, 1982, and enunciated by the principal officials at the Ministry of Health and Family Welfare and the Planning Commission, are:

- to coordinate, integrate and consolidate the achievements and institutions (medical schools and free-standing research institutes) developed under prior plans;

to reorient medical education and the health care delivery system to provide a more focused service orientation with greater emphasis on practical management rather than academic issues and on preventive rather than curative interventions. Specifically, it is intended that infant mortality be reduced below 60 by the year 2000, and to decrease the birth rate to 20.

These goals are planned to be achieved through:

a greatly expanded health infrastructure, delivering focused maternal, child and family planning services;

a reorientation of medical education with greater emphasis on the roles of clinical departments as well as departments of social and preventive medicine;

the introduction of epidemiological and complementary public health laboratory services at the state and district level; and

the development of a functional health information system which can be used both for disease control and eradication and management purposes.

The Seventh Five Year Plan for health services is being formulated based on these goals, and the means to achieve them will be

specifically articulated in the Plan. This major Government health initiative provides the opportunity on which this project is based, and the activities which it will support.

4. Need for an Integrated Approach

Reorienting India's clinical-curative medical system toward a system where decisions are grounded in epidemiology, and where there is a concomitant emphasis on preventive medicine, will be a long and difficult process. It will take decades, perhaps longer. Because it is a process, no single program or project activity will bring about the change that is needed. The five components comprising this project, taken together, represent an integrated approach to introduce epidemiology as a fundamental underpinning of the health system.

a. Field Epidemiology

As noted above, several postgraduate schools of public health and veterinary sciences have full fledged epidemiology departments. Short-term in-service courses are offered at the National Institute of Communicable Diseases, and the National Institute of Health and Family Welfare. However, most of the few trained epidemiologists are working in research and training institutes, in schools of public health, in some postgraduate veterinary sciences training institutes, in departments of social and preventive medicine in medical schools, and in vertical national disease control or eradication programs at headquarters, or sometimes at the state level. Very few field and service-oriented epidemiologists are in central, regional, state, union or territory health departments in epidemiology units or cells, or in health planning units.

Only five states have state epidemiologists (Tamil Nadu, Andhra Pradesh, Maharashtra, Gujarat and Karnataka). All health programs are administered at the district level, but no epidemiologic unit exists at that level.

Linkages between the limited information system and laboratory services are made only for the vertical programs such as the National Malaria Eradication Programme. Although the multipurpose worker scheme is operational, no attempt has been made to use worker-derived surveillance data to define or plan local action. Except for the presence of Cholera Combat Teams, states and districts have only limited capability to do more than react to reports of outbreaks. Epidemiologic activities at the Primary Health Center (PHC) are limited to processing data enroute to the district. Responses are usually limited to high mortality outbreaks. The medical officers at the PHC'S and district are preoccupied with curative functions and have only limited public health orientation. The data from health workers and the records which are kept of inpatient and outpatient visits are rarely looked at.

The Government of India has commissioned numerous studies and evaluations, independently and with the assistance of WHO, to assess the achievements and constraints of the health care delivery system. The need for an epidemiological and complementary public health laboratory-based infrastructure has repeatedly emerged as a pressing requirement.

In 1979 a National Workshop on Epidemiology took note of the need for enhanced epidemiological services and recommended that (1) a three-tiered epidemiological service be developed (center, state, district) throughout the country as an integral part of the health services; (2) that senior management officers be designated at the state level as Directors of Epidemiological Services; (3) that an Epidemiological Unit be established in each state; and (4) that well-equipped public health laboratories at regional, state, district and primary health center levels be established as an integral part of the epidemiological services.

As noted, the 1982 statement of National Health Policy states that a nationwide epidemiological service with complementary public health laboratory services needs to be established at the state and district, and where the situation directs, at the PHC level. This need has been reaffirmed a number of times since then.

The Workshop on Development of Epidemiological Services at the National Institute of Health and Family Welfare in March 1983 again emphasized the necessity for such services.

The Eighth Joint Meeting of the Central Council of Health and Family Welfare identified development of epidemiological services by the states as a priority program and resolved to develop an action plan.

The Report of the Working Group on the Control of Communicable Diseases and the Control of Blindness, which met in November 1983 at the request of the Planning Commission to assist in preparation of the Seventh Plan, recommended the establishment of epidemiological services at all levels of health care.

At a workshop on the Development of Epidemiological Services in February 1984 the functions of these services were delineated, organizational relationships at the state and district levels were proposed and staffing patterns and physical requirements were described.

A meeting on the Development of Epidemiological Services under the chairmanship of the Additional Secretary (Health), in September 1984 concluded that:

- the development of epidemiological services was essential;
- appropriate laboratory support for these services should be identified or developed;
- district epidemiological units should be developed during the Seventh Plan, dependent on the capacities of state health authorities; and
- until these services are well established the vertical programs should continue their independent surveillance systems.

In October 1984 the Director General of health services requested the states to designate a senior medical officer as Program Officer (Epidemiological Services). A workshop of these state program officers was convened in December 1984.

The major obstacle to this planned expansion of field epidemiological services into the field is training. The existing training institutions do not have the capacity to train the required number of epidemiologists, and their training is entirely didactic and thus not suitable for preparing epidemiologists to work in the field at the state and district level.

b. Laboratory Support Services

Quality epidemiological investigations cannot be done without quality laboratory services. Laboratories are increasingly important, not only in clinical medicine, but also in defining both numerators and denominators. That is, laboratory diagnostic techniques confirm numerators by deciding who has a disease, and also define who is at risk in the denominator (the population group as a whole - e.g. a village).

For the most part, advanced laboratory and epidemiological skills reside in the centrally funded national research institutes and universities. State directed health services have the barest minimum of laboratory and epidemiology technology. There is no on-going affiliation between the research institutes and state health institutes and no effective links between their research laboratories and the field.

Even where epidemiological services exist, epidemiological studies of regional morbidity and mortality based on laboratory diagnosis are extremely rare, because of the absence or inadequacy of diagnostic laboratory facilities in most state health departments. Due to the absence of accurate information on specific diseases, immunology techniques cannot be properly evaluated and improved. More-

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over, precise laboratory diagnosis is seldom carried out and those diagnostic techniques which are available are often cumbersome and time-consuming. Without timely, accurate diagnosis, appropriate treatment cannot be administered, and needed epidemiological data cannot be accumulated. Recent bio-technology breakthroughs, such as hybridoma techniques for the propagation of monochloral antibodies, give great promise of making rapid diagnostic techniques available as practical and effective means of disease control. These techniques need to be introduced into India and then passed down through the laboratory system to the lowest level where they can be used practically and effectively.

Thus, if the expanded epidemiology effort is to be successful, it will require the availability of accurate, timely and relevant public health laboratory services at the national, state, district (and eventually PHC) levels.

c. Clinical epidemiology

Because of their knowledge of disease and their use of resources, physicians play a crucial role with respect not only to individual health, but also to the health of the population and the economic health of the nation. They are at the heart of the system of health care, as practitioners and as planners and managers. Because of this, the concepts that physicians acquire in medical school are reflected throughout the health care system. This is certainly true in India, where the clinical-curative nature of the health care system clearly reflects the overwhelming emphasis on clinic-based curative medicine in India's medical colleges.

In all of the medical colleges one of the senior faculty of the department of social and preventive medicine must be trained in epidemiology. In these departments, the impact of epidemiology is diluted because it is coupled with other activities such as emergency medicine, nutrition, occupational medicine, family medicine, and a range of non-traditional activities. Their combined impact on the mainstream of medicine appears to have been minimal. Indeed, they have been described as "departments of miscellaneous medicine, which tend to be perceived as academically weak, lacking in prestige, out of the medical mainstream, and often irrelevant".

Several postgraduate schools of public health and veterinary sciences have full-fledged epidemiology departments. However, public health has traditionally been a training stream that is separate from medical training. One is either a physician or a public health graduate, and individuals with training in both fields are rare.

The other subprojects of this project are action programs, designed to begin the application of epidemiology in the field

and to create the necessary supporting services at the national, state and district levels. In the long run, these action programs will not prosper or expand if the climate they operate in is hostile or indifferent. The key to changing this climate lies in physician training. Epidemiology must become a basic science that is an important and integral part of the curriculum in India's medical colleges. This will expose all medical students to the concepts and methods of epidemiology and to perspectives broader than the bounds of the single patient and the walls of the hospital. Only then will physicians begin generally to use epidemiological concepts and methods as clinical research, teaching, and planning and management tools; only then will the overall climate fundamentally change.

d. Malaria Information System

A program of training for field epidemiologists will provide them with general and specific disease knowledge and the analytic techniques for applying that knowledge to specific populations. To do this, in addition to the data generated by accurate rapid diagnostic tests, there must be a combination of information from routine reporting, outbreak investigations, sentinel surveillance systems and special surveys.

The overall responsibility for the collection, analysis and reporting of such data rests with the Central Bureau of Health Intelligence (CBHI). The Bureau is currently attempting to implement an overall health data collection system based on the collection of data at the district level, with processing done centrally on a main frame computer. There lie the basic problems with this system. The first is that analyzed data is not available in the field, where most of the decisions are made. The second is that district data is not being sent to CBHI systematically.

The recent development of powerful, inexpensive microcomputers has made it technically feasible to extend computerization of health intelligence data down to the district level. However, a feasibility study of computer decentralization cannot be effectively conducted in the general health statistics system of CBHI. The system is not sufficiently established and too many extraneous variables exist. A preferred alternative would be to conduct such a test in an established vertical health program where such variables would be minimized.

The National Malaria Eradication Programme is a vertical program that is very well suited to this purpose. Malaria is a serious health problem in India which is retarding the economic and social development of the country by debilitating the work force, directly or indirectly causing infant deaths, and contributing to spontaneous abortions. Approximately 95% of the population in India is exposed to malaria.

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The Indian malaria control program has an established data collection system, and more than 20 years of surveillance data is available for studying new methodologies of control and management.

The malaria surveillance data flows from its source in all villages and towns in the country to about 6,200 PHCS. At the PHC level, the data are tabulated, and sent monthly to the district. A copy of the data is sent directly to NMEP's Central Office to expedite national information collection.

The surveillance data and the indexes derived for the data are used for three levels of decision-making. At the national strategic planning level, the information is used by policy makers to lay down national objectives for malaria control. At the management control level, it is used by the Directorate of NMEP to determine broad guidelines for the allocation of resources for malaria control. It is also used by scientists at NMEP to assess the most appropriate methodology for malaria control. At the operational level, the information is used by states and districts to manage their resources for malaria control.

Operational decisions for malaria control are made at the district level. For example, day-to-day decisions are made as to which villages will receive insecticide spraying next, or in which villages to increase active blood smear collection. Most of these operational decisions require village-level surveillance information. Village-level information is available at the PHC level, but the current manual information system does not provide this level of detail to the district level, and even if it did it could not be analyzed manually in time.

The lack of information for management is the root cause of inefficiencies in resource utilization. The volume of surveillance data is so vast that under the manual working system it is difficult to evaluate long term trends in the data except in the most general terms. Thus, state and district management decisions are currently based on broad averages and norms that often are not sufficiently specific to be effective. At the national level, because of the limitations of manual tabulation, comparable management opportunities are being lost. There is the potential for introducing selectivity and early warning analyses and simulation planning through computerization.

The successful demonstration of a decentralized, computerized management information system for malaria would not only improve the management and efficiency of the NMEP, but it would also be essential for the upcoming field trials of malaria vaccine. It will also provide a base to test the potential for expansion to cover other health data.

2. National Quality Control of Biologicals

A national quality control program for biological materials including vaccines, antigens and reagents, involves the establishment of national quality standards and the conduct of sample testing and other programs to insure that these standards are being met. Such a program is as essential to national health as is the quality control of drugs. Biological materials that meet minimum quality standards are essential for:

- the effective functioning of public health, hospital and medical research laboratories; and
- curative and preventive health care programs where the use of biological materials is involved. The most important of these is disease prevention through the use of vaccines. Substandard vaccines waste scarce resources on useless vaccination campaigns and increase the risk of infection in the recipients, because of the false sense of security that is engendered. A failed vaccination campaign for one disease may also create resistance to the next campaign.

Since 1940 the responsibility for the quality control of almost all biologicals has been vested in the Central Research Institute at Kasauli. An exception is BCG vaccine, which is produced at the King Institute, for which quality control is provided by the National Institute of Communicable Diseases. The Institute at Kasauli has the inherent conflict of being both a manufacturer of vaccines and the arbiter of quality control. Moreover, it has never been able to discharge its quality control functions fully because of inadequate laboratory facilities and equipment. Its relatively remote location has produced a concomitant continuing shortage of trained personnel. As a result, control has been exercised primarily through the review of manufacturing protocols of the public and private institutions that produce vaccines; the amount of actual testing of finished products has been limited. Moreover, Kasauli cannot be upgraded to enable it fully to discharge its biological quality control responsibilities. Physical space is not available for the necessary expansion of its laboratories, and, because of its remote location, it will never be able to attract the required numbers of adequately trained professional staff.

Because of this, the proposal to construct a new, fully independent National Quality Control Laboratory for Biologicals has been under consideration for a number of years. The proposal was first put forward in the early 1960's by two government committees on drug and equipment standards. It was supported at that time by separate consultant studies sponsored by WHO and UNDP. A proposal to establish such a laboratory was considered for the fourth plan (1970 - 1975), but it was not incorporated into the plan.

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The need for a National Quality Control Laboratory for Biologicals, first perceived over 20 years ago, is even more pressing today. The number and quantity of indigenously produced vaccines has increased dramatically since 1965. Vaccines produced in India now include: BCG, DPT, DT, TT, TAB, rabies, plague, cholera and a small amount of polio. The production of measles vaccine is expected to start in the near future. Top government health officials have expressed their desire to create the new laboratory and have requested U.S. assistance.

5. Other Donor Activity

The principal assistance by other donors in the areas covered by this project is being provided by the World Health Organization.

The WHO Regional Office has been involved in the development of epidemiological services and in the development of training for epidemiologists. Consultants, country assessments, and inter-country meetings have taken place and implementation plans have been developed which include the development of plans for epidemiology and support for training. The WHO-supported project, Promotion of Epidemiological Surveillance of Communicable Diseases, implemented in four states, has demonstrated the potential for developing a strengthened surveillance system below the district level, and how it might be used. This system should be built upon and expanded with WHO collaboration. WHO has tentatively budgeted funds to continue in the existing districts, and possibly to expand the system. Those districts where this surveillance system has been established should be selected for inclusion in the epidemiology training project, where possible.

In response to the need to improve unit and individual work performance, develop mechanisms for staff supervision and to improve the monitoring and evaluation of peripheral health services, WHO developed a simple survey technique for health management training which was applied in Gujarat. This management training approach will be used as an integral part of the proposed training for state and district epidemiologists with the collaboration of WHO. The WHO Regional Office has also provided consultants and other support for a wide variety of laboratories, including research, hospital and selected state laboratories. The laboratory support services activity will be coordinated with this WHO effort.

Responsibility for execution of the field epidemiology and laboratory support services subprojects will probably be vested in the Centers for Disease Control (CDC) in Atlanta. If this is done, the long term consultants for NICD and for field training will be hired through WHO. This same pattern has been applied successfully in CDC-supported projects in Thailand and Indonesia.

C. Project Description

1. Design approach

The design of this project was accomplished chiefly through extended collaboration with the health establishment in India, from those involved in Government planning and finance of health delivery systems, to private practitioners and institutions. Discussions centered on draft language which subsequently became part of this document. As a result, all substantive sections have been prepared in active collaboration with the ultimate project counterparts in the Ministry of Health and Family Welfare and NICD and NMEP, the Planning Commission and the participating states. Development of technical expositions and assembly of the paper was done with the capable assistance of a team of consultants and health professionals from the Centers for Disease Control and from private firms. Overall guidance was provided by W.B. Rogers Beasley, Chief of USAID India's Office of Health and Nutrition.

2. Project Goal and Purpose

The goal of the project is to reduce infant and child mortality, and morbidity in the labor force, and to reduce fertility.

The Project Purpose is to support a Government initiative to create a functioning program of field epidemiology in India, with its concomitant emphasis on preventive medicine. To this end the project will establish training for field and clinical epidemiologists; strengthen and modernize the necessary public health laboratory systems; improve the health information system; and upgrade the quality control of biological materials. It will strengthen and upgrade the capacity of the National Institute of Communicable Diseases to serve as the apex body for field epidemiology and public health laboratory services.

3. Strengthening NICD

The Government has determined that the National Institute of Communicable Diseases should be the apex body for field epidemiology and health laboratory support services. Its Epidemiology Division is to serve as the national center for planning a national program of field epidemiology and for managing and conducting a program of long and short term training toward this end. Its laboratory divisions are to be the national reference laboratories in their fields of specialty and are to develop and promote a continuing national program of laboratory decentralization. As these two elements develop they will contribute to the ability of NICD to become an apex body that is concerned not just with communicable disease, but with all diseases of epidemiological significance -- be they communicable, environmental or social due to practice.

While it is not a separate subproject activity, an important objective of this project is to strengthen NICD so that it can discharge these responsibilities. The field epidemiology and laboratory support services subprojects of this project have been designed with this objective in mind. However, these are important organizational issues that will need to be resolved in the long run if this objective is to be achieved.

These issues have to do with the nature of the position of Director of NICD and with its relationship to the Central Bureau of Health Intelligence. Historically the position of Director, NICD has been an end-of-career assignment for senior health officers. Occupants of the position seldom remain in it for more than two years. Moreover, the level of the position of Director is the same as the Director of the CBHI and lower than the level of the semi-autonomous Indian Council Medical Research (ICMR). These relationships are important. Many of the research institutes of ICMR now do laboratory support work that should be assumed by the national public health laboratory system, if only to free the ICMR institute to concentrate on their basic function of research. The relationship with the CBHI is also critical. Health intelligence data is as important to epidemiology as laboratory support. Its availability should not depend on cooperation between coequals.

An alternative that has been proposed is to create a new position in the Ministry of Health and Family Welfare at the level of Additional Director General. This proposed Additional DG for Disease Control would have sufficient status to deal with ICMR and would directly supervise NICD and the CBHI, thus insuring coordination.

4. Project Components

a. Field Epidemiology

This subproject activity will be executed through a direct A.I.D. agreement with the U.S. Centers for Disease Control (CDC) in Atlanta. The three long term consultants will be provided by CDC through the World Health Organization.

This subproject has three main objectives:

- To develop a national epidemiology services network, with NICD as the apex organization and a system that reaches down through the states to the districts;
- to develop a self sustaining capability in India to train substantial numbers of field epidemiologists; and
- to establish a pilot demonstration state which is fully staffed with trained epidemiologists down to

the district level. This state will serve to identify problems encountered in establishing statewide epidemiological services; to identify gaps in the newly developed training program; to identify what public health laboratory services need to be created and what surveillance system improvements are required; and, finally, to demonstrate the health impact of functioning statewide epidemiological and complementary public laboratory services.

During the first six months of the subproject, a long-term consultant provided through WHO will assist the Director of the National Institute of Communicable Diseases (NICD) and its Epidemiology Division in developing a one year curriculum for training service-oriented field epidemiologists. The curriculum will be based on a two year training program conducted in the U.S. by CDC, and adapted for use in Thailand, Indonesia, and other countries. During the life of the project 12 epidemiologists from NICD and selected states will also attend the two year CDC program in the U.S.

Once the curriculum is completed, this consultant, who will also serve as Chief of Party, will assist NICD in developing a long range program to extend epidemiological services to cover all of the states and districts in the country. The Consultant will also work with the Director to upgrade NICD's Epidemiology Division so that it has the capacity to conduct the didactic portion of long-term training courses; to conduct short courses in epidemiology for a wide range of government health officials; and to assist the states, on request, in outreach investigations.

The one year training in India will consist of six weeks of didactic training to be conducted at NICD by its present staff and Indian consultants who will be recruited for this purpose. This will be followed by a nine month period in which each trainee is assigned to a state epidemiological unit under the supervision of a tutor. On completion of the training a certificate or diploma will be awarded which will permit application to the examination in epidemiology for membership in the National Academy of Medical Sciences.

Each trainee will then serve an internship year in the state in which he or she is trained. Permanent assignment outside the training state will only occur after this internship. Since personnel cannot be transferred between states, those who are destined to work outside of the training state will have to be recruited at the beginning from their state or permanent assignment.

Initially, the training will be done in two states, each of which will have a full time training consultant provided through WHO. These consultants will be assigned to NICD and will be deputed to the selected states.

One state will be selected to serve as a pilot demonstration state. The state selected for this purpose will be one where public health services are relatively well developed, so that the health system has the capacity to respond to the needs identified by the new epidemiology service. Likely candidate states are Maharashtra and Karnataka. In order to staff the pilot state as quickly as possible, a training capability will be created in the first year. The first epidemiologists who are trained in the pilot state will be assigned to work there. However, once the state is fully staffed i.e. at the end of three years -- a limited training capability will continue to provide epidemiologists for assignment elsewhere.

The second state will be one where the health services are relatively less well-developed. This will serve to identify the problems of conducting training and doing field epidemiology under these conditions. Uttar Pradesh, the most populous state, is a likely candidate. This state will have training as its primary purpose, and only the state epidemiology unit and a few selected districts -- perhaps one division -- will be staffed during the life of the project. Beginning in the fourth year of the project, the training capability will be partly spun off to a third state, which will function as a training state, with limited oversight by the CDC training consultants.

Priority for assignment of field epidemiologists trained under this project will be: NICD (10 persons), the pilot demonstration state (about 27 persons); the epidemiology units in the 16 major Indian states (three persons each), and selected districts.

It is anticipated that by the end of the fifth year, the project will have produced:

- A critical mass of 132 well-trained epidemiologists capable of developing, understanding and using surveillance systems, outbreak control, program implementation, and decision-making; and capable of teaching methods of epidemiology to all levels of the health system;
- An effective, fully functioning Division of Epidemiology at NICD;
- A pilot demonstration state with a fully staffed and operating epidemiological service;
- Three states, including the pilot state, capable of conducting field training for an additional 40 field epidemiologists per year; with the potential of further expansion of the training to additional states.

b. Public Health Laboratory Services

The public health laboratory service, which is essential to field epidemiology, will be developed in a top-to-bottom pyramid fashion. The national (NICD) level will be a highly sophisticated laboratory providing applied research, specialty testing and serving as a reference laboratory to the other public health laboratories throughout India. The state laboratories will provide most of the diagnostic testing required. The district laboratories will provide basic laboratory support, such as water bacteriology. The technology and type of laboratory analyses are constantly changing because of the program and epidemiological needs. Thus, much of the testing should gradually be shifted from the national to the state to the district laboratories.

This subproject is based partly on the introduction of rapid diagnostic techniques into the public health laboratories. These techniques are both very new and in many cases quite simple. In lay terms, instead of putting a specimen on a slide and staining, drying and restaining it and finally spending 15 minutes on the microscope, one puts it on a slide with a modern reagent and immediately looks at the results. Similarly, instead of culturing a specimen for several days, one puts it into a tube with a modern reagent, shades it, and looks to see whether clues appear. These are very modern, indeed state-of-the-art techniques. They are, however, simple and quick and they offer the opportunity to expand India's public health laboratory services much more quickly than would have been possible a decade ago.

For several specific diseases, laboratory resources or potential resources have already been identified. These diseases include Japanese encephalitis, hepatitis, measles, diarrhoeal diseases, and polio. However, a comprehensive identification of resources needs to be completed on a national, state and district basis. To do this, a survey of the capabilities of all laboratories which conduct public health laboratory testing will be undertaken. The survey will include the service level laboratories as well as the research, specialty and reference laboratories of national and state universities and official agencies.

Analysis of the laboratory survey data will identify the available public health laboratory capabilities in India, and should indicate potential permanent or temporary laboratory support institutions. It is important to utilize as many existing Indian resources as possible, particularly because much of the laboratory technology that is needed to support an effective program of preventive health care is available in India now. The problem is that it is not being shared, or it is being applied on such a small scale that it has virtually no impact.

To assist in the development of laboratory support services, a laboratory management consultant will be provided for three years through WHO. The first objective of this consultancy will be to develop a specific long range plan for the upgrading and expansion of laboratory services down to the district level. While the consultant can be assigned to work with the Director of NICD, it will be more effective if NICD creates a position of Director of Laboratory Services in charge of all NICD laboratories.

Three advisory committees to NICD will be established. The first committee will be made up of 10 to 15 laboratory scientists representing national and state health laboratories. The national representatives will include the DGHS, ICMR, CRRI and other related public laboratory programs. The committee will provide technical advice and guidance to the Director, NICD in the development of laboratory services and a program to upgrade and expand the laboratory activities of the NICD.

The second committee will be comprised of national, state and district public health directors, epidemiologists and laboratory personnel. This committee will identify the requirements for laboratory services to support the public health program and establish priorities for laboratory development.

The third committee should consist of laboratory product manufacturers and representatives of public health laboratories. The importation of instruments and reagents to India will be necessary, but expensive. The purpose of this committee is to work with Indian manufacturers to develop product specifications and requirements, so that most of the needed laboratory supplies and equipment can be produced in India, reducing the total cost and ensuring that adequate supplies are available. In the implementation of new laboratory techniques down to the state and district levels, supply of reagents and kits will inevitably become critical. As technology spreads down to the states and then to the districts the number of individual tests that are used will increase geometrically. The demand for these materials will quickly outstrip in-laboratory production capability or available budgeted foreign exchange. It is imperative that this growth be planned for and that Indian production capacity be created in a timely fashion.

The present seven NICD laboratories will be formed into four laboratory groups - virology, bacteriology, microbiology and parasitology. A working relationship will be developed between each of the four NICD laboratory groups and an identified CDC laboratory in the same field of specialization. The process will work as follows:

- a representative of the CDC laboratory will visit India to become acquainted with the Indian laboratory, to help prepare a technical development plan

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for that laboratory, and to prepare a list of specific equipment requirements;

- the head of the Indian laboratory will spend about four months at the CDC laboratory, working with his or her counterpart;
- after the new equipment has been delivered and the first personnel from the Indian laboratory have been trained, the U.S. counterpart will return to assist in the implementation of new rapid diagnostic technology; and
- in succeeding years two-way exchange visits will take place to sustain the relationship.

The three principal ingredients for upgrading the public health laboratory system are equipment, training and supplies.

Equipment and general supplies for the NICD laboratories will be procured based on the technical laboratory development plan that will be prepared for each of them. Any equipment that is manufactured in India will be procured here. The project will also provide necessary supplies, such as rapid diagnostic tests and materials through the first two years. Over the last three years the cost of these supplies will increasingly be borne by the Government of India. The equipment and general supplies provided to the 16 state laboratories and sample district laboratories will be based on the laboratory survey and the recommendations of the advisory committee. As rapid diagnostic techniques are passed down from NICD to the states and districts, the Government will be responsible for procuring the necessary supplies.

Training will be provided three ways:

- Preference will be given to training provided in Indian institutions which are identified in the survey;
- In-country training at NICD will be provided through short courses utilizing existing CDC training modules and trainers;
- Selected individuals from NICD and state laboratories will be sent to the U.S. for short term (three to nine months) on-the-job training in U.S. laboratories at CDC and NIH.

c. Clinical Epidemiology

This subproject activity will be implemented with the advice and assistance of the Rockefeller Foundation by utilizing the training capabilities of, and establishing a working relationship with, the International Clinical Epidemiology Network (INCLEN). The INCLEN network has developed a structured program of formal postgraduate training and continuing professional association in clinical epidemiology, currently functioning in Australia, Canada, the U.K., the U.S., China, Thailand, the Philippines, Brazil and other developing countries. It is supported by the Rockefeller Foundation, the World Bank and other support institutions.

The objective of this association will be to create fully functioning clinical epidemiology cells in three Indian medical colleges. Each cell will be a multidisciplinary group consisting of six clinical epidemiologists and at least one biostatistician, one research assistant and one data processing analyst. The epidemiologists will all receive one year of post-doctoral training at one of the three existing INCLEN resource and training centers: the University of Pennsylvania, McMaster University in Canada, and the University of Newcastle in Australia; or, alternatively, because of the number of trainees that will be generated from India, a new resource and training center may be created by the Rockefeller Foundation to meet this requirement.

Clinical epidemiology cells are intended to create a critical mass in their medical colleges which will result in the incorporation of clinical epidemiology in the curriculum as an essential tool for practice. This installation of clinical epidemiology as a basic science is, in turn, intended to:

- educate physicians within a clinical setting to use interventions that are both effective and efficient;
- enable physicians to make more effective choices among the plethora of technical reading material that is available; and
- encourage, over time and on a broader scale, a more national approach to the allocation of resources for medical care in relation to the health status of the population.

Experience elsewhere has shown that, once such cells begin to function in a country, they become resource and training centers which serve to spread the concepts of clinical epidemiology to other medical colleges. This process will be fostered by providing INCLEN training for faculty members from other colleges after the staffs for the first three cells have been trained.

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This process will begin with a seminar in October 1985, attended by medical education and health officials which will be designed to introduce the general concept of clinical epidemiology and the specific approach of INCLEN to it. This seminar will be supported with funds available outside of the project (PD&S funds). The project itself will support a workshop in March 1986 involving a more detailed presentation to six to eight colleges which are interested in the program. It will increase the depth of their understanding and help to identify candidate colleges for participation in the program.

Once the three participating colleges have been identified, the project will provide the direct support costs (stipends, travel, etc.) for the epidemiologists to be trained in INCLEN centers. The Rockefeller Foundation will pay for the direct training costs. After the participants complete their training, the project will support the continuing costs of their participation in the INCLEN network, including research seed money, annual conference travel and limited support for the general costs of the new cells (\$25,000 each per year). At the same time, Rockefeller will be providing continuing support in the form of regular visits and consultations with the participating colleges by faculty members from the Rockefeller INCLEN centers.

Thus, this subproject activity will be only a contributing part of a coherent, defined project to create functioning clinical epidemiology cells in three Indian medical colleges. A.I.D.'s role will necessarily be limited to that of a donor. Primary responsibility for orchestrating, managing and monitoring the full project will rest with the Rockefeller Foundation in collaboration with the Ministry of Health and Family Welfare. A.I.D. will participate in that process to the extent feasible, but its role will necessarily be limited. A.I.D. will, however, remain fully cognizant of the status and progress of the broader project, to ensure that A.I.D. inputs are provided when needed and are not provided in instances where progress on the other elements does not justify it.

d. Malaria Management Information System

The objective of this subproject is to provide a computerized management information system for malaria control. The component will have two outputs: an automated information subsystem established at the national level and another subsystem established in a pilot test state (Gujarat) with microcomputers in each district of the state. The two outputs will be linked together to form an automated vertical malaria surveillance information system. The purpose of this project component is to test the application of computer technology to epidemiological surveillance and resources management for disease control.

In the course of the subproject, two 16-bit microcomputers with ancillary equipment and supplies will be installed in the central office of the National Malaria Eradication Programme; and 31 eight-bit microcomputers will be installed at the state level and each district in the pilot test state of Gujarat.

The design of the management information system for malaria control will evolve in an iterative process of design, implementation, evaluation, and revision. The design will be based on innovative research to determine the most appropriate ways to apply computer technology to malaria control. Lessons learned from the initial implementation of the NMEP subsystem will be used to design the prototype subsystem at the district level. As the subsystems mature, design modifications will be implemented that link the subsystems together.

The subproject will be implemented in four phases, and an Indian information systems design firm will provide leadership and technical expertise for the design and implementation of the system. The firm will provide technical support in the adaptation of standard software packages to meet the requirements of the information system, and will conduct seminars for administrative malaria staff and intensive microcomputer training courses for operational and technical staff.

The four phases of the subproject will cover a period of three years, and the precise definition of work to be done in each phase will be based on an evaluation of the preceding phase.

Three kinds of audiences will be provided training about the information system. Health policy makers and the NMEP operations control directorate will be trained in the use of the information system as a health strategy planning and biomedical research tool. Thirty professionals per seminar will participate in ten one-day seminars about the system. The malaria staff operating the system at the national, state, and district levels will be given training in the entry of data and the generation of output reports. Six NMEP staff, four state malaria staff and about 100 district malaria staff will be provided 20 days of training.

At the end of Phase 4 (three years) an overall end-of-subproject evaluation will be made. The evaluation will specifically address the feasibility and desirability of extending the management information system within the malaria program, and the economic limits of such an extension, if it is to be made. It will also assess the potential for extending the system in place in Gujarat to encompass health intelligence data from other vertical programs and from lay reporting and other sources.

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If either a vertical or horizontal extension of the system is found to be justified, consideration will be given to amending the Biomedical Research Support Project to include it, or a follow-on project will be considered.

e. National Quality Control Laboratory For Biologicals

No current estimate is available of the requirements for the establishment of a new national quality control laboratory for biologicals. Since most of the staff of the Quality Control Unit at the Central Research Institute at Kasauli (the present national quality control laboratory) will continue to be required there for internal quality control and vaccine production, a new national laboratory will have to be started anew. This will require acquisition of the land, construction of facilities, purchase of equipment and supplies, and hiring and training of personnel.

The only detailed forecast of the requirements for a new national control laboratory for biologicals is now out of date, both in terms of time and of the quantity and range of indigenous production to be monitored. The earlier study was premised on three laboratory divisions: bacterial products, viral products and immunochemistry, with three to five departments each. Support services included an animal house, a central statistical and record service, a workshop and administration. An estimated 101,000 square feet of floor space, 57 professional, technical and administrative and 75 support personnel were estimated to be required. Detailed equipment lists were also included. While it probably understates today's requirements, the prior forecast gives at least some indication of their magnitude and provides the basis for the financial estimates for this subproject.

The U.S. Food and Drug Administration (FDA) has expressed interest in collaborating in the development of a national control laboratory. This subproject will begin with a two month detailed project planning period with assistance from FDA. During this period a detailed, time-phased plan for the development of the laboratory will be developed, with implementation beginning upon completion and approval of the plan. It should be possible, for example, to use facility design and construction time to recruit and train key members of the staff so that they can be available as facilities are completed and equipment installed. Once the plan has been completed and agreed to by the Government, it will be incorporated into this project design in the form of an amendment to the Project Paper.

II. Cost Estimate, Financial Plan and Disbursement Procedures

A. Cost Estimates

1. Overall Costs

The total cost of the project over its six year life is estimated to be \$20.1 million (Rs. 26.1 crores at an exchange rate of 13.0). Of this total A.I.D. grants and loans will provide \$13.1 million (65 percent) and the Government of India will provide \$7.0 million (Rs. 9.1 crores). Of the A.I.D. share, \$9.3 million (71 percent) will be grant funds and \$3.8 (29 percent) will be loan funds.

Total costs by subproject are shown in Table II-1. In Table II-1 these costs are divided between those that will be disbursed directly to the Government, and those that will be disbursed through a direct A.I.D. PASA with the U.S. Centers for Disease Control. The table also shows the division between local currency and foreign exchange costs. Of the A.I.D. total of \$13.1 million, \$2.8 million (22 percent) will be used to pay local costs; and \$10.3 million (78 percent) will be for foreign exchange. Since the Government's share is all local costs, the total costs of the project are divided almost equally between local and foreign exchange costs - \$9.9 and \$10.2, respectively. Total costs by subproject are shown in Table II-2.

Table II-1
Total Costs by Subproject
(\$000)

Financial Plan
Grand Total

E L E M E N T S	G R A N T			L O A N			U.S. Total			GOI	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
Grants & Loans to the Government											
A. Field Epidemiology	748	817	1,565	0	232	232	748	1,049	1,797	2,646	4,443
B. Laboratory Support	586	806	1,392	368	2,037	2,405	954	2,843	3,797	1,745	5,542
C. Clinical Epidemiology	662	1,229	1,891	0	0	0	662	1,229	1,891	207	2,098
D. Malaria Information System	0	232	232	0	0	0	0	232	232	0	232
E. Quality Control of Biologicals	0	116	118	475	688	1,163	475	806	1,281	2,422	3,703
SUBTOTAL G/L TO THE GOVT.	1,996	3,202	5,198	843	2,957	3,800	2,839	6,159	8,998	7,020	16,018
AID Direct Costs											
A. Field Epidemiology		2,524	2,524			0	0	2,524	2,524		2,524
B. Laboratory Support	0	1,563	1,563	0	0	0	0	1,563	1,563	0	1,563
SUBTOTAL AID DIRECT COSTS	0	4,087	4,087	0	0	0	0	4,087	4,087	0	4,087
GRAND TOTAL	1,996	7,289	9,285	843	2,957	3,800	2,839	10,246	13,085	7,020	20,105

PERCENTAGE DISTRIBUTION

U.S. A.I.D. as percent of total 65%

Distribution of A.I.D. share

Percent Grant 71%
Percent Loan 29%

Percent LC 22%
Percent FX 78%

+ 28

Table II-2

Total Costs by Subproject
(\$000)

<u>Subproject</u>	<u>A.I.D. Total</u>		<u>G O I</u>		<u>Total</u>	
	<u>\$</u>	<u>%</u>	<u>\$</u>	<u>%</u>	<u>\$</u>	<u>%</u>
Field Epidemiology	4,321	33	2,646	38	6,967	35
Laboratory Support	5,360	41	1,745	25	7,105	35
Clinical Epidemiology	1,891	14	207	3	2,098	10
Malaria Information System	232	2	-	-	232	1
Quality Control of Biologicals	<u>1,281</u>	<u>10</u>	<u>2,422</u>	<u>34</u>	<u>3,703</u>	<u>18</u>
T O T A L	<u>13,085</u>	<u>100</u>	<u>7,020</u>	<u>100</u>	<u>20,105</u>	<u>100</u>

2. Input Costs

Table II - 3 shows costs by input category, by subproject and in total. The largest A.I.D. input will be training, which totals \$4.8 million (37 percent of the total). The other two main A.I.D. components are technical assistance (\$4.1 million) and commodities -- largely laboratory supplies and equipment -- which total \$3.7 million. The largest single item in the Government's contribution is the construction of the buildings for the national quality control laboratory for biologicals (\$1.7 million or Rs. 2.1 crore), but 67 percent of the Government share (\$4.7 million or Rs. 6.1 crore) is for salaries and other operating costs. The small amount of commodities (\$600,000 equivalent) to be funded by the Government comprises jeeps for the field epidemiology subproject and an increasing share of recurring supplies for the laboratories at NICD. The project cost estimates do not include the cost of recurring supplies -- mostly test kits and reagents for the state public health laboratories. This is an important input, and their cost will be significant, but it is difficult to estimate these costs until some experience has been gained with a fully functioning state laboratory. These costs will be borne by the GOI and state governments as part of their share of the project.

B. Financial Plan

Table II - 4 summarizes project costs by year, and Tables II-5 through II - 11 show the detailed financial plan, by item of expenditure, by fiscal year and in total. In these tables, fiscal years 1985 and 1986 have been combined, since project approval will come late in FY 1985 and expenditures will not be significant. As Table II - 4 shows, grant expenditures, which are primarily training and technical assistance, are spread relatively evenly over the life of the project. However, 70 percent of the loan expenditures occur in the first three years when most of the laboratory equipment and general supplies will be procured.

C. Disbursement Procedures

With the written approval of the Government, the funds (\$4.1 million) for technical assistance to be provided by the Centers for Disease Control, both directly and through WHO, will be disbursed by A.I.D. through a Participating Agency Service Agreement(PASA) with CDC.

Grant funds for U.S. and third country training will be expended directly by A.I.D. through its participant training program, following participant selection procedures for each subproject that will be agreed to with the Government. Funds for in-country training and operating costs will be reimbursed to the Government under standard procedures for such costs.

All supplies and equipment under the loan agreement will be purchased by the Government against requirement lists which are agreed to jointly in advance. A.I.D. disbursement will be in the form of reimbursement to the Government for expenditures incurred.

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Table II-3
(\$000)

GRAND TOTAL FINANCIAL INPUTS BY CATEGORY

ELEMENTS	Grant			Loan			US Total			--GOL--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
TRAINING (U.S./Third Country)											
Long-term Training	0	418	418	0	0	0	0	418	418	0	418
Short-term Training		399	399	0	0	0	0	399	399	0	399
TRAINING (In-Country)											
Per diem	748		748	0		0	748	0	748	0	748
COMMODITIES											
Equipment			0	186	186	186	0	186	186		186
Vehicles			0	46	46	46	0	46	46	414	460
OTHER COSTS											
Vehicle Operating Costs			0			0	0	0	0	1,017	1,017
Salaries	0		0			0	0	0	0	1,215	1,215
Subtotal Field Epidemiology	748	817	1,565 0	0	232	232 0	748	1,049	1,797 0	2,646 0	4,443
B. LABORATORY SUPPORT											
TRAINING (U.S./Third Country)											
Laboratory Exchange Visits		145	145			0	0	145	145		145
Short-term Training		661	661			0	0	661	661		661
TRAINING (In-Country)											
Training in India	586		586			0	586	0	586		586
COMMODITIES											
Equipment			0	50	900	950	50	900	950		950
General Supplies			0	318	725	1,043	318	725	1,043		1,043
Recurring Supplies NICD			0		412	412	0	412	412	198	610
Recurring Supplies States			0			0	0	0	0		0
OTHER COSTS											
Salaries			0			0	0	0	0	1,547	1,547
Subtotal Lab Support	586	806	1,392 0	368	2,037	2,405 0	954	2,843	3,797 0	1,745 0	5,542
C. CLINICAL EPIDEMIOLOGY											
TRAINING (U.S./Third Country)											
Fellowships		980	980			0	0	980	980	82	1,062
Intl Conferences		197	197			0	0	197	197		197
TRAINING (In-Country)											
Workshops and Seminars	171	52	223			0	171	52	223		223
OTHER COSTS											
Research Seed Money	131		131			0	131	0	131		131
Cell Support	360		360			0	360	0	360	125	485
Subtotal Clinical Epidemiology	662	1,229	1,891 0	0	0	0 0	662	1,229	1,891 0	207 0	2,098
D. MALARIA INFORMATION SYSTEM											
TECHNICAL ASSISTANCE											
System Implementation		70	70			0	0	70	70		70
COMMODITIES											
Equipment and Supplies		134	134			0	0	134	134		134
Software		28	28			0	0	28	28		28
Subtotal Malaria MIS	0	232	232 0	0	0	0 0	0	232	232 0	0 0	232
E. QUALITY CONTROL OF BIOLOGICALS											
TECHNICAL ASSISTANCE											
Consultants		118	118			0	0	118	118		118
TRAINING (U.S./Third Country)											
Short-term Training			0	213	213	213	0	213	213		213
COMMODITIES											
Equipment and Supplies			0	475	475	950	475	475	950		950
CONSTRUCTION											
Construction of Laboratory			0			0	0	0	0	1,655	1,655
OTHER COSTS											
Salaries			0			0	0	0	0	461	461
Other Recurring Costs			0			0	0	0	0	306	306
Subtotal Quality Control	0	118	118 0	475	688	1,163 0	475	806	1,281 0	2,422 0	3,703
SUBTOTAL G/L TO THE GOVT	1,996	3,202	5,198 0	843	2,957	3,800 0	2,839	6,159	8,998 0	7,020 0	16,018

Table II-3 (continued)

ELEMENTS	Grant			Loan			US Total			--601--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY											
TECHNICAL ASSISTANCE											
		2,524	2,524			0		0	2,524	2,524	2,524
B. LABORATORY SUPPORT											
TECHNICAL ASSISTANCE											
Long-term		431	431			0		0	431	431	431
Short-term		923	923			0		0	923	923	923
TRAINING (In-Country)											
Laboratory Exchange Visits		209	209			0		0	209	209	209
Subtotal Laboratory Support	0	1,563	1,563	0	0	0	0	0	1,563	1,563	0
SUBTOTAL AID DIRECT COSTS	0	4,087	4,087	0	0	0	0	0	4,087	4,087	0
GRAND TOTAL	1,996	7,289	9,285	0	43	2,957	3,800	0	2,839	10,246	13,085
										0	7,020
											0
											20,105

CATEGORY TOTALS

TECHNICAL ASSISTANCE	0	4,066	4,066	0	0	0	0	0	4,066	4,066	0	4,066
TRAINING (US/Third Country)	0	2,800	2,800	0	213	213	0	0	3,013	3,013	82	3,095
TRAINING (In-Country)	1,505	261	1,766	0	0	0	1,505	261	1,766	0	0	1,766
COMMODITIES	0	162	162	843	2,744	3,587	843	2,906	3,749	612	0	4,361
CONSTRUCTION	0	0	0	0	0	0	0	0	0	0	1,655	1,655
OTHER COSTS	491	0	491	0	0	0	491	0	491	4,671	0	5,162
GRAND TOTAL	1,996	7,289	9,285	843	2,957	3,800	2,839	10,246	13,085	7,020	0	20,105

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Table II - 4

Summary of Project Cost by Year
(C000)

<u>Fiscal Year</u>	<u>A. I. D.</u>		<u>Total</u>	<u>GOI</u>	<u>Project Total</u>
	<u>Grant</u>	<u>Loan</u>			
FY 1985-86	1,114	947	2,061	36	2,097
FY 1987	1,433	889	2,322	1,458	3,080
FY 1988	1,805	806	2,611	1,031	3,642
FY 1989	1,930	368	2,298	1,738	4,036
Fy 1990	1,866	397	2,263	1,427	3,690
FY 1991	<u>1,185</u>	<u>393</u>	<u>1,578</u>	<u>2,030</u>	<u>3,608</u>
TOTAL	9,285	3,800	13,085	7,020	20,105

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FINANCIAL PLAN
GRAND TOTAL

Table II-5
(\$000)

ELEMENTS	Grant			Loan			US Total			--BDI--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT	0										
A. FIELD EPIDEMIOLOGY											
Long-term Training	0	418	418			0	0	418	418		418
Short-term Training		399	399			0	0	399	399		399
Equipment			0	186	186	186	0	186	186		186
Per diem	748		748			0	748	0	748		748
Vehicles			0	46	46	46	0	46	46	414	460
Vehicle Operating Costs			0			0	0	0	0	1,017	1,017
Salaries	0		0			0	0	0	0	1,215	1,215
Subtotal Field Epidemiology	748	817	1,565 0	0	232	232 0	748	1,049	1,797 0	2,646 0	4,443
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		145	145			0	0	145	145		145
Training Abroad		661	661			0	0	661	661		661
Training in India	586		586			0	586	0	586		586
Equipment			0	50	900	950	50	900	950		950
General Supplies			0	318	725	1,043	318	725	1,043		1,043
Recurring Supplies MICD			0		412	412	0	412	412	198	610
Recurring Supplies States			0			0	0	0	0		0
Salaries			0			0	0	0	0	1,547	1,547
Subtotal Lab Support	586	806	1,392 0	368	2,037	2,405 0	954	2,843	3,797 0	1,745 0	5,542
C. CLINICAL EPIDEMIOLOGY											
Fellowships		980	980			0	0	980	980	82	1,062
Research Seed Money	131		131			0	131	0	131		131
Intl Conferences		197	197			0	0	197	197		197
Cell Support	360		360			0	360	0	360	125	485
Workshops and Seminars	171	52	223			0	171	52	223		223
Subtotal Clinical Epidemiology	662	1,229	1,891 0	0	0	0 0	662	1,229	1,891 0	207 0	2,098
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		134	134			0	0	134	134		134
Software		28	28			0	0	28	28		28
System Implementation		70	70			0	0	70	70		70
Subtotal Malaria MIS	0	232	232 0	0	0	0 0	0	232	232 0	0 0	232
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0	1,655	1,655
Equipment and Supplies			0	475	475	950	475	475	950		950
Training			0		213	213	0	213	213		213
Consultants		118	118			0	0	118	118		118
Salaries			0			0	0	0	0	461	461
Other Recurring Costs			0			0	0	0	0	306	306
Subtotal Quality Control	0	118	118 0	475	688	1,163 0	475	806	1,281 0	2,422 0	3,703
SUBTOTAL G/L TO THE GOVT	1,996	3,202	5,198 0	843	2,957	3,800 0	2,839	6,159	8,998 0	7,020 0	16,018
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY		2,524	2,524			0	0	2,524	2,524		2,524
B. LABORATORY SUPPORT											
Long-term Consultants		431	431			0	0	431	431		431
Short-term Consultants		923	923			0	0	923	923		923
Laboratory Exchange Visits		209	209			0	0	209	209		209
Subtotal Laboratory Support	0	1,563	1,563 0	0	0	0 0	0	1,563	1,563 0	0 0	1,563
SUBTOTAL AID DIRECT COSTS	0	4,087	4,087 0	0	0	0 0	0	4,087	4,087 0	0 0	4,087
GRAND TOTAL	1,996	7,289	9,285 0	843	2,957	3,800 0	2,839	10,246	13,085 0	7,020 0	20,105

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FINANCIAL PLAN
FY1985-86

Table II-6
(\$000)

ELEMENTS	Grant			Loan			US Total			--GOI--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
Long-term Training		48	48			0	0	48	48		48
Short-term Training			0			0	0	0	0		0
Equipment			0	10	10	0	0	10	10		10
Per diem	20		20			0	20	0	20		20
Vehicles			0	46	46	0	0	46	46	0	46
Vehicle Operating Costs			0		0	0	0	0	0	15	15
Salaries			0		0	0	0	0	0	13	13
Subtotal Field Epidemiology	20	48	68 0	0	56	56 0	20	104	124 0	28 0	152
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		60	60			0	0	60	60		60
Training Abroad		119	119			0	0	119	119		119
Training in India	96		96			0	96	0	96		96
Equipment			0	50	335	385	50	335	385		385
General Supplies			0	65	65	130	65	65	130		130
Recurring Supplies NICD			0		50	50	0	50	50		50
Recurring Supplies States			0		0	0	0	0	0		0
Salaries			0		0	0	0	0	0		0
Subtotal Lab Support	96	179	275 0	115	450	565 0	211	629	840 0	0 0	840
C. CLINICAL EPIDEMIOLOGY											
Fellowships			0			0	0	0	0		0
Research Seed Money			0			0	0	0	0		0
Intl Conferences			0			0	0	0	0		0
Cell Support			0			0	0	0	0		0
Workshops and Seminars	35	10	45			0	35	10	45		45
Subtotal Clinical Epidemiology	35	10	45 0	0	0	0 0	35	10	45 0	0 0	45
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		107	107			0	0	107	107		107
Software		28	28			0	0	28	28		28
System Implementation		70	70			0	0	70	70		70
Subtotal Malaria MIS	0	205	205 0	0	0	0 0	0	205	205 0	0 0	205
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0		0
Equipment and Supplies			0	145	145	290	145	145	290		290
Training			0		36	36	0	36	36		36
Consultants			0			0	0	0	0		0
Salaries			0			0	0	0	0	8	8
Other Recurring Costs			0			0	0	0	0		0
Subtotal Quality Control	0	0	0 0	145	181	326 0	145	181	326 0	8 0	334
SUBTOTAL G/L TO THE GOVT	151	442	593 0	260	687	947 0	411	1,129	1,540 0	36 0	1,576
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY											
		228	228			0	0	228	228		228
B. LABORATORY SUPPORT											
Long-term Consultants		95	95			0	0	95	95		95
Short-term Consultants		150	150			0	0	150	150		150
Laboratory Exchange Visits		48	48			0	0	48	48		48
Subtotal Laboratory Support	0	293	293	0	0	0	0	293	293	0	293
SUBTOTAL AID DIRECT COSTS	0	521	521	0	0	0	0	521	521	0	521
GRAND TOTAL	151	963	1,114	260	687	947	411	1,650	2,061	36	2,097

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Table II-7
(\$000)

FINANCIAL PLAN
FY1987

ELEMENTS	Grant			Loan			US Total			--GDI--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
Long-term Training		105	105			0	0	105	105		105
Short-term Training		65	65			0	0	65	65		65
Equipment			0	33	33	0	0	33	33		33
Per diem	49		49			0	49	0	49		49
Vehicles			0		0	0	0	0	0	89	89
Vehicle Operating Costs			0		0	0	0	0	0	63	63
Salaries			0		0	0	0	0	0	59	59
Subtotal Field Epidemiology	49	170	219 0	0	33	33 0	49	203	252 0	211 0	463
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		18	18			0	0	18	18		18
Training Abroad		173	173			0	0	173	173		173
Training in India	106		106			0	106	0	106		106
Equipment			0		0	0	0	0	0		0
General Supplies			0	407	407	0	407	407			407
Recurring Supplies NICD			0	100	100	0	100	100			100
Recurring Supplies States			0		0	0	0	0	0		0
Salaries			0		0	0	0	0	0		0
Subtotal Lab Support	106	191	297 0	0	507	507 0	106	698	804 0	0 0	804
C. CLINICAL EPIDEMIOLOGY											
Fellowships		60	60			0	0	60	60	7	67
Research Seed Money			0		0	0	0	0	0		0
Intl Conferences			0		0	0	0	0	0		0
Cell Support			0		0	0	0	0	0		0
Workshops and Seminars			0		0	0	0	0	0		0
Subtotal Clinical Epidemiology	0	60	60 0	0	0	0 0	0	60	60 0	7 0	67
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		8	8		0	0	0	8	8		8
Software			0		0	0	0	0	0		0
System Implementation		0	0		0	0	0	0	0		0
Subtotal Malaria MIS	0	8	8 0	0	0	0 0	0	8	8 0	0 0	8
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0		0	0	0	0	0	500	500
Equipment and Supplies			0	155	155	310	155	155	310		310
Training			0		39	39	0	39	39		39
Consultants		25	25			0	0	25	25		25
Salaries			0		0	0	0	0	0	24	24
Other Recurring Costs			0		0	0	0	0	0	16	16
Subtotal Quality Control	0	25	25 0	155	194	349 0	155	219	374 0	1,240 0	914
SUBTOTAL G/L TO THE GOVT	155	454	609 0	155	734	889 0	310	1,188	1,498 0	1,458 0	2,256
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY											
		427	427			0	0	427	427		427
B. LABORATORY SUPPORT											
Long-term Consultants		140	140			0	0	140	140		140
Short-term Consultants		231	231			0	0	231	231		231
Laboratory Exchange Visits		26	26			0	0	26	26		26
Subtotal Laboratory Support	0	397	397 0	0	0	0 0	0	397	397 0	0 0	397
SUBTOTAL AID DIRECT COSTS	0	824	824 0	0	0	0 0	0	824	824 0	0 0	824
GRAND TOTAL	155	1,278	1,433 0	155	734	889 0	310	2,012	2,322 0	1,458 0	3,080

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FINANCIAL PLAN
FY1988

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Table II-8
(\$000)

ELEMENTS	Grant			Loan			US Total			GDI	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
Long-term Training		116	116			0	0	116	116		116
Short-term Training		72	72			0	0	72	72		72
Equipment			0			0	0	0	0		0
Per diem	98		98			0	98	0	98		98
Vehicles			0			0	0	0	0		0
Vehicle Operating Costs			0			0	0	0	0	101	101
Salaries			0			0	0	0	0	113	113
Subtotal Field Epidemiology	98	188	286 0	0	0	0 0	98	188	286 0	214 0	500
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		20	20			0	0	20	20		20
Training Abroad		216	216			0	0	216	216		216
Training in India	116		116			0	116	0	116		116
Equipment			0		169	169	0	169	169		169
General Supplies			0	78	78	156	78	78	156		156
Recurring Supplies NICD			0		88	88	0	88	88	22	110
Recurring Supplies States			0		0	0	0	0	0		0
Salaries			0		0	0	0	0	0	109	109
Subtotal Lab Support	116	236	352 0	78	335	413 0	194	571	765 0	131 0	896
C. CLINICAL EPIDEMIOLOGY											
Fellowships		198	198			0	0	198	198	22	220
Research Seed Money	11		11			0	11	0	11		11
Intl Conferences		7	7			0	0	7	7		7
Cell Support	33		33			0	33	0	33	27	60
Workshops and Seminars			0			0	0	0	0		0
Subtotal Clinical Epidemiology	44	205	249 0	0	0	0 0	44	205	249 0	49 0	298
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		19	19			0	0	19	19		19
Software			0			0	0	0	0		0
System Implementation			0			0	0	0	0		0
Subtotal Malaria MIS	0	19	19 0	0	0	0 0	0	19	19 0	0 0	19
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0	550	550
Equipment and Supplies			0	175	175	350	175	175	350		350
Training			0		43	43	0	43	43		43
Consultants		28	28			0	0	28	28		28
Salaries			0		0	0	0	0	0	52	52
Other Recurring Costs			0		0	0	0	0	0	35	35
Subtotal Quality Control	0	28	28 0	175	218	393 0	175	246	421 0	637 0	1,058
SUBTOTAL G/L TO THE GOVT	258	676	934 0	253	553	806 0	511	1,229	1,740 0	1,031 0	2,771
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY											
		470	470			0	0	470	470		470
B. LABORATORY SUPPORT											
Long-term Consultants		154	154			0	0	154	154		154
Short-term Consultants		218	218			0	0	218	218		218
Laboratory Exchange Visits		29	29			0	0	29	29		29
Subtotal Laboratory Support	0	401	401 0	0	0	0 0	0	401	401 0	0 0	401
SUBTOTAL AID DIRECT COSTS	0	871	871 0	0	0	0 0	0	871	871 0	0 0	871
GRAND TOTAL	258	1,547	1,805 0	253	553	806 0	511	2,100	2,611 0	1,031 0	3,642

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Table II-9
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FINANCIAL PLAN
FY1989

ELEMENTS	Grant			Loan			US Total			--601--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
Long-term Training		127	127			0	0	127	127		127
Short-term Training		79	79			0	0	79	79		79
Equipment			0	24	24	0	0	24	24		24
Per diem	194		194			0	0	194	0	194	194
Vehicles			0			0	0	0	0	216	216
Vehicle Operating Costs			0			0	0	0	0	182	182
Salaries			0			0	0	0	0	212	212
Subtotal Field Epidemiology	194	206	400 0	0	24	24 0	194	230	424 0	610 0	1,034
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		22	22			0	0	22	22		22
Training Abroad		153	153			0	0	153	153		153
Training in India	128		128			0	0	128	0	128	128
Equipment			0	119	119	0	0	119	119		119
General Supplies			0	53	53	106	53	53	106		106
Recurring Supplies MICD			0		72	72	0	72	72		72
Recurring Supplies States			0			0	0	0	0		0
Salaries			0			0	0	0	0	280	280
Subtotal Lab Support	128	175	303 0	53	244	297 0	181	419	600 0	280 0	880
C. CLINICAL EPIDEMIOLOGY											
Fellowships		218	218			0	0	218	218	24	242
Research Seed Money	36		36			0	36	0	36		36
Intl Conferences		32	32			0	0	32	32		32
Cell Support	73		73			0	73	0	73	30	103
Workshops and Seminars	42	12	54			0	42	12	54		54
Subtotal Clinical Epidemiology	151	262	413 0	0	0	0 0	151	262	413 0	54 0	467
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		0	0			0	0	0	0		0
Software			0			0	0	0	0		0
System Implementation			0			0	0	0	0		0
Subtotal Malaria MIS	0	0	0 0	0	0	0 0	0	0	0 0	0 0	0
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0	605	605
Equipment and Supplies			0			0	0	0	0		0
Training			0	47	47	0	47	47			47
Consultants		31	31			0	0	31	31		31
Salaries			0			0	0	0	0	114	114
Other Recurring Costs			0			0	0	0	0	75	75
Subtotal Quality Control	0	31	31 0	0	47	47 0	0	78	78 0	794 0	872
SUBTOTAL G/L TO THE GOVT	473	674	1,147 0	53	315	368 0	526	989	1,515 0	1,738 0	3,253
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY											
		517	517			0	0	517	517		517
B. LABORATORY SUPPORT											
Long-term Consultants		42	42			0	0	42	42		42
Short-term Consultants		192	192			0	0	192	192		192
Laboratory Exchange Visits		32	32			0	0	32	32		32
Subtotal Laboratory Support	0	266	266 0	0	0	0 0	0	266	266 0	0 0	266
SUBTOTAL AID DIRECT COSTS	0	783	783 0	0	0	0 0	0	783	783 0	0 0	783
GRAND TOTAL	473	1,457	1,930 0	53	315	368 0	526	1,772	2,298 0	1,738 0	4,036

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Table II-10
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FINANCIAL PLAN
FY1990

ELEMENTS	Grant			Loan			US Total			--601--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT											
A. FIELD EPIDEMIOLOGY											
Long-term Training		70	70			0	0	70	70		70
Short-term Training		87	87			0	0	87	87		87
Equipment			0	35		35	0	35	35		35
Per diem	253		253			0	253	0	253		253
Vehicles			0			0	0	0	0	34	34
Vehicle Operating Costs			0			0	0	0	0	289	289
Salaries			0			0	0	0	0	328	328
Subtotal Field Epidemiology	253	157	410 0	0	35	35 0	253	192	445 0	651 0	1,096
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		25	25			0	0	25	25		25
Training Abroad			0			0	0	0	0		0
Training in India	140		140			0	140	0	140		140
Equipment			0		132	132	0	132	132		132
General Supplies			0	58	58	116	58	58	116		116
Recurring Supplies MICD			0		66	66	0	66	66	66	132
Recurring Supplies States			0			0	0	0	0		0
Salaries			0			0	0	0	0	468	468
Subtotal Lab Support	140	25	165 0	58	256	314 0	198	281	479 0	534 0	1,013
C. CLINICAL EPIDEMIOLOGY											
Fellowships		240	240			0	0	240	240		240
Research Seed Money	40		40			0	40	0	40		40
Intl Conferences		61	61			0	0	61	61		61
Cell Support	121		121			0	121	0	121	32	153
Workshops and Seminars	45	14	59			0	45	14	59		59
Subtotal Clinical Epidemiology	206	315	521 0	0	0	0 0	206	315	521 0	32 0	553
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies			0			0	0	0	0		0
Software			0			0	0	0	0		0
System Implementation			0			0	0	0	0		0
Subtotal Malaria MIS	0	0	0 0	0	0	0 0	0	0	0 0	0 0	0
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0		0
Equipment and Supplies			0			0	0	0	0		0
Training			0	48	48	0	48	48	0		48
Consultants		34	34			0	0	34	34		34
Salaries			0			0	0	0	0	125	125
Other Recurring Costs			0			0	0	0	0	85	85
Subtotal Quality Control	0	34	34 0	0	48	48 0	0	82	82 0	210 0	292
SUBTOTAL G/L TO THE GOVT	599	531	1,130 0	58	339	397 0	657	870	1,527 0	1,427 0	2,954
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY		569	569			0	0	569	569		569
B. LABORATORY SUPPORT											
Long-term Consultants			0			0	0	0	0		0
Short-term Consultants		132	132			0	0	132	132		132
Laboratory Exchange Visits		35	35			0	0	35	35		35
Subtotal Laboratory Support	0	167	167 0	0	0	0 0	0	167	167 0	0 0	167
SUBTOTAL AID DIRECT COSTS	0	736	736 0	0	0	0 0	0	736	736 0	0 0	736
GRAND TOTAL	599	1,267	1,866 0	58	339	397 0	657	1,606	2,263 0	1,427 0	3,690

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Table II-11
(\$000)

FINANCIAL PLAN
FY1991

ELEMENTS	Grant			Loan			US Total			--GDI--	PROJECT TOTAL
	LC	FX	Total	LC	FX	Total	LC	FX	Total		
GRANTS AND LOANS TO THE GOVERNMENT	0										
A. FIELD EPIDEMIOLOGY											
Long-term Training	0	0	0			0	0	0	0		0
Short-term Training		96	96			0	0	96	96		96
Equipment			0	84	84	84	0	84	84		84
Per diem	134		134			0	134	0	134		134
Vehicles			0			0	0	0	0	75	75
Vehicle Operating Costs			0			0	0	0	0	367	367
Salaries	0		0			0	0	0	0	490	490
Subtotal Field Epidemiology	134	96	230 0	0	84	84 0	134	180	314 0	932 0	1,246
B. LABORATORY SUPPORT											
Laboratory Exchange Visits		0	0			0	0	0	0		0
Training Abroad		0	0			0	0	0	0		0
Training in India	0		0			0	0	0	0		0
Equipment			0	0	145	145	0	145	145		145
General Supplies			0	64	64	128	64	64	128		128
Recurring Supplies NICD			0		36	36	0	36	36	110	146
Recurring Supplies States			0			0	0	0	0		0
Salaries			0			0	0	0	0	690	690
Subtotal Lab Support	0	0	0 0	64	245	309 0	64	245	309 0	800 0	1,109
C. CLINICAL EPIDEMIOLOGY											
Fellowships		264	264			0	0	264	264	29	293
Research Seed Money	44		44			0	44	0	44		44
Intl Conferences		97	97			0	0	97	97		97
Cell Support	133		133			0	133	0	133	36	169
Workshops and Seminars	49	16	65			0	49	16	65		65
Subtotal Clinical Epidemiology	226	377	603 0	0	0	0 0	226	377	603 0	65 0	668
D. MALARIA INFORMATION SYSTEM											
Equipment and Supplies		0	0			0	0	0	0		0
Software		0	0			0	0	0	0		0
System Implementation		0	0			0	0	0	0		0
Subtotal Malaria MIS	0	0	0 0	0	0	0 0	0	0	0 0	0 0	0
E. QUALITY CONTROL OF BIOLOGICALS											
Construction			0			0	0	0	0	0	0
Equipment and Supplies			0	0	0	0	0	0	0		0
Training			0		0	0	0	0	0		0
Consultants		0	0			0	0	0	0		0
Salaries			0			0	0	0	0	138	138
Other Recurring Costs			0			0	0	0	0	95	95
Subtotal Quality Control	0	0	0 0	0	0	0 0	0	0	0 0	233 0	233
SUBTOTAL G/L TO THE GOVT	360	473	833 0	64	329	393 0	424	802	1,226 0	2,030 0	3,256
AID DIRECT COSTS											
A. FIELD EPIDEMIOLOGY		313	313			0	0	313	313		313
B. LABORATORY SUPPORT											
Long-term Consultants		0	0			0	0	0	0		0
Short-term Consultants		0	0			0	0	0	0		0
Laboratory Exchange Visits		39	39			0	0	39	39		39
Subtotal Laboratory Support	0	39	39 0	0	0	0 0	0	39	39 0	0 0	39
SUBTOTAL AID DIRECT COSTS	0	352	352 0	0	0	0 0	0	352	352 0	0 0	352
GRAND TOTAL	360	825	1,185 0	64	329	393 0	424	1,154	1,578 0	2,030 0	3,608

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III. Implementation Plan

A. Overall Coordination and Direction

The five subprojects that comprise this project are relatively discrete activities. They have been designed to constitute a mutually reinforcing set of activities whose outcomes all contribute directly to the achievement of the overall project purpose and goal: "Development of an effective epidemiological intelligence/monitoring system and biomedical support institutions to permit health priority setting and clear evaluation of program impact". But they are not critically interrelated in the implementation phase. The one exception to this is the direct relationship between the field epidemiology and the public health laboratory services subprojects. Coordination of these two should not be difficult to achieve. They both involve the same parent agency, NICD; the same states and districts; and the same implementing agency, CDC.

The project will be implemented through the Ministry of Health and Family Welfare, where overall coordination and management of the project will be effected by the Director General of Health Services (DGHS). Because of the distinct nature of the subprojects, coordination problems will be rare, and recourse to the DGHS is more likely to be on problems of subproject progress and management rather than coordination. And, the progress and management problems will only be evaluated to the level of the Director General when they cannot be resolved by the Directorate staff.

The organizations with whom the subprojects will be executed directly are subordinate to the Ministry in varying degrees. The NICD and the National Malaria Education Programme are directly supervised by the DGHS. Although health is a state subject, the various state departments of health are heavily influenced by national health policy and by the allocation of central government funds for special purposes and projects and this is proposed as a centrally funded project. Moreover, all the states visited during the project preparation phase expressed definite interest in participating in the field epidemiology and laboratory support subprojects. This interest will be an essential element in selecting the pilot states. In addition, Gujarat has already indicated its interest in the malaria information system and has identified the pilot district. The new National Quality Control Laboratory for Biologicals will be directly under the DGHS as is the responsibility of the Drug Controller.

The implementation of the clinical epidemiology subproject will be more complicated. Most of the 108 medical colleges are state controlled and operated. Medical school curriculum is the province of the independent Medical Council of India, of which the Director General of Health Services is only one member. The likely primary implementing agency is the All India Institute of Medical Sciences,

the premier medical institute which is semi-autonomous and was established by Act of Parliament. Implementation of this subproject will require a collegial approach, but should be feasible because the subproject concept is based on a process of curriculum reform from within in three specific medical colleges, and not a direct change in national curriculum policy in the short run.

B. Field Epidemiology

The field epidemiology subproject will be implemented through the NICD, the 16 largest states, and selected districts. It will be closely coordinated with the development of public health laboratory services. Implementation will begin with the arrival of the principal consultant, who will also serve as chief of party for CDC and WHO. The two training consultants will arrive four months after the principal consultant. They will work at NICD through the first cycle of didactic training and then will be deputed and relocated to the first two participating states. During the first six months seven tasks will be accomplished:

1. NICD, with the consultants' help, will develop a detailed curriculum for the new field epidemiology course, and particularly the six weeks of didactic training at the beginning of the course. The curriculum will be based on job descriptions for state and district epidemiologists which will be prepared and approved by the Government;

2. Training plans will be prepared for the first year field training programs;

3. Faculty for the first cycle of didactic training will be identified and recruited;

4. Three participating states will be designated by the Government. The first will be the pilot demonstration state. The second will be the primary training state. The third will be the secondary training state, where a field training program will be started in the fourth year of the project. Initial planning will be undertaken with all three;

5. The fourteen trainees for the first year training cycle will be identified and arrangements will be made for them to be assigned to the training program. Of the fourteen:

- Seven will be from the pilot demonstration state;
- Five will be from the primary training state;
- Two will be from the secondary training state. They will return to that state in the fourth year of the project to begin a third field training program.

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6. The first three candidates for the two year Applied Epidemiology Training Program at CDC will be nominated by the Government. The nominees will be persons designated to join the faculty of the Epidemiology Division of NICD on their return;

7. Equipment required for NICD and the field training programs will be procured.

The first training cycle will begin six to eight months after the principal consultant arrives; that is, in the latter part of the first project year. After the didactic training is completed, the training consultants and trainees will move to the field. During the nine month field training period, NICD, with the assistance of the principal consultant, will:

- Prepare a long range plan for the development of a field epidemiology service program for all of India;
- Prepare a five year staffing and work plan for the development of the Field Epidemiology Division of NICD;
- Prepare a detailed five year training plan which will indicate the states to which the members of each succeeding graduating class will be assigned. This is essential because trainees must be recruited from their state of final assignment;
- Coordinate the training plan with plan for the development of public health laboratory services;
- Based on the five year training plan, identify and arrange for the assignment of the second group of fourteen trainees;
- Arrange for the first annual conference of field epidemiologists to be held under NICD auspices.

During succeeding years the primary consultant will work with NICD to continue the program of strengthening the Epidemiology Division's long term didactic training program, its short courses for health officials, and its outreach investigations and assistance to states in the development of state field epidemiology and public health laboratory service plans.

Implementation of the field training program and the development of a continuing Indian capability to conduct field training in epidemiology will proceed as follows :

- During the first year tutorial supervision of the trainees will be provided by the WHO training consultant;

- During the second year the WHO consultant will provide tutorial supervision of the second group of trainees and advice and assistance to the first group of trainees who will be in their internship year;
- During the third year this process will be repeated, but in addition, graduates from the first class (two in the pilot state and four in the training state) will be assigned as trainers. Each one will provide tutorial supervision of four trainees, under the general guidance of the WHO consultant;
- In the fourth year this supervised training program will continue, but two of the trainers from the primary training state will transfer to the secondary training state to begin a new independent field training program there. They will be replaced in the primary training state by graduates of the second class;
- In the fourth and fifth years all of the tutorial supervision in the pilot demonstration state will be provided by Indian trainers. This will free the WHO Consultant to concentrate on assisting the state to develop a fully functional service program of field epidemiology.

This training process is summarized in Table III-1.

The subproject plan provides for microcomputers to be procured for NICD and the pilot demonstration and training states. These will be 16 bit microcomputers, comparable to the IBM PC. They will be procured, with appropriate peripheral equipment and software, during the first project year. The contract will include the provision of a training program (approximately 30 hours) for personnel at NIDC, the training consultants, the initial group of trainees and personnel from the three states.

The subproject also includes provision for microcomputers to be supplied to the remaining 16 states and to each district where a graduate of the field epidemiology training course has been assigned. Before this equipment is procured, a feasibility study will be made of the computer requirements for field epidemiology. It will define the requirements, specify appropriate hardware and software, and determine the associated training requirements for personnel who will use the specified equipment. This study will be undertaken in the second project year in conjunction with the final evaluation of the pilot test district (phase 3) of the malaria information system subproject in Gujarat. Any resulting procurement contract will include all three essential elements: hardware, software and training.

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Table III-1

Epidemiology Field Training Program, By Year

Year	Pilot Demonstration State				Primary Training State				Secondary Training State				Trained Epidemiologists		Total
	1	2	3	4	1	3	3	4	1	2	3	4	NICD	States & Districts	
1	7	-	-	-	7	-	-	-	-	-	-	-	-	-	-
2	7	7	-	-	7	7	-	-	-	-	-	-	-	-	14
3	12	7	5	2	16	7	1	4	-	-	-	-	2	-	28
4	8	12	12	2	16	16	3	4	4	-	1	2	4	-	56
5	8	8	24	2	16	16	3	4	12	4	2	4	5	14	84
6	8	8	24	2	16	16	3	4	16	12	3	4	8	42	120

Notes:

The trained epidemiologists produced, after year 5, will exceed 40 per year

- Key 1 = persons in training
- 2 = persons in internship year
- 3 = persons in full time epidemiological work
- 4 = trainers.

The project will also include four jeeps for each training unit, one for the epidemiology unit in each of the remaining 13 states, and one for each district where a trained epidemiologist is assigned. They will be provided by the Government, as will be adequate operating and maintenance funds.

C. Public Health Laboratory Services

The Public Health Laboratory Service subproject will be implemented through several agencies. The primary Indian counterpart agency will be the NICD, but participation will include the 16 major states and selected districts. Long and short term consultant services, and training in India and in the United States, will be provided through a direct A.I.D. PASA with CDC, with the approval of the Government. The long term laboratory management consultant will be provided through WHO. Overseas procurement will be effected through a procurement agent contracted for this subproject. Procurement in India will be accomplished by NICD and the states, using established procurement procedures.

The first implementation step, to be initiated as soon as possible after project approval, is a survey of all laboratories which conduct public health testing. The survey will identify each laboratory, its physical and human resources, the types and makers of tests currently conducted, and the potential for expansion in the range and volume of testing. It will be conducted by a university, private company or other government organization under a contracted relationship with NICD. CDC will provide the services of a short term consultant to assist in the effort.

The long term(three years) laboratory management consultant to be provided through WHO will be scheduled to arrive at the same time as the principal consultant for field epidemiology. The laboratory consultant will work with and assist the newly appointed Director of Laboratory Services. For the first two years they will be assisted by an Indian consultant who will be hired under a contract with WHO or CDC. The Indian consultant will be an individual -- probably a retired government officer -- with broad knowledge of public health laboratories in India and experienced in managing a public health or production laboratory.

1. The First Year

During the first project year the two consultants will work with the new Director of Laboratory Services to accomplish seven groups of tasks, as discussed in the following paragraphs:

(a) Advisory Committees

The terms of reference will be developed, the membership will be identified and appointed and initial meetings will be scheduled for three separate advisory committees. The committees are:

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- An overall advisory committee made up of 10 to 15 laboratory scientists representing national and state public health laboratories, the Ministry, ICMR, CDRI and the Post-Graduate Research Institutes. The purpose of this committee is to provide technical advice and guidance to the Director of NICD in the development of services and a program to upgrade and expand the laboratory activities of NICD. This committee should be convened as early as possible to provide guidance for the development plans for the NICD laboratories;
- A second committee comprised of national, state and district public health directors, epidemiologists and laboratory personnel to identify the requirements for laboratory services to support the public health program; to help establish priorities for laboratory development; and to provide guidance for the development of a national public health laboratory plan;
- A third committee of laboratory product manufacturers and representatives of public health laboratories to develop product specifications and quantities, so that most of the needed laboratory supplies and equipment can be produced in India.

(b) Reorganization

A reorganization plan for the NICD laboratories will be prepared which will create four main laboratory groups - virology, bacteriology, microbiology and parasitology. A cooperating CDC laboratory for each group will be identified. The exchange process between the NICD and CDC laboratories will be initiated, beginning with a visit to India by a representative from each of the CDC laboratories. During these visits an initial list of equipment and supply requirements will be developed and procurement action will be initiated. The first candidates for short term training in the United States will also be identified. The head of each NICD laboratory group will then go to the United States to work with the head of the counterpart CDC laboratory for a period of four months. During this period a detailed development plan for the NICD laboratory will be developed. The plan will be based on guidance provided by the overall advisory committee, and will include:

- equipment, personnel and faculty requirements;
- a phased program for the introduction of specific rapid diagnostic techniques;
- a training plan;

- requirements, at least for the first year, for short-term advisory services; and
- an equipment and supply procurement plan, by source.

c) Long Range Plan

A long range plan for the development of public health laboratory services down to the district level will be prepared, utilizing the laboratory survey data and the guidance of the second advisory committee. This plan will be coordinated with the plan for the development of a national field epidemiology service and priority will be given to developing the state laboratories in the three states that will be involved in the field epidemiology training program and the district laboratories in the pilot demonstration state. More detailed plans will be prepared for the priority state and district laboratories that will include:

- specific equipment and supply requirements with a supporting procurement plan;
- personnel requirements with a supporting training plan. Priority will be given to training in India;
- facility requirements and a plan to provide what is needed;
- an initial identification of rapid diagnostic tests to be introduced, with a time-phased estimate of supporting supply requirements.

(d) Laboratory Safety

A full time Laboratory Safety Coordinator will be appointed and sent to the United States for three months to observe laboratory safety programs at CDC and elsewhere. After the Coordinator returns, a CDC Laboratory Safety Specialist will visit India for two weeks to assist in the preparation of a laboratory safety program for NICD.

(e) Computer Support

A 16 bit microcomputer, with appropriate peripheral equipment, software and training, will be procured for use by the four laboratory groups. It will be procured in a single contract together with the microcomputer for the Field Epidemiology Division.

(f) Quality Control

A quality control committee will be established at NICD to set standards and oversee the quality of the reagents and supplies

that are manufactured and used, the testing procedures that are established, and the tests that are conducted by the individual laboratories. The chairman of this committee will visit CDC to observe quality control systems and practices in use there.

(g) Maintenance

A laboratory equipment maintenance plan will be developed, drawing on the experience of the principal advisory committee, and using short term consultancy services, if needed. The plan will include a program for training of maintenance personnel.

2. The Succeeding Years

Implementation in project years two through six will be determined by the plans developed during the first year (section 1.b. and 1.c. above). To a large degree they will be reiterations of the detailed steps in the first year: training in India and abroad; equipment procurement for state and district laboratories; and short term consultant visits, both planned and problem oriented. Table III-2 summarizes the estimated training and consultancy requirements.

Table III-2

Estimated Training and Consultancy requirements
(In person Weeks)

<u>Training and Observation Visits Abroad</u>	Year				
	1	2	3	4	5
Four NICD laboratory directors	64	8	8	8	8
Laboratory Techniques (NICD);					
Hepatitis	12	12	12	-	-
Viral Respiratory Diseases	36	36	36	-	-
Bacteriological Respiratory Diseases	36	36	36	-	-
Viral Enteritis	24	24	24	-	-
Bacteriological Enteritis	24	24	24	-	-
Immunological practices (three States)	-	72	-	-	-
Quality control (NICD)	24	24	-	-	-
Equipment maintenance	24	24	-	-	-
Laboratory safety	12	-	-	-	-
<u>Short Term Consultancies</u>					
Directors of foreign "sister laboratories"	16	8	8	8	8
Laboratory survey	4	-	-	-	-
Training courses in India	18	18	18	18	18
Problem oriented consultancies (e.g. hybridoma)	26	50	40	30	12
Laboratory safety	2	2	2	-	-

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D. Clinical Epidemiology

The clinical epidemiology subproject will be implemented in coordination with the Rockefeller Foundation and the Foundation-supported clinical epidemiology research and training centers which constitute Rockefeller's International Clinical Epidemiology Network. These training centers are at McMaster University, the University of New South Wales, and the University of Pennsylvania. Within India, the subproject will interface with or work through the Ministry of Health and Family Welfare, the Medical Council of India (MCI), the All India Institute of Medical Sciences (AIIMS), and three medical colleges to be selected during the project to become centers for training in clinical epidemiology and India's members in the International Clinical Epidemiology Network.

The subproject will begin with a separately funded seminar of 2-1/2 days, which will be held at an isolated location (probably Srinagar) the week of October 7. Attendees will include the principals and leading clinical professors (two representatives from each) of 12 medical faculties, plus no more than six additional representatives from the Directorate of Health Services in the Ministry, and the Medical Council of India. It will be led by 10 participants from the Rockefeller INCLEN network, including professors and fellows currently in training. The administrative arrangements for the seminar, including international travel, will be made by AIIMS and paid for by A.I.D. with non-project funds. The purposes of the seminar are to provide a general introduction to clinical epidemiology, to demonstrate the essential role of epidemiology skills in medical education and clinical practice and to present illustrative findings from research in clinical epidemiology in order to expand the awareness of the concept among concerned leaders in medical education.

The Rockefeller INCLEN representatives will also visit some of the more interested colleges after the seminar. It is expected that the seminar and the visits will produce a consensus on at least one of the medical colleges that will ultimately be chosen for participation in the project. If so, two to three faculty members from that college will be identified as candidates for training at one of the existing INCLEN centers in the 86-87 academic year.

A three day project-funded workshop will follow this seminar. It will be administered by AIIMS and conducted by the Rockefeller INCLEN representatives. Attendees will be five or six mid-level faculty members from up to eight medical colleges that are already interested and active in clinical epidemiology, and representatives of the Ministry and MCI. The purposes will be to share teaching methodologies and materials and research experience with fellow faculty members; the workshop will also provide additional information on the participating colleges as a basis for selection of the three colleges who will participate in the project. The demonstrated commitment of

the principal and faculty to the concept of clinical epidemiology and INCLLEN is essential for selection.

After the workshop, the Government will nominate up to six colleges as potential participants. If more than three are nominated, final selection will be made by the INCLLEN Executive Committee. Once the colleges have been selected the process of identifying candidates for INCLLEN fellowships will begin. While this will, to a large degree, be a consensus process, final decision on the persons to be nominated will be made by the Ministry. The responsible INCLLEN center will, however, have the right to refuse any nominee who does not meet established INCLLEN standards.

The rate at which candidates are sent abroad for training will depend on how quickly qualified candidates can be identified -- it may take time to locate individuals who are motivated, academically qualified and of the right career status -- and the capacity of the INCLLEN centers to accept them. The projected rate at which candidates will be sent abroad by project year, is: (2) three; (3) six; (4) six; (5) six; and (6) six. This assumes that the capacity of the INCLLEN Centers will be expanded, probably by the addition of another university, in time to meet the training demand for six persons per year from India. If these rates can be met, the essential cluster of six clinical epidemiologists in each of the three participating colleges will be trained and there will be additional fellowships available in project years five and six. These will be used for faculty members from other colleges who have shown a strong interest in the program. The colleges and the candidates will be selected by the same process as used for the original three.

In the first year after a fellow returns he or she is expected to complete a research project to be presented at the next annual international INCLLEN conference. Each returning fellow will be provided with \$5,000 in research seed money for this purpose, and attendance of all returned fellows at the succeeding conferences will be supported throughout the life of the project. Annual support grants of \$25,000 for each of the three clinical epidemiology cells will be provided. Disbursement of these grants will be contingent on each cell meeting established, measurable INCLLEN progress criteria. Finally, it is expected that interest in clinical epidemiology will grow as the project progresses. In order to capitalize on this and to foster the spread of clinical epidemiology to additional colleges, three national workshops will be held in the later years of the project. The timing, venue and attendance at these workshops will be determined as the project progresses, in consultation with representatives from the Government and the Rockefeller Foundation.

E. Malaria Information System

A prototype design approach will be used to implement this sub-project in four phases. The first phase of the information system

will be limited to essential malaria surveillance information at the NMEP Central Office. Then, in three phases, the information system will be expanded to a comprehensive management information system for malaria control at the national level and in one pilot state. The purpose of this design approach is to provide for the opportunity to test and evaluate the application of computer technology to the malaria control problem as the information system evolves. The design and implementation of the information system will be closely integrated with training activities. As the system is developed, micro-computer training will be provided for the malaria staff who will have the responsibility of controlling and operating the system.

An Indian information systems design firm will provide leadership and technical expertise for the design and implementation of the information system. The firm will provide technical support in the adaptation of standard software packages to meet the requirements of the information system. Training specialists will conduct seminars for administrative malaria staff and intensive microcomputer training courses for operational and technical malaria staff. The training specialists and technical writers will prepare system documentation and training materials, including audio-visuals, to enhance these training activities.

All computer hardware, software and related equipment will be procured in advance of the phase in which it will be required. The equipment will be handed over to the Indian contractor for testing and installation at the sites of the end-users, as and when needed in the development of the information system. Local representatives for the computer hardware will assist the project component contractors in the installation of the systems as a part of the overall purchase order for the equipment.

1. Phase 1

The objective of the first phase is to create a data base at the NMEP Central Office which will serve as a foundation from which the information system can be expanded into a more comprehensive and useful tool for malaria control. Phase 1 will be implemented on a 16-bit microcomputer system at the NMEP Central Office. This phase will be limited to essential malaria surveillance data. The specific inputs will be the raw 1984 data reported to NMEP on malaria forms MF4, MF5, and MF6. These forms contain data on case

detections, radical treatment, and insecticide spraying. The outputs of Phase 1 will be the four malaria control indexes (ABER, API, SPR, SFR) for PHCs, district, state and national levels.

A one-day orientation seminar will be conducted at NMEP to introduce the potential applications of microcomputers to malaria control to the NMEP Directorate and other health policymakers. In a workshop at NMEP, the functions of the microcomputers installed in

the office will be demonstrated to staff. At the beginning of Phase 1, twenty days of intensive microcomputer training will be conducted for the six NMEP staff who will be responsible for operating the information system. During the training sessions, the staff will begin to load 1984 surveillance data.

By the end of the first nine months, NMEP and A.I.D. will evaluate Phase 1.

2. Phase 2

The objective of Phase 2 is to expand the information system from a data base of essential surveillance data to include resources management information. Issues to be addressed in the design of Phase 2 are: the definition of the essential parameters for malaria control, the design of improved malaria data collection and reporting formats, the design of appropriate automated graphs, and the application of automated statistical analysis to malaria control. The parameters for Phase 2 will be defined after the evaluation of Phase 1, and the scope of the parameters will be limited to the functions of the NMEP Central Office.

Once the Phase 2 software has been fully developed, a one-day seminar will be held at NMEP to demonstrate the system to the directorate. Then, about 50 health professionals involved in health administration and research will be invited to a half-day demonstration of the information system to introduce the application of microcomputer technology to malaria control. Training will continue for the technical staff to introduce Phase 2.

At the end of 18 months, NMEP and A.I.D. will evaluate Phase 2 and the performance of the Indian firm implementing the information system.

3. Phase 3

The objective of Phase 3 is to link the NMEP information system to one district of the pilot state. This phase will provide management information for district-level operations control and will enhance the flow of data from the district to the national level. Phase 3 will be implemented on the 8-bit microcomputer system installed at the District Malaria Office in Godhra, Panchmahals, Gujarat. Village-level information will be processed in Phase 3 to provide appropriate information for operational decision making at the district level.

During the development of Phase 3, a one-day seminar will be held at the pilot state level for the administrative and technical malaria staff to introduce the functions of the computers to be installed in the state and to demonstrate the capabilities developed in

Phase 2. Once the Phase 3 software has been developed, a workshop will be held at the District Malaria Office to introduce the staff to the decision-support capabilities of the information system. Twenty days of intensive microcomputer training will begin for the district staff who will be given the responsibility of operating the computers.

By the end of two years, NMEP, the state and district malaria directorate, the contractor and A.I.D. will evaluate Phase 3. Recommendations will be made regarding whether it is appropriate to expand Phase 3 to all districts of the pilot state. This evaluation will be coordinated with, and will provide inputs for, the study of computer requirements at the district level for field epidemiology services.

4. Phase 4

The objective of Phase 4 is to expand the information system to each district of the pilot state and to establish a node of the system at the state level. Phase 4 will also provide two innovative approaches to malaria control. This phase will include a simulation model of the malaria problem, based on the lessons learned in the development of the first three phases. The model will be designed for use in strategic planning by testing the consequences of 'what-if' conditions on the malaria control problem. Phase 4 will also test the feasibility of an early warning system model for malaria control based on relationships between the climatic conditions and the trend of incidence of malaria in a given region.

During the development of Phase 4, intensive microcomputer training will be given to the three malaria staff of each district office who will have the responsibility of operating the information system. About 85 people will be trained including four staff from the state office. Once the Phase 4 software has been developed, a one-day seminar will be held at the national and the state levels to demonstrate the capabilities of the new phase. A half-day demonstration will be held for about 50 health administrators and scientists who may be able to apply similar technology to other specific public health problems.

By the end of three years this subproject component will be completed and an in-depth evaluation of the management information system will be conducted. The evaluations will have two main objectives:

- a. To determine whether the system should be extended within the NMEP, and if so, how far it should be extended geographically. Some states and districts have so little malaria that computer installations there are almost not warranted;

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b. To assess the potential for extending the system in Gujarat horizontally on a pilot basis to encompass other health intelligence data.

F. Quality Control of Biologicals

When the project is approved, the Ministry of Health and Family Welfare will designate an officer who will be responsible for preparing a detailed plan for the construction, equipping and staffing of a national quality control laboratory for biologicals. A consultant from the U.S. Food and Drug Administration will be provided for two months to assist in the preparation of the plan. Once the plan has been approved by the Government (the middle of the first project year) and incorporated into this project paper by an amendment, it will provide a detailed, time-phased implementation schedule. The first step in that schedule will be for the Indian architect for the laboratory, and the laboratory director, once selected, to be sent to the U.S. to tour recently constructed laboratory facilities in the company of a U.S. architect with current laboratory design experience.

The second step will be to begin training of key laboratory personnel. The training will be vaccine-specific. Two persons will be trained in the quality control of each major vaccine. The training practices, the minimum qualifications for personnel to be trained, and recruitment and selection procedures will be set forth in detail in the laboratory plan. Training will be accomplished in Indian laboratories wherever possible. When in-country training is not available, individuals will be sent to the United States for three months training in the laboratories of the National Institutes of Health. Three such trainees are expected to be sent each year for five years.

There is little advantage in trying to anticipate now the schedule beyond these first steps. However, sufficient analysis has been done to confirm that this subproject, when it is planned in detail, can be accomplished within the life of the project.

IV. Monitoring Plan

A. Overall Management

The project will be managed by a fulltime, local hire project manager who will report directly to the Chief of the Office of Health and Nutrition. Because of the large volume of training, short-term consultants and other activities that will create a large administrative workload, the project manager will be supported by a full time local hire administrative assistant. The project manager will receive advice and assistance in such matters as negotiation with the Government from the Public Health Advisor, the Office of Health and Nutrition.

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General monitoring and management responsibilities of individual subprojects will be as follows:

B. Subproject Management

1. Field Epidemiology and Laboratory Support

Day-to-day management of these subproject activities will be the responsibility of the chief of party under the PASA with CDC. The project manager will monitor these activities through regular contacts and site visits, voucher approvals, etc. In addition, the chief of party will submit a quarterly progress report to A.I.D. covering the field epidemiology and laboratory support subprojects. The first report will include a work plan for the coming year. The workplan will be updated as necessary. At a minimum, the quarterly progress reports will summarize subproject activities during the preceding quarter and identify problems encountered and propose solutions for them.

2. Clinical Epidemiology

The project manager will directly manage the A.I.D. inputs to this subproject in support of the overall plan developed by the Rockefeller Foundation and the INCLN network. The project manager will also participate in the annual subproject evaluation workshops.

3. Malaria Information System

Day-to-day management of this subproject will be the responsibility of the contractor(s) who are employed to implement the system. The project manager will monitor contractor(s) activities through regular contacts and site visits, voucher approvals, etc. In addition, the contractor(s) will submit bimonthly progress reports covering their activities during the preceding two months. These reports will compare activities with a work plan which the contractor will prepare at the beginning of each of the four phases of the subproject. The project manager will also participate in the evaluations to be made at the end of each phase, and will attend the demonstration workshops which will be held for government officials at the end of each phase.

4. Quality Control of Biologicals

The management plan for this subproject will be developed as part of the detailed project plan.

V. Project Analyses

A. Financial Analysis

The total cost of the project is estimated to be \$20.1 million over a six year period. Out of this, A.I.D.'s contribution in the form of grant(\$9.3 million) and loan(\$3.8 million) will aggregate \$13.1 million, i.e. 65 percent of the total cost. The remaining \$7.0 million, i.e. 35 percent of the total cost, will be provided by the Government of India. Of A.I.D.'s total of \$13.1 million, \$10.3 million(78 percent) will be used to pay foreign exchange costs of technical assistance, training and equipment; and \$2.8 million(22 percent) will be for local costs. Since the entire GOI contribution of \$7.0 will be for local costs, the total costs of the project will be almost equally divided between local costs(49 percent) and foreign exchange costs(51 percent).

Recurring Costs

The above cost estimates of the project do not include the cost of recurring supplies. These are mostly test kits and reagents for the state public health laboratories. This is a vital input and their cost will be significant. It is, however, difficult to estimate these costs until some experience is gained with a fully functioning state laboratory. These costs will be borne by the GOI and state governments as part of their share of the project in addition to the GOI contribution of \$7.0 million. Given the very high priority accorded to health services in the Seventh Five Year Plan, the GOI should have no difficulty in providing necessary financing for this project.

B. Economic Analysis

Investments in the health sector are economical because of the obvious gains in productivity realized by the availability of a healthy workforce. Moreover, a strong health program can improve population quality or "human capital." This benefit derives from changes in attitudes towards education and skill development resulting from good health and longer life expectancies.

A.I.D.'s goal in the health sector is to reduce infant and child mortality and morbidity in the labor force, and concomitantly to reduce fertility. In determining how A.I.D. could best make a contribution to the achievement of that goal, various alternatives were considered. The final analysis proved that without a strong information base on which to determine priorities for resource allocation, all interventions are potential opportunities for uneconomical waste. Consequently, epidemiology was selected as the focus for A.I.D. support. A strong epidemiology capability will enable India to identify disease trends and evaluate the success of applied interventions. With this information in hand, the government can make

informed decisions on resource allocation and set policies that increase the effectiveness and the efficiency of health delivery systems. Preventive medicine campaigns can be launched against diseases determined to be prevalent in specific areas, and the necessity for high cost curative treatment accordingly decreased.

A secondary focus of support under the project will be the upgrading of national, state, and district laboratories and the creation of a national quality control laboratory. In upgrading the existing labs, the project will introduce new technologies, such as rapid diagnostic techniques. These will permit better use of valuable staff time and, by making accurate diagnoses possible, enable medical personnel to prescribe the proper therapy. This, combined with the creation of a national quality control laboratory which will ensure the efficacy of vaccines and the validity of diagnostic reagents, will significantly decrease wastage.

In sum, the economic viability of this project cannot be assessed in isolation from the long term benefits of effective application of epidemiological principles and findings to the entire health sector of India. The potential payoffs are very significant, and promise amply to justify the investment. Conversely, if the project succeeds in setting up an effective system which is then not used to its fullest potential by the Indian public and private medical establishment, its economic viability will be reduced.

C. Social Soundness Analysis

Although seventy percent of India's population lives in rural areas, only thirty percent of the country's health care resources are allocated outside the cities. One reason for this distorted distribution of resources is that it is difficult to collect and analyze data on disease prevalence in the rural areas. In urban areas the task is much simpler because of the concentration of population and the ability to survey readily available hospital records. This project will enable the Government to make a more balanced distribution of resources as epidemiological surveys pinpoint disease trends in rural areas and facilitate the evaluation of intervention effectiveness. The result will be a more responsive health care system for A.I.D.'s target population, the rural poor.

The primary beneficiaries of the project will be children. As indicated earlier, 45 percent of all deaths that occur each year in India are the deaths of children under five years of age, even though this population comprises only fifteen percent of the country's total population. With the increased availability of accurate data, health professionals will be better able to identify the major causes of morbidity and mortality among children. Appropriate interventions such as the vaccination of target populations can be justified on the basis of data collected and, thus, preventive rather than curative health

care can be promoted. Women will benefit as decreasing percentages of their time are spent tending to and worrying about sick family members. In sum, better health care will result in an improved quality of life for the entire population. As morbidity and mortality among children decrease, so should fertility, as parents realize that they need not conceive and bear more children to compensate for likely losses. This, too, will greatly benefit women.

By supporting rapid diagnostic techniques to identify agents of disease, and improving the efficacy of medicines through quality control, this project will improve health care treatment in the villages. As villagers begin to recognize these improvements, their trust in modern medicine and the suppliers of these medicines will grow. These attitudinal changes will foster a ripple effect through which further improvement in rural health status can occur.

D. Administrative Analysis

The project will be centrally sponsored and managed by the Ministry of Health and Family Welfare (MOHFW). Overall coordination and management of the project will be done by the Director General of Health Services (DGHS), MOHFW. MOHFW will ensure that all terms of the Project Agreement are fully met. A senior officer of the rank of Additional Secretary or Joint Secretary will be the Central Coordinator. The Central Coordinator will be assisted by the regular staff of MOHFW. A Central Project Advisory Committee (PAC) chaired by the Central Coordinator will meet annually to review various project components and render policy guidance. An A.I.D. representative will be a member of this Committee, and representatives from AID/W may be invited to attend.

Health is a state subject, but the state departments of health are heavily influenced by the national health policy because allocation of Central Government funds is made for special projects. This project is a centrally funded project. At the state level, the state ministries of health and family welfare will be responsible for implementing the respective component of the project in the participating states. Coordination and management will be undertaken by the state director or additional director of health services. The participating states will have a subproject governing board chaired by the chief secretary/health secretary. The board will meet biannually to review project progress and approve future plans. Representatives of the GOI, MOHFW and A.I.D. will be invited to the meetings of the governing boards. Within the districts, the Chief District Medical Officer (CDMO) will be responsible for project implementation. Funding at the state level for additional staff and for model districts will be provided from the project.

The implementation of five critical but mutually reinforcing components of the project will be undertaken as follows:

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i) Field Epidemiology - This component will be executed by the National Institute of Communicable Diseases (NICD) with assistance from the U.S. Centers for Disease Control (CDC) and the World Health Organization(WHO). These institutions are renowned for executing such projects.

ii) Laboratory Support Services - The public health laboratory service will be developed in a top to bottom pyramid fashion. NICD's highly sophisticated lab will serve as the reference lab to the other public health labs throughout India and will provide applied research and specially testing. The district labs will provide basic laboratory support and the state labs will provide most of the required diagnostic testing.

iii) Clinical Epidemiology - In three Indian medical colleges fully functioning clinical epidemiology cells will be established. These cells will serve as national training centers and thus create a critical mass of trained epidemiologists. This component will be executed with the advice and assistance of the Rockefeller Foundation's International Clinical Epidemiology Network.

iv) Management Information System for Malaria - This component will be managed by the National Malaria Eradication Programme (NMEP), a fully functioning and staffed unit under the general direction of the MOHFW. The GOI has made substantial investment in the malaria control program and the staff has valued experience in data collection and analysis.

v) Quality Control of Biologicals - This component will support the construction, equipping and staffing of a new national quality central laboratory for biologicals, including vaccines, reagents, rapid diagnostic test kits etc. The cooperation of the U.S. Food and Drug Administration will be sought for execution of this component.

VI. Conditions Precedent to Disbursement

1. Prior to the disbursement of any funds for the field epidemiology component of the project, the Cooperating Country will provide, or cause to be provided, evidence that:

a) the pilot demonstration state and the primary training state have been selected and an adequate number of positions have been sanctioned for each state epidemiological unit and, in the pilot demonstration state, one position has been sanctioned for each district epidemiological unit;

b) the principal long term consultant has been approved by the Cooperating Country.

2. Prior to the disbursement of funds for the field epidemiology component and the national laboratory component, the Cooperating Country will provide, or cause to be provided, evidence that the National Institute of Communicable Diseases has appointed an officer on special duty in tenure for three to five years, an individual responsible for managing the two efforts and for assisting the Director of the National Institute of Communicable Diseases.

3. Prior to the disbursement of funds for the creation of clinical epidemiology cells, the Cooperating Country will provide, or cause to be provided, evidence that three medical colleges have been selected as project sites in consultation with the Rockefeller Foundation.

4. Prior to the disbursement of funds for equipment and supplies for the quality control of biologicals component, the Cooperating Country will provide, or cause to be provided, evidence that the construction of the National Quality Control Laboratory has been sanctioned.

VII. Evaluation Arrangements

A. The Overall Project

Because of the independent nature of the subproject components, there will not be any interim or in-progress evaluations of this project as a whole. All evaluations during the entire life of the project will be subproject-specific. Nor will there be an overall end-of-project evaluation in the usual sense. Rather, separate end-of-project evaluations will be undertaken for each subproject, and the overall end-of-project evaluation will be a synthesis of these subproject evaluations.

It will summarize them and draw overall conclusions regarding the interaction among the subprojects and the combined effect. This evaluation will also assess overall project management to see what conclusion can be drawn from the Mission's performance in managing a project that presents at last four eventually independent management tasks. The evaluation will require two to three weeks to complete. It will be conducted by a representative from the Mission's Office of Health and Nutrition and a TDY person drawn from the Bureau of Science and Technology, the PPC evaluation staff or the Asia and Near East Bureau's Office of Project Development or Office of Development Planning.

B. Subproject Evaluations

1. Field Epidemiology and Laboratory Support

The field epidemiology and laboratory support subprojects will be evaluated jointly. A mid-project evaluation will be made at

the end of the third project year, and an end-of-project evaluation will be made in the final six months of the sixth project year. The evaluations will be conducted by teams consisting of one representative each from the Ministry, the Mission, CDC Atlanta and A.I.D.'s Bureau for Science and Technology. It is estimated that the evaluations will each require three weeks of work by the teams. Both evaluations will include assessment of:

- the achievement of projected outputs;
- A.I.D. and Government performance in funding projected inputs and meeting covenants on time;
- The performance of each subproject in relation to the implementation plan;
- The effectiveness of the field epidemiology training program as evidenced by the competence of graduates.

The mid-term evaluation will recommend specific actions to deal over the remaining life of the project with any problems identified. A major element in the end-of-project evaluation of the field epidemiology and laboratory support subprojects will be an assessment of the effectiveness of the epidemiology program in the pilot demonstration state. Ideally one would find a state with districts in which:

- There is a routine disease surveillance system which is providing data on disease incidence and causes;
- The system identifies trends and seasonal variations, and reports on immunization coverage;
- Outbreak investigations are being conducted when required;
- There is a program of regular water sample testing;
- The laboratory is conducting short examinations, using rapid diagnostic techniques and kits, to determine the causes of endemic and seasonal diarrhea (e.g. E-coli, rotovirus, cholera, etc.);
- Actions are being taken based on the above, such as immunization programs, special seasonal eradication campaigns, changes in supply patterns, etc., and, where surveillance data is available, these actions have produced discernible changes in the patterns of morbidity and mortality;

At the state level one would find an epidemiology and a state public health laboratory which:

- Provides technical direction to the districts;
- Provides assistance in outbreak investigations;
- Monitors summarized district surveillance data;
- Provides reference laboratory testing of respiratory diseases, special sero-diagnosis and other analyses which cannot be coordinated at the district level, using rapid diagnostic techniques;
- Takes actions based on the above, such as reassigning manpower or altering the types and quantities of medications that are provided to the districts.

This ideal will probably not be achieved at the state level and in all of the districts of the pilot state within the life of the project. However, it provides a benchmark against which accomplishments can be measured.

2. Clinical Epidemiology

An annual evaluation of the progress of this subproject will be made by at least one representative from the Rockefeller Foundation, the INCLEN network, the Mission, the All India Institute of Medical Science and the Medical Council of India. These evaluations will be in the form of a one to three day workshop. They will assess actual versus planned performance during the preceding year and recommend appropriate changes in planned activity for the coming year.

At the end of the fourth and sixth years of the project, these evaluations will include an assessment of the status of the three clinical epidemiology units (CEUs) against the following established INCLEN performance criteria:

a. Structure

(1) By the fourth year, the unit should have:

- adequate space;
- three to five clinical epidemiologists, and related staff;
- a management structure suited to its purpose and context;

- good institutional support for its activities.

(2) By the sixth year, the unit should show evidence of:

- links to other clinical departments;
- links to local health services and government.

b. Process

By the fourth year, the CEU's should be undertaking:

- research into the effectiveness of high resource-using clinical activities, or research into health problems of high national or regional priority in terms of morbidity and mortality;
- research which is at least 50% locally or nationally funded;
- substantial undergraduate and graduate education in clinical epidemiology;
- extensive dialogue on matters of proper health care and health priorities with other units in the institution, with health care policy makers, and government at all levels;
- the provision of research design advice to colleagues.

Outcome

(1) By the fourth year the CEU's should have underway:

- research which could have a measurable impact on health or health care policy;
- education programs which could alter the pattern of medical care in the institution.

(2) By the sixth year there should be evidence that the potential changes described above have been achieved, along with

- plans for self propagation;
- completed papers and research reports for publication;
- clear evidence of physician growth, an example of which would be to have significantly changed a

method of delivering health care based on critical appraisal of the evidence for and against the method.

3. Malaria Information System

As set forth in the implementation plan above, an evaluation will be made at the end of each of the four phases of this subproject. The evaluations will assess performance in the preceding phase and recommend whether to proceed with the next phase, and if so how. The evaluations at the end of phases 1 and 2 will be made by representatives of the Ministry, the NMEP, and the Mission. The phase 3 and 4 evaluations will include a representative from Gujarat state and one from the Central Bureau of Health Intelligence.

The evaluation at the end of phase 2 (i.e. after 18 months) will specifically include a formal assessment of the performance of the Indian firm implementing the project. As noted above, the final evaluation, which will come at the end of the third project year, will have two main objectives:

- To determine whether the system should be extended within the NMEP, and if so, how far it should be extended geographically. Some states and districts have so little malaria that computer installations there are not warranted;
- To assess the potential for extending the system in Gujarat horizontally on a pilot basis to encompass other health intelligence data.

C. Quality Control of Biologicals

The evaluation plan for the subproject will be developed as a part of the detailed implementation plan which will be prepared at the beginning of the project. It will be included in this project paper by an amendment.

ANNEX A

TO: SECSTATE WASHDC

SUB: BIOMEDICAL SUPPORT FOR HEALTH SERVICES (386-0492)

REF: STATE 303690

1. MISSION APPRECIATES APAC GUIDANCE AND NOTES THAT SEVERAL OF ISSUES RAISED REFTEL, E.G., RESEARCH UTILIZATION, POLICY DIALOGUE, AND THE ROLE OF THE PRIVATE SECTOR, HAVE BEEN AND WILL CONTINUE TO BE OF HIGH CONCERN TO THE MISSION DURING THE DEVELOPMENT OF THE PROJECT. BIO-MEDICAL RESEARCH IS A NEW AREA OF INVOLVEMENT FOR MISSION; CONSEQUENTLY, MISSION THINKING IN MANY OF THESE AREAS IS, AT THIS POINT, STILL EMERGING FROM THE EMBRYONIC STAGE. MISSION ANTICIPATES PROJECT STRATEGY CRYSTALIZING ONLY AFTER EXTENSIVE TALKS WITH GOVERNMENT HAVE TAKEN PLACE AND MISSION HAS BENEFIT OF THE KNOWLEDGE AND EXPERIENCE OF VARIOUS SPECIALISTS BEING REQUESTED FOR PROJECT DESIGN. AID/W'S ACTIVE PARTICIPATION THROUGHOUT THE DESIGN OF THIS PROJECT IS WELCOMED. IN PARTICULAR, WE WILL RELY HEAVILY ON AID/W TO SCREEN CANDIDATES FOR CONSULTANCIES AND ASSURE THAT THOSE NOMINATED POSSESS THE QUALIFICATIONS AND INTERPERSONAL SKILLS NECESSARY TO DEAL EFFECTIVELY WITH OUR INDIAN COUNTERPARTS.

2. MISSION DISAGREES WITH COMMENTS CONTAINED IN PARAGRAPH 7A THAT VACCINE DEVELOPMENT DOES NOT FIT INTO PROJECT AS STRUCTURED AND BELIEVES THAT AID/W ASSERTION MUST BE DUE TO MISUNDERSTANDING REGARDING MISSION INTENTIONS. CAREFUL READING OF THE PID INDICATES THAT MISSION DEFINES VACCINE DEVELOPMENT AS RESEARCH, ADAPTATION, TESTING AND PRODUCTION. RESEARCH, ADAPTATION, AND TESTING OF RAPID DIAGNOSTIC TECHNIQUES AS WELL AS VACCINES CLEARLY REPRESENT A MAJOR THRUST OF THE PROJECT. AS TO VACCINE PRODUCTION MISSION REGARDS IT AS AN AREA IN WHICH PRIVATE SECTOR PARTICIPATION COULD BE EXPANDED AND WOULD LIKE TO EXPLORE THIS POSSIBILITY DURING PROJECT DESIGN. IDEALLY, GREATER PRIVATE SECTOR PARTICIPATION IN VACCINE PRODUCTION WILL FOSTER A LARGER ROLE FOR THE PRIVATE SECTOR IN VACCINE RESEARCH AND WILL MOBILIZE PRIVATE SECTOR RESOURCES TO ACTIVELY PROMOTE THE DESIRABILITY OF A VACCINATED POPULATION. A SUCCESSFUL VACCINE DEVELOPMENT PROGRAM WILL CONTRIBUTE SIGNIFICANTLY TO THE ACHIEVEMENT OF THE PROJECT PURPOSE, I.E., TO STRENGTHEN HOST COUNTRY CAPABILITY TO DEVELOP BIOMEDICAL TECHNOLOGIES SO AS TO IMPROVE PREVENTIVE AND CURATIVE HEALTH COVERAGE, AND WILL HAVE A CONSIDERABLE IMPACT ON THE PROJECT AND USAID SECTOR GOAL OF REDUCING INFANT AND CHILD MORTALITY. DOLS 1 MILLION PRICE TAG FOR THIS COMPONENT IS ADMITTEDLY SOMEWHAT NOTIONAL AT THIS POINT BUT WILL BE CAREFULLY REVIEWED DURING DESIGN.

3. AS RECOMMENDED REFTEL, MISSION WILL CONSIDER LOAN FUNDING EQUIPMENT PURCHASED UNDER MALARIA DATA MANAGEMENT COMPONENT BUT WILL GRANT

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FUND ANY NECESSARY TRAINING OR TECHNICAL ASSISTANCE. AID/IRM WILL BE GIVEN OPPORTUNITY TO REVIEW EQUIPMENT PRIOR TO PROCUREMENT. MISSION BELIEVES THAT MALARIA CONTROL PROGRAM IS BEST SUITED TO DEMONSTRATE ADVANTAGES OF A COMPUTER DATA MANAGEMENT CAPABILITY FOR SEVERAL REASONS. DUE TO THE PRIORITY THE GOVERNMENT PLACES ON MALARIA CONTROL, THE PROGRAM HAS HIGH VISIBILITY WHICH IS ATTRACTIVE FOR DEMONSTRATION PURPOSES. ALSO, BECAUSE OF THE SUBSTANTIAL INVESTMENT THE GOVERNMENT HAS MADE IN THE PROGRAM, THE STAFF HAS EXPERIENCE IN DATA COLLECTION AND ANALYSIS UNMATCHED BY OTHER DISEASE-SPECIFIC PROGRAMS. AS TO APAC RECOMMENDATION THAT EQUIPMENT BE LOCATED WITHIN MOHFW OR STATE HEALTH MINISTRY, MISSION NOTES THAT MOHFW HAS HAD COMPUTER FOR 18 MONTHS AND HAS YET TO REALIZE SUBSTANTIAL INCREASES IN DATA MANAGEMENT EFFICIENCY. THIS IS PRIMARILY A RESULT OF THE DIVERSITY OF INTERESTS COMPETING TO BENEFIT FROM COMPUTER ACCESS. USAID BELIEVES FOCUSING ON SINGLE PURPOSE ORGANIZATION, I.E., NATIONAL MALARIA ERADICATION PROGRAM, IS MOST EFFECTIVE WAY OF DEMONSTRATING VALUE OF COMPUTERS AS A MANAGEMENT TOOL.

4. MISSION RESPONSES/REACTIONS TO OTHER AID/W ISSUES/QUESTIONS ARE AS FOLLOWS:

- A. RESEARCH UTILIZATION: MISSION AGREES THAT RESEARCH AND FIELD TRIALS SHOULD BE CONDUCTED WITH A VIEW TOWARD UTILIZATION OF RESULTS. TO THIS END THE PROJECT WILL(1) LIMIT RESEARCH ACTIVITIES TO THOSE DISEASES WHICH HAVE MAXIMUM IMPACT ON INFANT AND CHILD MORTALITY AND MORBIDITY IN THE LABOR FORCE;(2) STRENGTHEN LINKAGES BETWEEN THE RESEARCH CENTERS AND THE STATE EPIDEMIOLOGICAL UNITS; AND(3) SUPPORT THE PARTICIPATION OF THE STATE UNITS IN FIELD TRIALS. MISSION MAY BECOME DIRECTLY INVOLVED IN INTRODUCING RESEARCH RESULTS AT PRIMARY HEALTH CARE LEVEL THROUGH INNOVATIVE STUDIES COMPONENT OF INTEGRATED RURAL HEALTH AND POPULATION PROJECT.
- B. RESEARCH FOCUS: AS SUGGESTED REFTTEL, PROJECT WILL FOCUS ON PRODUCT ORIENTED RESEARCH. CRITERIA DEVELOPED FOR DISEASE SELECTION WILL TAKE INTO ACCOUNT FACTORS IDENTIFIED BY APAC.
- C. POLICY DIALOGUE: ISSUES THAT PROJECT INTENDS TO ADDRESS WILL BE IDENTIFIED DURING DESIGN PROCESS.
- D. INSTITUTIONAL ISSUES: MISSION FULLY AGREES WITH RECOMMENDATIONS OUTLINED UNDER THIS HEADING.
- E. ROLE OF PRIVATE SECTOR: MISSION WILL INCLUDE PRIVATE SECTOR CONCERNS TO THE MAXIMUM EXTENT POSSIBLE. A LOCAL FIRM WILL BE CONTRACTED DURING DESIGN TO IDENTIFY TARGETS OF OPPORTUNITY AND TO RECOMMEND A MODUS OPERANDI FOR TAPPING PRIVATE SECTOR RESOURCES.
- F. OPERATIONS AND BASIC RESEARCH: THIS COMPONENT WILL FINANCE RESEARCH GRANTS AS WELL AS PROVIDE SUPPORT TO GOI BUDGET. AGENCY RECURRENT COST POLICY HAS BEEN REVIEWED AND WILL BE DISCUSSED IN PP.

- G. HOST COUNTRY CONTRIBUTION: EXACT GOI CONTRIBUTION WILL BE DETERMINED ONCE DESIGN PROCESS IS FORMALLY INITIATED. MOST ASSUREDLY GOI WILL MEET IF NOT EXCEED STATUTORY REQUIREMENT OF 25 PERCENT OF TOTAL PROJECT COST.

- H. MISSION HAS INCLUDED FUNDS FOR ALL PLANNED CONSULTANCIES IN ITS PDS BUDGET. CURRENTLY, NO OE FUNDED TRAVEL FROM AID/W IS ANTICIPATED. BARNES##

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STATE 303690

TO: AMEMBASSY NEW DELHI

SUB: INDIA BIOMEDICAL SUPPORT FOR HEALTH SERVICES PID

REF: NEW DELHI 19390

1. APAC REVIEWED PID AND REFINEMENTS CONTAINED REFTEL ON SEPTEMBER 28, 1983. PID IS APPROVED AND MISSION MAY AUTHORIZE PROJECT. PLEASE ADVISE ASIA BUREAU IF THERE ARE SUBSTANTIVE CHANGES IN PROJECT DESIGN BEFORE AUTHORIZATION OF PROJECT. COMMENTS AND SUGGESTIONS FOR DEVELOPMENT OF PP ARE PRESENTED BELOW.

2. RESEARCH UTILIZATION. APAC ACCEPTED MISSION DECISION TO FOCUS ON TECHNOLOGY DEVELOPMENT/RESEARCH ADAPTION AND FIELD TESTING WITHIN THIS PROJECT, WITH UNDERSTANDING THAT CRITICAL DISSEMINATION/ADOPTION PHASE MUST BE ADDRESSED BY OTHER INTERVENTIONS AS PART OF HEALTH SECTOR STRATEGY. PLEASE ADDRESS UTILIZATION QUESTION AND HEALTH SECTOR DIRECTIONS IN NEXT CDSS. WHILE WE AGREE ON NEED TO KEEP LIFE OF PROJECT TO A REASONABLE LENGTH, APAC DECIDED TO ASK MISSION TO FORMULATE PROJECT WITH A VIEW TOWARD END-USE DELIVERY. APAC SEES IMPORTANT CONCEPTUAL LINKS BETWEEN RESEARCH DEVELOPMENT AND UTILIZATION, ESPECIALLY IN IDENTIFYING AND DEFINING RESEARCH OBJECTIVES SO THAT THEY HAVE MAXIMUM IMPACT ON IMPROVING HEALTH OF RURAL POOR. RESEARCH AND FIELD TRIALS SHOULD BE CONDUCTED WITH A VIEW TOWARD UTILIZATION OF RESULTS THROUGH PRIMARY HEALTH CARE SYSTEM. LIKELIHOOD OF THIS CAN BE INCREASED BY CAREFULLY ESTABLISHING APPROPRIATE CRITERIA TO FUND RESEARCH AND, AS DESCRIBED REFTEL, BY ENHANCING CAPABILITIES OF STATE HEALTH DEPARTMENTS TO USE NEW DIAGNOSTIC AND EPIDEMIOLOGIC TECHNIQUES. MEANWHILE, AID EFFORTS IN SERVICE DELIVERY THRU INTEGRATED RURAL HEALTH AND POPULATION (IRHP) PROJECT WILL GO TOWARD IMPROVING DELIVERY OF EXISTING TECHNOLOGIES SUCH AS ORT, IMMUNIZATIONS, AND FAMILY PLANNING SPACING. IN ADDITION, MISSION MAY WISH TO CONSIDER INCLUDING TECHNICAL ASSISTANCE IN THIS PROJECT WHICH COULD BE USED TO DEVELOP AND TEST APPROPRIATE PRELIMINARY IMPLEMENTATION MODELS FOR SUCCESSFUL RESEARCH ACTIVITIES.

3. RESEARCH FOCUS. APAC DISCUSSED THE SCOPE OF THE RESEARCH ACTIVITIES PLANNED AND CONCLUDED THAT PROJECT SHOULD FOCUS ON PRODUCT ORIENTED RESEARCH AND MINIMIZE OR AVOID PURE RESEARCH ACTIVITIES. ADDITIONAL CRITERIA MENTIONED IN REFTEL, FOR SELECTING RESEARCH TOPICS, SEEM SOUND. IN ADDITION, APAC FELT THAT ADAPTIVE RESEARCH SHOULD FOCUS ON LIMITED SET OF DISEASE PROBLEMS (THREE OR FOUR) THAT ARE MOST IMPORTANT CONTRIBUTORS TO INFANT MORTALITY. ALSO, CRITERIA SHOULD TAKE INTO ACCOUNT COSTS, AND SUBSIDIES, RETURNS, HEALTH MANPOWER REQUIREMENTS, DELIVERY SYSTEMS AND OTHER FACTORS TO ENSURE THAT TECHNOLOGIES DEVELOPED AND TESTED CAN BE APPLIED EFFECTIVELY ON A LARGER SCALE.

4. POLICY DIALOGUE. APAC VIEWED THIS PROJECT AS A MAJOR OPPORTUNITY TO ESTABLISH A POLICY DIALOGUE WITH THE GOI ON RANGE OF POLICY AND PROCEDURAL ISSUES AND REFORMS RELATED TO BIOMEDICAL RESEARCH, PREVENTIVE HEALTH, HEALTH DELIVERY ISSUES AND GETTING ADAPTIVE RESEARCH RESULTS INTRODUCED IN HEALTH CARE SYSTEM. APAC REQUESTS MISSION IDENTIFY KEY POLICY ISSUES THE PROJECT INTENDS TO ADDRESS.

5. INSTITUTIONAL ISSUES. APAC FELT THAT WHILE THE PROJECT CONCEPT HAS BEEN SIMPLIFIED, INSTITUTIONAL STRUCTURE REMAINS COMPLEX, AND POTENTIALLY PROBLEMATIC WITH COMPETING INTERESTS AMONG MOHFW, ICMR, RESEARCH INSTITUTIONS, STATE UNIVERSITIES, AND STATE HEALTH DEPARTMENTS. IT IS CRITICAL TO PROJECT SUCCESS THEREFORE THAT: (1) RESEARCH GRANTS BE AVAILABLE TO ALL RESEARCH INSTITUTIONS AND UNIVERSITIES (PUBLIC AND PRIVATE) ON A STRICTLY COMPETITIVE BASIS SO BEST AVAILABLE RESOURCES CAN BE PUT TO THE TASK, AND (2) THE LINKAGES BETWEEN STATE HEALTH DEPARTMENTS AND THE UNIVERSITIES BE STRENGTHENED AND REAL EXCHANGES TAKE PLACE. GIVEN THE SIGNIFICANT NUMBER OF INSTITUTIONS INVOLVED AT VARIOUS LEVELS AND LOCATIONS WITHIN THE HEALTH SECTOR, A CAREFUL ANALYSIS OF THEIR RESPECTIVE ROLES, OPERATING PROCEDURES, AND IMPLEMENTATION RESPONSIBILITIES SHOULD BE INCLUDED IN PP AND INSTITUTIONAL ARRANGEMENTS AGREED TO PRIOR TO THE INITIATION OF THIS ACTIVITY. MISSION SHOULD IDENTIFY AS PART OF INSTITUTIONAL ANALYSIS THE CRITERIA FOR SELECTING RESEARCH INSTITUTIONS IN PROJECT. ALSO, PROJECT COORDINATION, IMPLEMENTATION PLANS AND ENTITIES SHOULD BE SPELLED OUT AND AGREED TO IN DETAIL. MISSION MAY WISH TO CONSIDER INCLUDING IN PROJECT DESIGN A SYSTEM TO MONITOR INSTITUTIONAL OPERATIONS AND IMPLEMENTATION RESPONSES AS A BASIS FOR MODIFYING IMPLEMENTATION PLANS AS PROJECT PROGRESSES.

6. ROLE OF PRIVATE SECTOR. APAC CONCURRED WITH MISSION VIEW THAT PRIVATE SECTOR CAN PLAY A SIGNIFICANT ROLE IN THIS ACTIVITY. REQUEST MISSION FURTHER DEFINE THE ROLES AND AREAS WHERE THE PRIVATE SECTOR CAN BE INVOLVED. IN ADDITION, MISSION SHOULD ANALYZE WHAT WILL BE REQUIRED TO GET THE PRIVATE SECTOR INVOLVED IN PROJECT ACTIVITIES IN AREAS AS INDICATED IN PID, ADDITIONAL HEALTH SUPPLIES AND EQUIPMENT AREAS; AND LABORATORY AND RESEARCH ACTIVITIES. WE ENCOURAGE MISSION TO ESTABLISH A DIALOGUE WITH PRIVATE AND PUBLIC SECTOR REPRESENTATIVES TO SORT OUT THE TERMS AND CONDITIONS OF PRIVATE SECTOR INVOLVEMENT. WHAT WILL BE THE PROBLEMS, INCENTIVES, AND POLICY CHANGES NEEDED FOR PRIVATE ENTERPRISE PARTICIPATION? MISSION MAY WISH TO CONSIDER ENCOURAGING INVOLVEMENT OF PRIVATE SECTOR WITH FEASIBILITY OR PRE-FEASIBILITY STUDIES FINANCED THROUGH OTHER PROJECTS OR PRE FEASIBILITY STUDIES COST SHARING PROGRAM. INFORMATION ON PRE FEASIBILITY PROGRAM BEING POUCHED.

7. PROJECT BUDGET. REQUEST MISSION REVIEW PROJECT BUDGET ITEMS PRESENTED REFTEL.

- A. VACCINES. APAC WAS UNCERTAIN WHAT WAS INTENDED BY DOL.1,000,000 LOAN FUNDS FOR VACCINE DEVELOPMENT. APAC FELT THAT VACCINE PRODUCTION

DID NOT FIT INTO PROJECT AS NOW STRUCTURED WITH FOCUS ON BIOMEDICAL RESEARCH AND TESTING. DOES MISSION HAVE IN MIND BROADENING RESEARCH ACTIVITIES TO INCLUDE DEVELOPMENT OF PREVENTIVE VACCINE THERAPIES IN ADDITION TO DIAGNOSTIC TECHNIQUES? IF SO, THIS COULD BE ACCOMPLISHED WITH MUCH LESS THAN DOL.1 MILLION. THE AMOUNT FOR VACCINE PRODUCTION, HOWEVER, DOES NOT APPEAR TO BE JUSTIFIED IN VIEW OF PROJECT RESEARCH FOCUS AND SHOULD BE ELIMINATED FROM PROJECT.

- B. MALARIA DATA MANAGEMENT. SINCE THE MAJORITY OF THE FUNDING PLANNED FOR THIS LINE ITEM WAS FOR PURCHASE OF DATA MANAGEMENT EQUIPMENT, THIS AMOUNT SHOULD BE LOAN FUNDED. ALSO AS MISSION IS AWARE THERE HAVE BEEN ENORMOUS STRIDES IN ADVANCEMENT OF AUTOMATIC DATA PROCESSING EQUIPMENT. WE REQUEST CONSULTATION WITH DATA PROCESSING HARDWARE AND SOFTWARE EXPERTS IN ADDITION TO AID/IRM OFFICE RESPONSIBLE FOR REVIEW OF THIS EQUIPMENT. WE WERE ALSO UNCERTAIN WHETHER MISSION ANTICIPATED THAT ONLY MALARIA CONTROL PROGRAM WOULD USE THIS EQUIPMENT. FOR DEMONSTRATION PURPOSES IT WOULD SEEM THAT EQUIPMENT MIGHT HAVE MORE IMPACT IF STRATEGICALLY LOCATED WITHIN MOHFW OR STATE HEALTH DEPARTMENTS AND DEAL WITH PRIMARY ONGOING RESEARCH ACTIVITIES IDENTIFIED IN THE PROJECT. ALSO, MALARIA CONTROL PROGRAM MIGHT BE TOO SPECIALIZED TO SERVE AS A GOOD EXAMPLE FOR AUTOMATIC DATA PROCESSING.

- C. OPERATIONS AND BASIC RESEARCH. WE WERE UNCERTAIN WHAT MISSION INTENDED TO BE FUNDED UNDER THESE LINE ITEMS TOTALING DOLS.1.5 MILLION IN GRANT FUNDS. IF FUNDS ARE INTENDED TO SUPPLEMENT GOI BUDGET RESOURCES FOR SALARIES, REQUEST MISSION REVIEW AGENCY RECURRENT COST POLICY STATEMENT AND PLAN HOW GOI WILL PICK UP THESE COSTS IN THEIR OWN BUDGET OVER TIME.

- D. HOST COUNTRY CONTRIBUTION. REVIEW OF PID LIFE OF PROJECT FUNDING LEVELS INDICATES HOST COUNTRY CONTRIBUTION IS SLIGHTLY LESS THAN STATUTORY REQUIREMENT OF 25 PERCENT OF TOTAL PROJECT COST.

8. PDS. REQUEST MISSION CLARIFY WHETHER OE BUDGET ITEMS PLANNED FOR MISSION, BUREAU OR S&T/TDY? SHULTZ##

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Biomedical Research Support (386-0492)
Logical Framework

	Verifiable Indicators	Important Assumptions
<p><u>Sector Goal:</u> To reduce infant and child mortality and morbidity in the labor force and to reduce fertility.</p>	<p>Reduction in the infant mortality rate from 122 to 100</p> <p>Drop in birth rate from 33 to 28</p>	<p>Better information on disease prevalence and disease trends will lead to improved health policies and more effective resource allocation.</p>
<p><u>Project Purpose:</u> To support a Government of India initiative to create a functioning program of laboratory based field epidemiology with its concomitant emphasis on preventive medicine.</p>	<p>Information gathered during epidemiological surveys is used to stem epidemics, vaccinate against prevalent diseases, determine resources allocations, and set health care policies.</p>	<p>Medicines required for preventive health care are available on a timely basis.</p> <p>Trained staff are available to administer medicines.</p>
<p><u>Outputs:</u> An epidemiological network created in one state.</p> <p>A self sustaining capability to train field and clinical epidemiologists.</p> <p>An automated information system for malaria in one state and at the national level.</p> <p>A national quality control laboratory for biologicals.</p>	<p>Epidemiological data is being collected and analyzed in one state.</p> <p>A fully functioning division of epidemiology has been created at the National Institute of Communicable Diseases.</p> <p>Clinical epidemiology units created in three medical colleges.</p> <p>Malaria data is being collected and analyzed.</p> <p>Quality control lab has been constructed and equipped.</p>	<p>The GOI and the state governments are interested in strengthening their epidemiological capabilities.</p> <p>A.I.D. and the GOI are capable of managing the implementation of the project.</p>
<p><u>Inputs:</u> Technical Assistance Training Commodities</p>	<p>287 work man months of long and short term technical assistance provided.</p> <p>622 work months of long and short term training provided.</p> <p>Commodities and supplies valuing \$3.8 million procured.</p>	<p>Consultants acceptable to A.I.D. and the GOI can be identified.</p> <p>Appropriate training courses can be developed.</p> <p>Procurement is timely.</p>

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PROJECT CHECKLIST

Listed below are statutory criteria applicable generally to projects with FAA funds and project criteria applicable to individual fund sources: Development Assistance (with a sub-category for criteria applicable only to loans); and Economic Support Fund.

CROSS REFERENCES: IS COUNTRY CHECKLIST UP-TO-DATE? Yes.

HAS STANDARD ITEM CHECKLIST
BEEN REVIEWED FOR THIS PROJECT? Yes.

A. General Criteria for Project

1. Continuing Resolution Unnumbered:
FAA Sec. 653(b); Sec. 634A. (a) Describe how Committees on Appropriations of Senate and House have been or will be notified concerning the project; (b) is assistance within (Operational Year Budget) country or international organization allocation reported to Congress (or not more than \$1 million over that figure)?

(a) A Congressional Notification will be forwarded prior to the initial obligation of funds.

(b) Yes.

2. FAA Sec. 611(a)(1). Prior to obligation in excess of \$100,000 will there be (a) engineering, financial and other plans necessary to carry out the assistance and (b) a reasonably firm estimate of the cost to the U.S. of the assistance?

(a) Yes.

(b) Yes.

3. FAA Sec. 611(a)(2). If further legislative action is required within recipient country, what is basis for reasonable expectation that such action will be completed in time to permit orderly accomplishment of purpose of the assistance?

Not applicable.

4. FAA Sec. 611(b); Continuing Resolution Sec. 501. If for water or water-related land resource construction, has project met the standards and criteria as per the Principles and Standards for Planning Water and Related Land Resources dated October 25, 1973?

Not applicable.

5. FAA Sec. 611(e). If project is capital assistance (e.g., construction), and all U.S. assistance for it will exceed \$1 million, has Mission Director certified and Regional Assistant Administrator taken into consideration the country's capability to effectively maintain and utilize the project?

Not Applicable.

6. FAA Sec. 209. Is project susceptible to execution as part of regional or multilateral project? If so, why is project not executed? Information and conclusion whether assistance will encourage regional development programs.

This project is not susceptible to execution as part of a Regional Multilateral Project

7. FAA Sec. 601(a). Information and conclusions whether project will encourage efforts of the country to: (a) increase the flow of international trade; (b) foster private initiative and competition; (c) encourage development and use of cooperatives, credit unions, and savings and loan associations; (d) discourage monopolistic practices; (e) improve technical efficiency of industry, agriculture and commerce and (f) strengthen free labor unions.

- (a) Not applicable.
- (b) Not applicable.
- (c) Not applicable.
- (d) Not applicable.
- (e) Not applicable.
- (f) Not applicable.

8. FAA Sec. 601(b). Information and conclusion on how project will encourage U.S. private trade and investment abroad and encourage private U.S. participation in foreign assistance programs (including use of private trade channels and the services of U.S. private enterprise).

U.S. technical assistance will be provided under this project; Indo-U.S. collaboration will be encouraged.

9. FAA Sec. 612(b); Sec. 636(h). Describe steps taken to assure that, to the maximum extent possible, the country is contributing local currencies to meet the cost of contractual and other services, and foreign currencies owned by the U.S. are utilized to meet the cost of contractual and other services.

The Government of India will finance between 30 and 35 percent of all costs.

10. FAA Sec. 612(d). Does the U.S. own excess foreign currency of the country and if so, what arrangements have been made for its release?

U.S. owned rupees are being used for various U.S. government agencies programs and administrative support. India will shortly be declared a "Near-Excess" country.

11. FAA Sec. 601(e). Will the project utilize competitive selection procedures for the awarding of contracts, except where applicable procurement rules allow otherwise?

Yes.

12. Continuing Resolution Sec. 522. If assistance is for the production of any commodity for export, is the commodity likely to be in surplus on world markets at the time the resulting productive capacity becomes operative, and is such assistance likely to cause substantial injury to U.S. producers of the same, similar or competing commodity.

Not applicable.

B. Funding Criteria for Project

1. Development Assistance Project Criteria

a. FAA Sec. 102(b); 113: 281a. Extent to which activity will (a) effectively involve the poor in development, by extending access to economy at local level, increasing labor-intensive production and the use of appropriate technology, spreading investment out from cities to small towns and rural areas, and insuring wide participation of the poor in the benefits of development on a sustained basis, using the appropriate U.S. institutions; (b) help develop co-operatives, especially by technical assistance, to assist rural and urban poor to help themselves toward better life, and otherwise encourage democratic private and local governmental institutions; (c) support the self-help efforts of developing countries; (d) promote the participation of women in the national economies of developing countries and the improvement of women's status; and (e) utilize and encourage regional cooperation by developing countries?

- (a) This project will create an epidemiological capability designed to determine prevalent diseases and disease trends. The information will be used to provide better health care to the rural poor.
- (b) Not applicable.
- (c) This project entirely supports Indian self-help in the health sector.
- (d) Women will benefit as decreased percentages of their time will be spent tending sick family members or bearing children to compensate for anticipated deaths
- (e) Not applicable.

b.FAA Sec. 103, 103A, 104, 105, 106, & 107. Is assistance being made available: (include only applicable paragraph which corresponds to source of funds used. If more than one fund source is used for project, include relevant paragraph for each fund source.

(1) [103] for agriculture, rural development or nutrition; if so, extent to which activity is designed to increase productivity and income of rural poor.

The project is to improve the health status of the rural population. Improved health will foster increased productivity and, consequently, increased rural incomes.

c. [107] is appropriate effort placed on use of appropriate technology?

Yes, especially regarding the use of rapid diagnostic techniques

d.FAA Sec. 110(a). Will the recipient country provide at least 25% of the costs of the program, project, or activity with respect to which the assistance is to be furnished (or has the latter cost-sharing requirement been waived for a "relatively least-developed country)?

Yes, the recipient country will provide at least 25% of the costs of the program.

e.FAA Sec. 110(b). Will grant capital assistance be disbursed for project over more than 3 years? If so, has justification satisfactory to the Congress been made and efforts for other financing, or is the recipient country "relatively least developed"?

Not applicable.

f.FAA Sec. 281(b). Describe extent to which program recognizes the particular needs, desires and capacities of the people of the country; utilizes the country's intellectual resources to encourage institutional development; and supports civil education and training in skills required for effective participation in governmental and political processes essential to self-government.

This project addresses the need for improved health care. Indigenous institutions will be upgraded to enhance their technical performance.

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g. FAA Sec. 122(b). Does the activity give reasonable promise of contributing to the development of economic resources, or to the increase or productive capacities and self-sustaining economic growth?

Yes, especially by improving the health and thus the production capability of Indian labor.

2. Development Assistance Project Criteria (Loans Only).

a. FAA Sec. 122(b). Information and conclusion on capacity of the country to repay the loan including reasonableness of repayment prospects.

This \$3.8 million loan is well within India's capability to pay and given India's track record there is no reason to doubt that it will be paid.

b. FAA Sec. 620(d). If assistance is for any productive enterprise which will compete in the U.S. with U.S. enterprise, is there an agreement by the recipient country to prevent export to the U.S. of more than 20% of the enterprise's annual production during the life of the loan?

Not applicable.

3. Project Criteria Solely for Economic Support Fund Support Fund

This section not applicable.

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USAID India's Health Sector Strategy
A Summary Statement

I. The State of Indian Health; Problems, Causes and Contributing Factors:

The A.I.D. Health Sector Analysis has reinforced the recognition of the importance and more clearly articulated the nature, of the interlinked problems of high fertility and continuing high rates of infant and child mortality in India.

A. Major Health Problems:

The salient facts characterizing the health of the Indian population are:

1. The population of 730 million is growing at roughly 2% per year and will reach one billion by the year 2000. The crude birth rate, now about 30/1,000 population, has been slowly declining. About 21 million children are born each year and there are over 100 million children under age five.

2. The crude death rate is about 12 per 1,000 population. Although children under age five comprise 14% of the population, almost half of all deaths are in this age group, as compared to less than 3% in the same USA age group. One third of all deaths are in the under one year age group, and of these, sixty percent occur in the first month of life. Infant mortality declined from 200 deaths per 1,000 live births in 1911 to 129 in 1970, but the decline has been slow since then.

3. Urban: rural and sex differences in mortality remain pronounced. Child mortality for the age group 0-4 has changed little in the last decade, with rural levels remaining substantially higher than those in urban areas, and female rates continuing higher than males. Although infant mortality has slowly declined, the same urban/rural and sex differences persist.

Sex differences continue to be apparent in other indicators. In India, there are 23 million more men than women. During this century, the sex ratio (number of women per 1,000 men) has declined from 972 to 933. In some states, there are less than 900 women per 1,000 men. From infancy through the child-bearing years, females have a greater risk of death than males.

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4. Women's educational status, substantially lower than men's, has an important impact on infant mortality.

5. National rates of malnutrition among Indian children as reported by the National Nutrition Monitoring Bureau have not declined over the past decade, and 74% of all children under five years are affected by moderate to severe malnutrition. However, substantial declines in malnutrition have been documented in areas with intensive nutrition programs for mothers and children, such as the Integrated Child Development Services (ICDS) Scheme.

Although there have been major increases in wheat and rice production, per capita food grain availability has not improved since 1961 because of concomitant increases in population and a decline in availability of other major food grains, especially pulses. Per capita food grain availability meets only 85% of nutritional requirements. Per capita availability of edible oils is drastically short of the nutritional requirements of India's population, and there is a direct connection between children's nutritional status and their risk of death.

6. High fertility, in itself an obstacle to development, is also a major factor in sustained high mortality. Several studies in India and elsewhere have indicated that infant mortality rates are inversely related to the length of the birth interval, that is, the likelihood of a child surviving his first year of life is two to three times greater if the interval since the previous birth increases beyond two years.

B. Causes and Contributing Factors:

The Mission's Health Sector Analysis studies have provided a detailed picture of the major causes and key contributing factors which predispose the child population to sickness and mortality. Analysis of available data and studies indicates that 50% to 60% of all child deaths are caused by a small number of causes and inter-related conditions.

In summary, the chief causes of neonatal (newborn) mortality are immaturity (low birth weight), diarrheal diseases, tetanus, and pneumonia. Beyond the first month and up to the first year, diarrheal diseases, respiratory disease and measles are the most important causes of death, further intensified if the child was of low birth weight. Between age 1 and 4, diarrheal disease, respiratory disease, measles and its sequelae are the major causes of death, complicated by malnutrition. It should be noted that although deaths may be attributed to a specific cause, many result from multiple factors, e.g. an infant born with low birth weight, who is no longer breast fed and

sustains frequent infectious diseases resulting in malnutrition finally succumbs to diarrhea.

There is considerable variation in mortality rates and causes among the states and especially between rural and urban areas. Nevertheless, it is clear from most available data that a small number of causes and contributing factors account for over half of the child mortality in India.

It is clear that the major elements of the preponderant child mortality are diarrheal disease and immunizable diseases -- especially measles and tetanus -- whose impact is interlinked and intensified by poor nutritional status and frequent, closely spaced child-bearing. The majority of this mortality is rural. There are also proven technologies immediately available to deal with these problems: oral rehydration, improved immunization, particularly tetanus toxoid and measles, and expansion and strengthening of family planning spacing methods. The reasons for focus on these interventions in the A.I.D. health strategy are: (1) they represent available proven technologies, (2) the focus is on problems that available data indicates are of major epidemiological importance; (3) they can be carried out on a high-coverage basis, and they are of most benefit to the underserved women and children, the poor and the other relatively disadvantaged groups; and (4) they can be delivered through the existing health system at a cost which can be absorbed and sustained by the Indian authorities.

II. Indian Health and Nutrition Infrastructure and Services

The rural health infrastructure is steadily expanding but still covers less than 50% of the rural areas. However, its potential is chronically undermined by shortages of key service and managerial workers, who are often not adequately trained, equipped or housed to work effectively in village communities, nor able to manage large-scale priority programs. The government health delivery infrastructure is the only large scale provider of key interventions such as immunization, family planning, and oral rehydration, but the reach of the services to the most vulnerable population groups is still quite limited. Other key interventions, such as measles and an effective ORT program, are still lacking in the service program. Inadequate epidemiological and management information systems make it extremely difficult to prioritize problems and plan service interventions, and to monitor results, both in terms of program performance and impact on key fertility and mortality problems. Failure to coordinate services of the separate health and nutrition infrastructures blocks achievement of the full potential of either. The government has not adequately recognised the tremendous potential of private-sector marketing technology which could be utilized to create demand and to

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promote health and nutrition concepts and priority intervention programs.

III. Health Goals/Strategy

A. Mission Goals

The mission health goals are a significant reduction in fertility and child mortality and concomitant reduction in fertility within two or three Indian states.

The means to achieve this goal, or the subgoals that the mission will pursue are:

1. Establishment of proven, high-impact intervention programs to address selected, key fertility and mortality problems;
2. Development of an effective epidemiological intelligence/monitoring system and biomedical support institutions to permit health priority-setting and clear evaluation of program impact;
3. Creation of a client-centered health service orientation which incorporates a careful analysis of client needs, beliefs and behavior in creating and meeting demand.

B. Operational Strategy:

Sharing the GOI's fertility and mortality reduction goals, USAID will seek to assist the GOI in states and Indian private institutions and groups in developing, expanding and improving the quality of service programs which include high impact interventions such as ORT, measles, tetanus toxoid and other child immunizations, family planning spacing methods, and nutritional improvements, which have the highest potential to contribute to the reduction of the infant mortality rate to 60 and child mortality (age 1-4) to 10 by the year 2000. This strategy will focus not only on the small number of interventions which address the mortality problems of greatest epidemiological and social importance, but will also embrace support for strengthening key facilitating systems, without which the selected intervention programs will have limited reach and impact.

A.I.D. has established solid relationships and technical/managerial understanding, and has provided major support for completing the government's planned rural health and nutrition infrastructure in its current five project states. In the future, A.I.D. plans to continue working in only two, or at the most three, of these states, because managing five state projects -- in reality five separate projects -- does not permit adequate, in-depth attention to the spectrum of technical and managerial needs with current A.I.D. staffing. Not all of the current five states have demonstrated uniform in-

terest and capability, and the mission will therefore work with those which have demonstrated active interest and implementing skills.

USAID's strategy will emphasize:

1. An expansion of a small number of key intervention programs beyond the current two or three pilot districts to state-wide, mass scale implementation serving a population of nearly 100 million;

2. By moving to state-wide implementation of select programs, achievement of economies of scale, particularly in development of marketing and media strategies to create demand and produce behavioral change;

3. Continuation of the Integrated Child Development Service project, expansion and improvement of training, food supplementation, growth monitoring and nutrition education, and management information systems coupled with intensified efforts at improving immunization and oral rehydration.

4. Continuation of the Private Voluntary Organizations for Health project. Although involved in some current project states, is not limited to them. This project will continue support for private sector projects on a relatively small scale.

5. Development of approaches and strategies which could lead to pragmatic program implementation approaches amenable to state-wide expansion.

6. Further investigation and development of promising biomedical technologies of relevance to priority morbidity and mortality problems. Most immediately, this could include technical assistance and support for private sector production of measles vaccine or other commodities, such as ORS, in India; development and field testing of new vaccines, support for strengthening of the epidemiological training and monitoring system and its laboratory base, and support for epidemiological studies to monitor morbidity and mortality. Research on determinants of low birth weight is planned, and possible preventive interventions may be tested.

In summary, it should be emphasized that the multiple thrusts of the health strategy, and its programmatic components, are all channelled towards reducing the major causes of child mortality in India. The strategy is thus an interlinked set of critical components which reinforce each other in an integrated attack on these problems.