

Principal Investigator DR. F.C. PATRA

Trainee Investigator (if any)

Application No. 87-003

Supporting Agency (if Non-ICDDR,B) WHO

Title of study Safety and effectiveness

Project status:

of flavoured oral rehydration
solution for treatment of infectious
diarrhoea.

- () 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
 - (c) Physical risks Yes No
 - (d) Sensitive questions Yes No
 - (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

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 a 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 Cttee. for review.

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

Jakes Chaman Patra
Principal Investigator

(PTO)

87-003

15.2.87

SECTION 1 -- RESEARCH PROTOCOL

1. TITLE: SAFETY AND EFFECTIVENESS OF FLAVOURED
ORAL REHYDRATION SOLUTION FOR TREATMENT
OF INFANTILE DIARRHOEA.
2. PRINCIPAL INVESTIGATOR Dr. F.C. Patra
CO-PRINCIPAL INVESTIGATOR Dr. D. A. SACK
CO-INVESTIGATORS: Dr. A. Islam
Dr. A.N. Alam
A Medical Officer (to be named)
- CONSULTANT: Professor Roger Eeckels
3. STARTING DATE: 1st April 1987
4. COMPLETION DATE: 31st March 1988
5. TOTAL DIRECT COST: US \$ 34,661
SOURCE OF FUNDING: World Health Organization
6. SCIENTIFIC PROGRAMME: This protocol has been approved by the
Clinical Sciences Division



Signature of Acting Associate Director
of Clinical Sciences Division

Date: 10/02/87

7. ABSTRACT SUMMARY:

In a randomised study a total of 150 male patients aged between 3 months and 3 years and suffering from acute diarrhoeal dehydration will be studied in two groups to evaluate the effectiveness of flavoured oral rehydration solution and to compare it with the standard WHO recommended oral rehydration solution (ORS). The composition of the study ORS will be similar to the WHO recommended ORS but in addition it will be flavoured. The control group will receive the standard WHO recommended citrate containing ORS. All the patients will be rehydrated by ORS from the very beginning of the study. All the patients will be studied for 72 hours after inclusion into the study. After the initial rehydration all the patients will be offered appropriate feeds. Careful record of intake and output will be kept. All the patients will be kept under strict medical supervision by the investigators.

8. REVIEWS:

- (a) Chairman, Ethical Review Committee: -----
- (b) Chairman, Research Review Committee: -----
- (c) Director: -----

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. General objective

The general objective of the present study is to evaluate the safety and effectiveness of flavoured oral rehydration solution (ORS) for treating moderate dehydration in children less than 3 years of age with acute diarrhoea.

2. Background

Oral rehydration therapy (ORT) is recognised as a powerful intervention for the treatment of dehydration due to acute diarrhoea. Its scientific basis rests on the fact that glucose-linked enhanced sodium absorption in the small intestine remains largely intact during acute diarrhoea of diverse aetiology. The oral rehydration salt recommended by WHO contains glucose (20 g) and three salts - sodium chloride (3.5 g), trisodium citrate dihydrate (2.9 g) or sodium hydrogen carbonate (2.5 g) and potassium chloride (1.5 g) to be mixed in one litre of water. This WHO recommended oral rehydration salt (ORS) solution has been extensively and successfully used in the past decade for treatment of acute diarrhoea. Very few side effects have been associated with use of this product in hospitals, clinics or homes. It contains no artificial flavouring and is colourless.

Recently ORS preparations containing flavouring and/or colouring have been marketed extensively in some countries. More than 200 commercial ORS products are currently on the market; at least 34 of these are flavoured and some are also coloured (1). It is also known that the leading commercial product in the market are generally flavoured. Although in a few studies flavouring agents such as vanilla (2), cherry (3), orange (4,5) and staw berry (6) have been used no data are yet available comparing the use of flavoured ORS to standard ORS. In one study using effervescent oral solution with vanilla flavour (2) 50 patients were treated with this solution. Out of these 50 patients, 9 adults and 11 children graded the test of the solution as neutral, 16 adults and 12 children graded it as good. Only 2 children expressed that the solution had an unpleasant test. In another study using the cherry flavoured ORS (3) the acceptability of the flavoured ORS was compared with that from an unflavoured one. The authors concluded that unflavoured ORT solution was significantly more acceptable than the flavoured one. Although the design of the study was interesting, these findings can not be easily generalised due to methodological problems as composition of the ORT solution, initial I.V. fluid volume and other treatment details were not given.

The possible benefits of flavoured ORS are, (a) increased total intake of ORS leading to more frequent success in achieving hydration, (b) faster rate of intake leading to quicker hydration and return of appetite and more rapid control of vomiting, (c) increased acceptance and palatability leading to better acceptance and compliance by mother and better acceptance by children during

the maintenance phase. The possible disadvantages of flavoured ORS may be (1) hypernatraemia, (2) decreased breast milk and food intake, (3) increased stool output, (4) fluid overload and periorbital oedema (5) abdominal distention, (6) increased vomiting, (7) use when not indicated e.g. as a general tonic or pacifier, (8) excessive demand on production and distribution due to unnecessary consumption.

Therefore carefully designed and conducted prospective clinical trials are needed to evaluate the extent to which these potential risks and benefits actually occur.

8. Specific objectives:

The success of the ORS regimens will be determined by measuring the following:

- a. Volume of ORS intake during rehydration therapy and volume of ORS intake during maintenance therapy.
- b. Stool volume and number of stools during the study periods
- c. Frequency and magnitude of vomiting
- d. Effect on serum sodium concentration
- e. Effect on weight gain over 24 hours
- f. Urine output as a proxy indicator of ORS intake.

METHODS AND PROCEDURE

Study population

The study will be carried out in moderately dehydrated infants and younger children with acute watery diarrhoea in the study ward of the International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka.

Inclusion criteria

Age - 3 months to 3 years

Sex - male only, for convenience of separately collecting stool and urine.

Acute diarrhoea (3 or more watery or loose stool/day for less than 3 days).

Clinical signs of moderate dehydration defined by thirst, sunken eyes, rapid pulse rate, depressed fontanelle, loss of skin turgor, no tears.

Mothers must be willing to stay with and feed the child.

Exclusion criteria

- Presence of shock or other signs of severe dehydration
- No signs of dehydration
- Gross blood in the stool
- Other complicating illness such as pneumonia or sepsis
- Treatment of this illness with antibiotics
- Clinical sign of complete ileus
- Clinical evidence of severe malnutrition defined by weight for height less than 70% of NCHS median value

Sample size calculation

We calculated the sample size using published results based on stool volume (7) and ORS intake (8). We also assumed that by introducing the flavoured ORS the ORS intake as well as the stool volume will be increased by about 30%. The formula used to calculate the sample size is as follows:

$$n = \frac{2\sigma^2}{(u_2 - u_1)^2} \times f(\alpha, \beta)$$

$$\alpha = 0.05 \text{ and } \beta = 0.2 \text{ (80\% power)}$$

Stool output

HO : Stool output will be increased by 30% using the above formula and the figures from published results (7).

$$n = \frac{23039.45}{2631.69} \times 7.9$$

$$= 8.755 \times 7.9$$

$$= 69.2 = 69$$

ORS intake

ORS intake will be increased by 30% using the above formula and the figures from published results (8), we have

$$n = \frac{60151.68}{6464.16} \times 7.9$$

$$= 9.31 \times 7.9$$

$$= 73.5 = 74$$

To be on the safe side we took 75 patients in each group so that the total sample size of the experiment will be 150. With n=75 in each group the power of the test will be more than 80% as assumed in the sample size calculation.

Enrolment of subjects:

a. Informed consent

Each child's mother or father will be given an explanation as to the nature of the study and only those who give voluntary written consent (informed consent form is enclosed) will be included in the study. Parents reserve the right to withdraw from the study at any stage without affecting further care of the patient.

b. Assessment of eligibility

Patients will be assessed and included into the study according to inclusion and exclusion criteria and informed consent.

c. Baseline examination

A standard history and complete physical examination will be carried out according to a proforma. The following laboratory tests will be performed on admission.

- Micro hematocrit and plasma specific gravity
- Serum electrolyte and total CO₂
- Fresh stool/rectal swab for V. cholerae. V. cholerae will be identified by plating directly on to TTGA and TCBS medium and enriching into alkaline peptone water medium and subsequently subculturing onto TTGA and TCBS medium. Suspected vibrio like colonies will be conformed by agglutinating with polyvalent O group 1 antiserum and monovalent inaba and ogawa antiserum.
- Fresh stool for microscopy

The above blood test will require 2.0 ml of blood and will be repeated at 24 hours of the study period, and at discharge from the study.

d. Subject allocation

The trial will be conducted in a randomized way and patients will be randomly assigned to receive either the flavoured ORS formulation or the standard ORS. We first will divide the 150 patients into 15 groups of 10 each, so that the first 10 patients are more or less equally distributed between the two treatment groups. If the random number is 0 or even then we will call it Treatment 1 (WHO ORS) and if the random number is odd we we call in Treatment 2 (flavoured ORS). This way there is high probability that equal number of patient will be put to the two treatment groups. Top of the sealed envelop will show the patient number as they come and the contents of the envelop will show the treatment regimen. This way the contents of the envelope will not be known either to the patient or the nurse or doctor. It is proposed that the flavoured ORS packets and the standard ORS packets will be supplied by the WHO.

Intervention:

- a. Composition and preparation of the oral rehydration formulations.
Sufficient number of packets per patient will be prepared by WHO.

Composition of flavoured ORS formulation:

Sodium chloride	- 3.5 g
Potassium cholride	- 1.5 g
Tri sodium citrate dihydrate	- 2.9 g
Glucose	- 20 g
Flavour	- To be selected

When diluted in 1 litre of water this ORS will have Na 90, Cl 80, K 20, HCO₃, equivalent 30 and glucose 111 and in mmol per litre. Composition of standard ORS will be the same as flavoured ORS except the flavour.

b. Description of schedule

All patients admitted to the trial will be cared for by doctors and nursing staff assigned to the study. Nurses already experienced in metabolic collection in earlier studies will be assigned to the study. Immediately after recording weight and assigning the appropriate serial number the patient will be put on the study bed.

Stool volume will be determined by weighing pre-weighed diapers. Urine volume will be determined by collecting urine in paediatric urine collection bags. Vomitus will be mopped with preweighed gauze and measured by the difference in weight. Intake and output will be recorded 8 hourly till the completion of the study. The container with the assigned ORS and the cup and spoon will be kept by the bed side of the patient to facilitate measured intake.

All fluid therapy will be divided into two parts:

- i. Initial rehydration therapy
- ii. Maintenance therapy

Rehydration therapy

During the rehydration phase the patients will be encouraged to drink ORS which will be supplied ad-libitum. ORS will be administered by the mother with instruction to provide what the child will readily take. Instruction for fluid intake will encourage that at least the estimated requirement be offered which will be 25 ml/kg per hour plus the volume lost due to stool output. Intake of ORS will not be forced. ORS will be stopped if periorbital oedema develops. After the first 4 hours of rehydration therapy mothers can offer breast milk if the child is being breast fed.

Maintenance therapy

During the maintenance phase the ORS will be offered ad-libitum to the child. Offer of ORS will be stopped if periorbital oedema develops.

For the study the children will be hospitalised till the cessation of diarrhoea.

Feeding

During maintenance therapy all the children will be offered food. Breast fed babies will be allowed to breast feed or given other fluids (including water) and semisolid food in addition to ORS solution. The food offered will be standardised taking into consideration the age of the child and local feeding habits of the population. Breast milk and other liquid or foods will be offered at standard time intervals such as every 4 hours. Once offered the child will be allowed to take as much as he wants. The following are examples of feeding regimen that will be used.

Age 3-11 months :

1. Breast milk
2. Cow's milk or artificial milk (diluted with equal volume of water)
- e. Rice porridge

Age 12-36 months :

1. Cow's milk or artificial milk (diluted with equal volume of water)
2. Rice and dhal
3. Breast milk if still nursing

Antibiotics : No antibiotic will be used during the study period.

Treatment failure

1. If signs of dehydration do not improve or become worse within the first 8 hours of therapy or signs of dehydration reappear at any time during the 24 hours of observation then the route of fluid administration will be changed to intravenous route. Such patients will receive the

Dhaka solution by intravenous route and the child will reenter the study after receiving rapid intravenous rehydration. These will be included in the analysis.

2. Also the child will be removed from the study if he is unable to take oral fluids due to vomiting or lethargy. Such children will be considered as treatment failures and these data will be reported with the analysis.

Phases of the trial: The trial will involve 3 phase.

Phase I : (Preparatory phase) test taste of selected flavour.

During the preparatory phase of the trial selected flavours such as banana, lemon and orange etc. will be evaluated to select an appropriate flavour. WHO will provide 4 flavoured ORS formulations plus standard unflavoured ORS for this evaluation.

A total of 50 patients aged 8 to 10 years of either sex (10 in each group) will be studied at the outpatient clinic to select the preferred flavour.

Each patient will receive a score according to whether she/he likes it or not. Total score for each flavour can be found out just by adding the 10 scores together. The flavour that gets the maximum score will be selected as the preferred flavour. If necessary analysis of variance test or Kruskal-Wallis test may be applied to show the significance between flavoured groups.

Phase II : Pre-trial procedure

A total of 6 patients will be studied to standardise the 24 hour data collection. This will help the study ward personnel to become acquainted with the design of the study.

Phase III : Definitive study

As indicated in the sample size calculations a total of 150 patients (75 in each group) will be studied.

Data collection

1. Intake will be recorded accurately every 4 hours for the first 8 hours then every 8 hourly up to discharge.
2. The stool and urine output will be recorded separately every 4 hours for the first 8 hours and then every 8 hours. Stool volume will be estimated by wet and dry diaper weights.
3. Frequency of vomiting and weight of vomitus will also be recorded. Vomitus will be collected on a dry pre-weighed cloth and the volume determined by weight.
4. The child's weight will be determined at admission and at 24 hours intervals till discharge.
5. The child will be examined for signs of dehydration every 2 hours during the first 8 hours then every 4 hours till discharge.
6. The presence or absence of periorbital oedema will also be noted during each physical examination and recorded.

Data recording

WHO forms for history, physical examination, laboratory data and aetiological agents will be used. Specially designed forms will be used to record data during the rehydration phase and the maintenance phase.

Data analysis

Pre-treatment clinical data will be analysed to assess comparability between the two groups of patients. They will be presented in a table including the variables, the number of patients for each variable, the mean and standard deviation, median and range for each of the two groups.

The outcome variables such as ORS intake, stool output, urine output, weight gain, frequency and magnitude of vomiting, presence or absence of periorbital oedema, hematocrit, plasma specific gravity, serum electrolytes will be analysed taking into account the distribution. If the latter is normal, the t-test will be used, if not the Mann-Whitney U test will be applied.

REFERENCES:

1. Guidelines for the preparation of protocols to study the risks and benefit of flavoured and coloured ORS. CDD, WHO, Geneva 1986.
2. Ahmed SM et al. Effective treatment of diarrhoeal dehydration with an oral rehydration solution containing citrate. Scand J Infect Dis. 18:65-70,1980.
3. Carraza FR et al. Comparative clinical trial of the acceptability of two oral rehydration solutions in children with acute diarrhoea. Folha Med (Brazil), 77(5):611-614,1978.
4. Sugijanto et al. Oedema in oral rehydration. Paed Indonesia, 21:229-234,1981.
5. Sack DA et al. Oral rehydration in rotavirus diarrhoea : a double blind comparison of sucrose with glucose electrolyte solution. Lancet 2:280-283,1978.
6. Santosham M et al. Oral rehydration therapy of infantile diarrhoea: a controlled study of well nourished children hospitalised in the US and Panama. N Eng J Med 306(18),1070-1076,1982.
7. Patra FC et al. Can acetate replace bicarbonate in oral rehydration solution for infantile diarrhoea? Arch Dis Child 57:625-627,1982.
8. Patra FC et al. Is rice electrolyte solution superior to glucose electrolyte solution in infantile diarrhoea. Arch Dis Child. 57, 910-912,1982.

SECTION III - BUDGET1. Personnel services:

<u>Name</u>	<u>Position</u>	<u>% effort</u>	<u>US Dollar</u>
Dr. F.C. Patra	Principal Investigator	100%	18,000
Dr. D.A. Sack	Principal Investigator	10%	-
Dr. A. Islam	Co-Investigator	10%	576
Dr. A.N. Alam	Co-Investigator	5%	-
A Physician to be named	Co-Investigator	20%	511
Professor Roger Eeckels	Consultant	-	-
One Clerk (Study ward)		20%	360

 Sub Total=19,447
2. Operating expenses:

Urine collecting bag	300
Disposable diaper	500
Balance (Harvard trip Ohaus Dial-O-gram moder 2060)	200
Weight set	100
Data analysis	500
Stool microscopy	194
Stool culture	370
Blood electrolytes	1246
Serum specific gravity	207
Hematocrit	463
Rotavirus ELISA	495

 Sub Total= 4575
3. Patient cost:

Hospitalization of patient	9939
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4. Other expenditure:

Stationary goods	300
Xerox and mimioigraphy	200
Medical illustration	200

 Sub Total = 700

GRAND TOTAL = US \$ 34,661

Consent Form

International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) would like to carry out research on Flavoured oral rehydration solution (ORS) for the treatment of diarrhoea in children. The new flavoured ORS is palatable. The flavoured ORS will be compared with the currently WHO recommended ORS for the treatment of acute diarrhoea. The study will last till the cessation of diarrhoea and during this period the patient will be treated with either flavoured ORS or WHO recommended ORS.

Stool, urine and vomitus of the patient will be measured every 4 hourly for the 1st 8 hours then every 8 hourly till discharge from the study. Two milli litres of blood will be drawn from the patients on admission, at 24 hours and at discharge to assess the degree of dehydration and assessment of therapeutic response. Stool for microscopic examination and culture will be performed to determine the cause of diarrhoea. The result of investigation will be used to evaluate the effect of treatment. The patients will be discharged from the hospital after cessation of diarrhoea and completion of the necessary treatment.

All records of the patient's treatment in the hospital will be kept confidential. Taking part in the study totally depends upon your decision. The patient will be provided with all the available treatment facilities in this hospital even if you do not allow the patient to participate in this study. If you agree to the proposal that the patient should participate in this study then please sign here.

Signature of the investigator

Finger print/signature of the guardian

Relation to the patient:-----

Date: -----

সম্মতি পত্র

আনুষ্ঠানিক উদ্বোধন গবেষণা কেন্দ্র শিশুদের জায়গিয়ার চিকিৎসায় ব্যবহারের জন্য সুগন্ধযুক্ত মুখে খাবার স্যালাইনের ওপর একটি গবেষণা চালাতে ইচ্ছুক। এই মতন সুগন্ধযুক্ত স্যালাইন পান করতে সুস্থানু। প্রাথমিক জায়গিয়ায় এই সুগন্ধযুক্ত মুখে খাবার স্যালাইনের ব্যবহারের সাথে বর্তমান প্রচলিত বিশু-স্বাস্থ্য সংস্থার অনুমোদিত স্যালাইনের তুলনা করা হবে। রোগীর জায়গিয়া বন্ধ না হওয়া পর্যন্ত এই সুগন্ধযুক্ত খাবার স্যালাইন অথবা বিশু-স্বাস্থ্য সংস্থা অনুমোদিত স্যালাইন ব্যবহার করা হবে।

রোগী ভর্তি হওয়ার প্রথম আট ঘন্টায় প্রতি চার ঘন্টা এবং পরবর্তীতে রোগীর ছুটি বা হওয়া পর্যন্ত প্রতি আট ঘন্টা অন্তর রোগীর পায়খানা, পেশাব এবং বমির পরিমাণ মাপা হবে। গানি-শুদ্ধতা এবং চিকিৎসার অগ্রগতি নির্ণয়ের জন্য রোগীর ভর্তি হওয়ার পর, ২৪ ঘন্টা পর এবং ছুটির সময় ২ মিঃ লিঃ পরিমাণ রক্ত নেয়া হবে। জায়গিয়ার কারণ নির্ণয়ের জন্য পায়খানার বিভিন্ন রকম পরীক্ষা করা হবে। চিকিৎসার মূল্যায়নের জন্য এই পরীক্ষার ফলাফল ব্যবহার করা হবে। প্রয়োজনীয় চিকিৎসা এবং জায়গিয়া বন্ধ হবার পর রোগীকে হাসপাতাল থেকে ছুটি দেয়া হবে।

হাসপাতালে থাকাকালীন রোগীর চিকিৎসা সংক্রান্ত সকল তথ্য গোপন রাখা হবে। গবেষণায় অংশ গ্রহণ করা/কিংবা না করা সম্পূর্ণরূপে আপনার ওপর নির্ভরশীল। এই গবেষণায় আপনি আপনার রোগীকে অংশ গ্রহণে অনিচ্ছুক হলেও আপনার রোগী হাসপাতালের সকল সুবিধা ও চিকিৎসা পাবে।

আপনি যদি আপনার রোগীকে গবেষণায় অংশ গ্রহণে ইচ্ছুক থাকেন তবে নিম্নে স্বাক্ষর অথবা টিপ সহ দিন।

গবেষকের স্বাক্ষর

অভিভাবকের স্বাক্ষর / বৃদ্ধাংগুলের ছাপ

অভিভাবকের পরিচয়

তারিখ

CURRICULA VITAE

PRINCIPAL/~~CO~~-INVESTIGATOR DR. F.C. PATRA

1. Surname/Family Name: PATRA

First name/other names FAKIR CHARAN

2. Date of birth: 20th April, 1949

Place of Birth: Nargoda

Nationality: Indian

3. Degrees

<u>Degree</u>	<u>Year</u>	<u>Institution</u>	<u>Disciplines</u>
M.B.B.S.	1974	M.K.C.G. Medical College, Berhampur, Orissa	Medicine
D.C.H.	1976	Institute of Child Health, Calcutta	Paediatrics

4. Academic Distinctions:

Degree Year

5. Present post (Title, Institution, Dates)

Title: International Research Fellow

Institution: ICDDR,B

Dates: From 1st January 1986 onwards

6. Previous posts (Title, Institution Dates)

Title: a. International Research Associate

b. Research Fellow

c. Resident in Paediatrics

Institution:

a. ICDDR,B

b. Kathari Centre of Gastroenterology, Calcutta, India

c. Calcutta Medical Research Institute, Calcutta, India

Dates:

a. 1st January 1984 - 31st December 1985

b. October 1976 to December 1983

c. October 1974 to September 1976

7. Academic & Research Awards, Consultant & other posts

8. Other University & Institutional Posts

9. Current Research Interests including details of Projects of which Applicant is Principal Investigator.

Current research interest - Oral rehydration therapy

Principal investigator of the project entitled "Oral rehydration therapy with alanine-glucose ORS", a controlled clinical trial".

10. Publications & Communications

Please see attached paper
