[redacted] Attachment I

Date: 23 January 2000

(FACE SHEET) **ETHICAL REVIEW COMMITTEE, ICDDR,B.**

Principal Investigator: Prof. George J. Fuchs

Application No. 99--042

Title of Study: **Community-based protocolized management of severe malnutrition.**

Trainee Investigator (if any): _____

Supporting Agency (if Non-ICDDR,B) World Bank

Project Status: _____

[✓] New Study

[ ] Continuation with change

[ ] No change (do not fill out rest of the form)

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

1. Source of Population:
   - (a) Ill subjects } malnourished subjects — Yes / No
   - (b) Non-ill subjects } — Yes / No
   - (c) Minor or persons under guardianship — (Yes) / No

2. Does the Study Involve:
   - (a) Physical risk to the subjects — Yes / (No)
   - (b) Social risk — 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 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 the study — (Yes) / No
   - (b) Procedures to be followed including alternatives used — (Yes) / No
   - (c) Physical risk n.a. — Yes / No
   - (d) Sensitive questions n.a — 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 n.a. — Yes / No

5. Will Signed Consent Form be Required:
   - (a) From subjects n.a. — Yes / No
   - (b) From parents or guardian (if subjects are minor) — (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 with 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. Example 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

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

Principal Investigator

Trainee

International Centre for Diarrhoeal Disease Research, Bangladesh

RESEARCH PROTOCOL

FOR OFFICE USE ONLY
Protocol No: 99--042 Date:

PRC Approval: Yes/ No Date: 30.12.99
ERC Approval: Yes/No Date:

1. Title of Project (Do not exceed 60 characters including spaces and punctuation)
Community-based Protocolised Management of Severe Malnutrition

2a. Name of the Principal Investigator(s) (Last, Middle, First). Prof. George Fuchs
2b. Position / Title Director, CSD
2c. Qualifications M.D.

3. Name of the Division/ Branch / Programme of ICDDR, B under which the study will be carried out.
Clinical Sciences Division in collaboration with Public Health Sciences Division and Health and Population Extension Division

4. Contact Address of the Principal Investigator

4a. Office Location: ICDDR,B
Hospital Building
2nd floor

4b. Fax No: 988 5657
4c. E-mail: gfuchs@icddrb.org
4d. Phone/Ext: 988 2399 or Ext. 2300

5. Use of Human Subjects Yes [ ] No [x]

5a. Use of Live Animal Yes [ ] No [x]

5b. If Yes, Specify Animal Species

6. Dates of Proposed Period of Support
(Day, Month, Year - DD/MM/YY)
1 January 2000 to
30 September 2001

7. Cost Required for the Budget Period
7a. 1st Year *($)*: **138,394** *2nd Year ($)*: **118,872**
7 b. Direct Cost ($) **223,709** *Total Cost ($)* **257,266**

8. Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewer's comments and is approved.

George J. Fuchs — Name of the Division Director; Signature; 20/12/99 — Date of Approval

9. Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

10. Signature of PI

Date: 20/12/99

Table of Contents

[√] Check here if appendices are included

Principal Investigator: Last, first, middle — Fuchs, Prof. George J.

PROJECT SUMMARY: Describe in concise terms, the hypotheses, objectives, and the relevant background of the project. Describe concisely the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research. This summary must be understandable and interpretable when removed from the main application. **(TYPE TEXT WITHIN THE SPACE PROVIDED)**

Principal Investigator	Prof. George J. Fuchs			
Project Name	Community-based Protocolised Management of Severe Malnutrition			
Total Budget:	Beginning Date:	1 January 2000	Ending Date:	30 September 2001

Background: In urban Bangladesh, about sixteen percent of children age 6 to23 months have been found to be severely underweight (≤ -3 SD of NCHS reference population; BBS 1997), with another 30 percent being moderately underweight (≤ -2 to > -3 SD of NCHS reference; BBS 1997). In Dhaka urban slums, almost one child in four among children age 6 to 23 months is severely underweight (unpublished HKI surveillance data). In spite of the high prevalence of child malnutrition and its well-established contribution to child morbidity and mortality, only few of the existing primary health care clinics in Dhaka city seek to address child malnutrition as such (Operations Research Project 1999). Referral-level facilities for the management of severe child malnutrition are limited and expensive.

Objectives: The proposed protocol will strengthen capacities for the identification and management of severe child malnutrition among urban slum and low-income population at multiple levels. The Nutrition Unit of Dhaka Shishu Hospital will introduce protocolised management of severely malnourished children requiring hospitalisation. Staff of three urban primary health care clinics of an urban NGO (PSKP) will be trained to conduct nutritional assessments, refer severely malnourished children as needed or counsel caretakers on monitored home-based protocolised management, conduct growth monitoring and promotion in conjunction with weekly Satellite Clinics, and conduct quarterly outreach visits. Referral and discharge criteria and procedures to and from Dhaka Shishu Hospital, the three intervention PSKP clinics and homes will be well co-ordinated. Progress of children once identified as severely malnourished will be monitored until six months after improvement from severe to moderate malnutrition in terms of weight-by-age.

The protocol will test the following *hypotheses*:

1 Adoption of protocolised management of severe malnutrition by the Nutrition Unit of Dhaka Shishu Hospital, based on the ICDDR,B adaptation of the WHO protocol for management of severe malnutrition, will result in reduced case fatality, increased proportions with satisfactory weight gain, and lower rates of withdrawal among children hospitalised for severe malnutrition.

2 Severely malnourished children discharged to or referred for home-based protocolised management will achieve adequate rates of weight gain and will improve from severe to moderate malnutrition within an eight-week period.

3 Identification and referral of severely malnourished children from urban low-income areas for protocolised management at a hospital and/or in the home, complemented by community-level growth monitoring and promotion, will reduce the population-level prevalence of severe malnutrition in the Intervention Area as defined for the protocol.

Design and research methods: Hypotheses 1 and 3 will be tested by quasi-experimental designs. For the hospital-based component of the protocol (Hypothesis 1), outcomes for severely malnourished children after introduction of protocolised management will be compared with outcomes for children admitted one year ago. For hypothesis 3, outcomes will be evaluated by pre-and post-intervention household-level anthropometry in intervention and comparison clusters of households, but without randomised allocation. For Hypothesis 2, service statistics from PSKP Intervention Clinics as well as community-level investigations, will be used to monitor and assess outcomes.

KEY PERSONNEL (List names of all investigators including PI and their respective specialities)

Institutional Affiliation	Name	Professional Discipline/Speciality	Role in the Project
ICDDR,B	Dr. Tahmeed Ahmed	Paediatrics and nutrition	Co-Principal Investigator
	Dr. F. Anjuman Ara	Public health; training	Co-Investigator
	Dr. Abbas Bhuiya	Social sciences	Co-Investigator
	Dr. Lauren Blum	Medical/nutritional anthropology	Co-investigator
	Dr. Abdullah Brooks	Preventive medicine, paediatrics	Co-Investigator
	Prof. George J. Fuchs	Paediatric gastroenterology and nutrition	Principal Investigator
	Dr. Rukhsana Haider	Public health nutrition; breastfeeding promotion	Co-Investigator
	Dr. Iqbal Hossain	Paediatrics	Co-investigator
	Korshed Mozumder	Demography, surveillance systems	Co-Investigator
	Dr. Petra Osinski	Health systems research and management	Co-Principal Investigator
	Prof. Lars Åke Persson	Paediatrics; international public health; epidemiology	Co-investigator
	Dr. S. K. Roy	Clinical and public health nutrition	Co-Principal Investigator
Dhaka Shishu Hospital	Prof. Manzoor Hossain	Paediatrics	Co-Investigator
	Prof. Selim Shakur	Paediatrics	Co-Investigator
UFHP	Nutrition Specialist	Community nutrition	Co-Investigator
PSKP	Dr. Jerin Hyderi	Paediatrics	Co-Investigator
Radda MCH-FP Centre	Dr. Bushra Ameena	Program management	Co-investigator

DESCRIPTION OF THE RESEARCH PROJECT

Hypotheses to be tested:

Concisely list in order, in the space provided, the hypotheses to be tested and the Specific Aims of the proposed study. Provide the scientific basis of the hypotheses, critically examining the observations leading to the formulation of the hypotheses

1 Adoption of protocolised management of severe malnutrition by the Nutrition Unit of Dhaka Shishu Hospital, based on the ICDDR,B adaptation of the WHO protocol for management of severe malnutrition, will result in reduced case fatality, increased proportions with satisfactory weight gain, and lower rates of withdrawal among children hospitalised for severe malnutrition.

2 Severely malnourished children discharged to or referred for home-based protocolised management will achieve adequate rates of weight gain and will improve from severe to moderate malnutrition within an eight-week period.

3 Identification and referral of severely malnourished children from urban low-income urban areas for hospitalised and/or home-based protocolised management, complemented by growth monitoring and promotion, will reduce the population-level prevalence of severe malnutrition in the demarcated Intervention Area for the protocol.

The proposed protocol will build on ICDDR, B's experience with protocolised management of severe malnutrition among severely malnourished children hospitalised for diarrhoea and other associated acute illnesses at the Clinical Research and Services Centre of ICDDR,B (Ahmed et a. 1999) and on Ashworth and Khanum's experience with home-based management of severe child malnutrition (Ashworth and Khanum 1997). Dietary advice and other messages for home-based protocolised management of severely malnourished children will also be guided by recent experience among moderately malnourished children in communities served by the Bangladesh Integrated Nutrition Project, BINP (Roy et al. unpublished). Different from previous research, home-based protocolised management under the protocol will be supported and monitored by personnel of existing urban primary health care clinics. Clinic staff will, moreover, actively identify severely malnourished children through growth monitoring and promotion in conjunction with community-level weekly Satellite Clinics and through quarterly outreach visits to households in the Intervention Area for the protocol.

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions/rates/processes that will be assessed by specific methods (**TYPE WITHIN LIMITS**).

The specific aims of the proposal are:

1 To establish and test a replicable system for the active identification and appropriate referral and management of severely malnourished children from among urban low-income and slum populations by linking urban primary health care clinics with the Nutrition Unit of an urban referral hospital.

2 To establish within such a system improved capacities for the protocolised management of malnourished children requiring hospitalisation.

3 To extend, for malnourished children who do not require hospitalisation, protocolised management of severe malnutrition to the community level (primary health care clinics and homes).

Specific interventions introduced within this context will:

1 identify severely malnourished children through quarterly outreach visits, through enrolment of children under two in neighbourhood-based growth monitoring and promotion, and through routine nutritional assessments of all target-age children attending static clinics and Satellite Clinics;

2 provide a medical assessment and further nutritional assessment at a static clinic of severely malnourished children identified at the community level, followed by either outpatient management and referral for home-based protocolised management or by referral to hospital;

3 enable mothers or other caregivers to provide monitored home-based protocolised management to severely malnourished children who do not require hospitalisation;

4 ensure referral and access to protocolised hospital management to severely malnourished children who require hospitalisation, followed by discharge to monitored home-based protocolised management; and

5 track the further progress of children discharged from home-based protocolised management through their enrolment for monthly community-based growth monitoring and promotion at scheduled weekly Satellite Clinics.

Principal Investigator: Last, first, middle — Fuchs, Prof. George J.

Background of the Project including Preliminary Observations

Describe the relevant background of the proposed study. Discuss the previous related works on the subject by citing specific references. Describe logically how the present hypotheses are supported by the relevant background observations including any preliminary results that may be available. Critically analyse available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. Provide scientific validity of the hypotheses on the basis of background information. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the **significance and rationale** of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives. **(DO NOT EXCEED 5 PAGES, USE CONTINUATION SHEETS).**

The Dhaka metropolitan area, where the proposed protocol will be implemented, has an extensive network of primary health care clinics, most of them operated by NGOs. Many of these have recently broadened their services from an earlier concentration on family planning with some limited maternal and child health service to the provision of an essential services package with a strengthened focus on child survival interventions (Operations Research Project 1999). Existing primary care clinics are, however, not generally perceived as sources of nutrition services, nor are providers trained in the management of child malnutrition. This, together with the absence of systematic outreach to the community, has the consequence that severely malnourished children are usually only brought for treatment once they are also acutely ill and at high risk of dying.

ICDDR, B's Nutrition Rehabilitation Unit has achieved notable success with the acute-phase treatment and nutritional rehabilitation of severely malnourished children with diarrhoea (Ahmed et al. 1999), but costs of hospital-based rehabilitation are high and follow-up after discharge is difficult. Within the Dhaka metropolitan area as a whole, facilities for the initial management and nutritional rehabilitation are, moreover, extremely limited and are likely to remain so, given sectoral resource constraints. Against this background Ashworth and Khanum (1997) compared treatment options for severely malnourished children (< 60 percent W/H or oedematous) who were not critically ill, i. e., inpatient management at a Nutrition Rehabilitation Centre, day care at such a centre, and day-care-based initial treatment followed by home-based management. Among these three options, home-based management was found to be preferred by parents and was also the most cost-effective option, with mortality equally low in all three groups. A newly approved ICDDR,B protocol (Ahmed et al.) will now examine whether severely malnourished children (< 70 percent W/H or oedematous) and acutely ill children can receive protocolised nutritional rehabilitation at home after their clinical condition will have been stabilised.

The now proposed protocol will build on ICDDR, B's experience with protocolised in-patient management and Ashworth and Khanum's experience with home-based management of severe child malnutrition, but will differ from previous research on protocolised management of severe malnutrition in several respects:

1. The protocol will include weight-for-age (< -3 SD W/A) as one of the criteria for the community-level identification of severe malnutrition and will thereby identify and address a broader spectrum of severe child malnutrition than hospital or Nutrition Rehabilitation Centre-based approaches.
2. Children under home-based protocolised management will receive outpatient medical care from and be monitored by personnel of existing primary health care clinics, rather than specialised nutrition rehabilitation units.
3. The protocol will include active identification of severely malnourished children through community-based growth monitoring and promotion sessions and through outreach visits.
4. Identification and management of severe malnutrition as the focal intervention within the protocol will be complemented by breastfeeding promotion, growth monitoring and promotion and nutrition education so as to prevent development of severe malnutrition and help improve feeding and caring practices for moderately malnourished children.
5. The protocol includes a population-based controlled assessment of changes in nutrition status in an intervention and a comparison area. This will permit population-based assessments of coverage relative to community-level needs needs as well as comparisons with the planned piloting of community-based nutrition services under the Bangladesh Integrated Nutrition Project.

Research Design and Methods

Describe in detail the methods and procedures that will be used to accomplish the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project. **(DO NOT EXCEED TEN PAGES, USE CONTINUATION SHEETS).**

The objectives and specific aims of the protocol will be accomplished by implementing four major components:

1 Formative qualitative research for community-based protocolised management of severe malnutrition

2 Introduction of protocolised management at Dhaka Shishu Hospital

3 Integration of community-based protocolised management of severe malnutrition and other nutrition services into the child health services offered by initially one and thereafter two more static clinics run by an urban based Partner-NGO of the Urban Family Health Partnership under the USAID-financed National Integrated Population and Health Program (NIPHP) of Bangladesh

4 Impact evaluations of hospital and community-based protocolised management

Component 1: Formative qualitative research for community-based protocolised management of severe malnutrition (Dr. Abbas Bhuiya and Dr. Lauren Blum, PHSD)

The implementation schedule for the protocol foresees a four-month period of intensive formative research and piloting in only one PSKP clinic, involving six Satellite Clinic spots and six pilot Intervention Clusters.

Before starting the intervention at the PSKP facilities and at the community level, qualitative information on community perceptions about the PSKP clinics, and child nutrition and growth will be collected. This will be done through focus group discussions (FGDs) among mothers of children under two and key informant interviewing. Some selective participatory research techniques such as severity ranking of child malnutrition and mobility mapping for health seeking behaviour will be used. It is expected that one FGD and five key informant interviews will be conducted at each of the six pilot Satellite Clinic spots. .Data collected in this manner will be utilised to address perceptions and beliefs that could be barriers to the utilisation of PSKP clinics for nutrition services.

Home-based management of severe malnutrition will likewise be piloted at initially only one PSKP static clinic, e. g. through health education, counselling and outreach from six Satellite Clinics. During the pilot phase, there will be continuous participatory assessments of the feasibility and acceptability of recommended practices, including preparation, storage and feeding of the diet, breast-feeding, caring/stimulation, and infection prevention and management. For children under home-based management, this will include observations of children's actual intake. .With respect to children referred to the PSKP static clinic or to hospital, parents' willingness and ability to comply with recommended referrals and ability to pay related charges will be explored. Other potential constraints to be explored will include culturally conditioned feeding patterns, household resources and control over household resources, caregivers' knowledge, beliefs and education, time constraints, health and nutritional status of the caregiver, and emotional factors (WHO 1998). All recommended practices will be explored . Practices will be explored with a view towards potential barriers and constraints. Mothers and household decision-makers will likewise be consulted for their suggestions on where and by whom the agreed-upon diet would be prepared and when, where and by whom children would be fed, e.g., by individual mothers, other family members, by rotation within the neighbourhood, or by some other neighbourhood-level arrangement. Participatory assessments will be conducted through experience sharing meetings with participating mothers.

Time frame: Formative qualitative research as described above will be conducted over a five-month period (February-June 2000). Guided by findings, interventions will then be scaled up from one pilot clinic to a total of three PSKP Intervention Clinics for a full-scale trial, July 2000 to June 2001

Component 2: Protocolised Management of Severely Malnourished Children Admitted at Dhaka Shishu Hospital (Dr. Tahmeed Ahmed and Dr. Iqbal Hossain, CSD)

Acute-phase treatment and subsequent nutritional rehabilitation of severely malnourished children referred to hospital will be based on ICDDR, B's tested adaptation of the WHO protocol for management of severe malnutrition (WHO 1999; Ahmed et al. 1999). The ICDDR,B protocol has been developed on the basis of universally accepted principles of pathophysiology and treatment requirements of severely malnourished children. The WHO protocol for the management of severe malnutrition is based on the same principles and is, therefore, conceptually identical to that of ICDDR,B. Certain other differences basically reflect population characteristics of Bangladesh, e.g. a higher prevalence of dehydrating diarrhoea, as well as logistic issues, i.e., non-availability of vitamin-mineral mix, etc.

In view of the risk of fluid overload in children with kwashiorkor during the first few days of treatment, the volume of feeds to be given in kwashiorkor has been reduced in the ICDDR,B protocol. WHO recommends a low-sodium oral rehydration solution while the ICDDR,B protocol uses the standard WHO-ORS. While a low-sodium oral rehydration solution is expected to be superior to standard ORS in malnourished children, particularly those with kwashiorkor, documentation of a clear advantage is sparse. The efficacy of low-sodium ORS with increased

concentration of potassium and glucose in the management of severely malnourished children with diarrhoea is currently being assessed at the Clinical Services and Research Centre of ICDDR,B.

Training in the ICDDR,B protocol of about forty medical and paramedical personnel from Shishu Hospital will have been completed by the end of January 2000.

Time frame: Introduction of the ICDDR,B protocol for use at Shishu Hospital is expected to be completed by the end of February 2000. Outcomes for the protocol group would therefore be monitored and evaluated from March 2000.

Component 3: Community-based Protocolised Management of Severely Malnourished Children (Dr. Petra Osinski, Dr. S. K. Roy and Dr. Rukhsana Haider, and UFHP Nutrition Specialist)

Community-based protocolised management of severely malnourished children will mean a continuum of community, clinic and home-based interventions for the rehabilitation of severely malnourished children while seeking to prevent hospitalisation if possible. The target age group for the interventions will be children age 6 to 23 months, which is the age group of highest nutritional vulnerability and also the target age group for BINP and the forthcoming (Bangladesh) National Nutrition Program (NNP).

The community-based interventions under the protocol will be implemented by three out of five PSKP clinics in the Dhaka Metropolitan area, with the remaining two such clinics serving as comparisons. A description of the location of the clinics, with their catchment areas and staffing is given in the attached Schedule 1.

The Intervention Area for the community-based interventions under the protocol will consist of 36 clusters of about 120 contiguous household ("Intervention Clusters"). For each of the three PSKP Intervention Clinics, twelve Intervention Clusters will be demarcated in the vicinity oft twelve Satellite Clinic spots that are visited on a weekly basis by the three Satellite Clinic teams from each clinic. Within each of the areas, six of the clusters will consist of slum households and six of non-slum households. Based on BBS nutrition survey results in urban Bangladesh (BBS 1997), it is expected that only every fifth or sixth urban household will contain a child in the target age group (6 to 23 months). It is thus expected that each of the clusters would contain about 20 to 22 children in the target age group.

Community-based interventions under the protocol will consist of

1 Clinic and outreach-based identification of severely malnourished children

2 Referral to hospital of severely malnourished children requiring hospitalisation

3 Outpatient care and nutritional counselling for severely malnourished children who do not require hospitalisation

4 Home-based dietary management of severely malnourished children who do not require hospitalisation, complemented by multi-micronutrient supplementation and deworming

5 Education of mothers and other caretakers on caring practices and infection prevention and control for severely malnourished children under home-based management

6 Scheduled follow-up contacts with and/or home visits to severely malnourished children under home-based management who live within a 2 km radius of PSKP Intervention Clinics or their Satellite Clinics

7 Identification and special attention (e.g., clinical check-ups and in-depth counselling) of severely malnourished children under home-based management who fail to recover satisfactorily or relapse to severe malnutrition

8 "Tracking", monitoring and recording of outcomes (recovery without or with relapse, moved out of area, loss to follow-up or death) for all target-age children identified as severely malnourished

9 Conduct of growth monitoring and promotion session in conjunction with weekly Satellite Clinics

10 Community-based group health education on infant and child feeding and caring practices, including breastfeeding.

Schedule 2 shows the foreseen responsibilities of PSKP personnel for tasks to be performed under the protocol. Entry points for identification, and subsequent referral and or community-based protocolised management of severely malnourished children are shown in Figure 1.

Clinic and outreach-based identification of severely malnourished children will take place at initially one and later all three PSKP Intervention Clinics participating in the protocol. Entry points for the identification of severely malnourished children will be nutrition status assessments of target-age children in conjunction with self-referred visits to static clinics and Satellite Clinics, growth monitoring and promotion (GMP) sessions for target-age children held in conjunction with weekly Satellite Clinics, and quarterly outreach visits to households in the vicinity of Satellite Clinics. Identification criteria for "severe malnutrition" will differ according to entry points. During quarterly outreach visits and at Satellite Clinics, PSKP personnel will, in the first instance, apply IMCI nutritional criteria for urgent referral to hospital (visible severe wasting or bi-pedal oedema). During their outreach visits to homes, PSKP personnel will, after identifying children requiring urgent referral to hospital, invite all other children age 6 to 23 months to the weighing session at a nearby Satellite Clinic held that day. Satellite Clinics will *not* be equipped with length boards. Nutritional assessments at Satellite Clinic will, therefore, be conducted on the basis of weight-for-age, which will also be consistent with the practice under BINP and the forthcoming National Nutrition Program. Identification of "severe malnutrition" at Satellite Clinics will, however, be based on < - 3 SD weight-for-age as per WHO-recommendation, rather than on ≤ 60 percent weight-for-age as per current BINP practice.

Referral to hospital of severely malnourished children will based on a composite of criteria. Children identified at the outreach level as as visibly severely wasted or oedematous will be referred to the nearest-by PSKP static clinic and will receive same-day referral to hospital from there if the initial nutrition status assessment is validated. Children identified at a Satellite Clinic as severely malnourished by weight for age (< -3 SD weight-for-age) will likewise be referred to the nearest PSKP static clinic for a nutritional assessment by weight-for-length and a medical assessment. Children confirmed as oedematous *or* found to be severely wasted (< -3 SD weight-for length, i.e., about < 70 percent weight-for-length) *or* severely malnourished by weight-for-age (< -3 SD weight-for-age) *and* acutely ill or with other complication will then be referred to hospital, while the others will be referred to home-based protocolised management.[1] (see Figure 2).

Mothers or other caretakers for the child will, if desired, be accompanied to hospital by a PSKP Service Promoter. Transport expenses will, if necessary, be paid from a Welfare Fund established at PSKP Intervention Clinics for the purpose.

Outpatient medical care and nutritional counselling for severely malnourished children who do not require hospitalisation--Based on available national-level data for urban Bangladesh (BBS 1997) it is expected that about one third of children age 6 to 23 months as severely malnourished by weight-for-age would require hospitalisation because of severe wasting, while the others would receive outpatient care for any medical condition detected during the medical assessment, followed by intensive nutritional counselling by a dedicated Nutrition Counsellor. Nutritional counselling will comprise dietary advice, including breastfeeding promotion, as well as recommendations on caring practices and infection prevention and management. The PKSP Nutrition Counsellor will, in addition, seek to identify and advise on the reasons that caused the child's malnutrition in the first instance.

Home-based dietary management of severely malnourished children who do not require hospitalisation, complemented by multi-micronutrient supplementation and deworming.—Severely malnourished children (< -3 SD weight-for-age) who are neither severely wasted (<-3 SD weight-for-length) nor acutely ill will enter home-based protocolised management directly; initially hospitalised children will enter home-based management upon discharge from nutritional rehabilitation upon having attained ≥ 80 percent weight-for-length. Dietary and feeding advice for severely malnourished children under home-based management will be based on the existing experience with home-preparation of khichuri as advised by ICDDR,B's Nutrition Rehabilitation Unit (ICDDR,B 1999) and related community-level experience with moderately malnourished children in BINP communities (Roy, Fuchs, Mahmood, and Sharmeem 1999). To achieve an intake of at least 200 kcal per kg per day (inclusive of any intake from breastmilk) mothers will be advised to feed one measuring cup of khichuri (containing 190 kcal) per kg of the child's weight per day, divided into five or six feedings and complemented by breastfeeding "as often as possible day and night", i.e., about eight to ten times in a 24-hour period.

Home-based dietary management under the protocol will, for the main part, rely on education and the mobilisation of household-available resources. Household ability to command the time and money and/or ingredients for the recommended dietary regimen will be explored in depth during the four-month period of formative qualitative research (see Component 1). However, since supplementation of severely malnourished children it is a policy under GOB's ongoing Bangladesh Integrated Nutrition Project, a locally produced BINP-type supplement providing 600 kcal per day will be supplied to severely malnourished children under home-based protocolised management within the catchment area of one of the three PSKP Intervention Clinics.

Micronutrient supplementation of severely malnourished children under home-based management provide for vitamin-A supplementation and for supplementation with multivitamin drops and iron tablets.--If there is no xerophthalmia, infants 6 to 12 months will receive 100,000 U of vitamin A; children age one year and older will receive 200,000 U as a single dose; both age groups will thereafter follow a six-monthly supplementation schedule. Children with xerophthalmia will complete a therapeutic vitamin-A regimen. In the home, children will receive a once-daily dose of commercially available multivitamin drops containing per 1 ml vitamin A (as palmitate) 5,000 U, vitamin D 1,000 IU, thiamine hydrochloride 1.6 mg, riboflavin 1 mg, pyridoxine hydrochloride 1 mg, nicotinamide 10 mg, calcium D-panthothenate 5 mg, and ascorbic acid 50 mg. Children below the age of one will receive 1 ml once daily; children age one and older will receive 2 ml once daily. Children will, moreover,receive iron supplementation for the full duration of home-based protocolised management at a dose of about 3 mg of elemental iron per kg/day, given once daily between meals. Children weighing 4 to 6 kg will receive one-fourth of a commercially available iron tablet per day; children > 6 kg will receive half a table per day.

Severely malnourished children under home-based management age 12 months and older would, in addition, be placed on a six-monthly deworming regimen (single dose of Albendazole) which will be started upon the completion of acute-phase treatment or the start of home-based protocolised management and repeated thereafter at the six-monthly intervals until termination of follow-up.

Child malnutrition is now understood as resulting from the interaction of inadequate dietary intake and poor health status. Dietary advice, multi-micronutrient supplementation and deworming of severely malnourished children under home-based protocolised management will therefore be complemented by *education of mothers and other caretakers on caring practices and infection prevention and control*, including the importance of child immunisations, hygienic behaviours, and prompt seeking of care for signs and symptoms of infectious diseases.

PSKP personnel (Nutrition Counsellor and/or Service Promoters) will make *scheduled follow-up visits to homes of severely malnourished children under home-based protocolised management who live within a 2 km radius of PSKP Intervention Clinics or their Satellite Clinics*. This will include an initial visit by a dedicated Nutrition Counsellor for an in-depth familiarisation with household conditions. Follow-up visits will be continued until the child improves from severe to moderate malnutrition (≥ - 3 SD weight-for-age), i.e. for an expected duration of about eight weeks. Follow-up visits will be made weekly for the first four weeks and thereafter fortnightly. As weight gains cannot be assessed in the

[1] Medical criteria for admission to hospital applied by PSKP clinics will be the same as the ones applied for admission to hospital. However, because of the more limited diagnostic competencies of PSKP primary-care physicians it could only be determineduring training whether these criteria need to be modified.

home. follow-up contacts (except for the very first visit) would normally take place at a scheduled weekly Satellite Clinic, with home visits only being made to parents or caretakers who default on a scheduled follow-up contact.

Severely malnourished children under home-based management who fail to gain adequate weight between three contacts (i.e., over a two week or four-week period) *or to lapse to severe malnutrition* will be identified for *special attention*. This will include in-depth counselling and an invitation to the PSKP static clinic for a clinical check-up.

"Tracking", monitoring and recording of outcomes (recovery without or with relapse, moved out of area loss to follow-up or death). All target-age children ever identified as severely malnourished by PSKP personnel in the course of the protocol will be *"tracked"* by a relational record-keeping system that will be established for the protocol. Records for this purpose will consist of (i) the child's growth chart which will be held by the mother or other caretaker, (ii) referral and discharge information for severely malnourished children referred to hospital, (iii) a clinic-held record for the child with information on the child (age, immunisation status etc.), weights and lengths and corresponding anthropometric indicators with dates, medical findings, special advice and recommendations to the mother or caretaker, and outcomes, i.e., recovery without or with relapse, moved out of area loss to follow-up or death; and (iv) household and child information from the worker-held register established for quarterly outreach visits. For severely malnourished children from households in the Intervention Clusters of households, these data will normally be complemented by (v) data from the household-level baseline and follow-up survey on child anthropometry. Data for one and the same child will, in all instances, be linked by a unique Child Identification Number.

Conduct of growth monitoring and promotion sessions in conjunction with weekly Satellite Clinics. Child weighing for the protocol will, in most instances, be done at one of the scheduled weekly Satellite Clinics. Severely malnourished children under home-based protocolised management will, as mentioned, be invited to Satellite Clinics for their weekly or fortnightly follow-up contacts. PSKP personnel will, however seek to enrol *all* target-age children from the Intervention Clusters for monthly Growth Monitoring and Promotion (GMP). GMP will, particularly for moderately malnourished children, go together with nutrition counselling and group health education on caring practices. GMP will thus serve both as an entry point for the identification of severe malnutrition and as a means for its prevention.

Community-based group health education on infant and child feeding and caring practices, including breastfeeding.—In addition to individual counselling of mothers or other caretakers of severely malnourished children, PSKP Service Promoters and Paramedics will also be conducting community-level group health education sessions on infant and child nutrition. PSKP personnel will be trained and supported to conduct about five different sessions, covering, e.g., (i) complementary feeding, (ii) breastfeeding, (iii) rationale for specific foods, (iv) child caring practices (attention stimulation, washing/bathing; response to signs of illness), (v) and nutritional importance of immunisation, vitamin-A supplementation and child spacing.)

PSKP service providers will be trained for the performance of the above-mentioned tasks through competency-oriented training which will be planned and conducted in collaboration with ICDDR,B's Training and Education Department.(Please see Schedule 2 for an overview of tasks for which PSKP service providers will be trained.) Training will be held in the second half of January 2000, to permit trial implementation of the community-based interventions in the catchment area of one pilot PSKP clinic from February 2000.

The timeframe for the planned parallel implementation of the hospital-based and the community-based components of the protocol, and of the formative qualitative research is shown in Figure 3.

Component F: Impact Evaluations (Principal Investigator and Co-Principal Investigators in collaboration with Dr. Abdullah Brooks, Mr. Korshed Mozumder and Dr. Iqbal Hossain)

The protocol will test the following *hypotheses*.

1. At the Referral Hospital Level (Observations from hospital records).-- Transfer of the ICDDR,B case management protocol for severely malnourished children for implementation at an urban paediatric referral hospital will result in reduced case-fatality, increased proportions with satisfactory weight gain, and lower rates of withdrawal among severely malnourished hospitalised children.

2. At the Community-level (Observations from service statistics and field research) --Severely malnourished children discharged to or referred for home-based protocolised management will achieve adequate rates of weight gain and will graduate from severe malnutrition within an eight-week period.

3. At the Population Level (Observations from household-level baseline and follow-up survey of children under two in Intervention and Comparison clusters of households).-- Identification and referral of severely malnourished children from urban low-income areas for protocolised management at a hospital and/or in the home, complemented by community-level growth monitoring and promotion, will reduce the population-level prevalence of severe malnutrition in the Intervention Area as defined for the protocol.

Hypotheses at the referral-hospital level and at the population level will be tested by quasi-experimental designs. For the hospital-based component of the study, outcomes for severely malnourished children after introduction of protocolised management will be compared with outcomes for children admitted earlier. At the population level, outcomes of the intervention will be evaluated by pre-and post intervention child anthropometry in Intervention and Comparison clusters of households, but without randomised allocation. At the community-level, PSKP service statistics backed up by field-level investigations will be used to describe the outcomes of protocolised home-based management.

At the Referral Hospital Level: Severely malnourished children below 5 years of age admitted to Shishu Hospital's Nutrition Unit from March 2000 with weight-for-length -3 SD or oedema will receive protocolised management and will form the protocol group. Children admitted to the same unit by the same criteria in 1999, i.e., before the introduction of the protocol, will form the comparison group. Differences in case fa-

tality, outcomes of treatment and withdrawal rates etc. will be examined by tests for significant differences in proportions.—Recruitment of children into the protocol group would continue until 200 children would be in the study. The comparison group would be children admitted during the corresponding time period in 1999.

At the Community-level: Observations at this level will be children 6 to 23 months of age who were identified as severely malnourished (< -3 SD weight-for-age) through outreach visits or nutrition status assessments by Intervention Clinic personnel and enrolled for or discharged from hospital to home-based management. Available service statistics for these children will be examined to describe: (i) proportions of such children whose caretakers agreed to undertake home-based management, (ii) proportions of such children completing eight or more weeks of home-based management vs. proportions of children who were withdrawn ; (iii) proportions of children improving to weight-for-age ≥ - 3 SD W/A, (vi) observed rates of weight gain and duration of protocolised management until children improve to ≤ 80 percent weight-for-age; (v) proportions of children who relapse to weight-for-age < - 3 SD, after having "graduated" from home-based management with weight for age ≥ - 3 SD; (vi) proportions of children at ≥ 90% weight-for-length at six-month follow-up after initial identification as severely malnourished; (vii) proportions of children lost to monitoring and/or follow-up and (viii) proportions of children surviving until six months after completion of nutritional rehabilitation vs. proportions of children who died. *As the proposed protocol will be implemented through the already existing PSKP clinic personnel, with only one Nutrition Counsellor added per clinic, scheduled follow-up of children under protocolised home-based management will initially only be possible for severely malnourished children from the defined Intervention Area for the protocol within the (much larger) catchment areas of the three PSKP Intervention Clinics.*

With an initial prevalence of severe malnutrition (< - 3 SD W/A) of about 15 percent in the non-slum Intervention Clusters and of close to 25 percent in the slum Intervention, observations from the Intervention Area will initially consist of about 150 severely malnourished children who would be identified and brought under management from the start of the intervention.[2]

Estimated Numbers of Severely Malnourished Children Age 6 to 23 Month in the Intervention Area			
	Intervention Cluster	4 Intervention Clusters served by one SP	36 Intervention Clusters of the Intervention Area
Households in Intervention Cluster(s)	120	480	4,320
Target-age children (6 to 23 months) in Intervention Clusters	20-22 estim.	80-88 estim	720-792
Severely malnour (< -3 SD W/A) target-age children if prevalence remained constant at 20 percent	4	16-18	144-158

Thereafter, the additional numbers of severely malnourished children *newly brought under the intervention* would be much smaller (incidence, rather than prevalence), but are difficult to predict. Numbers of children brought under the intervention will, moreover, be reduced if coverage and compliance were—as is to be expected—less than 100 percent.

At the Population Level: Observations at this level will be children age 6 to 23 months of age in the demarcated Intervention Clusters in the catchment area of the three PSKP Intervention Clinics and in the Comparison Clusters in the catchment area of the remaining two PSKP clinics. A baseline and post-intervention household-level survey will be done to obtain child anthropometry (sex, exact ages, weights and lengths) of target-age children in the Intervention and Comparison Clusters before the start of the intervention and after 12 months. To control for possible confounders, selection of households for both the Intervention and the Comparison Area will be stratified to consist of about even numbers of slum and non-slum households. Criteria for differentiating between slum and non-slum settlements will be based on physical characteristics applied in previous ICDDR,B research, with emphasis on (i) predominantly poor housing, (ii) very high housing density, and (iii) poor sewerage and drainage facility (Thwin and Jahan 1996).

Survey data will be analysed to test for (i)statistically significant differences in key background characteristics between households in Intervention and Comparison Clusters and for (ii) significant differences in proportions of severely malnourished children (< - 3 SD weight-for age) between the pre-and post-intervention surveys (over and above the observed trend in the Comparison Clusters).

The size of the Intervention Area and Comparison area will be chosen so as to satisfy the following sample size parameters:

Difference in proportions to be detected: 10 percent (e.g., reduction of severe malnutrition in children under two from p_1= 20 percent to p_2 = 10 percent

Desired level of significance: 5 percent

Desired power: 90 percent.

Sample size per group:

$$\frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2} (z_\alpha + z_\beta)^2 =$$

$$\frac{0.20 \times 0.80 + 0.10 \times 0.90}{(0.20 - 0.10)^2} (1.96 + 1.28)^2 = 262$$

[2] At initial prevalence levels of severe malnutrition, each PSKP Service Promoter would be responsible for weekly and thereafter fortnightly contacts with an initial caseload of 16-18 severely malnourished children under home-based management, be it through homevisits or contacts at Satellite Clinics. The prevalence of severe malnutrition and hence caseload is, however, expected to decrease in the course of the intervention

In the Intervention Area, the required number of observations will come from the 36 clusters of 120 households that will be visited by PSKP Service Promoters during their quarterly outreach visits. In the Comparison Area, 24 clusters of households will be demarcated to contain a total of 300 children age 6 to 23 months, i.e., 12 to 13 children on average:

	Expected Numbers of Children Age 6 to 23 Months in the Demarcated Intervention and Comparison Areas by Type of Household Location					
	Intervention Area			Comparison Area		Urban BINP Comparison Area
	Clinic 1: Intervention (Mirpur Pilot)	Clinic 2: Intervention	Clinic 3: Intervention plus BINP Supplement	Clinic 4: Comparison Area 1	Clinic 5: Comparison Area 2	
Slum locations (6 clusters per clinic)	≈ 120-132	≈ 120-132	≈ 120-132	150	150	?
Non-slum locations (6 clusters per clinic)	≈ 120-132	≈ 120-132	≈ 120-132	150	150	?

The proposed design will thus permit to test for differences between the Intervention and Comparison Areas with a considerable margin for non-response due to e.g. household mobility and refusals. The stratified design would, moreover, allow for *separate comparisons of pre- and post intervention differences within slum vs. non-slum clusters of households.*

Tests for differences in proportions will be made

1. to test, separately for slum and non-slum households, for changes in the prevalence of severe child malnutrition in the Intervention and Comparison Areas. This would not only examine the community-level effectiveness of the intervention, but would also examine whether it worked equally well for children from both slum and non-slum households.
2. to test, for children from slum and non-slum households combined, whether the subsidised provision of a BINP-type supplement in 12 Clusters of the Intervention Area is associated with a greater decline in severe malnutrition than the one observed in the remaining 24 Clusters of the Intervention Areas where no supplement will be provided.

The proposed population-based impact evaluation will furthermore permit comparisons of declines in severe child malnutrition in the Intervention Area (with and without the subsidised provision of a BINP-type supplement) with declines in severe malnutrition in areas brought under the BINP Urban Model. This will, however, only be possible once piloting of the BINP Urban Model gets underway.

Ethical Considerations. Household-level surveys involving child anthropometry will be done in both the intervention area and the comparison area both at baseline and post-intervention. Children encountered during the survey who are severely wasted or oedematous would meet IMCI criteria for urgent hospitalisation and will in all instances – i.e., regardless of whether from the Intervention or Comparison Area—be urgently referred and, if desired, accompanied to hospital by survey personnel. At current levels of child malnutrition in urban areas, about five percent of children age 6 to 23 months are expected to be severely wasted (< -3 SD weight-for-length). It is therefore expected that about 70 children would be identified and referred to Dhaka Shishu Hospital in the course of the baseline survey, i.e. over an eight-week period. As many of these children would not be acutely ill, children would receive care either at Dhaka Shishu Hospital or its affiliated Nutrition Unit. Nevertheless occurring capacity constraints will be addressed by providing, under a forthcoming addendum to this protocol, day-care based acute-phase management and or day care-based nutritional rehabilitation at Radda MCH/FP Centre in Mirpur. For caretakers of moderately malnourished children identified during the survey, survey personnel will be providing feeding and caring advice.

Facilities Available

Describe the availability of physical facilities at the place where the study will be carried out. For clinical and laboratory-based studies, indicate the provision of hospital and other types of patient's care facilities and adequate laboratory support. Point out the laboratory facilities and major equipment that will be required for the study. For field studies, describe the field area including its size, population, and means of communications. **(TYPE WITHIN THE PROVIDED SPACE).**

The proposed service and research protocol will be implemented by ICDDR,B working in collaboration with Dhaka Shishu (Children's) Hospital, and with staff of initially three Intervention Clinics operated by Progoti Samna Kallyan Protisthan (PSKP).

Dhaka Shishu Hospital is the leading national-level tertiary-level paediatric referral hospital in Bangladesh. Dhaka Shishu Hospital has currently ten paediatric ward beds that are dedicated for the acute-phase management of severely malnourished children, but does not currently have any facilities for the nutritional rehabilitation phase of management. Severely malnourished children, after being treated for the acute phase, are transferred to an affiliated Nutrition Unit housed in the same locality. This unit, run by an NGO, Food for the Hungry, provides nutritional rehabilitation to the children on a residential basis, as opposed to a day care-based management. Paramedics provide the nutritional management under the active supervision of the staff of the Nutrition Unit of Shishu Hospital. This arrangement is routine for severely malnourished children admitted to Shishu Hospital. Three paramedics of the affiliated unit have recently completed the ICDDR,B sponsored course on management of severely malnourished children.

The here-proposed protocol is expected to result in the identification and referral to Shishu of greater numbers of severely malnourished children. Nutrition rehabilitation beds at Shishu are, however, even now normally fully occupied and, in fact, inadequate for admission of all severely malnourished children referred for in-patient care. The proposed protocol will seek to overcome this resource constraint by

- referring, in accordance with WHO criteria (IMCI and WHO 1999), for hospitalised management only very low weight children (< -3 SD W/A) who are also severely wasted (< -3SD W/L) or have bipedal oedema *or* who are also severely ill or have other complications. Very low weight children (< -3 SD W/A) who are neither wasted nor oedematous nor acutely ill will be kept at the community-level for monitored protocolised home-based management.
- utilising hospital-facilities only until completion of the acute-phase treatment,[3] followed by residential rehabilitation at an affiliated Nutrition Unit housed in the same locality and run by an NGO, Food for the Hungry.

Facilities for hospital-based acute-phase management may be further extended by providing day-care-based acute-phase management followed by day care-based rehabilitation in those instances where hospital admission is not possible due to space constraints. Envisaged procedures for daycare-based management are under discussion with Radda FP/MCH Centre of Mirpur and will be described in an addendum to this protocol.

The *Urban Family Health Partnership (UFHP)*, which is a project implemented by John Snow Inc. (JSI), is one of six Collaborating Agencies (CAs) for USAID's National Integrated Population and Health Program (NIPHP) in Bangladesh. UFHP collaborates with 24 urban-based non-governmental organisations (NGOs) to offer an Essential Services Package (ESP) with emphasis on family planning, other reproductive health and child survival interventions. UFHP will support the proposed protocol through collaboration of an Nutrition Specialist and NGO Liaison Officer serving with UFHP and by providing financing for additional personnel, required equipment and certain other costs arising from the protocol. *Progoti Samaj Kallyan Protistahn (PSKP)* is one of 24 urban-based partner NGOs of UFHP. Within the Dhaka metropolitan area, PSKP operates five static primary health care clinics of which three are located in Mirpur (Mirpur Clinic, Manikdi Clinic and Pallabi Clinic) and two others in Badda and Tejgaon. Together, these clinics serve a catchment area with an estimated total population of 1,013,000. Each of the these clinics is staffed by one medical officer, one clinic-based paramedic, one counsellor, and three outreach teams[4], each consisting of one paramedic and one Service Promoter, both of whom are normally females. Each outreach team conducts in each week at least four Satellite Clinics serving the general population. Static clinics and Satellite Clinics provide a package of Essential Services as defined for NIPHP, with emphasis on family planning, antenatal care, child survival interventions, and limited curative care. Current clinic attendance at PSKP clinics remains, however, below capacity. Attendance may, moreover, be selective for better-cared-for children and/or children from relatively better off households. This, together with the absence of systematic outreach to the community, makes it unlikely that severely malnourished children will be brought to the clinics for assessment and management. The proposed intervention will therefore strengthen PSKP's outreach capabilities through a systematic effort for bringing malnourished children to existing clinics.

During the first year of the proposed intervention, three of PSKP's five existing clinics within the Dhaka metropolitan area will be designated as Intervention Clinics that will offer the full range on nutrition interventions as described above. The remaining two clinics will continue to offer the Essential Services Package as currently defined, which includes only a more limited package of nutrition services (vitamin A supplementation and promotion of breastfeeding and appropriate infant feeding practices). Intensified nutrition services, as described in this proposal, will thus be offered at three static clinics and a total of 36 Satellite Clinic sites. In addition, Service Promoters will be conducting quarterly outreach visits to 36 Intervention Clusters of households, each consisting of about 120 household and containing approximately 30 children below the age of two. If the proposed intervention can be shown as effective and cost-effective, the intervention will be scaled up to include the remaining two PSKP clinics. For the purposes of the protocol, PSKP's staff will be strengthened by appointing one Nutrition Co-ordinator at PSKP's Headquarters Office and one dedicated Nutrition Counsellor at each of the three Intervention Clinics.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analysed by the investigators themselves or by other professionals. Specify what statistical software packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to monitor further progress of the study. **(TYPE WITHIN THE PROVIDED SPACE).**

Data analyses for tests of the three hypotheses described above will be done by tests for differences in proportions, using a Windows-based package for statistical analyses (SPSS 7.5 for Windows). Data management and data analyses will be performed by a Data Manager who will be working under the guidance of the Project Management Consultant engaged for the project.

Ethical Assurance for Protection of Human Rights

Describe in the space provided the justifications for conducting this research in human subjects. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how subject's rights are protected and if there is any benefit or risk to each subject of the study.

Extension of protocolised, monitored management of severe malnutrition to the community level is a means of overcoming current capacity constraints for hospital-based management which prevent many severely malnourished children from obtaining the care they require for recovery. Research included in this service and research protocol will be conducted to demonstrate the safety, effectiveness and sustainability of home-based protocolised management of severe malnutrition. If scaled up and/or replicated elsewhere based on the results of the proposed research, community-based protocolised management of severe malnutrition could reduce malnutrition-associated mortality and improve the quality of life of numerous young children who would not have been reachable with hospital-based care.

3 Criteria: stabilised condition, good appetite returned, transition to catch-up diet accomplished, thereafter: at least three consecutive days of rapid growth

4 two in the case of the Badda Clinic

Individual children brought in contact with the protocol will in each instance benefit from such contact. In the Intervention Areas, the protocol will introduce currently unavailable nutrition services that will benefit both severely and moderately malnourished children. Identification of already severely malnourished children in both the Intervention and the Comparison Areas, will, similarly benefit all participating children and their caretakers by initiating referrals for such children, including for children whose malnutrition would otherwise have remained unattended.

For the baseline and follow-up survey, standard procedures for the protection of privacy of information on individual children, their caretakers and households will be followed.

Use of Animals

~~Describe in the space provided the type and species of animal that will be used in the study. Justify with reasons the use of particular animal species in the experiment and~~ the compliance of the animal ethical guidelines for conducting the proposed procedures

The proposed service and research protocol does not involve the use of animals.

Literature Cited

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however exercise judgement in assessing the "standard" length.

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Thwin, Aye Aye and Shamim Ara Jahan. 1996. Rapid Appraisal of Urban Health Needs and Priorities. Urban FP/MCH Working Paper No. 22. And ICDDR,B Working Paper No. 67. MCH-FP Extension Project (Urban). International Centre for Diarrhoeal Disease Research, Bangladesh.

World Health Organization. 1998. Complementary feeding of young children in developing countries: a review of current scientific knowledge. Geneva. WHO/NUT/98.1

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Dissemination and Use of Findings

Describe explicitly the plans for disseminating the accomplished results. Describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Mention if the project is linked to the Government of Bangladesh through a training programme

The proposed service and research protocol will receive funding from a World Bank DGF (Development Grant Facility) grant to ICDDR,B's Nutrition Centre of Excellence. The agreed grant objectives are (1) development of a package on nutrition interventions that can be applied in a variety of countries at the household, community and health facility levels; (2) conducting multidisciplinary nutrition research at the community and health facilities level .... and training international health practitioners to identify malnutrition and apply tested protocols. The proposed service and research protocol would therefore, if demonstrated as effective, be included in the international dissemination foreseen for year 3 of the grant agreement.

Within Bangladesh itself, the protocol would be potentially replicable to all of the 24 NGOs collaborating with CFHP, with a total of 119 static clinics throughout Bangladesh.

Principal Investigator: Last, first, middle

Fuchs, Prof. George J.

Collaborative Arrangements

Describe briefly if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organisations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organisation and the collaborating organisation. **(DO NOT EXCEED ONE PAGE)**

The proposed protocol involves collaboration with Progoti Samaj Kallyan Protisthan (PSKP), which is one of the 24 Partner NGOs of the Urban Family Health Partnership (UFHP). By agreement with UFHP, PSKP service providers will, in initially three of PSKP's five Dhaka Metropolitan Area clinics, be offering nutrition services as described in this protocol as integral part of their job duties. The PKSP Intervention Clinics will for this purpose be strengthened through the appointment of one dedicated Nutrition Counsellor. UFHP will contribute to the design, implementation and evaluation of the community-based interventions under the protocol through the part-time collaboration of one UFHP Nutrition Specialist who will contribute to the protocol under terms of reference agreed with ICDDR,B.

Dhaka Shishu (Children's) Hospital will participate in the protocol by applying the ICDDR,B-tested adaptation of the WHO protocol for management of severe malnutrition in ten paediatric-ward beds which constitute the Nutrition Unit of Shishu Hospital and in its affiliated Nutrition Unit for residential nutritional rehabilitation. This includes adherence to admission and discharge criteria and referral procedures as agreed for this protocol.

A Letter of Agreement with UFHP and a Memorandum of Understanding with Dhaka Shishu Hospital for collaboration under this protocol are in advanced stages of preparation.

Principal Investigator: Last, first, middle — Fuchs, Prof. George J.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Petra Osinski DrPH	Project Management Consultant Nutrition Centre of Excellence ICDDR,B, Dhaka, Bangladesh	31 August 1944

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Freie Universität, Berlin	Diplom-Soziologe	1969	Sociology
Johns Hopkins University School of Hygiene and PH	MPH	1984	International Public Health
Johns Hopkins University School of Hygiene and PH	DrPH	1991	International Public Health (organisation and management of health systems)

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES. USE CONTINUATION SHEETS).**

June 1999 and August 1999-present	Project Management Consultant with the ICDDR,B Nutrition Centre of Excellence for collaboration on design and planning of a protocol for Community-based Protocolised Management of Severe Malnutrition
June, July 1998 and Jan. 1999 – May 1999	Consultant to World Bank, Dhaka for drafting of draft Project Concept Document(PCD) and draft Project Appraisal Document (PAD) as background for World Bank managerial decision-making on preparation and appraisal of the first of a series of World Bank-financed projects under the (Bangladesh) National Nutrition Program (NNPI)
Jan. 1998—April 1998	Quality Assurance Consultant to Urban Family Health Project, Bangladesh
Jul. 1996—Jan. 1998	International Consultant-Chief Technical Adviser to Project Preparation Cell, MOHFW, Government of Bangladesh under contract with World Bank
Nov. 1993—Dec. 1995	Team Leader, Management Development Unit, MOFHW, Government of Bangladesh
Nov. 1991—present	Research Associate, Associate, Department of International Health,
Mar. 1987—May 1989	Child Survival Fellow, Institute for International Programs (IIP), Department of International Health, The Johns Hopkins University School of Hygiene and Public Health
May 1982—Febr. 1987; June 1989—Oct. 1993	numerous consultancies for German Kreditanstalt für Wiederaufbau in connection with German financial-contributions to population and health programs in Bangladesh
April 1979- March 1981	Population Specialist, Population, Health and Nutrition Department, The World Bank, Washington, D.C.
Oct. 1970—March 1979	Project Officer at UNFPA Headquarters, New York; then Resident UNFPA Co-ordinator, Jakarta, Indonesia

Bibliography

Osinski, P. and R. E. Black. Determinants of continuous use of oral rehydration therapy in Rural and Urban Bangladesh. Report for the Programme for Control of Diarrhoeal Diseases, World Health Organisation, Geneva (unpublished)

Osinski, P., K. H. Hill, R. E. Black and J. Gehret. The assessment of levels and causes of child mortality in Bangladesh by Retrospective survey methods. Report prepared for UNICEF, Dhaka (unpublished)

Osinski, P., R. E. Black and M. R. Karim. Clinical characteristics of diarrhoeal episodes as determinants of ORT use in rural and urban Bangladesh: Observed differentials and their programmatic implications (unpublished)

Osinski, P. in collaboration with Mitra and Associates. Bangladesh Diarrhoeal Morbidity and Treatment Survey—1987/88. First Report. Institute for International Programs, The Johns Hopkins University, 1989.

FF Principal Investigator/Program Director::

BIOGRAPHICAL SKETCH

Give the following information for all ***new*** key personnel.
Copy this page for each person.

NAME	POSITION TITLE
George J. Fuchs	Director, Clinical Sciences Division, ICDDR,B

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Missouri-Columbia, MO	BA	1974	Zoology
University of Missouri-Columbia, MO	MD	1980	Medicine
Good Samaritan Hospital, Phoenix, AZ	Internship	1980-81	Internal Medicine
Dept Pediatr, Phoenix Hospitals Affiliated, Phoenix, AZ	Internship	1981	Pediatrics
Tufts-New England Medical Center, Boston Floating Hospital for Infants and Children, Boston, MA	Residency	1981-83	Pediatrics
Tufts-New England Medical Center, Boston, MA	Fellow	1983-84	Geographic Med/Ped Gastroenterol-Nutr
Univ Texas Health Science Center, Houston, TX	Fellow	1984-85	Ped Infectious Diseases
Univ Texas Health Science Center, Houston, TX	Fellow	1985-86	Ped Gastroenterol/Nutr

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experie honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and references to all publications during the past three years representative earlier publications pertinent to this application. If the list of publications in three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

PROFESSIONAL EXPERIENCE

1986-1992: Assistant Professor of Pediatrics, Louisiana State University School of Medicine, New Orleans, LA
1992-1994: Visiting Professor, Pediatrics and Research Associate, Research Institute for Health Sciences, Chiang Mai University, Thailand
1992-1998: Associate Professor of Pediatrics, Louisiana State University School of Medicine, New Orleans, LA
1995- present Director, Clinical Sciences Division, ICDDR,B, Dhaka, Bangladesh
1998- Professor of Pediatrics, Louisiana State University School of Medicine, New Orleans, LA
1998-1999 Interim Director, ICDDR,B, Dhaka, Bangladesh

Selected Publications in Nutrition (last 3 years)

1. Roy SK, Islam A, Molla A, Akramuzzaman SM, Jahan F, and Fuchs GJ. Impact of a single megadose of vitamin A at delivery on breastmilk of mothers and morbidity of their infants. *Eur J Clin Nutr* 1997;51:302-07.
2. Battacharya MK, Teka T, Faruque ASG, and Fuchs GJ. Cryptosporidium infection in children in urban Bangladesh. *J Trop Pediatr* 1997;43:282-86.
3. Fuchs GJ, Tienboon P, Khaled MA, Nimsakul S, Linprisarn S, Faruque ASG, and Suskind RM: Nutrition support and growth in thalassemia major. *Arch Dis Child* 1997;76:509-12.
4. Roy SK, Tomkins A, Akramuzzaman SM, Behrens RH, Haider R, Mahalanabis D, Fuchs GJ. Randomized controlled trial of zinc supplementation in malnourished Bangladeshi children with acute diarrhoea. *Arch Dis Child* 19[illegible]77:196-200.
5. Mitra AK, Akramuzzaman, Fuchs GJ, Rahman MM, Mahalanabis D. Long-term oral supplementation with iron is not harmful for young children in a poor community of Bangladesh. *J Nutr* 1997;127:1451-55.
6. Sarkar SA, Mahalanabis D, Bardhan PK, Alam NH, Rabbani G, Kiber A, Islam S, Fuchs GJ, Gyr K. Non-invasive assessment of gastric acid secretion in man: application of electrical impedance tomography. *Dig Dis Sci* 1997;42:1804-09.
7. Faruque ASG, Hoque SS, Fuchs GJ, Mahalanabis D. Randomized, controlled, clinical trial of rice ORS versus glucose oral rehydration solution in infants and young children with acute watery diarrhoea. Acta Pediatr 1997;86(12):1308-11.

Principal Investigator: Last, first, middle — Fuchs, Prof. George J.

Detailed Budget for New Proposal

Project Title: Community-based Protocolised Management of Severe Malnutrition

Name of PI: George J. Fuchs

Protocol Number: Name of Divisions: Clinical Sciences in Collaboration with Public Health Sc. Division

Funding Source: World Bank DGF Amount Funded (direct): 234,898 Total:257,266 Overhead (%) 15

Starting Date: 1 January 2000 Closing Date: 30 September 2001

Strategic Plan Priority Code(s):

Part 1: Formative Qualitative Research (PHSD)

Sl. No	Account Description	Salary Support			US $ Amount Requested
	Personnel	Position	Effort%	Salary level	1st Year
1	Abbas Bhuiya	Social Scientist	0.5 PM	P4/5	2,500
2	Lauren Blum	Social Scientist	2.0 PM	P4/1	9,000
3	Ruchira Tabassum	Gender & Rep. Hlth Sc.	2.0 PM	NOD/1	2,500
4	To be named	Med. Anthropologist	5.0 PM	GS6/1	2,000
5	Sabrina Rasheed	Applied Nutritionist	3.0 PM	GS5	0
6	2 PRA Trainers		0.5 PM		800
7	2 Field Research Officers		8. PM		2,000
	Sub Total				**18,800**
	Transport				**500**
	Supplies and Materials (Description of Items)				**100**
	Xeroxing/printing				**50**
	Total				**19,450**
	Overhead (15%)				**2,918**
	Grand Total:				**22,368**

8. Sarker SA, Mahalanabis D, Hildebrand P, Rahaman MM, Bardhan PK, Fuchs GJ, Beglinger C, Gyr K. *Helicobacter pylori*: prevalence, transmission and serum pepsinogen II concentrations in children of a poor periurban community in Bangladesh. *J Clin Infect Dis* 1997;25:990-5.
9. Unicomb LE, Kilgore PE, Faruque ASG, Hamadani JD, Fuchs GJ, Albert MJ, Glass RI. Anticipating rotavirus vaccines: hospital-based surveillance for rotavirus diarrhoea and estimates of disease burden in Bangladesh. *Pediatr Infect Dis* 1997;16:947-51.
10. Rahman MM, Mahalanabis D, Ali M, Mazumder RN, Wahed MA, Fuchs GJ. Absorption of macronutrients and nitrogen balance in children with dysentery fed an amylase treated energy-dense porridge. *Acta Pediatr* 1997;86(12)-6.
11. Islam S, Faruque ASG, Fuchs GJ, Wahed MA, Mahalanabis D. Shelf-life of pre-cooked rice oral rehydration salt packets. *Southeast Asian J Trop Med Pub Health* 1998;28:862-4.
12. Hossain I, Kabir I, Fuchs GJ, McCutcheon ML, Alvarez JO, Khaled MA. Intra- and extra-cellular water dynamics during rehydration in cholera and non-cholera patients. *Dig Dis Sci* 1998;43:663-7.
13. Hossain S, Biswas R, Kabir I, Sarker S, Dibley M, Fuchs GJ, Habte D, Mahalanab D. Single dose vitamin A treatment in acute shigellosis in Bangladeshi children:randomized double blind controlled trial. *Br Med J* 1998;316:422-6.
14. Casswall TH, Sarker SA, Albert MJ, Fuchs GJ, Bergstrom M, Bjorck L, Hammarstrom L. Treatment of Helicobacter pylori infection in infants in rural Bangladesh with oral immunoglobulins from hyperimmune bovine colostrum. *Aliment Pharmacol Therapeut* 1998;12:563-68.
15. Hossain I, Kabir I, Khan WA, Fuchs GJ. *Acinetobacter* bacteremia in patients with diarrheal disease. *Epidemiol Infect* 1998;120:139-42.
16. Roy SK, Islam A, Islam KE, Khan RA, Ara SH, Saifuddin NM, and Fuchs GJ. A randomized clinical trial to compare the efficacy of erythromycin, ampicillin and tetracycline for the treatment of cholera in children. *Trans Roy Soc Trop Med Hyg* 1998;92:460-62.
17. Dewan N, Faruque ASG, Fuchs GJ. Nutritional status and enteric diarrhoeal pathogen specificity in children: a clinic based study in Bangladesh. *Acta Pediatr* 1998;87:627-30.
18. Fuchs GJ. Possibilities for zinc in the treatment of acute diarrhea. *Am J Clin Nutr* 1998;68 (suppl):480S-483S.
19. Ahmed T, Smazaki R, Shin K, Skikasaki M, Fuchs GJ, Takita H. Humoral immune and clinical responses to food antigens following acute diarrhoea in children. *J Pediatr Child Hlth* 1998;34:229-32.
20. Rahman MM, Alvarez JO, Mahalanabis D, Wahed MA, Unicomb L, Habte D, Fuchs GJ. Effect of vitamin A administration on response to polio vaccination. *Nutr Res* 1998;18:1125-33.
21. Mitra AK, Alvarez JO, Wahed MA, Fuchs GJ, Stephensen CB. Predictors of serum retinol in children with shigellosis. *Am J Clin Nutr* 1998;68:1088-94.
22. Faruque ASG, Salam MA, Faruque SM, Fuchs GJ. Aetiological, clinical and epidemiological characteristics of a seasonal peak of diarrhoea in Dhaka, Bangladesh. *Scand J Infect Dis* 1998;30:393-6.
23. Mitra AK, Alvarez JO, Guay-Woodford L, Fuchs GJ, Wahed MA, Stephensen CB. Urinary retinol excretion and kidney function in children with shigellosis. *Am J Clin Nutr* 1998;68:1095-1103.
24. Fuchs GJ, Mahalanabis D, Alnwick D. Syposium and Workshop on zinc and health in South Asia. Indian Pediatr 1998;38:1193-4. (Report and Recommendations)
25. Brooks, WA and Fuchs, GJ. Recent advances in research on zinc and health in developing countries. Indian Pediatr 1998;35:1173-6. (Editorial)
26. Roy SK, Tomkins AM, Mahalanabis D, Akramuzzaman SM, Haider R, Behrens RH, Fuchs GJ. Impact of zinc supplementation on persistent diarrhoea in malnourished Bangladeshi children. *Acta Pediatr* 1998;87:1235-9.
27. Islam MS, Hossain MS, Hasan MK, Rahman JJ, Fuchs G, Mahalanbis D, Baqui AH, Albert MK. Detection of *Shigellae* from stools of dysentary patients by culture and polymerase chain reaction techniques. *J Diarrhoeal Dis Res* 1998;16:248-51.
28. Teka T, Faruque ASG, Hossain MI, Fuchs GJ. Aeromonas-associated diarrhoea in Bangladeshi children: clinical and epidemiological characteristics. *Ann Trop Paediatr* 1999;19:15-20.
29. Bhatacharya MK, Teka T, Fuchs G. Pediatric HIV infection: a brief review. *J Indian Med Assoc* 1998;96:279-81.
30. Bardhan PK, Sarker SA, Mahalanabis D, Rahman MM, Hildebrand P, Beglinger C, Fuchs G, Gyr N. Helicobacter pylori infection in infants and children of Bangladesh. *Schweiz Rundsch Med Prax* 1998;87:1814-6.
31. Faruque ASG, Teka T, and Fuchs GJ. Shigellosis in children: a clinico-epidemiological comparison between *Shigella dysenteriae type 1* and *Shigella flexneri*. *Annals Trop Paediatr* 1998;18:197-201.
32. Ashraf H, Rahman MM, Fuchs GJ, Mahalanabis D. Folic acid in the treatment of acute watery diarrhoea in children: a double-blind, randomized, controlled trial. *Acta Pediatr* 1998; 87:1113-5.
33. Sarker SA, Casswall TH, Mahalanabis D, Alam NH, Albert MJ, Brussow H, Fuchs GJ, Hammerstrom L. Successful treatment of rotavirus diarrhoea in children with immunoglobulin from immunized bovine colostrum. *Pediatr Infect Dis J* 1998;17:1149-54.

34. Faruque ASG, Mahalanabis D, Hoque S, Fuchs GJ, Habte D. Double-blind, randomized, controlled trial of zinc or vitamin A supplementation in young children with acute diarrhoea. *Acta Paediatr* 1999;88:154-60.
35. Roy SK, Tomkins AM, Haider R, Behrens RH, Akramuzzaman SM, Mahalanabis D, Fuchs GJ. Impact of zinc supplementation on subsequent growth and morbidity in Bangladeshi children with acute diarrhoea. *Eur J Clin Nutr* 1999;53:529-34.
36. Alam NH, Majumder RN, Fuchs GJ, and Choice. Randomized double blind clinical trial to evaluate the efficacy and safety of a reduced osmolarity oral rehydration solution in adults with cholera. *Lancet* 1999; 354: 296-99
37. Ahmed T, Ali M, Ullah MM, Choudhury IA, Haque ME, Salam MA, Rabbani GH, Suskind RM, Fuchs GJ. Reduced mortality among severely malnourished children with diarrhoea through the use of a standardized management protocol. *Lancet* 1999;353:1919-22.
38. Alam DS, Marks GC, Baqui AH, Yunus M, Fuchs GJ. Association between clinical type of diarrhea and growth of children younger then five years of age in rural Bangladesh. *Pediatrics* (in press)
39. Rahman MM, Akramuzzaman SM, Mitra AK, Fuchs GJ, Mahalanabis D. Long-term supplementation with iron does not enhance growth in malnourished Bangladeshi children. *J Nutr* 1999;129:1319-22
40. Qadri F, Das SK, Faruque ASG, Fuchs GJ, Albert MJ, Sack RB, Svennerholm AM. Prevalence of toxin types and colonization factors in enterotoxigenic *Escherichia coli* isolated during a two year period from diarrhoeal patients in Bangladesh. *J Clin Mic*robiol (in press)
41. Haider R, Kabir I, Fuchs G, Habte D. Neonatal diarrhoea in a diarrhoea treatment centre in Bangladesh: clinical presentation, breastfeeding management and outcome. *Indian J Pediatr* (in press)
42. Haider R, Kabir I, Hill AA, GJ Fuchs. Are breastfeeding messages influencing mothers in Bangladesh? *Trop Pediatr* (in press)
43. Islam S, Kabir I, Wahed MA, Goran MI, Mahalanabis D, Fuchs GJ, Khaled MA. Multifrequency bioelectrical impedance analysis to assess human body composition. *Nutr Res* (in press)
44. Osendarp SJM, van Raaij JMA, Airfeen SE, Wahed MA, Baqui AH, Fuchs GJ. A randomized placebo-controlled trial on the effect of zinc supplementation during pregnancy on pregnancy outcome in Bangladeshi urban poor. *Am J Clin Nutr* (in press)

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Principal Investigator

Name	Position	Date of Birth
Dr. S. K. ROY	Scientist, Clinical Sciences Division, ICDDR,B	November 12, 1950

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of study
Dhaka Medical College. University of Dhaka, Bangladesh	MBBS	1973	
London School of Hygiene and Tropical Medicine, UK	M.Sc	1984	Nutrition
University of London	Ph. D		Nutrition

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in, chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES, USE CONTINUATION SHEETS).**

1. 1992-Present Scientist, Clinical Sciences Division, ICDDR,B
2. 1987-92 Associate Scientist, Clinical Sciences Division, ICDDR,B
3. 1981-87 Senior Medical Officer, ICDDR,B

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Dr. Tahmeed Ahmed	Associate Scientist	24 November 1959

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Mymensingh Medical College, Univ. of Dhaka	MBBS	1983	Medical Science
University of Tsukuba, Japan	PhD	1996	Food allergy in children

Research and Professional Experience

1. In-service training, majoring in internal medicine, from December 1983 to December 1984, at Mymensingh Medical College Hospital.
2. Medical Officer (Maternal & Child Health and Family Planning), Rural Health Complex, Ministry of Health, GoB, till February 1985.
3. Joined as Medical Officer, Clinical Research Centre, ICDDRB, on 25 February, 1985.
4. Worked in Dhaka Childrens' Hospital as a resident in Pediatrics from August 1989 to August 1990, on deputation from the Centre.
5. Clinical training in the Department of Pediatrics, University of Tsukuba Hospital, Japan from October 1990 to March 1992.

RECENT PUBLICATION (no more than five).

1. Mortality in severely malnourished children with diarrhoea and use of a standardised management protocol. Ahmed T, Ali M, Ullah M, Choudhury I, Haque E, Salam A, Rabbani G, Suskind R, Fuchs G. Lancet 1999;353:1919-22.
2. Humoral immune and clinical responses to food antigens following acute diarrhea in children. Ahmed T, Sumazaki R, Shibasaki M, Nagai Y, Shin K, Fuchs GJ, Takita H. *J Paediatr Child Health* 1998;34:229-232.
3. Circulating antibodies to common food antigens in Japanese children with IDDM. Ahmed T, Komota T, Sumazaki R, Shibasaki M, Hirano T, Takita H. *Diabetes Care* 1997;20:74-76.
4. Immune response to food antigens: Kinetics of food-specific antibodies in the normal population. Ahmed T, Sumazaki R, Shibasaki M, Takita H. *Acta Paediatr Japonic* 1997;39:322-328.
5. Gastrointestinal allergy to food: a review. Ahmed T and Fuchs G. *J Diarrhoeal Dis Res* 1997;15:211-223.

Selected Publications:

1. **Roy SK**, Chowdhury AKMA, Rahaman M. Excess mortality among children discharged from hospital after treatment for diarrhoea in rural Bangladesh. Br Med J 1983;287:1097-9.

2. **Roy SK**, Chowdhury AKMA, Rahaman MM. Excess mortality among children discharged from hospital after treatment for diarrhoea in rural Bangladesh (letter). Br Med J 1983;287:1553.

3. **Roy SK**, Speelman P, Butler T, Nath S, Rahman H, Stoll BJ. Diarrhoea associated with typhoid fever. J Infect Dis 1985;151:1138-43.

4. **Roy SK**, Haider R. Is nutritional status deteriorating in Bangladesh? Health Pol Plann 1988;3:325-8.

6. **Roy SK**, Alam AN, Majid N, Khan AM, Hamadani J, Shome GP. Persistent diarrhoea: a preliminary report on clinical features and dietary therapy in Bangladeshi children. J Trop Pediatr 1989;35:55-9.

7. **Roy SK** and Tomkins A. The effects of severe zinc deficiency on growth, food intake, diarrhoea and pathological changes in intestinal tissue. Bangladeh J Nutr 1989;2:1-7.

8. **Roy SK**, Haider R, Akbar MS, Alam AN, Khatun M, Eeckels R. Persistent diarrhoea: clinical efficacy and nutrient absorption with a rice based diet. Arch Dis Child 1990;65:294-7.

9. **Roy SK**, Akramuzzaman SM and Akbar MS. Persistent diarrhoea: total gut transit time and its relationship with nutrient absorption and clinical response. J Pediatr Gastroenterol Nutr 1991;13:409-14.

10. **Roy SK**, Behrens RH, Haider R, Akramuzzaman SM, Mahalanabis D, Wahed MA, Tomkins A M. Impact of zinc supplementation on intestinal permeability in Bangladeshi children with acute diarrhoea and persistent syndrome. J Pediatr Gastroenterol Nutr 1992;15:289-96.

11. **Roy SK**, Rahman M, Mitra AK, Ali M, Alam AN, Akbar MS. Can mothers identify malnutrition in their children?. Health Pol Plann 1993;8:143-9.

12. **Roy SK**, Akramuzzaman SM, Haider R, Khatun M, Akbar MS, Eeckels R. Persistent diarrhoea: efficacy of a rice-based diet and role of nutritional status in recovery and nutrient absorption. Br J Nutr 1994;71:123-34.

13. **Roy SK,** Zinc Supplementation in the treatment of childhood diarrhoea. Indian J Paediatr. 1995;62:181-193.

14. **Roy SK,** Tomkins AM, Akramuzzaman SM . Current management of persistent diarrhoea and malnutrition in developing countries. Hong Kong J Paediatr. 1995;1(suppl):100-113.

15. **Roy SK**, Islam A,Molla A, Akramuzzaman SM, Jahan F, Fuchs G. Impact of single megadose of vitamin A at delivery on breastmilk of mothers and morbidity of their infants. Eur J Clin Nutr 1997;51:302-307.

16. **Roy SK**, A M Tomkins S M Akramuzzaman, R H Behrens R Haider, D Mahalanbis, G Fuchs. Randomized controlled trial of zinc supplementation in malnourished Bangladeshi children with actue diarrhoea. Arch Dis Child 1997;77:196-200.

17. **Roy S.K**. Complementary feeding in children of South Asia. UNICEF Special Publications. Regional Office of South Asia, Kathmandu, 1997.

18. **Roy S.K.,** Islam A, Ali R, Islam K.E, Khan R. A, Ara S. H, Saifuddin N.M, Fuchs G.J. A randomized clinical trial to compare efficacy of erythromycin, ampicillin and tetracycline in the treatment of cholera in children. Trans. Royal. Soc.
1998 Vol;92: 460-2.

19. **Roy S.K.,** Tomkins A.M., Akramuzzaman S.M., Haider R, Behrens R.H., Fuchs G. Impact of zinc supplementation on persistent diarrhoea in malnourished Bangladeshi Children. Acta Pedeatrica. 87;1235-9:1998.

20. **Roy S.K.**, A.M. Tomkins, R. Haider, R.H. Behrens, S.M. Akramuzzaman, D.Mahalanbis, G.J. Fuchs. impact of zinc suplementation on subsequent growth and morbidity in bangladeshi children with acute diarrhoea. European Journal of Clinical Nutrition 53;529-34:1999

Principal Investigator: Last, first, middle: Fuchs, Prof. George J.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Petra Osinski DrPH	Project Management Consultant Nutrition Centre of Excellence ICDDR,B, Dhaka, Bangladesh	31 August 1944

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Freie Universitat, Berlin	Diplom-Soziologe	1969	Sociology
Johns Hopkins University School of Hygiene and PH	MPH	1984	International Public Health
Johns Hopkins University School of Hygiene and PH	DrPH	1991	International Public Health (organisation and management of health systems)

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES. USE CONTINUATION SHEETS).**

June 1999 and August 1999-present	Project Management Consultant with the ICDDR,B Nutrition Centre of Excellence for collaboration on design and planning of a protocol for Community-based Protocolised Management of Severe Malnutrition
June/July 1998 and Jan 1999 – May 1999	Consultant to World Bank, Dhaka for drafting of draft Project Concept Document(PCD) and draft Project Appraisal Document (PAD) as background for World Bank managerial decision-making on preparation and appraisal of the first of a series of World Bank-financed projects under the (Bangladesh) National Nutrition Program (NNP1)
Jan. 1998—April 1998	Quality Assurance Consultant to Urban Family Health Project, Bangladesh
Jul. 1996—Jan. 1998	International Consultant Chief Technical Adviser to Project Preparation Cell, MOHFW, Government of Bangladesh under contract with World Bank
Nov. 1993—Dec. 1995	Team Leader, Management Development Unit, MOHFW, Government of Bangladesh
Nov. 1991—present	Research Associate/Associate, Department of International Health,
Mar. 1987—May 1989	Child Survival Fellow, Institute for International Programs (IIP), Department of International Health, The Johns Hopkins University School of Hygiene and Public Health
May 1982—Febr. 1987, June 1989—Oct. 1993	numerous consultancies for German Kreditanstalt fur Wiederaufbau in connection with German financial-contributions to population and health programs in Bangladesh
April 1979- March 1981	Population Specialist, Population, Health and Nutrition Department, The World Bank, Washington, D.C.
Oct. 1970—March 1979	Project Officer at UNFPA Headquarters, New York; then Resident UNFPA Co-ordinator, Jakarta, Indonesia

Bibliography

Osinski, P. and R. E. Black. Determinants of continuous use of oral rehydration therapy in Rural and Urban Bangladesh. Report for the Programme for Control of Diarrhoeal Diseases, World Health Organisation, Geneva (unpublished)

Osinski, P., K. H. Hill, R. E. Black and I. Gehret. The assessment of levels and causes of child mortality in Bangladesh by Retrospective survey methods. Report prepared for UNICEF, Dhaka (unpublished)

Osinski, P., R. E. Black and M. R. Karim. Clinical characteristics of diarrhoeal episodes as determinants of ORT use in rural and urban Bangladesh: Observed differentials and their programmatic implications (unpublished)

Osinski, P. in collaboration with Mitra and Associates. Bangladesh Diarrhoeal Morbidity and Treatment Survey—1987/88. First Report. Institute for International Programs, The Johns Hopkins University, 1989

BIOGRAPHICAL SKETCH

Give the following information for all ***new*** key personnel.
Copy this page for each person.

NAME	POSITION TITLE
Lars Åke Persson	Director, Public Health Sciences Division, ICDDR,B the Centre for Health and Population Research, Dhaka

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Uppsala University, Sweden	MD	1973	Medicine
Sandöskolan, Sweden	Certificate	1972-73	Aid and disaster relief training
Swedish Board of Health and Welfare	Certificate	1973	Tropical/international medicine
Gävle Hospital and Västernorrlands landsting, Sweden	Internship	1973-74	Medicine, Surgery, General practice
Dept Pediatr, Örnsköldsviks sjukhus, Sweden	Residency	1974-76	Pediatrics
Dept Pediatrics, Umeå University, Sweden		1978-79	Pediatrics
Dept Child Psychiatry, Umeå University, Sweden	Residency	1979	Pediatrics/child psychiatry
Dept Infectious Diseases, Umeå University, Sweden	Residency	1979	Pediatrics/inf dis
Swedish Board of Health and Welfare	Residency	1980	Pediatrics
Umeå University, Sweden	Specialist	1984	Pediatrics/Pediatric Nutrition
Dept Pediatrics, Umeå University, Sweden	PhD	1990	Pediatrics
	Docent		

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experie honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and c references to all publications during the past three years representative earlier publications pertinent to this application. If the list of publications in t three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

PROFESSIONAL EXPERIENCE

1976-1978:	Medical Officer, Ndolage Hospital, Tanzania
1980-1983	Fellow, Social Medicine, Umeå University, Sweden
1983-1984	Fellow, Dept Pediatrics, Umeå University, Sweden
1984-1985	Medical Advisor, Institute for Protection of Children's Health, Hanoi, Vietnam
1985-1986	Fellow, Dept Pediatrics, Umeå University, Sweden
1986-1990	Senior lecturer/researcher in Pediatrics/Epidemiology, Umeå University, Sweden
1990-1997	Associate professor, Dept Epidemiology and Public Health, Umeå University, Sweden
1998-	Professor in International Public Health, Umeå University, Sweden
1999	Director, Public Health Sciences Division, ICDDR,B, Dhaka, Bangladesh

Publications

Original papers

1. Dewey KG, Peerson JM, Brown KH, Krebs NF, Michaelsen KF, Persson LA, Salmenpera L, Whitehead RG, Yeung DL. Growth of breastfed infants deviates from current reference data: A pooled analysis of U.S., Canadian and European datasets. Pediatrics 1995;96:495-503.
2. Tylleskär T, Banea M, Bikangi N, Nahimana G, Persson LÅ, Rosling H. Dietary determinants of a non-progressive Spastic Paraparesis (Konzo): a case-referent study in a high incidence area of Zaire. Int J Epidemiol 1995;24:949-56.
3. Hoa DP, Thanh HT, Höjer B, Persson LÅ. Young child feeding in a rural area in the Red River delta, Vietnam. Acta Paediatrica 1995;84:1045-9.
4. Hoa DP, Thanh HT, Hoa VT, Höjer B, Persson LÅ. Maternal factors influencing the occurrence of low birth weight in northern Vietnam. Ann Trop Pediatr 1996;16:327-33.
5. Persson LÅ, Hernell O, Lundström M, Lönnerdal B. Are weaning foods causing impaired iron and zinc status in one year-old Swedish infants? A cohort study. Acta Paediatrica 1998;87:618-22.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Dr. Rukhsana Haider	Associate Scientist	25 November 1951

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Fatima Jinnah Medical College, Lahore, Pakistan	MBBS	1975	Medical Science
London School of Hyg. & Trop. Med. Univ. of London	M.Sc.	1989-90	Human Nutrition
London School of Hyg. & Trop. Med.	PhD	1998	Public Health Nutrition

Research and Professional Experience

Associate Scientist, ICDDR,B from 1994 till date.

Acting Coordinator, BINP-ORP (Bangladesh Integrated Nutrition Project - Operations Research Project) July - Sept. 1999.

Part-time Consultant, UNICEF, 1992-1995.

Assistant Scientist, ICDDR,B, 1992-1994.

Medical Officer, ICDDR,B, 1984-1992.

RECENT PUBLICATION (no more than five).

1. Haider R, Kabir I, Fuchs GJ, Habte D. Neonatal diarrhoea in a diarrhoea treatment centre in Bangladesh: clinical presentation, breastfeeding management and outcome. Indian Pediatrics (in press)
2. Haider R, Kabir I, Ashworth A. Are breastfeeding messages influencing mothers in Bangladesh? Results from an urban survey in Dhaka, Bangladesh. *J Trop Pediatr* (in press)
3. Roy SK, Tomkins AM, Haider R, Behrens RH, Akramuzzaman SM, Mahalanabis D, Fuchs G. Impact of zinc supplementation on subsequent growth and morbidity in Bangladeshi children with acute diarrhoea. *Eur J Clin Nutr* (in press)
4. Haider R. Impact of peer counsellors on breastfeeding practices in Dhaka, Bangladesh. PhD thesis, London School of Hygiene and Tropical Medicine, UK, 1998.
5. Kabir I, Rahman MM, Haider R, Maumder RN, Khaled MA, Mahalanabis D. Increased height gain of children fed a high-protein diet during convalescence from shigellosis: a six-month follow-up study. *J Nutr* 1998;128:1688-91.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Dr. Lauren S. Blum	Social Scientist	

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Univ. of Colorado	B.A.	1983	English
Columbia University	M.A	1988	Master's in Public Health
University of Connecticut	Ph.D.	1999	Med/Nutritional Anthrop.

Research and Professional Experience

Graduate Research Assistant, Department of Anthropology, University of Connecticut, 1992-1993.
Conducted research on sociocultural factors influencing alcohol and drug use among White Mountain Apache.

Teaching Assistant, Department of Anthropology, The University of Connecticut, 1992.
Assisted in the design of a course schedule. Taught weekly sessions in cultural anthropology.

Manager Education, Training and Publications, Helel Keller International, 1988-1991.
Provided technical assistance to government and NGO representatives on the development of policies and integration of vitamin A nutrition activities in child health programmes. Assessed sociocultural factors affecting health-related practices and designed interventions to improve child health and nutritional outcomes.

Public Health Technical Trainer, Institut Supérieur Pédagiguqye, D.R. Congo, 1987-1988.
Evaluated training needs in western, southern and eastern Congo and designed a training curriculum. Coordinated all training activities.

Graduate Assistant, Operations Research, Columbia University, 1987.
Backstopped personnel working in a family planning program in Africa and Asia.

Nutrition Researcher, International Red Cross, Niger 1986.
Conducted research to assess household economic resources and to evaluate the health and nutritional status of women and children in a northern region of Niger.

Nutrition Technical Training Programme Coordinator, Peace Corps, Niger, 1985.
Trained a group of Peace Corps volunteers on public health and health and nutrition education strategies.

Nutrition Educator, Peace Corps, Niger, 1983-1985. Working in maternal/child health clinic assisting with prenatal consultations and well-baby weighings.

RECENT PUBLICATION (no more than five).

1. Blum L. 1997. Community Assessment of natural Food Sources in Niger: Hausas of Filingué. *In:* Kuhnlein H. Pelto G. Pelto P. editors. Culture. Environment. and Food to prevent vitamin A deficiency. Boston: International Nutrition Foundation for Developing countries.

2. Blum L. Pelto G. Kuhnlein H. Pelto P. 1997. Guidelines for conducting community-based ethnographic studies of vitamin A consumption. Boston: International Nutrition Foundation for Developing countries.

3. Blum L. 1996. Vitamin A supplementation. OMNI Micronutrient Facts Sheet Technical Sereis Paper #2. Arlington. VA: OMNI.

4. Blum L. 1988. 1989. 1990. and 1991. Vitamin A News Notes. a bi-annual publication of Helen Keller International. author and editor.

5. Blum L. 1991. L'Alimentation et les conséquences pour la Santé. New York: Helen Keller Internationa.

Principal Investigator: Last, first, middle: Fuchs, Prof. George J.

Part 2: Protocol Interventions and Impact Evaluations (CSD)

Sl. No	Account Description	Salary Support			US $ Amount Requested		
	Personnel	Position	Effort%	Salary	1st Yr	2nd Yr	3rd Yr
	[illegible] see separate table				27,402	25,717	
	Sub Totals				**27,402**	**25,717**	
	Consultants	Project Management Cons.	50	P5-1	36,000	48,000	
	Local Travel						
	International Travel						
	Sub Totals				**36,000**	**48,000**	
	Supplies and Equipment (Description of Items)						
	Office furnishings for one rented field office				2,000		
	Mobile phones for field office and three senior and supervisory field personnel				640		
	Scales for 3 Intervention Clinics (3 x 6) and 2 Static Clinics designated as Comparison Clinics (2)				2,500		
	Offset paper, diskettes, printer cartridges, pending files, file covers, pens and other stationery items for 3 persons for 22 months (3 + 9 + 12 months)				1,500	1,500	
	Stationery and reproduction costs for survey forms, registers and survey reports				2,000	2,000	
	Locally prepared food supplements for 12 months in one Intervention Cluster				650	900	
	Micronutrient supplements for children under home management				1,350	650	
	Sub Totals				**10,640**	**5,050**	

	Other Contractual Services	1st Yr	2nd Yr	
	Communication costs of investigators and field research assistants	2,250	2,400	
	Field research office rental	1,500	1,500	
	Clinic-level welfare fund administered by PSKP	2,000	3,000	
	Incremental cost support at Shishu Hospital	5,000	5,000	
	Review/Monitoring meetings, workshops, seminars ($300.–/mo)	2,700	2,700	
	Printing of growth charts (4,000)	400		
	Printing and publications		500	
	Sub Totals	**13,850**	**15,100**	

	Interdepartmental Services	1st Yr	2nd Yr	
	Training of PSKP personnel—2nd Phase training of 30 staff (10 half-days in yr 1, 5 in yr. 2)	6,000	3,000	
	Local transport for investigators and supervisory staff	2,700	3,000	
	Local transport for field research assistants	3,300	2,500	
	Xerox, mimeographs etc.	500	500	
	Sub Totals	**12,500**	**9,000**	
	Contingencies	500	500	
	Annual Totals and Total Direct Cost	100,892	103,367	204,259
	Overhead (15 percent)	15,134	15,505	30,639
	Total Cost Part 2	116,026	118,872	234,898

	Total Costs Part 1 (PHSD) and Part 2 (CSD)	138,394	118,872	257,266

Personnel budget: Community-based Protocolised Management of Severe Malnutrition (amount in US$)

				Year 1 (Jan.-Sep. '00)			Year 2 (Oct.'00-Sep.'01)			
Personnel	Pay Level	# of Staff	Monthly salary & benefits	Mo.s	Pct. of effort	Amount	Mo.s	Pct. of effort	Amount	Total
Prof. G Fuchs PI*	D2	1		9	10	n.a.	12	10	n.a.	n.a.
Dr. S.K. Roy, Co-PI	NO-D	1	1,700	9	10	1,622	12	10	2,244	3,866
Dr. T Ahmed, Co-PI*	NO-C	1		9	25	n.a.	12	20	n.a.	n.a.
Prof. Lars Ake Persson*	D1	1		9	5	n.a.	12	5	n.a.	n.a.
Dr. R Haider, Coinvestigator*	NO-C	1		9	10	n.a.	12	10	n.a.	n.a.
Dr. Abbas Bhuiya, Coinvestigator (see separate budget)	P-4	1		9						
Dr. Lauren Blum, Coinvestigator (see separate budget)	P-4	1		9						
Dr. A Brooks, Coinvestigator**	P4	1		6	10	n.a.	-	-	n.a.	n.a.
Mr. ABM Khorshed A. Mazumder, Coinvestigator***	NO-D	1		9	5	n.a.	12	5	n.a.	n.a.
Dr. Iqbal Hossain, Coinvestigator	NO-A	1	825	9	20	1,574	12	20	2,178	3,752
Data Manager/ Programmer	GS-6	1	443	9	100	4,226	12	100	5,848	10,074
Data Entry Technician/Office Clerk	GS-4	1	263	9	100	2,509	12	100	3,472	5,981
Senior Mapper	GS-5	1	341	9	100	3,253	12	100	4,501	7,754
Mapper	GS-4	2	263	2x6	100	3,345	-	-		3,345
Field Research Officer/Supervisor	GS-6	1	443	8	100	3,757	9	100	4,386	8,142
Field Research Assistant - Surveys	7.2 daily	2		2x5	100	1,984	2x3	100	1,236	3,220
	7.2 daily	3		3x3	100	1,786	3x3	100	1,853	3,639
Field Research Assistant - Qualitative	GS-4	2	263	2x6	100	3,345				3,345
Sub-total Personnel						27,402			25,717	53,119

* Funded seperately under World Bank DGF grant to ICDDR,B/NCOE
** Funded under Health and Child Survival Programme
*** Funded unded Operations Research Project, HPED

Principal Investigator: Last, first, middle

Fuchs, Prof. George J

Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item. Justify use of manpower, major equipment, and laboratory services.

Personnel: The proposed budget provides partial salary support for one Co-PI with responsibility for the contents of the interventions for home-based management (diet, micro-nutrient supplementation, and caring practices), for two PHSD Co-investigators overseeing formative and qualitative Research, and for one Co-investigator/Associate Scientist responsible for liaison with Shishu Hospital. Salary support for other existing professional staff who would be collaborating on the proposed project is provided from other sources, including salary support under the World Bank grant to ICDDR,B's Nutrition Centre of Excellence.

The budget includes salary support at 50 percent of effort for one Project Management Consultant, reporting directly to the PI and responsible for the overall management and progress monitoring of the proposal and the impact evaluation at the community and population level.

The project budget also provides for contract personnel to establish and maintain the database for the project, collect data for formative and impact evaluations, and to provide clerical and data entry support.

Supplies and Equipment: Field research staff for the proposed project will be accommodated in rented premises near the Mirpur area; the project budget therefore includes provisions for furnishing the field office. Communications with the field office and with field staff on duty will be supported by mobile phones (one for the office, three or senior and/or supervisory field staff). Scales for the PKSP clinics will be procured from the project budget.

Dietary supplements of the type used by BINP/ will be provided in one of the three intervention clusters and have been included at the rate of taka 3 per child per day (for an average duration of eight weeks). Also included are the costs of micronutrient supplements at the rate of U.S$ 4 per child under protocolised home management.

Other Contractual Services: The proposed budget includes rental of one field office, communication costs, and cost of meetings and workshops for progress monitoring in consultation with the collaborating institutions (Shishu Hospital and PSKP). PSKP will be administering a Welfare Fund, funded by the project budget, which will be drawn upon as needed to overcome fund constraints by parents and caretakers, especially for transportation costs. The proposed budge also includes a provision for increased operating costs at Shishu Hospital after adoption of the ICDDR,B-tested management protocol for severe malnutrition, e.g., for recruitment of Health Workers for round-the-clock care.

Interdepartmental Services: Transport for the project investigators and field staff will, to the extent available, be requisitioned from ICDDR,B's Logistics and Transport Office.

Overhead: Overhead has been included at the rate of 15 percent applicable to the World Bank grant to ICDDR,B's Nutrition Centre of Excellence.

Other Support

Describe sources, amount, duration, and grant number of all other research funding currently granted to PI or under consideration. (DO NOT EXCEED ONE PAGE FOR EACH INVESTIGATOR)

Principal Investigator: Last, first, middle Fuchs, Prof. George J.

APPENDIX

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project:	**Community-based Management of Severe Malnutrition**
Principal Investigator:	**George J. Fuchs**

Before recruiting into the study, the study subject must be informed about the objectives, procedures, and potential benefits and risks involved in the study. Details of all procedures must be provided including their risks, utility, duration, frequencies, and severity. All questions of the subject must be answered to his/ her satisfaction, indicating that the participation is purely voluntary. For children, consents must be obtained from their parents or legal guardians. The subject must indicate his/ her acceptance of participation by signing or thumb printing on this form.

Objectives of the Study

As you may have heard, "doctors" from Progoti Samaj Kallyan Protisthan and from the Cholera Hospital would like to work together with people from this community/neighbourhood to improve the health and nutrition [status] of young children. You probably also know that good nutrition is very important so that young children are strong and active and do not fall sick so easily. But studies that have already been done show that quite a few children are not well nourished. We also find that parents may feel shy or helpless once their children have become malnourished and do not know where to go for help. For this reason, we would like to advise parents on what can be done to cure or to prevent malnutrition of their young children. To do this, we would first like to find out about the nutrition [status] of all young children under two years of age that live in this neighbourhood.

Details of the Procedure

The very best way of finding out about the nutrition status of a young child in a scientific manner is to weigh measure the child. This means that we measure the child's length while lying down and also take the child's weight. We would, in addition, like to know the date when the child was born and some details about the circumstances of this household. Also, whether the child has received health services such as immunisation or other health services.

Potential Risks of Participating in the Study

Weighing and measuring a child involves no risk or possible harm of any kind. In fact, many parents like to have their children weighed and measured regularly so that they can know for sure whether their child is growing well.

Potential Benefits of Participating in the Study [differentiated by Intervention and Comparison Clusters]

Once we will have measured and weighed you child, we will be able to tell you whether your child is well nourished or moderately malnourished or even severely malnourished. We will then, if you like, take some time to mention some points of advice on how parents should feed and care for their young children so that the children will be well-nourished. But if we should find any child that is severely malnourished we would advise you to take the child to a hospital and could go to that hospital with you if you like. After completing our survey, we will know better how many young children are malnourished and will then develop our plans on how the "doctors" of Progoti Samaj Kallyan Protisthan can best work together with parents to save such children from becoming even more malnourished or sick. [**For Intervention Clusters only:** You will therefore see that in a few months' time, "doctors" from Progoti Samaj Kallyan Protisthan will come to this house and this neighbourhood regularly for more advice and help on how to keep young children from becoming malnourished.]

Maintaining Confidentiality

Information about your household's address and the child's name, age, weight and size will be entered in a register which will help us to visit you and the child again later. But we will keep all answers to other questions strictly confidential so that no person other than the researchers and Ethics Committee of the Cholera Hospital will have access to information you give us.

Offer to Answer Any Questions

If you have any question about our study, please tell us about it. It is important to us that you should not be unclear or doubtful about anything regarding our study.

Voluntary Participation

For the purposes of our study, we would like to be sure that not even a single malnourished child has been overlooked and would therefore like to have the collaboration of all parents of young children in this neighbourhood. We therefore sincerely request you to participate in this survey. But you are the one to decide whether or not we may weigh and measure your child. You may also, if you so decide, not give an answer to any of the questions in our questionnaire. But, as we said, we would really like to have your co-operation.

If you agree to our request for your and your child's participation in our survey, please put your signature or left thumb print on the space below.

Thank you for your co-operation.

Signature of Investigator/or Agents **Signature of Subject/Guardian**

Date: **Date:**

সামাজিক পরিবেশে তীব্র অপুষ্টির চিকিৎসা

আপনি মনে হয় শুনেছেন যে, প্রগতি সমাজ কল্যাণ প্রতিষ্ঠান ও কলেরা হাসপাতালের ডাক্তাররা একত্রে মিলে এই এলাকার শিশুদের স্বাস্থ্য ও পুষ্টিগত অবস্থার উন্নতির জন্য কাজ করবেন বলে ঠিক করেছেন। আপনি সম্ভবত আরও জানেন যে, শিশুরা যাতে সহজে রোগাক্রান্ত না হয়, তাদের সুস্থতা ও সজীবতার জন্য ভাল পুষ্টি অত্যন্ত জরুরী। কিন্তু, বিভিন্ন গবেষণায় দেখা গেছে যে, খুব বেশী সংখ্যক শিশু সুস্বাস্থ্যের অধিকারী নয়। আমরা আরো দেখি যে, যখন কোন শিশু পুষ্টিহীনতায় ভোগে তখন তার পিতা-মাতা/অভিভাবকগণ লজ্জা পান বা অসহায় বোধ করেন এবং তারা জানেন না যে, তারা সাহায্যের জন্য বা চিকিৎসার জন্য কোথায় যাবেন। এই কারণে, আমরা শিশুদের পিতামাতাকে বুঝাতে চাই যে, কি করলে শিশুদের পুষ্টিহীনতা ভাল করা যাব বা তা প্রতিরোধ করা যাবে। এটা করার জন্য, প্রথমে আমরা এই এলাকার অনুর্দ্ধ দুই বছর বয়সের সকল শিশুদের পুষ্টিগত অবস্থা নিরূপণ করবো।

বিজ্ঞানসম্মত উপায়ে একটি শিশুর পুষ্টিগত অবস্থা নিরূপণের সবচেয়ে ভাল পন্থা হচ্ছে শিশুর ওজন নেয়া ও উচ্চতা বা দৈর্ঘ্য মাপা। অর্থাৎ শিশু শোয়া অবস্থায় আমরা তার দৈর্ঘ্য মাপবো এবং ওজন নেবো। এই সাথে, আমরা শিশুর জন্ম তারিখ, শিশু কোন স্বাস্থ্য সেবা পেয়েছে কিনা যেমনঃ টিকাদান বা অন্য কোন স্বাস্থ্য সেবা এবং এই বাড়ীর অবস্থা ও পরিবেশ সম্বন্ধে কিছু কিছু জানতে চাইবো।

ওজন ও দৈর্ঘ্য মাপার মধ্যে কোন ঝুঁকি বা ক্ষতির সম্ভাবনা নেই। বাস্তবে দেখা গেছে যে, অনেক শিশুর মাতা পিতা তাদের শিশুর নিয়মিত ওজন ও দৈর্ঘ্য মাপতে চান, কারণ তারা নিশ্চিত হতে চান যে তাদের শিশু সত্যিই ভালভাবে বাড়ছে কিনা।

প্রথমবার আপনার শিশুর ওজন ও দৈর্ঘ্য মাপার পর আমরা বলতে পারবো যে, আপনার শিশুর পুষ্টিগত অবস্থা ভাল অথবা সে মাঝারী মানের পুষ্টিহীনতায় অথবা তীব্র পুষ্টিহীনতায় ভুগছে কিনা। তখন আপনি যদি চান, তবে আমরা আপনার কিছু সময় নেবো এবং কেমন করে খাওয়ালে এবং যত্ন নিলে আপনার শিশুর পুষ্টিগত অবস্থা ভাল হয় এই ব্যাপারে আপনাকে উপদেশ দেয়া হবে। কিন্তু যদি আমরা দেখি যে কোন শিশু তীব্র পুষ্টিহীনতায় ভুগছে, তবে তাকে আমরা হাসপাতালে নিয়ে যেতে বলবো। যদি আপনি চান তবে আমরা আপনার সাথে হাসপাতালে যেতে পারি।

আমাদের এই জরিপ শেষ হওয়ার পর, আমরা আরো ভালভাবে জানতে পারবো যে কতজন শিশু পুষ্টিহীনতায় ভুগছে; তখন আমরা আমাদের কার্যপ্রণালী নির্ধারণ করবো যাতে করে সবচেয়ে ভালভাবে প্রগতি সমাজ কল্যাণ প্রতিষ্ঠানের চিকিৎসকরা শিশুদের মাতা-পিতার সাথে কাজ করে শিশুদের আরো বেশী পুষ্টিহীনতায় ভোগা ও অসুস্থতা থেকে রক্ষা করতে পারে।

[হস্তক্ষেপিত এলাকা/জনগণের জন্য

এরপর, বেশ কিছুদিন এমন কি কয়েক মাস পর্যন্ত প্রগতি সমাজ কল্যাণ প্রতিষ্ঠান থেকে চিকিৎসকরা আপনার এলাকা ও বাড়ীতে নিয়মিত আসবেন। কেমন করে আপনার শিশুকে পুষ্টিহীন হওয়া থেকে রক্ষা করা যায় সে ব্যাপারে তারা সাহায্য করবেন ও উপদেশ দেবেন।]

আপনার বাড়ীর ঠিকানা, শিশুর নাম, বয়স, ওজন এবং উচ্চতা একটি খাতায় লেখা থাকবে; যা পরে আপনি ও আপনার শিশুকে পরিদর্শন করতে আমাদের সাহায্য করবে। আমরা আপনার সকল তথ্য গোপন রাখবো; শুধুমাত্র গবেষকগণ এবং কলেরা হাসপাতালের নীতি নির্ধারক পরিষদের সদস্যগণ সেগুলি জানতে পারবেন।

এই গবেষণা সম্পর্কে আপনার যদি কোন প্রশ্ন থাকে তবে তা এখনই আমাদের বলুন। এটা আমাদের কাছে খুব জরুরী যে, এই গবেষণার কোন কিছু আপনার কাছে অস্পষ্ট ও সন্দেহযুক্ত থাকা উচিত নয়।

এই গবেষণার স্বার্থে, আমরা চাই যে একটি পুষ্টিহীন শিশুও যেন এই জরিপ থেকে বাদ না পড়ে, সেজন্য আমরা এই এলাকার সকল শিশুর পিতা-মাতার সহযোগিতা কামনা করি। আমরা এই জরিপে অংশগ্রহণ করার জন্য আপনাকে সনির্বন্ধ অনুরোধ করছি। কিন্তু, আপনিই ঠিক করবেন যে আমরা আপনার শিশুর ওজন ও দৈর্ঘ্য মাপবো কিনা। আপনি যদি ঠিক করেন যে, আপনি আমাদের কোন প্রশ্নেরই উত্তর দিবেন না, তবে আপনি তাও করতে পারেন। তবে, বাস্তবে আমরা আপনার সহযোগিতা কামনা করি।

আপনি যদি আমাদের অনুরোধ রাখেন এবং এই জরিপে আপনার শিশুকে অংশগ্রহণ করাতে রাজী থাকেন, তবে দয়া করে নীচে স্বাক্ষর করুন অথবা বাম হাতের বুড়ো আঙ্গুলের টিপ সই দিন।

গবেষকের স্বাক্ষর	সাক্ষীর স্বাক্ষর	পিতা-মাতা/অভিভাবকের স্বাক্ষর/টিপ সহি

Figure 1: Entry Points for Identification, and Subsequent, Referral , Management and Monitoring of Severely Malnourished Children Age 6 to 23 Months

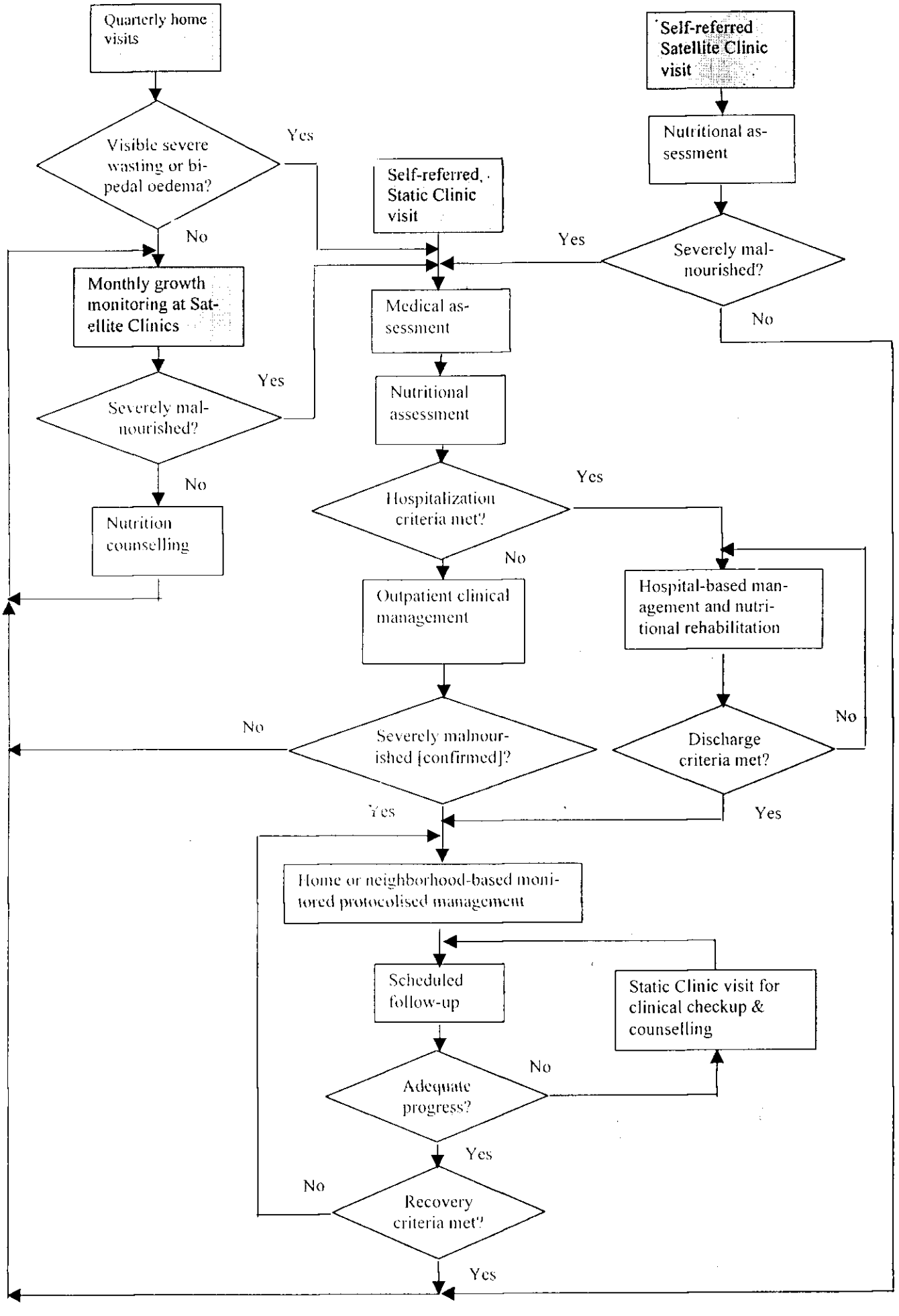


Figure 2: Community-based Protocolised Management of Severe Malnutrition. Identification. Classification/Referral and Discharge and Monitoring Criteria

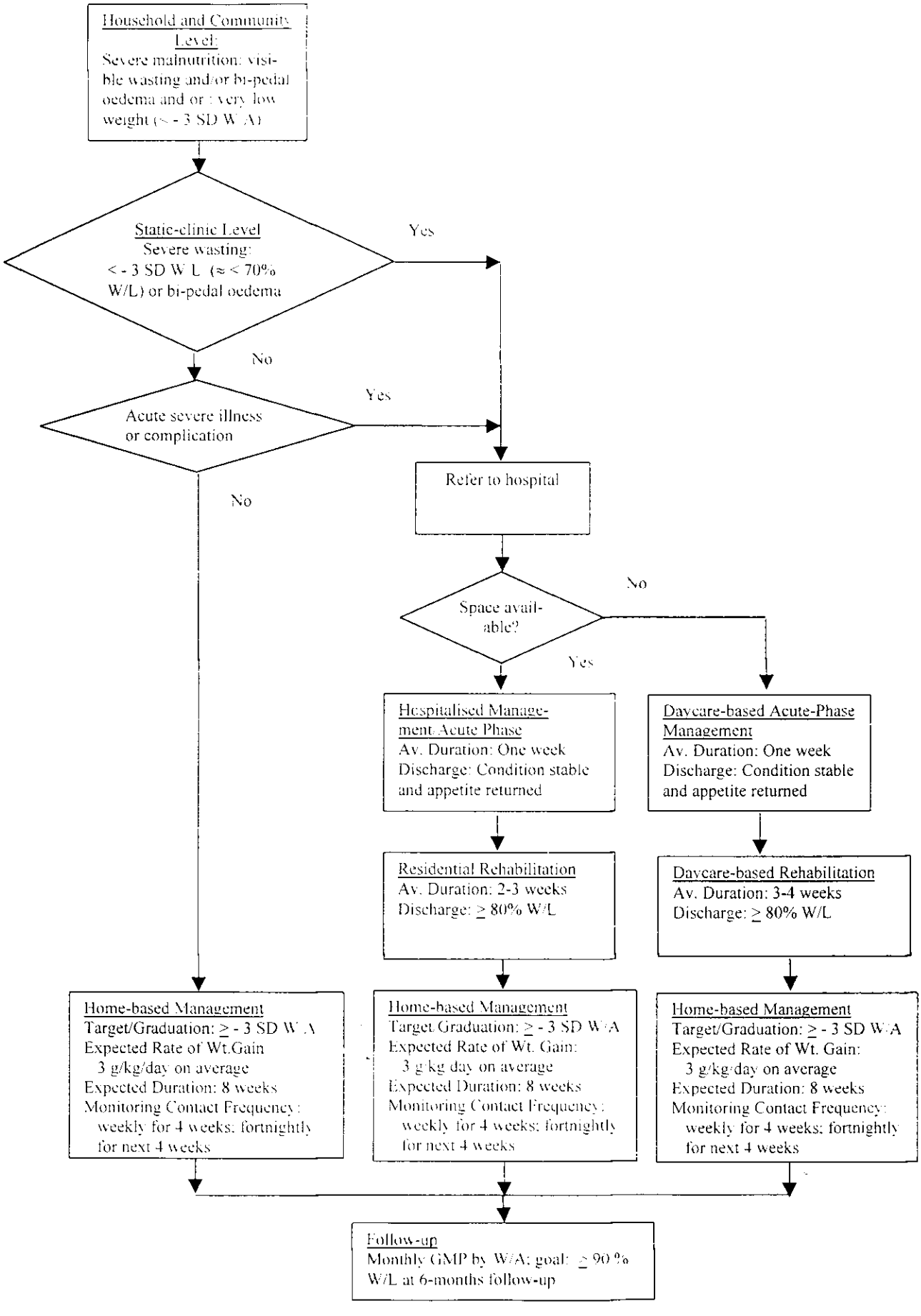
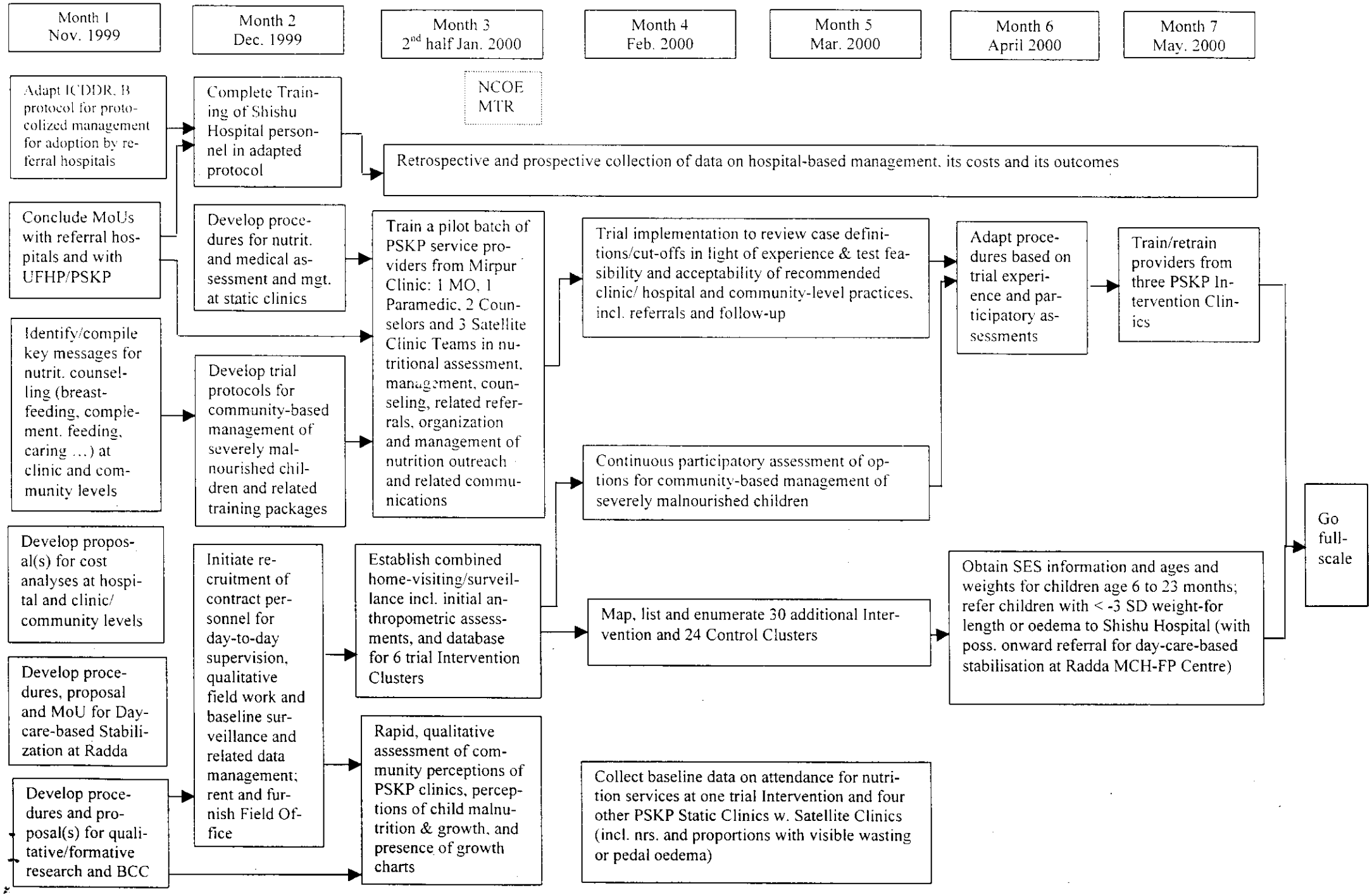


Figure 3: Schedule of Activities for Protocolised Community-based Management of Severely Malnourished Children



Schedule 1

Description of the Intervention Area

Clinic Name and Location	Wards	Estim. Population in Clinic Catchment Area	Nr.s of Satellite Clinic Teams	Nr.s of Satellite Clinic Spots
Mirpur Clinic	3, 4, 5	335,149	3	17
Manikdi Clinic (Mirpur)	15 and 17	148,945	3	16
Pallabi Clinic (Mirpur)	2	223,745	3	18
Badda Clinic	18	175,647	2	15
Tejgaon Clinic	37and 38	130,000	3	19
Total		1,013,486	14	85

Personnel of PSKP Clinics in Dhaka Metropolitan Area					
Static Clinic	Mirpur	Manikdi	Pallabi	Badda	Tejgaon
Medical Officer	1	1	1	1	1
Part-time MO	1	1			
Senior Service Promoter	1	1	1	1	
Paramedic	1	1	1	1	1
Counselor	2	1	1	1	1
Clinic Aide	1	1			
Laboratory Assistant	1	1			
Aya	1	1	1	1	1
Guard	1	1	1	1	1
Satellite Clinic Teams	3	3	3	2	3
Paramedics	3	3	3	2	3
Service Promoter	3	3	3	2	3

Schedule 2: Community-based Protocolised Management of Severe Child Malnutrition. Tasks for PKSP Clinic Teams

Task	SP	SSP	Para medic	MO	Nutr. Couns.[1]
Entry Point: Outreach Visit (Baseline and Quarterly)					
Update household roster for Intervention Cluster Hhs.	√				
Screen children age 6 to 23 months for severe malnutrition	√				
Invite for GMP to nearby Satellite Clinic held that day	√				
Entry Point: Nutrit. Assessment/GMP at Satellite Clinic					
Issue or replace growth card; enter child information			√		
Weigh the child and plot on growth card			√		
Interpret growth card information to mother/caretaker			√		
Counsel individually acc. to child's growth and nutr. status			√		
Refer severely malnourished children to static clinic			√		
Hold group nutrition education talks near Satellite Clinic	√				
Entry Point: Self-referred Visit to Static Clinic					
Issue or replace growth card			√		
Weigh the child and plot on growth card			√		
Interprete growth card information to mother/caretaker			√		
Counsel individually acc. to child's growth and nutr. status			√		
Refer to Satellite Clinic-based GMP			√		
Entry Point: Static Clinic Management of the Severely Malnourished Child					
Repeat weighing; obtain length; classify W/A & W/L			√		
Medical assessment				√	
Classify for outpatient & homebased management *or* hospitalisation				√	
Refer to hospital if hospitalisation criteria met				√	
Provide necessary outpatient medical care and intensive counselling for severely malnourished children to be managed at home				√	√
Schedule home visit and follow-up visits	√				√
Entry Point: Enrolment for Home-based Management					
Home visit of newly enrolled severely malnourished children and of children discharged from hospital or day-care based stabilisation					√
Scheduled home visits to refer for weighing to Satellite Clinic held that day, reinforce advice on feeding and inquire about any problems	√				
Weighing and weight gain assessment of children under home-based management			√		
Home visit of the severely malnourished child with inadequate catch-up growth or special problems				√	

[1] Additional clinic-level position to be established at initially only one pilot Intervention Clinic and, if needed, at all PSKP Intervention Clinics

Task	SP	SSP	Para medic	MO	Nutr. Couns.[1]
Management Tasks				√	√
Professional leadership, motivation					
Community liaison		√		√	√
Supervision of Service Promoter's outreach visits (schedule, quality)		√			
Quality assurance of weighing, plotting and interpretation					√
In-service training on nutrition counselling and group education					√
Record-keeping and report writing					√
Maintain Welfare Fund					√
If included: Manage/supervise supplement preparation					√
If included: Manage supplement logistics		√			

Incremental Workload Estimation for Service Promoters (SPs)				
	Period-based		Area-based	
	"Satellite Clinic Day"	Quarter (13 weeks)	Intervention Cluster	4 Intervention Clusters served by one SP
Households Intervention Cluster(s)			120	480
Target-age children (6 to 23 months) in Intervention Clusters			20-22 estim.	80-88 estim.
Outreach visits to households	10	120	120	480
Attendance from Intervention Clusters for monthly GMP at weekly Satellite Clinics, assuming 100 pct. coverage	5 - 6			
Severely malnour. target-age children if prevalence remained constant at 20 percent			4	16-18
Required contacts per Satellite Clinic session for weekly or bi-weekly follow-up with severely malnourished children (if all were under home management and prevalence remained constant)	2; max. 4			

Workload Estimation Relative to Severe Malnourished Children from Outside of Intervention Clusters Identified through Self-referred Visits to a Satellite r Static Clinic (Incidence-based Estimation)	
4 sites (one static clinics, 3 Satellite Clinic) each attended by 6 target-age children per day:	24 children per day
For a month with 20 working days	480 children per month
With 5 percent prevalence of severe malnutrition among self-referred attenders	24 children per month
Total follow-up need per Service Promoter[2]	8 newly identified children per SP per month
With bi-weekly follow-up	16 follow-up visits per SP per month
Conclusion: Since "self-referred" severely malnourished children could come from anywhere in the geographically large catchment area of PSKP static clinics, follow-up visits to such children will most likely not be feasible. For this reason, the protocol will only include management of children from within a 2-km radius of static clinics or Satellite Clinics that are intervention sites under the protocol.	

[2] remains incidence-based; should ideally be converted to a "steady state" prevalence estimate

ABSTRACT SUMMARY FOR THE ETHICAL REVIEW COMMITTEE

Community-based Protocolised Management of Severe Malnutrition. Principal Investigator: Prof. George J. Fuchs

Purposes of the Study: In urban Bangladesh, about sixteen percent of children age 6 to23 months have been found to be severely underweight, with another 30 percent being moderately underweight In Dhaka urban slums, almost one child in four among children age 6 to 23 months is severely underweight. In spite of the high prevalence of child malnutrition and its well-established contribution to child morbidity and mortality, only few of the existing primary health care clinics in Dhaka city seek to address child malnutrition as such.. Referral-level facilities for the management of severe child malnutrition are limited and expensive. The proposed investigations are part of a service and research protocol that will seek to strengthen existing capacities for the identification and management of severe child malnutrition among urban slum and low-income populations. Specific interventions under the *services component* will be:

- The Nutrition Unit of Dhaka Shishu Hospital will introduce protocolised management of severely malnourished children requiring hospitalisation.
- Staff of three urban primary health care clinics of an urban NGO (PSKP) will be trained to conduct nutritional assessments, refer severely malnourished children as needed or counsel caretakers on monitored home-based protocolised management, conduct growth monitoring and promotion in conjunction with weekly Satellite Clinics, and conduct quarterly outreach visits.
- Well-co-ordinated referral and discharge criteria and procedures to and from Dhaka Shishu Hospital, the three intervention PSKP clinics and homes will be developed and piloted.
- Progress of children once identified as severely malnourished will be monitored until six months after improvement from severe to moderate malnutrition in terms of weight-by-age.

The *research component* of the protocol will test the following *hypotheses*:

1. Adoption of protocolised management of severe malnutrition by the Nutrition Unit of Dhaka Shishu Hospital, based on the ICDDR,B adaptation of the WHO protocol for management of severe malnutrition, will result in reduced case fatality, increased proportions with satisfactory weight gain, and lower rates of withdrawal among children hospitalised for severe malnutrition.
2. Severely malnourished children discharged to or referred for home-based protocolised management will achieve adequate rates of weight gain and will improve from severe to moderate malnutrition within an eight-week period.
3. Identification and referral of severely malnourished children from urban low-income areas for protocolised management at a hospital and/or in the home, complemented by community-level growth monitoring and promotion, will reduce the population-level prevalence of severe malnutrition in the Intervention Area as defined for the protocol.

Item 1: Rational for using children as the study population.--The target population for the services as well as the research component of the study will be children age 6 to 23 months of age. Children of this age group are nutritionally at greatest risk and are also the target age group for the Bangladesh Integrated Nutrition Project and for the National Nutrition Program of Bangladesh.

Subjects for investigations under the research component of the study will be:

- Severely malnourished children below 5 years of age admitted to Shishu Hospital's Nutrition Unit from March 2000 with weight-for-length < -3 SD or oedema will receive protocolised management and will form the protocol group. Children admitted to the same unit by the same criteria in 1999, i.e., before the introduction of the protocol, will form the comparison group

- Children age 6 to 23 months of age who have ever been identified as severely malnourished (< -3 SD weight-for-age during any kind of contact with the pilot clinics for the intervention, i.e., visit to Satellite Clinic, static clinic or household-level outreach visit). Such children will be brought under protocolised management and will be longitudinally monitored for outcomes (recovery; relapse; moved out of area/loss to follow-up and death).

- All children age 6 to 23 months living in households belonging to 36 intervention and 24 comparison clusters of households which will evenly come from slum and non-slum urban low-income areas in the vicinity of Satellite Clinics on three pilot and two comparison clinics.

Item 2: Potential physical, psychological, social, legal or other risks posed by the study.—Neither the services nor the research component of the proposed protocol poses any risks to target-age children included or their guardians.

Item 3: Procedures for protecting against or minimising potential risks and an assessment of their likely effectiveness.—Not applicable.

Item 4: Methods for safeguarding confidentiality and protecting anonymity.—Investigations related to the first two study populations will be based on information extracted, respectively, from hospital records at Dhaka Shishu Hospital and from service statistics for the intervention maintained by three pilot clinics. Related information will not be divulged to any person not involved with the study , or to any other organisation.

Investigations for the population-level impact evaluation will be generated by household-level anthropometry of children age 6 to 23 months of age, complemented by about 15 to 20 questions and/or observations related to household socio-economic status, child's participation in growth monitoring and promotion, and utilisation of health care for the child. To protect the anonymity of children and household members, observations from the household-level interviews will receive an identifying number; identifying information for the household and its members will then be removed from individual records.

The fully-developed questionnaire for the interview questions in connection with child anthropometry will be submitted to the ERC meeting o March 2000.

Item 5: Informed consent procedures for the household-level child anthropometry and related interview. Participation in the research component of the protocol implies no risks of any kind.. In view of the privacy aspects, voluntary informed consent for the child anthropometry and related information will, however, be requested from children's parents or legal guardians at the outset of each household visit. The informed consent form drawn up for that purpose, which will be read out in Bangla by the Research Assistants conducting the baseline and follow-up surveys, will inform about the objectives of the study, details of the child anthropometry, absence of risks, potential benefits, maintenance of confidentiality, offer to answer any question and voluntary participation.

Item 6: Place and context of the household-level interviews and duration of household visits for child anthropometry and related interview questions: Child anthropometry and related interviewing will be done in the privacy or semi-privacy of rooms/houses or courtyards of households with target-age children. Visits to households with a target-age child will take an estimated 30 minutes—ten for introductions, explanation of study purposes and obtaining informed consent and ten each for the child anthropometry and related interview questions. Additional time (about 30 minutes) would be required for nutrition counselling if so requested by parents of moderately malnourished children identified by household-level anthropometry. Such time would, however, be spent as a service to the child and its parents, not for research purposes.

Item 7: Potential benefits to individual subjects as well as society in general:

- Compared to conventional management, introduction of protocolised management of children who are hospitalised with severe malnutrition, as foreseen under the services component at Shishu

Hospital, is expected to significantly lower the mortality risk of such children, when compared to case fatality under non-protocolised management.

- In the catchment area of the three pilot clinics for the protocol, interventions piloted under the service component of the protocol will offer otherwise unavailable nutrition services for the identification and management as well as prevention of severe malnutrition.

- In the catchment area of the two comparison clinics, identification of children who are either severely or moderately malnourished during the baseline and follow-up surveys will result in access to otherwise unavailable referral and/or nutrition counselling.

Demonstrating the effectiveness of protocolised management of severe malnutrition at Dhaka Shishu Hospital in terms of lowered case fatality will be an incentive for the introduction of protocolised management in other referral-hospital level nutrition units in Bangladesh and other South-Asian countries.

Demonstrating the effectiveness of community-based protocolised management in terms of recovery of severely malnourished children and reduction of the community-level prevalence of severe malnutrition will, similarly, provide an incentive and a rationale for including such nutrition services as part and parcel of the services offered by primary-care clinics throughout urban Bangladesh and in urban low-income areas in other developing countries.

Item 8: Use of Hospital and Medical Records: For hospitalised children, testing of hypothesis 1 above will require the use of hospital records. Hypothesis 2 above will be tested by the use of longitudinal clinic records for individual severely malnourished children, which will be developed specifically for use with the intervention.

Principal Investigator: Last, first, middle — Fuchs, Prof. George J.

Check List

After completing the protocol, please check that the following selected items have been included.

1. Face Sheet Included ✓
2. Approval of the Division Director on Face Sheet ✓
3. Certification and Signature of PI on Face Sheet, #9 and #10 ✓
4. Table of Contents ✓
5. Project Summary ✓
6. Literature Cited ✓
7. Biography of Investigators ✓
8. Ethical Assurance ✓
9. Consent Forms ✓
10. Detailed Budget ✓