EThICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: Sthila ZEinlyN
Trainee Investigator (if any)________

Application No. 92-04

Supporting Agency (if Non-ICDDR,B)____

Title of study: An Ethnographic Study of the Effectiveness of Rape Precautionary Behaviours in các Morte, Bangladesh

Project status: 

[ ] New Study
[ ] Continuation with change
[ ] No change (Do not fill out rest of form)

---

Circle the appropriate answer to each question.

1. Source of Population:
   (a) All subjects Yes No
   (b) Non-all 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 corpora 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 Yes No
   (c) Physical risks Yes No
   (d) Sensitive questions Yes No
   (e) Benefits to be derived Yes No
   (f) Right to refuse to participate or withdraw from study Yes No
   (g) Confidential handling of data Yes No
   (h) Compensation for treatment where there are risks or privacy is involved Yes No

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I/we agree to obtain approval of the proposal involving the rights and welfare of the subjects making such changes.

Principal Investigator ________
Trainee Investigator (if any) ________

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Date: [Date]
TITLE OF PROJECT: AN ETHNOGRAPHIC STUDY ON FEEDING BEHAVIOUR AND THE ACCEPTABILITY OF ARG FORTIFIED WEANING FOOD

PRINCIPAL INVESTIGATOR: Dr. Zeitlyn,  
CO-PRINCIPAL INVESTIGATORS: Dr.'s Faruque and Mahalanabis

CO-INVESTIGATORS: Ms. Rabeya Rawshan, Mrs. Mujib and Mr. Mahmudur Rahman.

STARTING DATE: AS SOON AS POSSIBLE

Amount:

Donor:

Division: Clinical Sciences Division

Signature: Dr. D. Mahalanabis, Associate Director, CSD
ABSTRACT

This study will investigate the acceptability of promoting amylase rich germinated cereal flour (ARGC) as an additive to usual home based family foods. ARGC will be demonstrated to parents of 60 weanling children aged between 6 and 24 months suffering from mild diarrhoea. Parents will be given dietary advice, a demonstration and some ARGC on discharge from the out-patients clinic and advised to add it to the normal family diet to make it more acceptable as a weaning food. A comparison group will be given similar dietary advice and a demonstration but will not be told about or given ARGC. The mothers’ immediate responses will be recorded and follow up visits and interviews in the home will be made to assess the parents compliance with and acceptance of the advice. The aim is to see whether ARGC can increase the acceptability of giving infants and children a greater share of family foods.

Approval - Committees

Research Review Committee: ......................... date: ........

Ethical review Committee: ......................... date: ........

Director: ................................................. date: ........
SECTION II
RESEARCH PLAN

OBJECTIVES

(1) To assess the acceptability of promoting Amylase rich germinated wheat flour (ARGC) as an additive to the normal family diet for weanlings and to identify which parts of the desired behaviour (adding ARGC to the child's food) are readily adopted.

(2) To identify barriers to acceptance and utilization in the community.

(3) To compare compliance with nutrition advice between the study and comparison groups in order to see whether ARGC promotes improved weaning practice.

(4) To develop an appropriate replicable strategy to improve weaning practices through promotion of ARGC.

HYPOTHESIS

Our central hypothesis is that Amylase rich germinated wheat flour can increase the acceptability of normal family foods to infants and children.

BACKGROUND

In many developing countries the weanling child (the breast fed child who is regularly receiving additional food) suffers a high level of morbidity and mortality. The initiation of adequate weaning is a critical event (1). Mortality is closely related to morbidity and nutritional status so that undernourished children have a higher risk of death from diarrhoeal disease than their well nourished counterparts. For this reason nutritional rehabilitation for malnourished children with diarrhoea has been proposed (2).

Nutritional status is related to the socio-economic status of the child's family, nutritional status has been postulated to be one of the main pathways by which socio-economic status influences child mortality (3). If rehabilitation is to be effective it must be sustainable in the home environment after the child has been discharged from the clinical setting. Nutritional status is determined not only by availability but also by distribution both within the community and the household. At the household level age, gender and kinship may all influence the pattern of distribution. Thus females may receive less than male household members and similarly the nutritional needs of weanling children may be underestimated.
The weanling child has to make a gradual transition from pure breastfeeding to his or her share of the family diet. In a context where resources are very limited, weaning advice should be appropriate if the diet is too expensive or requires extra fuel or time to prepare parents may be unable to provide it. Similarly, if it is culturally unacceptable people are unlikely to follow advice. Nutrition education must be realistic and relevant (4). Cheap locally available foods which are already part of the usual family diet should be stressed. In Bangladesh since the energy and protein deficits for normal growth are very large the total amount of food may be more important than the exact composition of it as families may not be able to afford protein foods. At the same time sustained breastfeeding is essential (5,10).

Economic factors are not the only barriers to good weaning. Many infants find swallowing solid food difficult. Foods may be high in dietary bulk but low in nutritional density (6). If food is diluted with water the energy density is reduced and the child may receive less nourishment. Oil and fats have been identified as one way of escaping the dilemma of how to increase viscosity without reducing nutritional density (4). Oil is, however, relatively expensive. Furthermore, Bangladeshi parents are reported to be reluctant to give foods such as oil, pulses, vegetables and fish to children under one or even two years of age because it is widely believed that they will be unable to digest these foods and that such food may cause or exacerbate diarrhoea (7). Thus the child who suffers from diarrhoea may also suffer from a very restricted and inadequate diet. The concept of digestion is reported to be central in South Asian systems of health belief such as the Ayurvedic system in which all diseases are believed to be caused by "unripe food juices" produced when the digestive process does not occur correctly (8). Preoccupation with digestive problems has been reported in several ethnographic accounts elsewhere in the sub-continent (9).

Amylase rich germinated cereal flour has been successfully used in other developing countries including India. Studies in India suggest that it has the potential to improve the energy intake and growth of young children (6). ARGC is prepared from germinated wheat flour in the ICPDR, B laboratory and the advantage of it is that it could be easily and cheaply manufactured locally. When added to solid foods such as rice it liquefies them without reducing the energy density or the nutritional quality of the food. The amylase powder can be simply added to the family foods while they are warm to make the food easier for the weanling to consume. If this ARGC powder could be used to promote the idea that small children need and should receive an adequate share of the normal household diet it might contribute to improving the nutritional status of weanlings in Bangladesh. Because ARGC is an enzyme and because people are concerned about their children’s digestion the powder will be called "Hojni Gouta" or digestive powder. We do not want to mystify parents and for this reason we shall emphasise that the ARGC powder has no medicinal or nutritional properties in
itself and will stress the nutritional message that weanlings can and should eat a modified share from the family pot.

In order to develop an appropriate and replicable strategy, an understanding of existing practices and community perceptions on the weaning process and the relationship between diarrhoeal disease and diet is needed. We need to know specifically how parents react to the idea of ARGC and whether it makes them less resistant to the idea of introducing normal family foods to the weanling infant. Will nutrition education combined with amylase encourage beneficial changes in beliefs and practices? This kind of qualitative information is hard to obtain through normal survey questionnaire methods and for this reason an anthropologist will be trained and used in this study.

METHODS AND PROCEDURES

Because this is a study of actual attitudes and practices we shall use qualitative quasi anthropological methods.

SELECTION

Parents of children aged between six and twenty-four months who have been admitted to out-patients with mild diarrhoea will be selected and randomly allocated either to the study or to a comparison group. Because focus group discussions require a minimum number of people to be present at one place and time patients will be allocated to the intervention or comparison groups on different days.

INITIAL INTERVIEW

After selection a brief initial interview will be conducted to obtain basic demographic and socio-economic data and information on the child’s previous dietary history as well as the family’s normal diet. (See Appendix A).

DEMONSTRATION

The parents will be then invited to participate in the study. Groups of four to five mothers will be given a demonstration using either ARGC plus ordinary food or only ordinary food. Participants will be invited help themselves to taste and eat the foods and feed them to their children. Their immediate reactions to the food tasting and demonstration will be observed and recorded. In both the experiment and the control groups the importance of diet in the survival of children who have suffered from diarrhoea will be explained. In both groups the mothers will be asked to describe what they usually eat and what they feed to their children, they will then be advised to give their infants whatever foods are available from the family pot and to add sufficient oil to the food. Sustained breastfeeding will be strongly encouraged (10).
FOCUS GROUP
This will be followed by focus group discussions where the parents' initial responses to the dietary advice and demonstration will be recorded. Research assistants will help and observe each mother and child and their feeding practices and observation sheets will be completed and attached to the focus group transcripts. The observation sheets will record which foods the child eats or rejects, how he eats, the amount and the mothers' observations and responses. Focus Group guidelines have been designed (see Appendix B). The focus groups will be semi-structured to allow for general ideas about infant weaning, digestion, the dietary management of diarrhoea and other concerns to be voiced. Ideas on the relevant qualities of food, such as its consistency, temperature and taste, that make it acceptable or not for weanlings will be probed. Focus groups will be moderated by a trainee anthropologist assisted by a Field Research Officer under supervision of the PIs. The focus group tapes will be transcribed in Bangla immediately after the sessions, and will then be translated into English by the anthropologist who will assist in their analysis.

Both groups will be advised to give their children a modified version of their normal family diet as part of their rehabilitation at home. The study group will also be given some Amylase rich germinated wheat flour powder and advised to use this at home.

SECOND FOLLOW UP HOME VISIT and INTERVIEW
After two weeks each patient's home will be visited and an individual semi-structured interview will be conducted to inquire about the child's progress and detailed information on-diet and recall and compliance with the dietary advice received in the hospital. Further follow up visits will be made to families who have accepted and are using ARGC as well as to those who have not complied. A special interview instrument has been designed, (see Appendix C). We shall not be measuring the outcome in terms of nutritional status, because this has been done in other studies and for this reason anthropometric data will not be gathered. Parents will be asked to demonstrate and explain their feeding practices in the course of the home interview. The study will take approximately one year including time for training, preparation, selection, data collection and detailed analysis and write up of the data.

RATIONALE
Impaired nutritional status carries with it the increased risk of morbidity and mortality (1). In a community where nutritional status is generally poor and resources are scarce it is important to develop a realistic strategy for weaning. Appropriate promotion and use of ARGC may help to overcome some of the barriers to increasing the early introduction of family foods to the weanling child. An effective weaning strategy can only be devised on the basis of a thorough understanding of community perceptions and parental responses. This kind of data is hard to obtain through normal survey methods and for this reason, a qualitative
anthropological study is proposed. As well as providing useful and important data this study will provide an opportunity for a Bangladeshi MSS anthropologist to gain practical, applied training and experience which will be of future benefit to applied health research in ICDDR, B.

DATA COLLECTION AND ANALYSIS

Basic socio-economic, demographic information and other questionnaire data will be coded and entered in the computer. Qualitative data from interviews and focus groups will be recorded, transcribed, translated and entered on the word processor and analyzed separately by the anthropologists using TALLY a text analysis tool. The pre-intervention and post-intervention data will be summarized and compared. The analysis will provide a general description of parental responses to the idea of introducing solid foods from the family pot. In particular it will compare the responses of those who were offered ARGC with those offered only nutritional advice.
ETHICAL IMPLICATIONS

This study will not involve taking any samples or performing invasive procedures. All participants will be asked to sign a written consent form (see Appendix C) and strict confidentiality will be maintained. Any children who require treatment at the time of the home visit will be bought for treatment at the ICDDR,B treatment centre.

REFERENCES


8) Tabor, D. C., Concepts of Ripe and Unripe. Social Science and Medicine, 15B 1981.


Personnel Requirements:

A. Professional scientific staff

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<th># months</th>
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<td>Ms. Rabeya Rawshan</td>
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<td>Mr. Mahmudur Rahman</td>
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<td>Dr. Sushila Zeitlyn</td>
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B. Technical Staff

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SUMMARY BUDGET

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<td>Personnel</td>
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<td>Local Travel</td>
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Total: 57,300
CHILDS ID NO  /  /  /  /  /  /  /  /
Control /  /  /  /  /  /  /  /
Study /  /  /  /  /  /  /  /

Form I  Hospital interview  ARGC STUDY

Date /  /  /  /  /  /  /  /  / Time

Interviewer

(1) Name of child

(2) Name of Mother

(3) Address

(4) Date of birth : /  /  /  /  /  /  /  /  / 7 - 12 Date

dd mm yy
(5) HOUSEHOLD COMPOSITION

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<th>age</th>
<th>sex</th>
<th>income</th>
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6) total household members /_/_/|
7) total income /_/_/_/_/|

8. Father’s Occupation.

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<td>1</td>
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<tr>
<td>unskilled day labourer</td>
<td>2</td>
</tr>
<tr>
<td>skilled day labourer</td>
<td>3</td>
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<tr>
<td>salaried labourer</td>
<td>4</td>
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<tr>
<td>rikshaw puller</td>
<td>5</td>
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<tr>
<td>Street vendor</td>
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<td>small businessman</td>
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<td>10</td>
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9. Father’s monthly income taka /_/_/_/_/|
10. Mother's occupation:  
   - Housewife = 1  
   - Garment worker = 3  
   - Helper/servant = 0  
   - Service = 4

11. Mother's income: __/__/__

12. What are your main expenditures?

13. What weight of rice do you cook every day? __/__/__

14. Own House __/__ (yes=1, no=2) Rent __/__ squat __

15. House rent __/__/__/__

16. Father's education __/__/__

17. Mother's education __/__/__

18. Number of rooms __/__/__

19. Number of beds __/__/__

20. Floor type __/__/__
   - Earthen = 1
   - Pucca = 2

21. Radio __/__/__

22. Fan __/__/__
   - Yes = 1, No = 2
23. Why do you think your child became sick?

24. What did you do when your child became sick?
FEEDING HISTORY

25. Is child breast fed now? yes=1, no=2. /_/.

26. If no how many months was the child breast fed /_/

27. If no, Why was breast feeding stopped?

28. Is child bottle fed? (yes=1, no=2) /_/.

29. How many months old was child when it started to regularly eat solid food other than breast milk? /_/ /_/ /_

30. What solid food did you first give your child?

..............................................................
31. On the day before the sickness what did child eat and drink?

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<th>Why?</th>
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Breast milk /_/  Eggs /_/  Cows milk /_/  dal /_/  Powder milk /_/  veg /_/  Suji + milk /_/  ruti /_/  Biscuit /_/  fruit /_/  Rice /_/  Fish /_/  Other /_/  Meat /_/  

32. Were any foods or liquids withheld because of diarrhoea?

Yes = 1, No = 2, /_/  

33. If yes which ones?

34. If yes why were these withheld?
35. What does your child normally eat when well?

Breast milk /\ Egg /\ (yes=1, no=2)
Powder milk /\ Dal /\ 
Suji + milk /\ veg. /\ 
Rice /\ rutti /\ 
Fish /\ biscuit /\ 
Meat /\ fruit /\ 
cow's milk /\ commercial baby food /\ 
others /\ barley /\ 

36. What kinds of food does your child like best?

37. Why?
38. What consistency does he or she like?

39. Does he or she prefer soft/ / hard/ / semi-hard/ /

40. How many times a day does he or she eat food other than milk? / / /
FOCUS GROUP GUIDE LINES (ARGC)

We have shown you this demonstration of rice, dal, vegetables and small fish mixed with some hojmi goura powder because we believe that some or all of these foods should be included in your children's diet every day to help them recover their strength and resist further attacks of diarrhoea. The powder changes the food and helps to make the food easier for the child to swallow. Each child has its own likes and dislikes and every family has its own routine. Mothers have to find their own ways to persuade their children to eat a share of the family food. This powder is not a medicine it will not stop diarrhoea but we would like to see whether it can make eating easier for small children because we have found that those small children who are well fed are more likely to survive diarrhoea. Breast milk combined with other family foods is the best way to help your child build strength to resist the bad effects of diarrhoea on health. In many cases there is no quick cure for diarrhoea but a healthy well nourished child will recover more quickly. These ideas may not be popular with older members of the community, some people may say it is unnatural or dangerous to feed an infant under one year of age with dal or vegetables for example.

Have you heard this kind of opinion?
Do neighbours or family members believe this? Why?
(Probe for ideas about immature digestion.)

What did you think of our demonstration?

Did you and your children like the taste?

What about the texture of the different foods?

Do you think that the Hojmi Gura powder made the food easier for the child to eat?

If so why?

What do your children normally eat at home?

What difficulties do you have in feeding them?

What age do you think children might start to eat such food?

Do you have difficulties persuading them to eat?

Do they find it easier to eat soft, liquid or solid foods?

What foods do they like?
(give positive reinforcement to all mentions of cheap locally available foods such as suji, muri, rice, roti or any other snacks)

Will you be able to use this powder in your own home? How will you use it
HOME INTERVIEW ARGU STUDY

Child ID Number: __/__/__/__/__/__/__

Date: __/__/__/__/ Time: __/__/__/__

Interviewer's name: __________________________

(1) Child's name: __________________________

(2) Date of birth: __/__/__/__

(3) How is child now? __________________________

Diarrhoea Better/__/ Worse/__/ Same/__/ 

(4) What did your family eat yesterday? ______________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
(5) How much rice did you cook yesterday /__/ Kg.
(6) Did you use oil /__/ (1=yes, 2=no)
(7) If yes how much did you use?  /__/
(8) What did child eat yesterday?

<table>
<thead>
<tr>
<th>Time</th>
<th>Food</th>
<th>Why?</th>
<th>ARGC</th>
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(9) What dietary advice did you get in hospital?

(10) Has the child's diet changed since leaving hospital /__/
     (yes=1 no=2)

     If yes HOW?

(11) Increased frequency solid food /__/
(12) Increased quantity solid food /__/
(13) Is child still breast fed /__/
(14) Has breastfeeding increased /__/
ARGC GROUP

(15) Have you been using the Hojmi Gura? /_/ (yes=1, no=2)

(16) Have you any left? /_/ 

(17) How does your child like it? ..............................................

.................................................................

.................................................................

(18) Has it helped him/her to eat more? .................................

.................................................................

....................

(19) Tell them to show how they use it and describe

.................................................................

.................................................................

.................................................................

.................................................................

.................................................................

.................................................................

.................................................................

(20) Would you like more ARG? /_/
OBSERVATION

(21) Is child present / / (yes=1 no=2)
(22) Is mother present / / 
(23) If not who is caring for child.................................

(24) Did child eat during your visit? / / (1=yes, 2=No)
(25) If yes describe....................................................

(26) No of beds / / / / 
(27) No. of rooms / / 
(28) Own chula / / (yes=1, no=2)

(29) Where is chula....................................................

(30) Floor pacca/ / mud / / 
(31) Fan / / 
(32) Other electrical goods...........................................

(33) Can you see a feeding bottle / / 
(34) Can you see powdered milk? / / 
(35) Can you see any food / / 
(36) Where is food for child stored?.........................

(37) Source of drinking water pipe / / tube well / / 
     other..........................................................
CONSENT FORM (Study Group)  Appendix D

ARGC STUDY
The purpose of this study is to improve the nutritional status of young children. The International Centre for Diarrhoeal Disease Research Bangladesh is testing the acceptability of Amylase rich germinated cereal powder when it is added to weanlings food. We want to know how young children and their mothers like the taste and whether it makes eating easier for young children. We would like you to taste it and to take some home to try it there and tell us how you use it and whether your child enjoys it. We will give a demonstration meal in the hospital and some samples of ARGC powder to take home and will then visit you at home two weeks later to ask you some questions. If you do not wish to participate this will in no way influence the treatment that your child receives in the hospital.

If you are willing to agree to participate in this study please sign.
CONSENT FORM (Comparison Group) Appendix D2

ARGC STUDY
The purpose of this study is to improve the nutritional status of young children. The International Centre for Diarrhoeal Disease Research Bangladesh is testing the acceptability of giving weanling children a greater share of the normal family diet. We want to know how young children and their mothers like the taste and what foods are easiest for mothers to feed their children. We would like you to taste our food and to try feeding your child a share of your own normal family foods at home. We would like you to tell us your experiences and how your child enjoys his or her food. We will give a demonstration meal in the hospital and will then visit you at home two weeks later to ask you some questions. If you do not wish to participate in the study this will not influence the treatment your child receives in the hospital.

If you are willing to agree to participate in this study please sign.
অর্থনীতি (Study Group)  পরিকল্পনা

ARKC Study

শেষ গবেষণার দৌড়ের ছানা বাঞ্ছাবদ্ধ করেছিলেন, পুলিষার ছানা বেরিয়ে আসছে। আত্মরক্ষিত দূষণবাহী সাহায্য করেজ গবেষণার শুরুতে বাঞ্ছাবদ্ধ করেছি। আগারুর আঁকা আঁকাইনো মুক্তি অনুকূলিত করে শুরু করতে হবে। একটি পানি ও উষ্ণতা অনুযায়ী পানি করতে হবে। ফলস্বরূপ, আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি। ফলস্বরূপ, আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি।

আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি। আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি। আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি। আঁকাগুলো আঙ্গনে আঙ্গনে আঁকা আঁকা হয়েছে বেশি।

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নমস্তে অনুবাদকের হ্যালো, আমার নাম দীপাত্মা। আমি ARGC প্রতিষ্ঠানের কর্মচারী। আমি এই চিঠিপত্রটি দিয়ে আপনাকে বলতে চাই যে, আমি আপনার কাজে সমর্পিত একজন ছাত্র।

আমি এই চিঠিপত্রটি দিয়ে আপনাকে বলতে চাই যে, আমি আপনার কাজে সমর্পিত একজন ছাত্র।
Title: An ethnographic study of acceptability of ARGC fortified weaning food

Summary of Referee's Evaluation: Please use the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

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CONCLUSIONS

I support the application:

a) without qualification

b) with qualification
   - on technical grounds
   - on level of financial support

I do not support the application
- Analyze those parts of the desired behavior (adding ARGC to the food and giving it to the child) which are, and are not, readily adopted;

- Identify material, cognitive, and/or behavioral barriers to the adoption of the new practices;

- Identify what works best to reinforce learning;

- Refine teaching and reinforcement strategies for the desired behavior (Rasmussen et al. 1988).

In addition, in this study acceptability of foods to which ARGC has been added will be examined. It would be desirable to have a list of all the variables to be studied and, in the case of acceptability, its operationalization (for example, if the child eats all the food, asks for more, etc.) and a simple method of assessment. I know there are established nutritional methodologies to do this. Acceptability in both mothers and children should be examined.

Other comments:

1. Demonstration focus groups can begin with the discussion of the participants' knowledge, beliefs, concerns and (reported) practices of infant and child feeding. Then the demonstrations is performed and, finally, a discussion of the immediate reactions to the demonstration can take place. The mothers and children could also taste the different (?) foods to which ARGC has been added for the demonstration and acceptability could be observed and recorded (focus group discussion guide and acceptability instrument should be prepared). Also, the name given to the product can be tested, if that has not been done already.

2. I would not recommend transcription of tapes recorded during group discussions because that can take too long. It is preferable to work from the notes taken by the observer/recorder and compile notes while listening to the tapes. This should be done right after the group session.

3. A special interview instrument should be designed and tested for the follow-up visit. Again, a list of the variables to be explored would be desirable, as well as a draft instrument. Aspects to explore are: what does the mother remember about the recommendations provided? could she follow them? what part could she follow? why not other parts? etc.

4. Having found that some mothers could perform the desired behavior ("adopters") and others could not ("non-adopters"), the beliefs, motivations, perceptions, explanations of these two different groups of mothers could be explored in focus group sessions.

5. The hospital interview instrument presented would be unnecessary if children were recruited at the community level.

6. A detailed calendar of activities could be helpful to demonstrate feasibility of conducting the study within time period. I think, though, that it is feasible.
The experimental design is not generally used in qualitative/exploratory/descriptive research. However, for this study an experimental design (with random allocation to a treatment and a control group, post-test only comparison) has been chosen. This doesn't mean that a study with the proposed design cannot be conducted, but if it were, sample size calculations should be performed and presented; that is, how many children should be studied in each of the two groups if the investigators wish to be 90% or 95% confident of rejecting the null hypothesis. Also, outcome variables should be clearly defined. These clinical trials are usually conducted before community trials and acceptability measures can be part of them.

However, on the other hand, you are also proposing to conduct an acceptability - behavior trial at the community level. I don't think a control group is really necessary for that. Maybe, if some control is still wanted, it could be done with a more loose comparison group or with a one group pretest - post test design. The amount of particular foods that study children consumed in eating episodes before the intervention and after the intervention (adding ARGC to foods) can be compared. Or maybe you already have data on usual intake of children that age and of that socioeconomic background against which to compare intake with ARGC. Also, since the central hypothesis doesn't deal with the nutritional management of children with diarrhea, I don't understand well why would children recently having diarrhea be used - is it just because it would be easier to recruit them in the hospital? Is that the best option?

A behavior trial (which I think this is, although the behavioral part is not reflected in the title of the proposal) is a small-scale field test of a new behavior to help determine its viability as an intervention on a larger scale. In this study, the behavior trial will help determine the mother or caretaker's ability to add ARGC to the family food given to the young child. This study can help:

- Identify acceptability looking at baseline behavior
- Identify at what point
- If the intervention does or does not change behavior
COMMENTS ON PROJECT PROPOSAL: AN ETHNOGRAPHIC STUDY ON ACCEPTABILITY OF ARG C FORTIFIED WEANING FOOD

This is a good proposal, one with a clear rationale and appropriate design. An exploratory study depending primarily on qualitative methods, it is likely to produce important insights that could inform future programs intended to have large scale impact on morbidity and mortality of infants and young children.

To name of the product 'digestive powder' seems to be an excellent idea and may improve acceptability.

The use of a control group seems reasonable, though not strictly necessary in this type of study; an important justification for this is that it will show whether or not ICDDR,B has a patient education program that can induce patients to improve young children's diet without any extra features, such as a 'digestive powder'. I suggest, however, that if the group receiving ARG C is found early on to be accepting the product to the benefit of treatment group children, and if control group children are not doing as well as the others, the use of a control group not be prolonged.

The team's methods of record-keeping are all-important, as I am sure the principal investigators are fully aware, and I suggest that computers may be used for all data, not just tabulation of demographics. For example, indexed notes kept on a word processor would help to fully exploit all verbal comments for important insights they are sure to provide.

Without any question lists or other study protocols, I am
unable to evaluate the study methodology beyond making certain general suggestions (most of which I am sure already have been integrated into the design). I would like to know, for example, just how children’s nutritional status will be assessed during home visits, and how many visits are to be made to each home during the year. I trust that researchers plan to determine exactly why parents do or do not give all types of available foods to children during the weaning period, in order to expand knowledge, but also to understand the reasons why ARGC is or is not eventually accepted by the study treatment group. Ideas about ARGC itself are sure to be developed by users, and the research team will, I assume, be looking for the 'hot/cold' or other properties that come to be attributed to the product.

Without detailed information on staffing or budget, I cannot comment on this aspect of the proposal, except to offer the suggestion that guidance of very skilled ethnographers is essential to a good outcome in an exploratory study of this type.
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