Date 27.7.85

ETHICAL REVIEW COMMITTEE, ICDDR,B.

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Principal Investigator Drs. Bonita Stanton & A. Briend

Trainee Investigator (if any)

Application No. 85-005(P)

Supporting Agency (if Non-ICDDR,B)

Title of Study Pilot Protocol for Community Health (Nutrition Rehabilitation) Centre in Urban Area"

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

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

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

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

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

Principal Investigator

Trainee

1. Title: Pilot Protocol for establishing Community Health (Nutrition Rehabilitation) Center

2. Principal Investigators: Bonita Stanton,
Andre Briand,
Brenda Root

Co-Investigator: Naomi Phillips,
John Clemens

3. Starting Date: As soon as possible

4. Completion Date: 6 months

5. Total Direct Cost: 3,000 (funding under consideration by CIDA)

6. Associate Director for CSR:

This protocol has been approved by Community Services Research Working Group.

Signature: _____ *

Date: 27 Jan 95

7. Abstract Summary: In preparation for designing a full protocol to establish a community based health centre and to evaluate the long term impact of this center on weight, we wish to undertake a pilot protocol to determine the prevalence and severity of malnutrition, expected maternal participation, expected rate of weight gain, and address other issues related to the operation of a community based nutrition center.

8. Ethical Research Review Committee

Research Review Committee

Director

* Cover letter to chairman

BACKGROUND:

Need for Community Nutritional Rehabilitation Centers:

An estimated 22% of children less than 5 years of age suffer from malnutrition in rural Bangladesh [1]. Although accurate statistics for the incidence of malnutrition in urban Bangladesh are not available, malnutrition in the urban areas of most developing countries is at least as great a problem as it is in the rural areas [2]. In response to a growing appreciation of the magnitude of this problem UNICEF sponsored a workshop on urban malnutrition which listed the 7 most important nutritional-health interventions. Two of these interventions were promotion of breastfeeding and proper weaning practices, and nutritional rehabilitation for severely malnourished children (as well as ORT, immunization, and family planning) [3]. The report emphasized the importance of designing a program at the community level with community participation.

Need for Evaluation of Feeding Programs:

The report also emphasized the need for evaluation of programs. Although increasing evidence suggests the effectiveness of targeted nutrition rehabilitation programs [4] and community level nutrition programs are being advocated and funded in Asia, Africa and Central America by major organizations such as UNICEF [3], WHO [5] and the WFP there exists no prospective evaluation of the longterm effects of a community based nutrition center. Clearly, since an estimated US$227 million per year [6] is being spent on feeding programs and because, as an economic analysis prepared for the World Bank

suggested, food programs will be necessary to reduce the severity of malnutrition [7], carefully conducted studies of their efficacy is mandatory.

Another reason for the importance of evaluation of community nutrition centers is provided by Beaten and Ghassem in their elegant review of the major feeding programs. "We remain unconvinced that either the true effects or the full benefits of food distribution programs have been measured..." Currently available evaluation and program reports have limitations which include insufficient details for analysis, lack of baseline data, inadequate statistical testing, subjective conclusions, lack of controls and inadequate follow-up [8]. Clearly then a carefully designed evaluation of the impact of a nutrition center is of great importance.

Community Involvement and the role of the Urban Volunteer Program:

First however a good community based nutrition center must be established. Ingredients for a community center include: (1) a proper community involvement in the realization of and identification of their specific health needs; (2) the initiative for aid coming from the community; (3) the construction, development and running of a program by the community along with the consultants; and (4) the eventual independence of the community from the consultants (3,4). This process has already occurred (and resulted in 1 free standing community health centers) in several communities in the Urban Volunteer Program since it was begun 4 years ago. The most

recent request, which was formulated by several community members and articulated through the local chairman is to aid the community of Kaliganj, Keraniganj to address its problem of malnutrition. The community has donated land, a building and labor in request for our aid in establishing a nutrition rehabilitation center.

This center, once established, and if demonstrated to be effective in delivering a lasting improvement in growth, should be able to exist independently of the ICDDR,B by means of wider government involvement. The mechanism for achieving this will be explored and the issue will be further addressed in the full protocol.

PILOT PROTOCOL

Before implementation of such major intervention and evaluation more information about the prevalence and severity of malnutrition, expected maternal participation, and expected rate of weight gain in this community is necessary. Also, other issues related to the operation of a community based nutrition center need to be addressed (triage algorithms, etc...). For these reasons a pilot study is being proposed.

OBJECTIVES

Overall Objective:

To obtain necessary information to establish a community nutrition rehabilitation center and evaluation program in urban Dhaka.

SPECIFIC OBJECTIVES:

1. To define the extent of the problem of malnutrition and test the relevance of the chosen cut-off point.

2. To identify the target sub-population

3. To provide supplementary feed, using local and inexpensive feeds, nutrition education, other health inputs.

4. To assess efficacy and acceptability of this input against a realistic timescale.

5. To test the various instruments required for this exercise.

6. To investigate ways of integrating these activities in the existing government and other civil bodies capable of running such a program (if shown to be of value) on a long term autonomous basis.

7. To develop realistic algorithms for the treatment of triage of ill children who either are in the nutrition rehabilitation unit or are in the community but not in the center who seek advice, medicine or treatment.

8. To assess how rapidly a weight gain occurs in the malnourished children attending this center and determine if attaining a weight of 70% of median is an appropriate end-point.

9. Monitoring of direct costs.

MATERIALS AND METHODS:

Site: Kaliganj, Keraniganj. This community has an estimated population of 180,000 of whom 70% are described as "poor". A tin roofed, 2 room, (30 ft. by 8 ft. single standing dwelling) with tubewell, and concrete latrine, that is centrally located in Kaliganj has been donated for this purpose.

Selection of Patients: 1 bustee of approximately 300 families will be surveyed for patient selection during this phase of project. We anticipate that approximately 280 children <4 years will reside there. Children will be screened for malnutrition using arm circumference. Our target group will be

children with an arm circumference of <11.5 cm. These children will be screened by a pediatrician and any felt to be in critical need of emergency medical care will (not be entered into the nutritional rehabilitation center but rather will) be brought to the appropriate medical facility (ICDDR,B feeding unit, NU, etc.) Children will be ranked inversely according to arm circumference and % median weight for age and the lowest 15 will be invited to enroll in the feeding center at a time. Prior to their entrance into the Nutrition Unit all selected children (and their sibling and all other children from the participating bustee whose parents are interested) will be escorted by an Urban Volunteer to the government run EPI subcenter to receive measles vaccination (as well as DPT and OPV).

Centre Operation: The center will be open 6 days a week (closed Friday) from 8:00 AM to 5:00 PM. Children will be fed 3 meals; mothers will be fed 1 meal. Mothers will be obligated to stay from 8:00 A.M. until 12:30 to attend classes and on a rotational basis, clean-up, prepare food and assist in gardening. Afternoons, on a rotational basis some mothers will stay to help but the others may go home and return for the final feeding. Malnourished children will be encouraged to remain at the centre from 8:00 A.M. to 5:00 P.M. They will attend the center for 4 weeks.

Staffing: The center will be run by 3 trained urban volunteers. Two of these volunteers have received a 2-month training course at the New Life Center. All 3 are active

volunteers, literate, and currently enrolled in a 8-week nutrition training session at the ICDDR,B feeding center.

Nutrition Education: A series of 12 nutrition demonstrations and discussions will be given to mothers. Topics for discussion will include: breastfeeding, how children become malnourished, introduction of solid foods to child's diet, eating nutritious foods to stay healthy, nutrition in pregnancy and lactation, diarrhea, keeping food and water clean and environmental health.

Mothers will be taught how to prepare foods for their malnourished children. They will be involved on a rotational basis in marketing and preparation of foods at the center. All foods will be made from foods available from the local market.

Others Courses: Weekly lectures from local agencies (Agriculture Extension, EPI etc...) will be presented to all interested community members, not just nutrition rehabilitation participants. During this pilot phase we shall be organizing our panel of speakers and coordinating their efforts and investigating the most appropriate route for government involvement..

Analysis We shall be determing (1) mean number of days required to obtain the goal of 70% weight for height; (2) mean number of days of participation in the center; (3) percent acceptors of program; and (4) percentage distribution of malnutrition. We shall evaluate the statistical significance of contrasts with unmatched categorical data using the ch square

test and for matched categorical data the MacNamara chi square test.

Food: See Appendix I.

Duration of Stay: Children will stay until their weight reaches 75% median for age but not longer than 4 weeks. Children failing to gain weight will be brought to the ICDDR,B in hospital feeding unit for further evaluation.

Screening of Other Sites: During the pilot phase of the feeding center we shall begin screening for nutritional status of a large bustee (population approximately 10,000) which would be the target of the first phase of the full protocol.

Significance: Information obtained from the pilot will permit the construction of an appropriate sized sample size and experimental design in the full protocol to answer the desired questions regarding the long term effcacy of a community based nutrition rehabilitation center.

Facilities Required:

1. Office - no additional
2. Laboratory - no additional
3. Logistic - no additional
4. Equipment - length board
5. Field space - provided by community.

ABSTRACT SUMMARY

1. See materials.

2. None - only invasion of privacy.

3. Data will be maintained using code numbers.

4. None.

5. a) As most patients are illiterate, a verbal explanation will be made.

   b) NA

   c) NA

6. Home and for selected children only in center.

7. Participating children will receive additional food, immunization and education of mothers. All community children will be aided in procuring basic childhood immunizations. Additional health information will be made available to the entire community.

8. NA.

Budget

Personal:

	Percent Effort	Amount in U.S. $
Pediatrician	25	-
Nutrionist Physician	20	-
Nutrionist (Naomi Phillips)	100	-
Health Educator (Brenda Root)	50	-
Nursing (Mrs. Gafar)	50	-
Community Health workers	100	500
Interviewer for 3 months		500

Supplies:

Food - 250 tk day x 6 days x 25 weeks	1500
Local Transport	200
Measuring Board, office supplies	300

Some Recipes for Demonstration[1]

Halua 1

Mix
- 3 parts rice powder
- 1 part dal
- little oil
- few pieces of shag

Cook with water until soft.
Cut shag into little pieces.

Halua 2

Mix
- 3 parts atta
- 3 tsp fish powder
- ½ part shag
- little oil

Cook with water until soft.
Cut shag into little pieces.

Dal-Bhat and Vegetable: Khichuri

Add
- 1 part dal
- 2 parts unpolished rice
- 4 parts water
- 3 small onions
- Add little oil

Shag/sweet potato/sweet pumpkin/carrot

Cook with water until soft
Cut shag into little pieces

Fish Powder

Use small fish like puti and khalisha
Clean the inside of the fish
Put the fish in the sun a few days until it is dry
Grind the whole fish, including the head and bones until it is like powder.

Banana Mix

Mix together
- 1 mashed banana
- 1 small egg (if available)
- 3 tsp sugar

Fry in small amount of oil.

Suji

Mix
- 4 tsp of atta with a little cold water
- 1 cup water

Add
- 1 tola gur (molasses)
- 1 small egg
- little oil

Cook for a few minutes
Add some cooked shag and cut into small pieces

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[1] Used by Radda Barnen, Nutrition Centre, Mirpur, Dhaka, Bangladesh.