Dec 26 '84

ETHICAL REVIEW COMMITTEE, ICDDR,B. December 1, 1984

(2)

Principal Investigator Dr. Patrick R. Kenya Trainee Investigator (if any) nil

Application No. 84-049

Supporting Agency (if Non-ICDDR,B) Aga Khan Foundation.

Title of Study Field Comparison Between Glucose-ORS and Maize-ORS.

Project status:
(✓) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

1. Source of Population:
   (a) Ill subjects — Yes No
   (b) Non-ill subjects — (Yes) No
   (c) Minors-or persons under guardianship — (Yes) No
2. Does the study involve:
   (a) Physical risks to the subjects — Yes (No)
   (b) Social Risks — Yes (No)
   (c) Psychological risks to subjects — Yes (No)
   (d) Discomfort to subjects — Yes (No)
   (e) Invasion of privacy — Yes (No)
   (f) Disclosure of information damaging to subject or others — Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) — Yes (No)
   (b) Use of fetal tissue or abortus — Yes (No)
   (c) Use of organs or body fluids — Yes (No)
4. Are subjects clearly informed about:
   (a) Nature and purposes of study — (Yes) No
   (b) Procedures to be followed including alternatives used — Yes No N.A.
   (c) Physical risks — Yes No N.A.
   (d) Sensitive questions — Yes No N.A.
   (e) Benefits to be derived — (Yes) No
   (f) Right to refuse to participate or to withdraw from study — (Yes) No
   (g) Confidential handling of data — (Yes) No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure — Yes No NA
5. Will signed consent form be required:
   (a) From subjects — Yes (No)
   (b) From parent or guardian (if subjects are minors) — Yes (No)
6. Will precautions be taken to protect anonymity of subjects — (Yes) No
7. Check documents being submitted herewith to Committee:
   - ✓ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   - ___ Protocol (Required)
   - ✓ Abstract Summary (Required)
   - ✓ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   - ___ Informed consent form for subjects
   - ___ Informed consent form for parent or guardian
   - ✓ Procedure for maintaining confidentiality
   - ✓ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Committee for review.

I agree to obtain approval of the Ethical Review Committee for any changes affecting the rights and welfare of subjects before making such change.

31 DEC 1984

Principal Investigator

84-049

SECTION I - RESEARCH PROTOCOL

I. TITLE : Field Comparison between Glucose-ORS and Maize-ORS

II. PRINCIPAL INVESTIGATOR : 1. Dr. Patrick R. Kenya

CO-INVESTIGATORS : 1. Dr. L.W. Okombo/Coordinator

2. Medical officer (to be named later)

3. Nutritionist -

4. Sociologist -

5. Demographer -

6. Public Health Nurse - Mrs. B. Were

COLLABORATING INVESTIGATORS : 1. Dr. Abdul Bari

2. Dr. A. Majid Molla

3. Dr. S. K. Nath

CONSULTANT : 1. Dr. W.B. Greenough III

III. STARTING DATE : 1st May 1985

IV. COMPLETION DATE : 30th April 1988

V. TOTAL DIRECT COST : US $ 284,200.00

The protocol has been approved by the Project Development Committee.

Acting Chairman
Project Development Committee
I.C.D.D.R.B

24/12/84

ABSTRACT SUMMARY:

The objectives of the study is to compare the long term effect of Maize-ORS with Glucose-ORS under field conditions. Clinical effect, nutritional status, chemical composition of the solutions and cost effectiveness for home management of diarrhoea will be assessed. This study will be implemented in 3 areas of Kakamega District, Kenya for 3 years. Mothers in two areas will be trained to prepare and use either Maize-ORS packets or Glucose-ORS packets for home management of diarrhoea. Packets will be supplied by field workers. A third area will serve as comparison with no packets supplied at the household level or training provided through the study.

All diarrhoeal episodes will be followed up for seven consecutive days of home visits. Anthropometric measurements to assess nutritional status of children 0-59 months will be done by weight at monthly and height at 3 monthly intervals. During diarrhoea episodes, weight will be taken every other day.

Chemical composition of ORS prepared by mothers will be determined by 5% random sampling. Diarrhoea surveillance data and anthropometric data from the 2 years study period will be analysed to decide the value of more general implementation of Maize-ORS.

REVIEWS:

A. Research involving human subjects - both Kenya and ICDDR,B

Approved/Disapproved: _____

B. Research Review Committee - MRC, Kenya; ICDDR,B

Approved/Disapproved: _____

C. Director KEMRI (Kenya Medical Research Institute)

: _____

D. Director MRC (Medical Research Centre) - Kenya

: _____

E. Administrator - KEMRI/MRC - Kenya

: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. General Aims:

The purpose of this study is to compare the effects of Maize based Oral Rehydration Solution (M-ORS) and Glucose based Oral Rehydration Solution (G-ORS) in the home treatment of diarrhoea over a 3 year period (Table I). Points of comparison will be adequacy of rehydration,duration of diarrhoea, changes in weight and height of children 0-59 months old, safety of solution prepared and cost per episode of diarrhoea. This study should provide evidence of the relative merits of these two oral rehydration solutions (ORS) and help in the formulation of recommendations to the Ministry of Health, Kenya.

2. Background:

Introduction of Glucose in ORS

Of the 750 million children affected annually by diarrhoea, 3-6 million die globaly (1). This toll is highest in developing countries. For centuries various combinations of cereal, salt and sugar solutions have been used to treat the diarrhoeal patients in many developing countries. Pioneering studies in the early 1960's provided understanding of linked co-transport of sodium, water and glucose in the small intestine (2,7). This crucial observation was soon trans-lated into clinical success with development of an oral glucose containing solution at the then Cholera Research Laboratory (8-10). In recognition of its vital role, the World

Health Organisation has establised ORS as the mainstay of treatment of diarrhoea with a fixed composition (11-15).

Introduction of Substitute of Glucose in ORS

Although glucose is a successful carrier of sodium and water, it is still quite expensive and not readily available in many parts of developing countries where diarrhoea is a major health problem. Thus, alternatives to glucose have been sought. Sucrose has been found to be a successful substitute (15-18). Unrefined cane sugar ORS (labon Gur) has also proved satisfactory (20). Other alternatives to glucose or sucrose have also been tried (19).

Introduction of ORS to Community

Although much information is available on the efficacy of ORS in hospital based studies, less is known of its acceptance and impact on mortality in rural communities. There are many possible approaches to deliver the ORS packets or knowledge of ORS preparation to rural people (21-25). The results of community approaches to application of ORS are encouraging in regard to acceptance and impact on mortality. Still, ORS is simplified further could be more easily and widely used at home.

Nutritional Effects of ORS

With success in controlling dehydration by ORS, research to simplify, reduce cost and provide nutrition during diarrhoea becomes more urgent (26). Field studies have shown direct or indirect nutritional benefit from oral rehydration thereapy in diarrhoea (27-29).. But the amount of calories obtained from available ORS is not sufficient to satisfy nutritional needs during diarrhoea. A major hurdle to

provision of a high calorie oral solution has been osmolality. An oral glucose solution able to provide additional calories would be hypertonic to plasma and therefore cause increased output and dehydration.

INTRODUCTION OF CEREAL AS A SUBSTITUTE OF GLUCOSE IN ORS

Cereals are staple foods, therefore oral rehydration using a cereal in common use will be advantageous. This would simplify ORS distribution and its application will be more practicable at the level of vunlerable population. In Kenya, Maize is most commonly used and is easily available. Maize is composed of about 60% carbohydrate, 12% protein, 4% fats and vitamins. The polysaccharides can be slowly hydrolyzed intraluminally in small intestine to yield glucose while protein is converted to amino acids. These molecules supply calories and are needed for co-transport of sodium and water. Thus, the slowly liberated glucose and amino acids are absorbed from the lumen at optimum concentration without causing any osmolar problem. This leaves viscosity and solubility as the limiting factors to provision of calories by cereal in ORS (30-33). Maize strarch yields 80-86% glucose (after acid hydrolysis).

Advantages of Maize flour in the use of ORS

1. Maize is cheap and easily available in Kenya.
2. It is a staple food in Kenya.
3. An amount sufficient to provide full calorie needs is feasible.
4. Fewer storage problems.
5. Usual household reserve for maize will suffice.
6. No osmolar problem.
7. Maize ORS requires boiling and thus provides safety from contamination and without additional fuel cost.

Selection of Maize flour as an ingredient of ORS is based on the findings of studies done at ICDDR, Bangladesh where encouraging results have been achieved using Rice powder-ORS.

Considering the advantages of rice powder, ICDDR, B carried out a pilot study with rice powder (30 g/l) electrolyte solution as oral rehydration therapy. The results are encouraging and the success rate was comparable with the sucrose electrolyte group (34). The second study performed by Patra et al (35) compare rice powder (50 g/l) ORS with WHO-ORS. The results also confirm rice powder is more effective than glucose/sucrose ORS. The studies of Molla et al have demonstrated that carbohydrate absorpition is the least impaired of all fodd components in acute diarrhoea (36), giving further support to the belief that provision of more carbohydrate (rice powder 80 g/l) of ORS will lead to more carbohydrate absorption. Molla et al performed a clinical study comparing the rice (80 G/L) ORS with WHO-ORS (37) and evaluated the efficacy, calorie balance, digestibility, percent of absorption of calories and rate of reduction in stool output in patients with acute

diarrhoea. Successful results of these studies inspired ICDDR, B investigators to start a pilot study on feasibility of Rice-ORS in the community training project at Chandpur, Bangladesh (49). The results are encouraging and indicate a study to do field comparison between Maize-ORS and Glucose-ORS.

Diarrhoea Malnutrition Cycle

The immediate impact of acute diarrhoea on health is fluid electrolyte malnutrition (FEM) (38). The more insidious accompaniment of diarrhoea is protein energy malnutrition (PEM) (34-41). Nutritional consequences following diarrhoea might be due to:

a. Anorexia during and after diarrhoea.

b. Starvation therapy or diet modification to control diarrhoea.

c. Malabsorption during and after diarrhoea.

d. Increased catabolism.

Recurrent episodes of diarrhoea and its nutritional cost causes malnutrition which is in turn produces compromised immunological status. Thus, the malnourished patients are susceptible to not only diarrhoea but also to infections (42-43) which ultimately affects the growth of children. Diarrhoea-Malnutrition cyle is set up through which the victims has to pass and in case of children the end result is disastrous. Therefore, treatment of the acute and delayed effects of diarrhoea has tremendous significance especially for the children of developing countries, where the nutrient intake and nutritional status of children may be at a critical level. An oral rehydration therapy capable of providing substantial calories along with diarrhoea therapy can be the effective intervention to break the diarrhoea malnutrition cycle with low cost.

In a study at ICDDR, Bangladesh rice powder ORS (R-ORS) appears to be the most advantageous ORS in regard to calories obtained and cost in comparison to other available ORS (50).

Type of carrier media	Amount/ 10 litre	Cost per litre	Calories obtained	Electrolytes
Glucose	200 g.	Tk.10	800 Kcal	WHO standard
Surcose	400 g.	Tk. 8	1600 Kcal	"
Gur	400 g.	Tk. 5	1600 Kcal	"
Rice powder	1000 g.	Tk. 7	4000 Kca-	"

* (Hypothetically 100% absorption of carbohydrates from different carrier media)
1 KSH = 1.6 Taka (Bangladesh)

Nutritional Impact on Children of Oral Rehydration Therapy (Field Study)

In a field trial in the Philippines by international study gorup (27) a significant weight gain was found in children 1-5 years with intensive home use of WHO-ORS, health care and proper feeding practice. In 1975, in Turkey there was a study of oral rehydration therapy (WHO-ORS) by midwives for 16 months. In the treatment group, there was more weight gain than in the control group. Another study in Iran (44) conducted by Buzargan et al showed that children treated with WHO-ORS gained weight more than the comparison group. But in Gambia, Rowland and Cole (45) failed to demonstrate any significant nutritional impact of WHO-ORS in children.

Confusion may arise about the nutritional impact of ORS following study of Rowland and Cole. A field study of ICDDR, Bangladesh in 1983 showed that homemade rice based ORS is acceptable and feasible as an alternative to glucose based ORS. Thus, the issue of nutritional impact of ORS deserves further study in the field.

In summary, we propose a definitive 3 years prospective longitudinal controlled study at Kakamega District, Kenya to compare Maize ORS and Glucose ORS and current village therapy in the treatment of diarrhoea. We expect to provide data on effects on nutritional status effectiveness of ORS, safety of ORS prepared and cost effectiveness. This study may have major implications for future oral rehydration recommendation.

3. Rationale

Selection of maize flour as a replacement of glucose or sucrose in the oral rehydration solution is based on the following theoretical considerations:

a. Maize flour can replace relatively more costly glucose/sucrose for use in ORS and shown to be equally effective as carrier molecules for transport of sodium through the gut mucosa.

b. Being a staple food it is almost always available in most households of Kenya.

c. Maize is cheap and its nutrient value is superior.

d. Osmolar problem is nil due to slow release of glucose through digestion in gut. Maize flour provides more carrier molecules and more calories in cute phase of diarrhoea. Thus, a single solution will be able to correct both electrolyte imbalances and prevent development of malnutrition due to diarrhoea.

e. A successful introduction of Maize-ORS in a community will thus have major implications in home based treatment of diarrhoea, nutrition and rehabilitation during and following diarrhoea.

4. Specific Objectives

a. To find out the extent of acceptance of the two kinds of ORS.

b. To assess the effectiveness (correction of dehydration, reduction in duration of diarrhoea, reduction in case of failure and case fatality rate) of Maize-ORS and G-ORS through training of mothers to prepare and use of ORS from packets supplied.

c. To evaluate the safety of M-ORS and G-ORS prepared by mothers from the packets supplied.

d. To assess and compare the nutritional effect of M-ORS and G-ORS in terms of longitudinal growth.

e. To find out cost effectiveness in order to develop a cheap and easily available ORS for the management of diarrhoea in home condition.

5. Methods and Procedures

a) Size and Population

Kakamega district is the largest district in Western Province with an area of 3,558 square kilometers and an estimated population of 1,030,887 people (1979 census). The district is 400 km west of Nairobi and is somewhat centrally placed with Busia district on the west; Bungoma district in the North west; Nyanza Province in the south-west and Rift Valley in the east and north. It is one of the most thickly populated districts in the Republic of Kenya. The major inhabitants of the district are Abaluhya comprising of twelve ethnic groups.

b) Administratively, Kakamega district is divided into nine divisions: Hamisi, Emuhuya, Vihiga, Butere, Lurambi, Kabras, Mumias, Ikolomani and Lugari. There are one hundred and seventy one (171) sublocations in the district. A sub-location is the smallest administrative unit in Kenya.

c) Temperature and Rainfall

The temperature varies between a mean maximum of 36^{o} - 32^{o} and a mean minimum of 13^{o} - 18^{o}c. Rainfall increases both with altitude and with the rainfall belt. It varies from 1,250 mm to 2,000 mm. There is no dry season in the district. Rainfall is highest between March and October, being maximum in April/May and August/September. December, January and February are usually characterized by low rainfall.

d) Fertility rate for Kakamega district is approximately 7.8% per woman in the reproductqve age. The approximate population growth rate for the district is 3.6% per year. The district has an average literacy rate of 53% with a very high number of institutions of learning, especially primary schools.

e) Transport and Roads

The road system in Kakamega District is very important in that it almost exclusively makes up the physical infrastructure. There is a branch of a railway line from Kisumu to Butere via Luanda and Yala and the main Nairobi Kampala line crossing the district between Turbo and Webuye. Generally, the regional distribution of the road network meets the necessities of the area.

f) Environmental Sanitation

About 40% of the population in Kakamega district, has access to clean water which is obtainable from rivers, springs streams, wells and roof attachment. There were one hundred and five (105) springs in the district which were protected by the Ministry of Health in 1981. During this period there were one thousand (1000) planned springs to be protected.

g) Health Status

The mortality rate from all diseases, at all ages, in the district is estimated at 8 per thousand, whereas mortality rate in the age group 0-2 years old is at 143 per thousand children from all causes. We have extrapolated from this overall death rate, an age specific death rate for pre-school (0-5) children of 30 per 1000 live births for calculations of sample size. Available data from notifiable diseases information system (cases reporting to health facilities) show that the disease pattern in the district is not very different from the rest of the country. Malaria (clinical) is the highest cause of morbidity in the district followed by Acute Respiratory Infections.

NOTIFIABLE DISEASES IN KAKAMEGA DISTRICT, 1980

RANK	DISEASE GROUP	NO. OF CASES	RATE PER (1000) POP.
1	Clinical Malaria	451,799	438.3
2	Acute Respiratory Infections	215,005	208.6
3	Diarrhoea	115,158	114.7
4	Diseases of the skin	73,068	70.9
5	Intestinal worms	66,220	64.2
6	Gonorrhea	23,652	22.9
7	Acute Eye Infection	23,569	22.9
8	Rheumatism (joint pains)	22,159	21.5
9	Accidents	20,439	19.8
10	Pyrexia - unknown origin	18,733	18.2
11	Ear Infection	17,857	17.3
12	Pneumonia	13,888	13.5
13	Anaemia	8,983	8.6
14	Measles	8,550	8.3
15	Malnutrition	7,668	7.4

Diarrhoea was the third leading cause of morbidity with a rate of 115 episodes per thousand (1,000) individuals in 1980. Mortality due to diarrhoea in the age group 0-5 years is estimated at 30 per cent per year as many cases are not brouhgt to health facilitites, unlike malaria. Most of the ten leading diseases identified at page 13 are environmentally caused.

h) Halth Facilities

There are twenty four (24) health centres in the district excluding Mbale Rural training Health Centre. There are only 2 sub-health centres in the district with eight (8) dispensaries. The provincial General Hospital MCH/FP mobile unit runs about nineteen (19) mobile services in the district. Of the seven (7) hospitals in the district one is government whereas the rest are missionary. The government health facilities have 422 beds whereas mission and others account for 734 beds in the district, making a total of 1,156 beds.

i) Structure/Administration of Health Facilities

Health centres consist of a clinical officer (patient care), a public health technician (environmental health in the area), statistical clerk, community nurses (immunization,weighing), antenatal clinic, health advice) and a family field educator who makes home visits and gives health education (in the field). Dispensaries usually have a clinical officer and community nurse. A Rural Health training unit exists which trains this cadre in the team approach to health care and consists of a senior clinical officer, a registered public health nurse, a registered public health officer, and a health educator. This unit reports to the Provincial Medical Officer and trains through seminars.

j) Advantage of Area

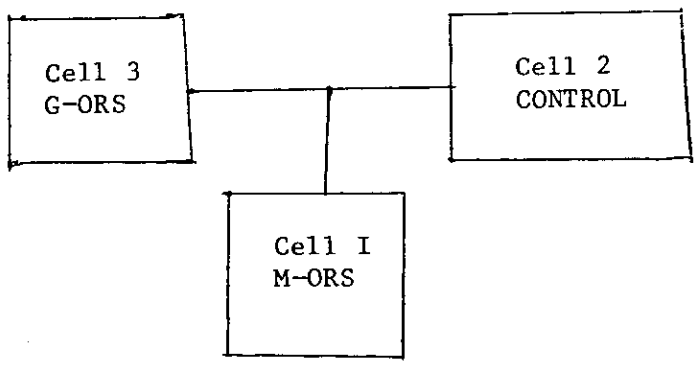
i. Representation of a rural population with serious child health problems i.e. high infant mortality rate, and high diarrhoeal disease morbidity and mortality.

ii. High population density, good infrastructure for logistical feasibility. This allows a sensitive, cost effective test of the interventions planned.

k) Study Design

A longitudinal study to compare the long term effect of Maize-ORS with Glucose-ORS under field conditions. Clinical effect, nutritional status, chemical composition of the solutions and cost effectiveness for home management of diarrhoea will be assessed. This study will be implemented in three areas of Kakamega District for 2 years. Mothers in two areas will be trained to prepare and use either Maize-ORS packets or Glucose-ORS packets for the home management of diarrhoea. Packets will be supplied by field workers. A third area will serve as a comparison group with no packets supplied at the household level or training provided through the study.

The study design will consist of three "cells" (Fig. 1). Essentially, one of these cells will be a "control cell" whereas the other two would be "treatment cells".



1.) Study Cells and Inputs

Study Cells	Inputs
Cell I (treatment)	Maize-ORS at HH
Cell 2 (control)	No-ORS at HH
Cell 3 (treatment)	Glucose-ORS at HH

ORS = Oral Rehydration Solution
HH = Household

m.) Criteria for Selection and Comparison of Sublocations for Study Area

i. 0-59 months age group. The age of the children is accurate as most of these children have birth certificates or immunization cards on which date of birth is recorded.

ii. All the study cells are approachable throughout the year which will provide uninterrupted information necessary for evaluating the nutritional impact of ORS during diarrhoea.

iii. Comparability of socio-economic and educational status of the mothers in the 3 cells will be ensured during the pilot phase of the study.

iv. Samples size and sample number will be comparable in 3 Cells (Table 2).

v. Cell 3 will be supllied with G-ORS packets. This cell will have field worker trained to prepare G-ORS.

vi. Cell 1 will be supplied with Maize-ORS packets. It will be provided with field workers trained to prepare M-ORS in household conditions.

vii. Cell 2 will act as control area. No ORS of any kind will be provided at household level except for those attending health facilities where they may be provided with ORT. Field workers in this cell will be trained only in diarrhoea and nutritional surveillance.

n.) Sample Size

In the course of planning for the study, it was decided to select a district with high infant and child mortality and at the same time with good infrastructure in health facilities, roads, schools and high population density.

Assumptions and estimations of sample size included the following factors:

(a) Childhood mortality (0-5) years = 30/1000

(b) Expected mortality reduction due to ORS = 50%

(c) Sample size in (0-5) age group = 2000

6. OTHER INPUTS

(a) Training of Personnel Required for the Direct Field Study

Thirty six (36) field workers with secondary level education will be trained for assessment of nutrition, anthropometric assessment, preparation of ORS, diarrhoea and other common diseases.

(b) Training of Mothers

Before the beginning of the study, the mothers of Cell I and 3 with children 0-59 months will be trained about continued feeding during diarrhoea. Only mothers in Cell 1 and 3 will receive instruction in preparation of solution from supplied

ORS packets (Table 3). Instruction will be provided by a trained field worker who will demonstrate preparation in the home and encourage its use during diarrhoea.

During the study period, the primary care giver of any detected case of diarrhoea of 0-59 months in Cells 1 & 3 will be instructed in ORS preparation and use on the day of case detection. Mothers who have has instruction will receive reinforcement of ORS packets at the detection of each new case among their children 0-59 months. Mothers of children born during the study period will receive instructions regarding diet, feeding and preparation of the respective ORS within three months of the child's birth. Thus, all care givers and mothers of children 0-59 months in Cells 1 and 3 will receive intensive training in preparation of their respective ORS. Because diarrhoea is difficult to define objectively and more difficult to confirm in a field setting, we have chosen respondents definition of diarrhoea in all cases.

(c) Diarrhoea Surveillance

Diarrhoea cases detection will be carried out weekly by experienced field workers through visits to each household and will be recorded on a specific form (Table 4). Cases will be followed to recovery or for seven consecutive days. Case continuing beyond seven consecutive visits will be referred to the project Medical Officer in charge of evaluation. The following data will be collected: date of onset, date of visits, presence of diarrhoea, presence of dehydration, presence of blood and/or

mucus in stool, identification of care giver, identification of treatment and amount of ORS used and outcome. Any case developing complications or getting worse will be referred to the nearest Health Centre or hospital.

(d) ORS Packet Supply

Maize-ORS twin packet and Glucose-ORS single packet will be prepared by one worker in Kakamega Hospital according to the requirement of the study. Quality control will be done through biochemical analysis of ORS-packets from weekly batches. Packets of G-ORS and M-ORS will be made continuously available through the field workers free of charge. Field workers will keep records (Table 5) of ORS packets distributed and their recipients. The stock and records of ORS supply will be routinely checked and verified by the nutrition nurse and field supervisor fortnightly.

(e) Safety of ORS Preparation

1. Chemical safety or ORS prepared by mothers of 0-59 months old children in Cells A and 3 will be assessed by chemical analysis of 5% random samples.

2. Bacteriological safety will be assured on the following basqs:
    a. M-ORS preparation is boiled.
    b. Discard the unused prepared ORS after 12 hours.
    c. Advise mothers about personal cleanliness and handling the ORS hygenically. Health assistants will supervise the preparation.
    d. 10% of the 5% random samples collected for chemical analysis from the ORS prepared by the mothers of children 0-59 months will be sent for culture.

(f) Hypothetical Calculation of Total Packets of ORS Required For the Study in Cells 1 and 3:

Taking an average of three episodes of diarrhoea needing two packets of ORS, in a population of 8000 total number of packets for a single type of ORS is about 100,000 for two years consumption. This means that the number of packets for both the types of ORS is about 200,000.

(g) Process of Randomization

From the diarrhoea surveillance record, the number of ORS prepared by the mothers of 0-59 months old children in 15 days will be calculated and 5% of this number will be selected randomly. Duplication of samples prepared by the same mother of 0-59 months old chidren would be avoided.

Each ORS sample will measure about 10 ml. will be coded with specific identification and sent on the day of collection to Kakamega Provincial Hospital for deep freezing. From there they will be shifted to Biochemistry Unit, TMDCRC, Nairobi for analysis of sodium, chloride, potassium, bicarbonate and glucose concentration. Table 4 contains a column to indicate where and when a sample was taken. Table 6 shows the proposed ORS sample analysis form.

(h) Nutritional Surveillance

The assessment of nutritional status of children 0-59 months of age will be done by taking weight monthly and height at 3 monthly intervals. Presence of edema, breat feeding, dietary history and some common infectious diseases e.g. measles, respiratory tract infections (TB, whooping cough, URTI, pneumonia), Avitaminosis A, skin diseases and malaria will also be noted. Duration of these illnesses, treatment received and outcome will be recorded. Salter scales will be used for weight (up to 50 gms). A length board will be used for babies and a height stick for older children (up to 1 mm) for measuring

the height. Finger pressure over the tibia for one minute will be used to assess the presence of edema. It is expected that by taking monthly weight and 3 monthly height during the anthropometric surveillance of 2 years, each child will have 25 (100%) records of weight measurement and 9(100%) records of height measurement. The anthropometry will be carried out from house to house surveillance by 2 anthropometric teams. Each team consists of 2 trained field workers and one assistant. One senior field supervisor will supervise and coordinate the anthropometry team in the field. Routine and spot verification of anthropometric records will be carried out by the Field Supervisor. Each child should be measured within $\pm$ 7 days of routine surveillance date and at specified routine intervals. In case of diarrhoea, children will be weighed daily until recovery with a scale (1 gram).

(i) Precaution to Maintain Accuracy in Anthropometry

1. Daily checking and adjustment of anthropometric instruments.
2. For each round of anthropometry separate specified form should be used in the field. Then records will be plotted to the respective anthropometric data collection form (Table 7).
3. Rotatory change of field workers in between anthropometric surveillance team and diarrhoea surveillance team to reduce subjective bias.
4. Routine checking and spot checking of record by supervisors and investigators.

5. Children having abnormal skeletal growth and stature should be verified by project Medical Officer, referred for investigations & should be excluded from the present study.

(j) Training of Personnel

Thirty (30) field workers, 6 field supervisors who will be recruited for the study will require intensive training in height and weight measurement, assessment of edema, recognition of dehydration, identification of malnutrition, recognition of common diseases (measles, whooping cough, respiratory tract infections, vit. A deficiency, skin diseases, malaria) before the beginning of the study. A pre and post test questionnaire will be served to evaluate field workers diagnostic competency. A medical officer will be trained in a Provincial hospital in Paediatrics.

Overall Supervision of the Project

Dr. P. R. Kenya and Dr. L. W. Okombo will supervise activities of the project. One of them will visit the study area at least twice a month.

7. SIGNIFICANCE

The assessment made through the study will provide information to select an ORS which would be effective, cheaper, safe, easily available and nutritious for home management of diarrhoea.

8. FACILITIES REQUIRED

a. Biochemistry Department of TMDCRC, Nairobi will be used for ORS sample analysis.

b. Complicated cases will be referred to the nearest health delivery point.

c. Computer Branch at MRC will be used for data processing.

d. Biostat Unit, MRC will be used for data analysis.

e. An office accomodation will be made inside the study area.

f. Two vehicles and four motorcycles will be used for study purposes.

9. ANALYSIS OF DATA

Effectiveness of ORS will be assessed by comparing Cells 1, 2 and 3 on the following basis:

i. Diarrhoea attack rate

ii. ORS acceptance rate

iii. Reduction of diarrhoea period per episode.

iv. Failure rate of ORS therapy.

v. Diarrhoeal case fatality rate.

vi. Diarrhoeal mortality rate.

vii. Number of cases referred to health facilities for not responding to ORS.

10. PROCEDURE FOR ANALYSIS OF EFFECTIVENESS OF ORS

1. The age of study population will be stratified as 0-6 months, 7-12 months, 13-24 months, 25-36 months, 37-48 months and 49-59 months.

2. Diarrhoea attack rate (Table 8)

In 0-59 month age groups, those are included in nutritional study.

3. ORS acceptance rate (Table 9)

   0-59 month age groups, those are included in nutritional study.

4. Reduction of diarrhoea duration per episode

   0-59 month age groups, those are included in nutritional study.

5. Failure rate of ORS therapy (Table 9)
   ORS therapy failure includes:
   - Refer to health facilities because of lack of response to ORT
   - Death associated with diarrhoea.
   - Refusal of particular ORS by patient
   - Continuation of diarrhoea after 7 days

6. Failures will be compared between M-ORS and G-ORS

7. Diarrhoeal case fatality (Table 10)

   In 0-59 months age children

8. Diarrhoeal mortality rate (Table 10)

   In 0-59 months age children

11. USE OF REFERENCE AND STANDARDS FOR NUTRITIONAL ASSESSMENT

a. It is assumed that each child has an inherent growth potentiality that cannot be achieved under unfavourable conditions.

b. For comparing anthropometric indices NCHS (National Centre for Health Statistics) standards of growth will be used (46). Gomez classification will be used for classification of anthropometric indices. (47). Welcome classification will be used to classify malnutrition.

Procedure of Analysis of Nutritional Status: (Table 10-15)

i. The age of study children will be stratified as 0-6 months, 7-12 months, 13-24 months, 25-36 months, 37-48 months, 49-59 months.

ii. For standardization each anthropometric measurement will be expressed as percentage of the median values of NCHS standards

of corresponding age and sex.

iii. Anthropometric indices which will be used are -

a. Weight for age

b. Height for age

c. Weight for height

iv. Classification of anthropometric indices according to Gomez classification (47)

v. Welcome classification will be used to classify malnutrition.

The nutritional status will be estimated according to above procedure for each round of surveillance. The change in nutritional status of the children will be estimated by cross tabulation for evaluation of ORS therapy intervention in comparison Cells (1, 2 & 3).

Chi-square test (X^2 test) "t" test and Standard Normal Deviation (SND) test will be applied for statistical significance..

12. CLARIFICATION OF SOME TERMS AND ABBREVIATION

a. Home Made ORS - ORS made by the dwellers of a household without help from trained people.

b. Rice ORS - 50 grams of rice powder + WHO recommended electrolytes salts in one litre of water.

c. Glucose ORS - WHO/UNICEF packet ORS.

d. Maize ORS - 60 grams of Maize flour + WHO recommended electrolytes in one litre of water.

e. KEMRI - Kenya Medical Research Institute

f. CMR - Centre for Microbiological Research, Kenya

g. TMDCRC - Traditional Medicine & Drug Control Research Centre, Kenya

h. MRC - Medical Research Centre, Kenya

i. CRC - Clinical Research Centre, Kenya

13. COLLABORATIVE ARRANGEMENTS

Scientific collaboration with International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) has been arranged. Dr. A. Molla, Dr. A. Bari, Dr. Samir K. Nath, Dr. Asma Khanum, Dr. F. C. Patra, Dr. Ayesha Molla have agreed to help start the running of the study. Experienced nurses and field workers will also be available from time to time. Collaboration is supposed to be ensured by frequent visits of these people to the project area. Dr. Greenough will be available as a consultant for the project.

Aga Khan Foundation has kindly agrreed to provide funds.

Table 1

Composition of ORS in Packet Supply to Prepare 1 Litre of Solution

	Maize-ORS	Glucose-ORS
NaCl	3.5	3.5
$NaHCO_3$	2.5	2.5
KCl	1.5	1.5
Maize powder	60 g.	-
Glucose	-	20 g.

M-ORS - Twin packets (one for maize flour, other for electrolytes)

WHO-ORS - Single packet

Maize Flour - Prepared by milling of dry white maize cereals

TABLE 2

BASE LINE DATA FROM INITIAL SURVEY

Parameters	Cell 1	Cell 2	Cell 3
1. ORS Packet supply			
2. Population for diarrhoea surveillance			
3. 0-59 months age children for nutritional study			
4. Mothers having 0-59 months age children			
5. Overall diarrhoea attack rate			
6. Diarrhoea attack rate in 0-59 months children			
7. Diarrhoea mortality/1000 population			
8. Diarrhoea case fatality			
9. Socio economic condition according to baseline information			
10. Previous training about ORS			
12. Proposed training			

Table 3

Instruction for Preparation & Use of ORS

Maize-ORS	Glucose-ORS
1. Take a litre and a litre more (1100 ml) (to make up evaporation loss) of water.	1. Take one litre of safe drinking water.
2. Add Maize flour (60 grams) from bigger packet and mix thoroughly.	2. Add Glucose-ORS packet.
3. Heat the mixture with continuous stirring till mixture boils to a homogenous solution (about 5 minutes).	3. Stir thoroughly to dissolve.
4. Let the solution to cool.	4. Use the solution as required.
5. Add salts from smaller packet and stir thoroughly to dissolve.	5. Discard the unused solution after 12 hours.
6. Use the solution as required.	
7. Discard unused solution after 12 hours.	

DIARRHOEAL SURVEILLANCE FORM

Field comparison between Maize-ORS & Glucose-ORS

Diarrhoea Community Based Project, Kakamega District, Kenya

Sub-location | Village: | Family: | Name : | Age: | Sex

	1	2			3	4	5	6	7	8	9	10	11	12	13
		Date													
		Year	Month	Day	Diarrhoea	Watery	Blood Mucoid	Dehydration	Treated by	Treated with	Volume of ORS used	Sample	Signature of worker	End result	Remarks
OS															
1V															
2V															
3V															
4V															
5V															
6V															
7V															
INV															
1T															
2T															
3T															
4T															
5T															
6T															
7T															
8T															
9T															
10T															

Col. 1: OS-ON Set
V-Visit
Inv: Investigation
T: Treatment

Col. 3-6
Yes=1 No=2

Col.7: 1.Self
2.Mother
3.Other family member
4.Neighbour
5.Trained practitione
6.Untrained practitio
7.Other person
8.Hospitalised
9.Untreated

Col.8: 1.G-ORS packt. suppl
2.M-ORS packt. suppl
3.I.V. fluid
4.Drug
5.Others
6.Hospital treatment
7.Untreated

Col.12: 1.Cured at home
2.Cured at hospital
3.Continued
4.Expired in home
5.Expired in hospita
6.Still in hospital
7.End result absent

Table 5

Maize/Glucose - ORS Packet Supply System

Field Comparison Between M-ORS and G-ORS
Diarrhoea Community Based Project, Kakamega

Sublocation _____ Village _____ Name of field worker _____

Sl. No.	Date			Name of day	Name of patient	Head of family	Name of village	No. of packet supplied	Remarks
	Year	Month	Day						

Table - 6

ORS Sample Analysis Form

Field Comparison Petween Maize-ORS & Glucose-ORS
Community Diarrhoea Project, Kakamega District, Kenya.

Sl. No.	Date of Collection			Sub-loc. No.	Village No.	Family No.	Indv. No.	ORS Type	Lab. No.	Date of Analysis Y M D	Na^+ mmol/L	K^+ mmol/L.	HCO_3 mmol/L	Glucose mmol/L.
	Year	Month	Day											

NUTRITION STUDY FORM

Field Comparison between M-ORS & G-ORS Diarrhoea Community Based Project, Kakamega District, Kenya.

Comparison 2-5. ID No. 6-13. Census No. of children Name of children 14-19. Date of birth 20. Sex

21-22	23-28	29-32	33-37	38	39	40	41	42-43	44	45-48	49	50-53	54	55-56	57	58	59	60-61	62	63		
Sl. No. of visit	Date of visit (Y Y M M D D)	Height in m.m.	Weight in gram	Oedema	Breast feeding	Meals in 24 hours	Diarrhoeal episode type	Duration of Diarrhoeal Episode	Dehydration	G-ORS used in m.l.	No. of days used	M-ORS used in m.l.	No. of days used	Treated with	End result of ORS use	End result of diarrhoea	Episode (Non-diarr)	Duration of episode	Type of treatment	Outcome of episode	Remarks	Signature of worker

Table 8. Diarrhoea Surveillance on Person Year & Attack Rate in Cells 1, 2 & 3.

	Person Years of observation						Diarrhoeal Episode					
							Number			Attack Rate/1000		
	1		2		3		1	2	3	1	2	3
	N	%	N	%	N	%						
0 - 6 mos.												
7 -12 mos.												
13-24 mos.												
25-36 mos.												
37-48 mos.												
49-59 mos.												
0-59 mos.		100%		100%		100%						

Table 9 : Age specific ORS consumption after diarrhoeal attack & failure rate, Diarrhoeal case fatality, mortality rate.

Age	Use of ORS						ORS therapy failure Rate %						Diarrhoeal case fatality Rate/100						Rate/1000		
	1		2		3		1		2		3		1		2		3		1	2	3
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%			
0-6 mos.																					
7-12 mos.																					
13-24 mos.																					
25-36 mos.																					
37-48 mos.																					
49-49 mos.																					
0-59 mos.																					

Table 10 Anthropometric Samples No. of Children measured in each nutritional surveillance.

	Cell 1		Cell 2		Cell 3		Total
	N	%	N	%	N	%	N
Enlisted for Nutritional study							
Base line data collected for Nutritional study							
1st Nutritional Surveillance							
2nd							
3rd							
Upto 24th Nutritional Surveillance.							

Table 11 : Age and Sex distribution according to comparison Cell in each nutritional surveillance

	Cell 1						Cell 2						Cell 3					
	Male		Female		Total		Male		Female		Total		Male		Female		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%

Table 12. Episodes of Diarrhoea occuring with in study period.

	Cell 1						Cell 2						Cell 3					
	Male		Female		Total		Male		Female		Total		Male		Female		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%

Table 13. No. & % of children according to their % of standard (NCHS) Weight for Age/Ht for Age/Weight for Height

Cells 1, 2 & 3

Sex - Male/Female

Nutritional Surveillance - Baseline, 1st, 2nd to 24th Nutritional Surveillance records.

Age	% of Standard
0-6 mos.	
7-12 mos.	
13-24 mos.	
25-36 mos.	
37-48 mos.	
49-59 mos.	

Table 14. Mean weight/height gain according to age & cells with the frequency of diarrhoeal episodes 1-2 episodes, 3-5 episodes, 6+ episodes)

	Cell 1		Cell 2		Cell 3	
Age	Mean wt. gain	N	Mean wt. gain	N	Mean wt. gain	N

Table 15. Number & % of Male/Female children 0-59 months (in different age groups) showing nutritional status wt. for age height for age weight for height.

	Cell 1		Cell 2		Cell 3	
	N	%	N	%	N	%
Decrease of Nutritional status						
No change						
Improve of Nutritional Status						

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ABSTRACT SUMMARY

(For Ethical Review)

The objective of the study is to compare the long term effect of Maize-ORS with Glucose-ORS under field condition. Clinical effect nutritional status, chemical composition of the solutions and cost effectiveness for home management of diarrhoea will be assessed.

1. The study will be implemented in 3 areas of Kakamega in Kenya Training Project for 3 years. The subject population would be the mothers of under five children. Since children have the highest attack rate of diarrhoeal episodes & because the mothers are mostly involved in the care of sick children. So mother would be trained to use & prepare oral rehydration solution. Children from 0-59 mos. of age are used for height and weight measurement to assess nutritional status. It is expected that mothers would give consent to measure their children.

2. The study method include training of mother, interview of mother about the preparation and use of ORS with rice powder or WHO-ORS. And surveillance to detect episodes of diarrhoea to observe the extent of utilization of training and use of packet supplied ORS, measurement of children at routine intervals. There is no potential risk involved.

3. Not applicable.

4. The confidentiality of data collected will be maintained and information will not be assured through use of code numbers for households, mothers and children.

5. Since there is no potential risk involved and no invasion of privacy is contemplated, a signed consent will not be obtained. However, the mothers would be explained the purpose of the proposed interview, training and measurement of children and only those who will be willing to participate in the interview, training & measurement of children will be included in the study.

6. The interview, training and measurement of children will take place in an informal sitting in households of subject population. Approximately 30 minutes time will be needed for training and interview. And 10 minutes time will be required for measurement of each child.

7. The results of the study will help to introduce a cheaper, readily available and nutritionally effective ORS for household preparation and treatment of diarrhoea.

8. The study will not require any hospital records, body tissues, body fluids or abortus.

A. DETAILED BUDGET FOR 3 YEARS

(1 May 1984 - 30 April 1988)

1. Personnel service:

Position	No.	% of effort	Allowence US $	Salary US $	Project requirement (US $)
Principal Investigator	1	50%	12000	-	12000
Co-Investigator (Cordinator)	1	20%	48000		48000
do (Medical Officer)	1	100%	-	10000	10000
do (P.H.N.)	1	50%	27000	-	2700
do (Demographer)	1	25%	6100		6100
do (Nutritionist)	1	40%	2000	-	2000
do (Sociologist)	1	25%	6100	-	6100
Supervisors	6	100%	-	14400	14400
Field workers	30	100%	-	64800	64800
Subordinate staff	10	100%	-	15000	15000
Lab. Technologist	1	100%	-	3200	3200
Lab. Technician	1	100%	-	2400	2400
Subordinate staff	1	100%	-	1500	1500
Data Entry Technician	1	100%	-	2560	2560
Clerk	2	100%	-	4800	4800
Subordinate staff	2	100%	-	3000	3000
Security Guards	2	100%	-	320	320
Drivers	3	100%	-	8640	8640
			33700	130620	164320

Sub Total = US $ 164,320

			Project Requirement Dollars
2.	Office Stationery		
	Papers, Files, Pencils etc.		5.000.00
		Sub Total	5,000.00
3.	Materials:		
a.	Glucose - ORS Packets 100,000 pcs.		4,000.00
b.	Haize - ORS Packets 100,000 pcs.		4,000.00
c.	Candy for children		1,000.00
		Sub Total	9,000.00
4.	Equipment :		
a.	Balance (capacity 310 grams) Model-310, OH AUS SCAL CORP.,USA.	1 pc. x $ 300	300.00
b.	Mettler Balance, 5000g capacity	1 pc. x $1500	1,500.00
c.	Sealing Machine, SEAL BOY, Holland	1 pc. x $ 300	300.00
d.	Salter Scale	12 pcs.x $ 200	24.00
e.	Toledo Scale	3 pcs.x $ 300	900.00
f.	Length Board	12 pcs.x $ 15	180.00
g.	Drum tube	1000 pcs.x $ 0.1	100.00
h.	Wide mouth thermoflask	10 pcs.x $ 20	200.00
i.	Micro Computer, KAY PR-04, 400 K Bytes	1 pc. x $2000	2,000.00
		Sub Total	7,800.00
5.	Emergency Medicine		1,000.00
		ST	1,000.00
6.	Vehicles:		
a.	Land Rover Jeep 2 pcs.x $ 10,000.00 (10 seats)		20,000.00
b.	Motor Cycles 3 Pcs.x $ 15,000.00		4,500.00
		Sub Total	24,500.00
7.	Transport Cost & Maintenance:		
a.	Jeep 2x80 km/dayx240 days/yearx3 yrsx.50¢		20,000.00
b.	Motor Cycle 3x100 km/dayx240 days/yr.x3 yrs.		5,000.00
		Sub Total	25,000.00

8.	Transportation of Materials between Kakamega and Nairobi 30 trips x 800 km x .50¢		$ 500.00
		Sub Total	$ 500.00
9.	Accommodation & Utilities:-		
a.	Rent of Office, 36 month x 150		$ 6,000.00
b.	Furnishing the office		$ 2,500.00
c.	Office maintenance (electricity, water supply etc.)		$ 5,000.00
		Sub Total	$ 9,000.00
10.	Printing & Production:-		
a.	Diarrhoea Surveillance Forms		
b.	Nutritional Study Forms		
c.	Health Cards		
d.	ORS Packets Records Forms		
e.	Sample Collections Forms		
f.	Cencus Questionnaires		$ 25,000.00
g.	KAP Forms		
h.	Socio Economic Questionnaires		
i.	Family Visit Record Forms		
j.	Supervising Forms		
k.	Sp. Study Forms of Nutrition		
l.	Death Report Form		
		Sub Total	$ 25,000.00
11.	Laboratory Tests:-		
a.	Biochemistry - 1500 samples x 1		$ 1,500.00
b.	Microbiology - 200 samples x 5		$ 1,000.00
		Sub Total	$ 2,500.00
12.	Communication & Mailing		
	To & From - Kakamega, Dhaka and Nairobi		$ 500.00
		Sub Total	$ 500.00
13.	Miscellaneous		$ 10,000.00
		Sub Total	$ 10,000.00

B. BUDGET SUMMARY FOR 3 YEARS

CATEGORY:	K.S.	PROJECT REQUIREMENT U.S. $
1. Personnel (local)		164,320.00
2. Office stationery		5,000.00
3. Materials		9,000.00
4. Equipment		7,800.00
5. Emergency Medicines		1,000.00
6. Vehicles		24,500.00
7. Transport cost & Maintenance		25,000.00
8. Transportation of Materials		500.00
9. Accommodation & Utilities		9,000.00
10. Printing & Productions		25,000.00
11. Laboratory Tests		2,500.00
12. Communication & Mailing		500.00
13. Miscellaneous		10,000.00

Total = US $ 284,200.00

(A)

DETAILED BUDGET OF PERSONNEL

(From: 1 May to 31 Dec.1985)

1. PERSONNEL SERVICES:

Personnel/Position	No.	% of effort	Salary US $	Allowance US $
Principal Investigator	1	50%	-	2667
Co-Investigator (Cordinator)	1	20%	-	1067
do (Medical Officer)	1	100%	2100	
do (P. H. N.)	-	-	-	-
do (Demographer)	1	100%	-	3500
do (Nutritionist)	1	50%	-	800
do (Sociologist)	1	100%	-	3500
Supervisors	6	50%	2400	-
Field worker	15	100%	8400	-
Field subordinate staffs	10	500%	2400	-
Lab. Technologist	1	100%	960	-
Lab. Technician	1	100%	710	
Lab. Subordinate staff	1	100%	440	-
Data entry Technician	1	100	720	-
Clerk	2	100%	1360	-
Log. subordinate staff	2	100%	980	
Security guard	2	100%	96	
Drivers	3	100%	1680	
			18646 +	11534

Personnel cost from
1 May to 31 December, 1985 = US $ 30180

(B)

DETAILED BUDGET FO PERSONNEL

(From: 1 Jan. - 31 Dec. 1986)

1. PERSONNEL SERVICES:

Personnel/Position	No.	% of effort	Salary US $	Allowance US $
Principal Investigator	1	50%	-	4000
Co-Investigator (Cordinator)	1	20%	-	1600
do (Medical Officer)	1	100%	3300	-
do (P. H. N.)	1	50%	-	1800
do (Demographer)	1	25%	-	1300
do (Nutritionist)	1	25%	-	600
do (Sociologist)	1	25%	-	1300
Supervisors	6	100%	7900	-
Field worker	30	100%	28600	-
Field subordinate staffs	10	100%	8100	-
Lab. Technologist	1	100%	1500	-
Lab. Technician	1	100%	1120	-
Lab. Subordinate staff	1	100%	720	-
Data entry Technician	1	100%	1200	-
Clerk	2	100%	2240	-
Log. Subordinate staff	2	100%	1580	-
Security Guards	-	100%	170	-
Drivers	3	100%	2860	
			59290	+ 10600

Personnel cost from
January to December, 1986 = US $ 69890

(C)

DETAILED BUDGET OF PERSONNEL

(From: January - December,1987)

1. PERSONNEL SERVICES:

Personnel/Position	No.	% of effort	Salary US $	Allowance US $
Principal Investigator	1	50%	-	4000
Co-Investigator (Cordinator)	1	20%	-	1600
do (Medical Officer)	1	100%	3400	-
do (P. H. N.)	1	25%	-	900
do (Demographer)	1	25%	-	1300
do (Nutritionist)	1	25%	-	600
do (Sociologist)	1	25%	-	1300
Supervisors	6	50%	4100	-
Field workers	30	100%	31400	-
Field subordinate staffs	10	50%	4500	-
Lab. Technologist	1	50%	740	-
Lab. Technician	1	50%	570	-
Lab. Subordinate staff	1	50%	340	-
Data entry Technician	1	50%	640	-
Clerk	2	50%	1200	-
Log. Subordinate staff	2	25%	440	-
Security Guards	2	25%	54	-
Drivers	3	100%	3060	-
			50444	+ 9700

Personnel cost from
January - December, 1987 = US $ 60144

(D)

DETAILED BUDGET OF PERSONNEL

(1 January - 30 April, 1988)

1. PERSONNEL SERVICES:

Personnel/Position	No.	% of effort	Salary US $	Allowance US $
Principl Investigator	1	50%	-	1333
Co-Investigator (Cordinator)	1	20%	-	533
do (Medical Officer)	1	100%	1200	-
do (P. H. N.)	-	-	-	-
do (Demographer)	-	-	-	-
do (Sociologist)	-	-	-	-
Supervisors	-	-	-	-
Field worker	-	-	-	-
Field subordinate staffs	-	-	-	-
Lab. Technologist	-	-	-	-
Lab. Technician	-	-	-	-
Lab. Subordinate staff	-	-	-	-
Data entry Technician	-	-	-	-
Clerk	-	-	-	-
Log. subordinate staff	-	-	-	-
Security guard	-	-	-	-
Drivers	3	100%	1040	-
			=======	=========
			2240 +	1866

Personnel cost from
1 January to 30 April, 1988 = US $ 4106

YEAR WISE COST FOR PROJECT REQUIREMENT OTHER THAN PERSONNEL COST

CATEGORY:	1/5/1985 to 31/12/1985	1/1/1986 to 31/12/1986	1/1/1987 to 31/12/1987	1/1/1988 to 30/4 /1988
	US $	US $	US $	US $
2. Office stationery	3000	1000	750	250
3. Materials	4000	4000	1000	-
4. Equipment	7880	-	-	-
5. Emergency Medicines	500	250	250	-
6. Vehicles	24500	-	-	-
7. Transport cost & Maintenance	6000	10000	8000	1000
8. Transportation of Materials	100	200	200	-
9. Accommodation & Utilities	4000	2000	2000	1000
10. Printing & Productions	15000	3000	3000	4000
11. Laboratory Tests	250	1500	750	-
12. Communication & Mailing	100	150	150	100
13. Miscellaneous	5000	1000	1000	3000
Total =	70330 +	23100 +	17100 +	9350 = US $ 119880

YEAR WISE PROJECT REQUIREMENT

CATEGORY:	1/5/1985 to 31/12/1985 US $		1/1/1986 to 31/12/1986 US $		1/1/1987 to 31/12/1987 US $		1/1/1988 to 30/4/1988 US $	
1. Personnel	30180	+	69890	+	60144	+	4106	= US $ 164320
2. Category No. 2 to Category No. 13.	70330	+	23100	+	17100	+	9350	= US $ 119880
	100430		92990		77244		13456	= US $ 284200

TOTAL DIRECT COST = US $ 284200