

20

Investigator: Macdonald Hubba (if any)
 Sponsor: (if Non-ICM B.B.)
 Project No. s:
 (X) New Study
 () Continuation with change
 () No change (do not fill out rest)

Investigation No. 85-003
 Title of Study: EVALUATION OF COST-EFFECTIVENESS OF THE NUTRITIONAL REHABILITATION UNIT OF DHAKA HOSPITAL

- Circle the appropriate answer to each of the following (If Not Applicable write N/A)
- Source of Population:
 - (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No
 - 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
 - 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
 - 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
 - (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
 - Will signed consent form be required:
 - (a) From subjects Yes No
 - (b) From parent or guardian (if subjects are minors) Yes No
 - Will special precautions be taken to protect privacy of subjects Yes No
 - Check documents being submitted herewith:
 - Initial proposal & initially signed 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:
- 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.
 - Examples of the type of specific questions to be asked in the sensitive areas.
 - An indication as to when the questionnaire will be presented to the Cttee. for review.

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

Principal Investigators

Trainee

85-003

27-1-85

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Section-1 : Research Protocol.

Title:
EVALUATION OF THE COST-EFFECTIVENESS OF THE
NUTRITIONAL REHABILITATION UNIT OF DHAKA HOSPITAL

Principal Investigators: A. Briand, M. Chibba.

Starting date: 1st april 1985

Completion date: 1st april 1985

Total direct cost: US\$ 63 340. (External funding is being sought)

Scientific Programme Head: Dr. M. M. Rahman.

This protocol has been approved by the nutrition
working group.



Signature of the Scientific programme head: _____

Date: 23/1/85

Abstract summary: Children who stay for at least 7 days in
the nutritional rehabilitation unit (NRU) of ICDDR,B's Dhaka
Hospital will be followed-up for one year along with a cohort of
fair-matched controls who leave the hospital just after treatment
for acute diarrhoea. This surveillance will facilitate an
estimation of the number of deaths avoided every year by the
unit. The cost of children's stay in the NRU and relevant costs
associated to the follow-up period will be estimated and
expressed in terms of net costs (direct plus indirect costs minus
indirect savings). The cost-effectiveness of the NRU, or the
total cost of every death averted by it, will be determined to
permit comparisons with other health interventions. The data base
developed by this study will serve to support other complementary
research.

Reviews:

Ethical review Committee: _____

Research Review Committee: _____

Director: _____

02 JUL 2002

2.1.1: Research Plan

Introduction:

Objectives

To determine whether children treated in a nutritional rehabilitation unit have reduced mortality compared to those treated for diarrhoea only, at ICDDR,B's Dhaka hospital.

To determine the cost-effectiveness of the NRU or to estimate the cost of every death averted by it.

An equally important objective is to use the data developed by this study for other complementary research on effectiveness and/or efficacy (not the same thing) of nutrition interventions.*

Background

In a world of limited or scarce health resources, the determination of the most cost-effective approach to solving a given health objective is a rational and practical means to achieve an efficient allocation of resources. An important objective of ICDDR,B is to reduce diarrhoeal mortality of children in the under-five age group. Theoretically, this goal can be achieved through several potential interventions: of case management; by increasing host resistance to infection and/or illness and/or death; or reducing transmission of the pathogenic agents of diarrhoeal diseases; and by controlling and/or preventing diarrhoea epidemics (1). ICDDR,B is involved in all of these areas, including interventions in child nutrition as a means to increase host resistance to infection and/or illness and/or death. The NRU is one such intervention with a primary objective to decrease mortality in the under-five age group through intensive feeding of children and appropriate education of mothers.

Cost-effectiveness analysis ascertains either a project or program's capability to achieve a specified objective at the least possible cost or its capability to maximize benefits to be gained from a given budget (2-3). According to available published information, cost-effectiveness of a NRU in a developing country has never been adequately done. In a recent review of 128 articles on nutrition education programmes or integrated intervention programmes with a nutrition education component, it was found that only 30% of them contained any information on costs (4); and, of the latter, very few contained cost-effectiveness information (5). In our survey of literature on nutritional rehabilitation centers, we found that cost data is available on a direct cost basis only (6-12). Without a comprehensive consideration of costs - viz. direct, indirect and opportunity costs - an adequate or satisfactory cost-effectiveness analysis study cannot be done.

Malnourished children discharged from hospital after treatment of diarrhoea have an excess of mortality, mainly during the first three months following their return to the community (6). This may be due to several reasons. One may argue that these children were discharged from the hospital at too early a stage and that if they could have been fed a few more weeks until their nutritional status is back to normal, then death could have been avoided. Alternately, one may think that the environmental factors which lead these children to suffer from diarrhoea and malnutrition had again a negative effect on their health status as soon as they went back to the community and that this fatal outcome is hardly preventable. The practical implications of these two interpretations are radically opposed, with the latter implying that any attempt to rehabilitate malnourished children is doomed to failure. Although it seems likely that both interpretations have some truth, the efficacy of nutritional rehabilitation of severely malnourished children cannot be assessed with available information: very few studies have evaluated this problem with a satisfactory methodology and none is relevant to the situation in Bangladesh.

The concept of nutritional rehabilitation, developed in South America by Bengoa (7) received much attention after it was realised that treatment of malnourished children in classical hospital wards had very poor results and was very expensive (8). In a review of statistics published between 1952 and 1969, Cook showed that mortality of malnourished children in hospitals varied between 20% to 40% which was apparently higher than mortality of non-treated children. Modern treatment of malnourished children, entailing more emphasis on anti-infectious therapy and based primarily on frequent high-energy feeding have now greatly reduced these figures but Cook's criticism about the cost of hospital treatment of malnutrition remains valid: if all severely malnourished children were to be treated in a classical hospital, all the health budget of most developing countries would be used up in this task alone. A cheap alternative to hospital treatment of malnutrition has to be found. The nutrition rehabilitation units are supposed to serve this purpose. Their aim is to educate the mothers by involving them in feeding their malnourished children back to health using locally available foods and indigenous cooking methods outside the classical hospital ward (9). They are indisputably cheaper to run than a sophisticated paediatric nutrition unit.

Several attempts have been made to evaluate the effectiveness of nutritional rehabilitation. Most authors measured the weight gain of treated children and found that it was constantly above the expected weight gain for children of the same age (10). This finding, however, is not conclusive since these malnourished children may have been recovering from an acute infection and they might have had the same catch-up during recuperation with the traditional family diet as with nutritional support. Ideally, of course, treated children should be compared with controls who did not receive treatment. A study with pair-matched controls by Beghin et al. (11) did show a greater weight gain in treated children. However, the sample size was quite

all and the 4 month follow-up did not render any conclusion on the effectiveness of rehabilitation to prevent relapses. More recently, a study of randomly selected children in Saint Lucia who received no nutritional treatment after the initiation of rehabilitation showed that intensive feeding had no long term effect on the nutritional status of malnourished children (12). However, children admitted in this study were selected if their weight for age was below 75% of standard which means that its results cannot be considered as relevant for Bangladesh where children below 30% weight for age are frequently admitted for nutritional rehabilitation.

Even if most positive results obtained from previous studies are real and observed increased weight gains were due only to nutritional treatment, the relevance of these findings is still open to question: recent reviews raise the issue of the significance of the observed weight gains which in the long term are usually minor, even if statistically highly significant (13). Since these nutritional rehabilitation units are comparatively expensive to run, it is important to know if they have other advantages for the child than an observed weight closer to the international standards whose relevance is periodically questioned (14). Unfortunately, no significant functional benefit such as a reduced mortality has ever been clearly shown. The negative findings of supplementation studies on large segments of the population can be explained by an inappropriate sample selection. If supplemented children were initially moderately malnourished and had a low risk of death by malnutrition, the effect of a nutritional intervention may be minor and remain unnoticed. The nutritional rehabilitation units which usually treat a limited number of children receive the most severely malnourished children of the community. Their impact on mortality is likely to be more pronounced. Unfortunately, none of the studies done before to evaluate the impact of these units have ever attempted to measure their effect on mortality. In any event, none followed-up a treatment and a comparison cohort of a sample size large enough to ascertain the detection of such an effect.

After treatment for acute diarrhoea in Dhaka hospital a small proportion of children, selected among the most malnourished, stay a few days to a few weeks in a NRU where they receive a high energy diet. Mothers receive practical training in nutrition and hygiene and information about family planning; and they are taken to a nearby clinic to have their children immunized. However, as a result of shortage of space and lack of staff to assist the mothers who have family problems and thus cannot proceed with their children to the NRU after treatment for diarrhoea, it can be roughly estimated that now, only one severely malnourished child out of four or five visits the NRU. ICDDR,B's Dhaka hospital receives a large number of very severely malnourished children who, one may assume, have a high risk of death if they return to their environment without nutritional treatment. This provides an unique opportunity to assess the effectiveness of nutritional rehabilitation to reduce the risk of death. The group of children going home before nutritional

habilitation can be used for comparison with those who stay in the feeding unit.

Rationale:

The cost-effectiveness of a NRU in a developing country has never been adequately undertaken as relevant economic concepts and techniques have not been utilized in similar studies (6-12).

The impact of nutritional rehabilitation on mortality has never been tested on a large sample of malnourished children.

It is important to know whether such an impact is present. The relevance of NRUs has been criticized on the ground that no other benefit other than a moderately higher weight gain of treated children with an unknown functional consequence has ever been reported.

Specific aims:

To follow-up a cohort of severely malnourished children, who receive intensive feeding and whose mothers receive practical training in nutrition before returning home, with a cohort of matched controls who leave the hospital just after treatment of their acute diarrhoea.

In undertaking cost-effectiveness analysis, to calculate or estimate net costs (direct plus indirect costs minus indirect savings) of averting deaths through nutrition intervention (15).

To determine life tables and to test whether there are significant differences between the treated and control groups.

Methods of procedure.

Selection of patients

Children referred to the NRU with an arm circumference below 200mm in the age group 6-60 months will be included in the study if the parent/guardian of each child accepts to stay for at least 5 days. Arm circumference has been chosen as an indicator of malnutrition in preference to weight for age since it is likely to be a better predictor of death (16). However, weight and height information will also be taken routinely.

Selection of controls

The group of treated children will be compared with another group of children leaving the hospital just after treatment for diarrhoea. Since these two groups of children will not be randomly selected, every treated child will have to be compared to a control matched for the variables which are likely to affect long term growth or survival: the control and the treated

children should be of the same sex, age (adjusted to the nearest three months), have a similar arm circumference (the greatest accepted difference will be 5mm) and they should come from the poorest families (monthly family income lower than Tks 1250 per month). Other variables which may influence long term progress but may prove difficult to match such as the death of an older sibling, the marital status of the mother, presence of latrines in the house, distance from a clean source of water will be nevertheless monitored (see attached questionnaire).

3. Follow-up.

When a child and mother voluntarily leave the NRU (they are free to leave the NRU at any time though we encourage them to stay for as long as possible) a community nurse will invite them to return to the clinic each month on a fixed calendar day for a reunion. Each reunion will offer an opportunity to monitor the nutritional progress of children who have returned to their home after treatment and to monitor other relevant information (eg: morbidity data, cost associated with other community interventions, changes in socio-economic status). The reunions will be designed following the model described by Cutting in South India (17). Several incentives will be offered to ensure a high rate of participation in the reunions. At each reunion, a large meal will be offered to the mother and child. Compensation for transportation expenses and for loss of a day's wages will be given to each mother. Children will be immunized at a nearby clinic and prizes will be given to mothers in recognition of progress in the child. Informal education will again be offered to reinforce the training which was initially given in the NRU.

A health worker will visit those families that do not, or are unable to, attend the reunions and extend to them the same services and obtain the same set of information as is expected to be received from those who do attend the reunions. In this manner, reliable data on nutritional status, mortality, morbidity, socioeconomic status and cost will be maintained for the treatment group.

Children from the control group will be followed-up by the same procedure. They will receive measles immunisation and the first dose of DPT before leaving the hospital. Health workers will be recruited to follow-up the children through home-visits and to extend the same services and to gather parallel information as that obtained from treated children.

4. Costs.

There are two types of costs that will be measured or estimated - direct and indirect. Direct costs are simply costs directly linked to the operation of the NRU, such as, wages and salaries, rent and utilities, food, supplies and services. These costs will be obtained largely from accounting records available from ICDDR,B's Finance and Administration division. Indirect costs, which are costs incurred by the patient and his family, will have to be estimated using information contained in questionnaires (see Chart 4). Indirect costs include expenses for

transportation and time lost from work by members of the family (usually only the mother) due to illness of the child. In addition, medical expenses incurred after release from the NRU (in the case of the control group, after release from Dhaka Hospital) will also be monitored, again using the questionnaires. In the latter case are included expenses for visits to other clinics or hospitals, such as cost of drugs, medical fees, transportation costs of the trip to a clinic or hospital. These costs are related to treatment sought or measures taken by the family to avert death or sickness of a child, hence they must be included in this study.

The formula for measurement or estimation of cost effectiveness is:
Cost Effectiveness (CE) = Net Costs (C) / Effectiveness (E),
the numerator and denominator being defined as follows:

Net Costs (C) = C(d) + C(R/HV) + C(IF) - S(TGF) where:

C(d) = All direct costs associated with treating children at the U. This includes salaries and wages (physician's and nurse's fee), cost of medicines, utilities, food and other supplies and services.

C(R/HV) = Direct costs of reunions (as indirect costs are negligible here - eg. time lost from work to attend the reunion) and/or costs of follow-up at home (as similar services, with the sole exception of food, are offered at home as at reunions).

C(IF) = Indirect costs to the child's family during the follow-up period. This component measures the impact of other health interventions (eg. visit to a clinic or hospital for treatment of child's illness). Again, costs for medicines, medical fees, etc. are monitored.

S(TGF) = Savings to the treatment group during the follow-up period. These are estimated to be the same as the difference in costs between C(IF) for the control group minus the C(IF) for the treated group.

Cost calculations will be eventually made on a constant currency basis - example: if we use constant 1985 ^{takas} figures for 1986-87, all will be deflated using CPI data; if, instead, we use constant 1987 takas, figures for 1985-86 will be inflated appropriately, again using the CPI.

Effectiveness (E) = number of deaths averted by the program.

A discussion on opportunity cost will also be offered. Opportunity cost is the value of the alternatives or other opportunities which have to be foregone in order to support the NRU. Thus, this definition of cost differs from direct costs or outlays as it includes the value of alternative uses of resources. Opportunity cost of direct expenses is included in the discounting process. However, since there are no future costs of any significance involved in this study, discounting and sensitivity analysis will not be necessary. Consideration of opportunity cost, in the form of a discussion item, would thus complement the consideration of direct and indirect costs.

In addition to estimation of cost-effectiveness as elaborated above, a useful and complementary way to express cost-effectiveness is to compute the cost per patient treated by the NRU. The costs involved in this measure are direct only but may serve us well in making comparisons with other interventions with an identical objective.

j. International Comparisons of Costs.

To facilitate comparisons with similar interventions undertaken internationally, the following tasks will be performed:

- (a) cost figures in takas will be converted to "constant takas" - e.g. 1985 takas - using the Consumer Price Index as an indicator of inflation;
- (b) conversion of takas to U.S. dollars will be done using both official and shadow exchange rates.

k. Sample size.

The number of children who have to be followed-up to obtain statistically significant results between treated and untreated children is shown in Table 1. Different hypotheses on the survival of untreated children and on the effect of treatment on survival are presented. The figures are somewhat arbitrary since there is hardly any data on the risk of death associated with different levels of nutritional status after discharge from the Dhaka hospital. Apparently, the largest follow-up study was done by the Urban Volunteer Program which traced 69 children in the community and found that 2 of them died in the four months following discharge (18). However, this sample is quite small to draw conclusions about the risk of death after treatment for diarrhoea. Moreover, while children under surveillance were selected from treatment centre, they did not have the same degree of malnutrition as children referred to the NRU. Another study done in ICDDR,B's Matlab hospital which followed-up 551 children found that 12 of them died in one month and 19 in 6 months after discharge from the hospital (6) and a survey in the community showed that 1-4 years children with an arm circumference below 100 mm had a 15% risk of death within 6 month (18). The mortality of treated malnourished children is also little known. Experience of Save the Children Fund at the Children's Nutrition Unit in Dhaka suggests that it is negligible. At the ICDDR,B's NRU, mortality is also very low during the first weeks following referral from the hospital when the post-diarrhoeal peak of deaths is supposed to be present. Hence hypothesis 3 from table 1 seems reasonable and one may assume that following-up 200 pairs of children should provide significant results. Also, analysing survival with a log rank test on the life table (19) may give significant results before this total sample size is reached. This suggest that following up every child who stayed in the NRU for more than 5 days and one matched control will give a sample big enough to test the hypothesis of a reduced mortality in

approximately 18 months, even when taking into account that a substantial number will move during the study and will be lost or follow-up.

Duration of follow-up

The study on post-diarrhoeal mortality of malnourished children in Matlab (6) showed that 50% of deaths in the year following admission to the hospital occurred in the first month and 70% in the first three months. After that initial peak, the rate of deaths was comparable to what was observed for other children of the same age group (18). The same pattern has been observed in Nepal (20). This suggests that even a short follow-up period should be suitable to determine if the nutritional rehabilitation unit has an effect on survival. However, as this study is of a comprehensive nature, follow-up for one year is seen as adequate. (The nature and frequency of follow-up are discussed in section 3 above).

Determination of cause of deaths during follow-up.

When a death occurs in the treatment or the comparison group during follow-up, an attempt will be made to determine its cause. If a death is clearly unrelated to the child's nutritional status, the case-comparison couple will be censored for statistical analysis. Accidental deaths which are frequent in this are an example of deaths which should not be taken into account. In addition, we have little information on the nature of diseases which kills malnourished children after hospital treatment for diarrhoea. A better knowledge of the possible cause of death is necessary to improve their prevention during follow-up. This will be done by a detailed interview after informed consent of the legal guardian (see questionnaire). To improve reliability of the diagnosis, the interview by the health worker who followed-up the child will be tape recorded and the possible cause of death will be discussed by two medical doctors after audition of the tape.

Statistical analysis, interpretation of results.

At the end of the study, life tables of treatment and comparison groups will be represented graphically. This method allows one to detect whether the risk of death is constant or whether, as shown previously in Matlab, it decreases rapidly with time. The numbers of children surviving at 6 and 12 months will then be compared by a chi-square test. If the results are not significant, a log rank test which is more adapted for analysis of survival will be done. To determine which factors in addition to treatment influenced the risk of death, a logistic regression with all potential predictors will be run. The matching of treated and comparison groups will be tested for any possible confounding variable which will be found to have an influence on

Survival. The effect of the duration of the treatment will also be assessed: treated children will be pooled in different categories of duration of treatment and the odds of surviving for these different groups will be compared by a logistic regression. The statistical analysis for this protocol will be carried out on an IBM-PC.

If no difference in mortality is found at the end of the study, a low difference in weight gain between the two groups will suggest that the NRU unit was ineffective in providing adequate training or support to the mothers. On the other hand, if there is no difference in mortality with a better weight gain in the treated group, this will raise questions on the relevance of this indicator to estimate the impact of a nutrition intervention on the health of children in the community.

Significance

Financial resources are the major factor limiting the delivery of health care in developing countries. There are several potential health interventions that can reduce infant and child mortality. In practice however, only cost-effective interventions are ultimately adopted or seen as appropriate. In this study, the estimation of the cost of every death averted through nutritional rehabilitation will provide a basis to rank this type of programme in the wide range of possible health interventions.

Table 1:

Estimation of the number of treatment-control pairs needed to be 95% certain to reach statistical significance at the 5% level ().

Expected deaths (%)	hyp 1	hyp2	hyp3	hyp4	hyp5
Control group	20	15	15	15	10
Treated group	10	10	7.5	5	5
Number of treatment control pairs	163	570	228	112	358

Chart 1: control and treated children
(at the beginning of the study).

Name of the child _____ Hosp. No: _____
Date of admission to the hospital ___/___/___ to NRU ___/___/___

Age ___ yrs. ___ mos; Arm circum. _____; Height _____; Weight: _____

Does the parent want the child to be treated at the NRU? [Y/N]
If no, why? (obtain specific info.: is it because he has another child at home? and/or for employment reasons? etc.) Reasons: 1. _____
2. _____
3. _____

Parent/guardian: Mother _____ Father _____ Other: _____

Name of the parent/guardian: _____

Name of most important person in your 'ghor': _____

Address _____

Name of 'para' or locality: _____

Name of para leader: _____

The most prominent landmark near your 'ghor' is _____

Marital status of the mother: married, divorced, second wife, single, widow, no mother

Birth order of the child: _____ Last born? [Y/N], Twin? [Y/N]

Children	sex	age	alive,	dead,	cause of death
1. _____	M, F	_____	[]	[]	_____
2. _____	M, F	_____	[]	[]	_____
3. _____	M, F	_____	[]	[]	_____
4. _____	M, F	_____	[]	[]	_____
5. _____	M, F	_____	[]	[]	_____
6. _____	M, F	_____	[]	[]	_____
7. _____	M, F	_____	[]	[]	_____
8. _____	M, F	_____	[]	[]	_____
9. _____	M, F	_____	[]	[]	_____

Attitude towards family planning:
Family planning [Y/N] Method employed: _____

DIETARY HISTORY

Never breast fed [] Still breast fed []
 Breast feeding stopped at _____ months
 Never bottle fed [] Still bottle fed []
 Bottle feeding stopped at _____ months

Does the child get any of these liquid foods ?

	Quantity; (per week/per day)	HMET/HMTPD	Plain?	diluted?	w/sugar?
Cow's milk	____/____/____/____	[]	[]	[]	[Y/N]
Goat's milk	____/____/____/____	[]	[]	[]	[Y/N]
Dry skim milk	____/____/____/____	[]	[]	[]	[Y/N]
Full cream milk	____/____/____/____	[]	[]	[]	[Y/N]
Rice water	____/____/____/____	[]	[]	[]	[Y/N]
Barley water	____/____/____/____	[]	[]	[]	[Y/N]

(Note: HMET=how much each time; HMTPD=how many times per day)

Does the child get any of these solid foods ?

	How many times a day?	How much each time?
Rice	_____	_____
Dhal	_____	_____
Shak Sobji	_____	_____
.....	_____	_____

MORBIDITY HISTORY:

Is there any history of [TB] [Diabetes] [] in the family?

History, number and frequency of illnesses/diseases of child:

(Note approx. date/age, type frequency)

Does the child have any symptoms suggestive of:

TB:

Chronic bronchites:

Juvenile diabetes:

Urinary tract infections:

Other (specify):

Summary of hospitalisation:

Admitted to ICDDR,B on: ___/___/_____

Initial weight: _____g

On admission:

No oedema [], feet oedema [], generalised oedema []

No dehydration [], moderate dehydration [], severe dehydration []

Weight after rehydration/loss of oedema: _____g

Brief history:

Vitamin A: on admission [], the day after [], 2 weeks later []

Hct: _____ Protein _____

Attendant accepted to transfer the child to the feeding unit [Y/N]

If refused, reasons? _____

Examination after discharge from ICDDR,B General Ward:

Weight: _____g Height: _____mm Arm circumference _____mm

No oedema [], feet oedema [], generalised oedema [].

Flaky paint dermatitis [Y/N]

Oral thrush [Y/N]

Angular stomatitis [Y/N]

Scabies [Y/N]

Eyes lesions: L: _____ R: _____

Liver: cm below costal margin: _____ Spleen _____

Observations:

Chart 2: Nutritional Rehabilitation

Examination after 1 week of feeding.

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm
 No oedema [], feet oedema [], generalised oedema [].
 Flaky paint dermatitis [Y/N]
 Oral thrush [Y/N]
 Angular stomatitis [Y/N]
 Scabies [Y/N]
 Eyes lesions: L: _____ R: _____

Liver: cm below costal margin: _____ Spleen _____

Observations:

Examination after 2 weeks of feeding.

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm
 No oedema [], feet oedema [], generalised oedema [].
 Flaky paint dermatitis [Y/N]
 Oral thrush [Y/N]
 Angular stomatitis [Y/N]
 Scabies [Y/N]
 Eyes lesions: L: _____ R: _____

Liver: cm below costal margin: _____ Spleen _____

Observations:

Examination after 3 weeks of feeding.

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm
 No oedema [], feet oedema [], generalised oedema [].
 Flaky paint dermatitis [Y/N]
 Oral thrush [Y/N]
 Angular stomatitis [Y/N]
 Scabies [Y/N]
 Eyes lesions: L: _____ R: _____

Liver: cm below costal margin: _____ Spleen _____

Observations:

Examination after 4 weeks of feeding.

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm

Observations:

Examination after 5 weeks of feeding.

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm

Observations:

Examination at discharge:

Date: ___/___/___

Weight: _____ g Height: _____ mm Arm circumference _____ mm

Observations:

Date of discharge from the NRU: ___/___/___

Immunisations:	Dates:
BCG	_____
Measles	_____
DT Polio	_____

Family planning: _____

Chart 3: first home visit

Name of the child _____ Hosp. No: _____

Name of the community Nurse _____

Date _____ Arm circumference at discharge _____ mm

Name of the attendant _____

Detailed address of the child _____

Name and detailed address of 'para leader' knowing the family: _____

Education of mother: _____

Education of father: _____

Earning members of the family:

	Profession	income/day	days/week
Father	_____	_____	_____
Mother	_____	_____	_____
.....	_____	_____	_____

Type of housing: paka [] , katcha [] , other: _____

Rented: [] owned: []

Number of rooms: _____ Total number of people living in the bari: _____

Tubewell at home [] , nearby [] : distance: _____ no tubewell []

Latrines at home [] , nearby [] , distance: _____ no latrines []

Electricity: [Y/N] Appliances: _____

Chart 4: Follow-up visits:

at home [], on a reunion []
 Name of the child _____ Hosp. No: _____
 Name of health worker: _____
 Date _____
 Any change in the family?: Maternal marital status ? New child?
 Work status? Housing? _____

 Child health: Has he been weaned? [Y/N] sick? [Y/N] How many times?
 type of illness: _____
 Has he been treated? [Y/N] Describe treatment _____

 Has he been referred to a medical facility [Y/N], which? _____
 Money spent for drugs: _____

 Money spent for transport: _____
 Money spent on traditional healers: _____ religious services _____
 Time off work: mother [] father [] other [] How much time _____

 Arm circumference _____ mm.

Chart 5: Additional dietary/nutritional questionnaire for 6th and 12th follow-up

Weight of the child _____g Height _____mm

Dietary recall: Is the child eating solid foods? [Y/N]

How many times a day?

Can the attendant describe in detail what the child ate yesterday? _____

Chart 6: Interview of parent/guardian of child who dies during follow-up

What was the exact age of the child: _____ years _____ months.

When did the child die? Where? at home [] in an hospital []?

Can the parent/guardian give a detailed account of the illness/disease and the treatments received by the child? _____ Tape record the answer _____

If the child did not die from an accident ask the following questions:
(Tape record the answers _____)

Did the child have a fever? For how long? Was it a (high; moderate; low) fever?

Did he have diarrhoea? ___; dysentery? ___; blood in the stool? ___; liquid diarrhoea? ___.

Any signs of dehydration? depressed eyes ___; thirst ___; infrequent urine ___;

Any vomiting? _____.

Did the mother attempt to give oral rehydration solution? _____.

Any convulsions? If yes, ask for details:

Did the child have difficulty breathing? ___ rapid breathing? _____

Did he cough? if yes, for how long at a time?

Did he vomit after coughing?

Any oedemas? If yes, for how long?

Was urine normal? Did the child cry when he passed urine?

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Effectiveness is described as net benefits or net effects of a health or social intervention; whereas, efficacy is the net of benefits and risks of an intervention. For examples and details, useful articles are:
Tier, Howard S. and Howard H. Hiatt. Evaluation of Medical Practices. In Health Care: Regulation, Economics, Ethics, Practice; edited by Abelson, P.H. Washington, D.C.: American Association of Advancement of Science, 1978.
Board DS, Thompson MS. First Principles of Cost-Effectiveness Analysis in Health. Public Health Reports, November-December 1979, pp.535-543.

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

This protocol aims at determining the cost-effectiveness of a nutrition intervention at ICDDR,B's Dhaka hospital. Two cohorts of children will be followed: namely, 200 children who stay at least five days in a Nutrition Rehabilitation Unit (NRU) along with 200 who leave the hospital after treatment for diarrhoea. All mothers of malnourished children will be free to choose to stay in the NRU for treatment and return home if they want at any time. The comparison group will be composed of children whose mothers are unable to stay in the NRU (reasons for which will be noted to ensure that there is no bias). All children will be in the 6-60 months age group as the prevalence rate for malnutrition is highest in this group. Moreover only children from the poorest families (defined as earning less than 1250 Takas per month) will be included in the study as it is assumed that this group has the highest risk of death after discharge.

This protocol's proposed research will not interfere with routine treatment of malnourished children at ICDDR,B's Dhaka hospital. It involves no risks to patients; however, it is conceivable that questions about family income and social situation of the family may be embarrassing for some families.

Non applicable.

The confidentiality of data collected will be maintained throughout the study and only hospital patient numbers will be used during analysis of data.

Informed consent will be obtained from the authorized legal guardian before a child is sent back home with a community nurse (see attached form). In the case of a child's death, a special interview will take place, after a second informed consent has been obtained, to try to determine cause-of-death.

In addition to some routine questions related to the history of illness and diet, this study requires interviews on socio-economic conditions of each family. These will take place in the child's household after an informed consent has been obtained and each such interview will last no more than fifteen minutes. In case of a child's death during the follow-up period, a separate interview on the history of the terminal illness will take place only after informed consent has been obtained. This interview will be tape recorded and will last less than twenty minutes.

Regular home visiting of malnourished children may lead to early detection of certain health problems and, in this regard, home visits will be potentially beneficial for the child. It is expected that the immunization rates for the treatment and comparison groups will increase as a result of our intervention.

*The study requires the use of hospital records. No organs, tissues or body fluids will be used.

ed consent form for follow-up.

(signed by the legal guardian before the child leaves the hospital)

Doctors at ICDDR,B would like to know more about the children who leave the hospital after treatment for diarrhoea. We would like to follow-up your child and send a health worker to your home to enquire about his health. If you agree, a health worker will accompany you to your home to facilitate the follow-up. She will ask you some questions about you and your family but if they are embarrassing to you, you are free not to answer them. You are free to withdraw from this study at any time and to ask for cessation of home visiting.

Signature/fingerprint of the guardian _____

Signature of the investigator _____

see consent for interview after a death during follow-up.

(signed by the legal guardian before interview)

Doctors who treated your child in ICDDR,B would like to know why the child died. This will help them to prevent deaths of other children. Although this may be painful for you, we would be grateful if you could give a detailed account of the illness or disease which led to your child's death. If you have no objections, we would like to tape record the interview to be sure not to miss important details. This tape will remain confidential and only the doctors who treated your child will listen to it. You are free to refuse this interview or stop it at any time.

Signature/fingerprint of the guardian _____

Signature of the investigator _____

Section III: Budget.

A: Detailed Budget:

1. Personnel and services:

Designation	1st. year: <u>1985-1986</u>	2nd. year: <u>1986-1987</u>
1 physician, nutritionist: (40% of time)	salary supported by the Government of France	
1 health economist: (40% of time)	salary supported by the Government of Canada	
4 health workers: (Tks 40 000 per year each)	160 000	185 600
1 Junior Physician: (Tks 40 000 p.a. = 30% of time)	40 000	46 400
1 Research Officer: (Tks 70 000 p.a.)	70 000	81 200
1 clerk/coder/secretary: (1/2 time; grade I sec'y.)	32 500	37 700
Computing Services:	25 600	29 696
Training of physicians:	25 600	29 696
2. Supplies and Material:		
Stationery, xeroxing, diskettes,	24 000	27 840
3. Travel and transportation		
a. health workers for follow-up and mothers for reunions	240 000	278 840
b. international travel	97 280	112 845
4. Library and publications	10 112	11 730
5. Consultants:	25 600	29 696
Total: Takas:	750 692	870 803
US \$:	29 324	34 016
Grand total US \$:	63 340 for 2 years.	

Budget summary for
(US \$)

Personnel and services
Supply and material:
Transport:
Library and publications
Consultants:

1 year:

13 816
938
13 175
395
1 000

2 years:

29 842
2 026
28 459
853
2 160

Total:

29 324

63 340

(Note: US\$ 1.00 = Takas 25.6)
(Inflation 16% per annum
is included in the above budget).
