

Rev. Allen Ph.D.  
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Date 20th April 1972

Form 1.  
(PAGE THREE)

ETHICAL REVIEW COMMITTEE, ICDDR, B.

Principal Investigator SUSHILA ZEITLYN Trainee Investigator (if any) \_\_\_\_\_

Application No. 92-014 Supporting Agency (if Non-ICDDR, B) \_\_\_\_\_

Title of study An Ethnographic Study of Feeding Behaviour & the Acceptability of RSC Formed Weaning Food 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)

- Source of Population:
  - (a) All subjects Yes No
  - (b) Not all subjects Yes No
  - (c) Minors or persons under guardianship  Yes No
- Does the study involve:
  - (a) Physical risks to the subjects Yes  No
  - (b) Social Risks Yes  No
  - (c) Psychological risks to subjects Yes  No
  - (d) Discomfort to subjects Yes  No
  - (e) Invasion of privacy Yes  No
  - (f) Disclosure of information damaging to subject or others Yes  No
- Does the study involve:
  - (a) Use of records, (hospital, medical, death, birth or other) Yes  No
  - (b) Use of Fetal tissue or abortions Yes  No
  - (c) Use of organs or body fluids Yes  No
- Are subjects clearly informed about:
  - (a) Nature and purposes of study  Yes No
  - (b) Procedures to be followed including alternatives used  Yes No
  - (c) Physical risks Yes  No
  - (d) Sensitive questions Yes  No
  - (e) Benefits to be derived Yes  No
  - (f) Right to Refuse to participate or to withdraw from study  Yes No
  - (g) Confidential handling of data  Yes No
  - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure  Yes No

- Will signed consent form be required:
  - (a) From subjects  Yes No
  - (b) From parent or guardian (if subjects are minors)  Yes No
- Will precautions be taken to protect anonymity of subjects  Yes No
- 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)
  - Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
  - Informed consent form for subjects
  - Informed consent form for parent or guardian
  - Procedure for maintaining confidentiality
  - Questionnaire or interview schedule

\* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

- A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
- Examples of the type of specific questions to be asked in the sensitive areas.
- An indication as to when the questionnaire will be presented to the Cttee. for review.

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

Sushila Zeitlyn  
Principal Investigator

Trainee

TITLE OF PROJECT: AN ETHNOGRAPHIC STUDY ON FEEDING BEHAVIOUR AND  
THE ACCEPTABILITY OF ARGC 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 ICDR, 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 liquifies 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 "Hojmi Gouda" 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 s/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 brought for treatment at the ICDDR,B treatment centre.

## REFERENCES

- 1) Rowland, M.G.M. The Weanlings Dilemma: Are we making progress? Acta Paediatr Scand, Suppl. 323:33-42, 1986
- 2) Roy, S.K., Chowdhury, A.K.M.A., Rahman, M.M. Excess mortality among children discharged from hospital after treatment for diarrhoea in rural Bangladesh. British Medical Journal 15 October 1983, 287, 1097-1099.
- 3) Abbas Bhuiya et al, Socio-Economic Determinants of Child Nutritional Status: Boys Versus Girls. Food and Nutrition Bulletin, Vol, No.3
- 4) Church, M.A. Evaluation as an integral part of nutrition education. In Evaluation of Nutrition Education in Third World Communities. A Nestle Foundation Workshop Sep. 1982.
- 5) Evaluation of Nutrition Education Messages for Supplementary Feeding: The Bangladesh Experience. Report Prepared by L. Brown and Marian Zeitlin for USAID 1989.
- 6) The ARF Story: A Compendium of Research on Amylase Rich Food 1980-1989 Prepared on the occasion of IDRC sponsored national/international workshop on ARD Technology, Oct. 1990 Dept. of Foods and Nutrition, Faculty of Home Sciences MS University of Baroda, India.
- 7) Zeitlyn, S. J. and Islam, F. Patterns of Child Feeding and Health Seeking Behaviour in Bangladesh: Two Case Studies. Unpublished Report.
- 8) Tabor, D. C., Concepts of Ripe and Unripe. Social Science and Medicine, 15B 1981.
- 9) Nichter, M. Anthropology and International Health: South Asian Case Studies. Kluwer Academic Publishers: 1989.
- 10) Briend A, Wojtyaniak, Rowland MGM, Breastfeeding, nutritional state and child survival in rural Bangladesh. Br.Med J 1988;296:879-82.

**Personnel Requirements:**

A. Professional scientific staff	%time	# months
1. Dr. Mahalanabis	5	12
2. Dr. A.S.G. Faruque	5	12
3. Ms. Rabeya Rawshan	100	12
4. Mr. Mahmudur Rahman	5	12
5. Dr. Sushila Zeitlyn	30	12
B. Technical Staff		
1. Female Interviewer	4	100
		12

**SUMMARY BUDGET**

1. Personnel	US \$	35,000
2. Local Travel	US \$	7,000
3. Supplies	US \$	5,300
4. Interdepartmental Services.		7,000
5. Data analysis	US\$	3,000
	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 :   /  /   /   /  /   /   /  /    
  dd     mm     yy

7 - 12

Date

✓

(5) HOUSEHOLD COMPOSITION

name    relationship    age    sex    income

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

6) total household members    /\_/\_/

7) total income                          /\_/\_/\_/\_/

8.      Father's Occupation.....

Beggar	=1	Street vendor	=6
unskilled day labourer	=2	small businessman	=7
skilled day labourer	=3	Big businessman	=8
salariied labourer	=4	Proffessional	=9
rikshaw puller	=5	migrant	=10
		unknown	=99

9.      Father's monthly income taka    /\_/\_/\_/\_/

10. Mothers occupation .....  
.....

Housewife =1 garment worker=3 /\_  
helper/servant = ① service =4

11. Mothers 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. Mothers education /\_/\_/\_/

18. Number of rooms /\_/\_/

19. Number of beds /\_/\_/

20. Floor type /\_/\_/  
Earthen =1  
pucca =2

21. Radio /\_/\_/  
Yes = 1 No = 2

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?  
When? Why?

- i).....
- ii).....
- iii).....
- iv).....
- v).....
- vi).....
- vii).....
  
- viii).....
- ix).....
- x).....

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 /_/ | Eggs /_/ (yes=1,no=2)   |
| Powder milk /_/ | Dal /_/                 |
| Suji + milk /_/ | veg. /_/                |
| Rice /_/        | ruti /_/                |
| 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?

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## } 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 ARGC STUDY

Childs 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?

Time	Food	Why?	ARGC
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....

(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  
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.....

(20) Would you like more ARGC /\_/\_/

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.



ARAC study

প্রথমে গবেষনার উদ্দেশ্য হলো বাণিজ্যিক ক্ষেত্রে  
 কিস্তিদের পুষ্টির মান উন্নয়ন করা। আন্তর্জাতিক উদ্যোগ  
 গবেষণা করছে গবেষনার মাধ্যমে বাণিজ্যিক ক্ষেত্রে  
 আনার্থের মাধ্যমে খাদ্যমানে মুক্ত অকুশলিত স্বাস্থ্য  
 প্রশ্নন যোগ্যতা উপলব্ধি করতে ইচ্ছুক মত্মস তা হোনা  
 আবারের সাহায্য মিসিত করে কিস্তিদের খাদ্যমানে  
 আনার উন্নতি চাওয়া মা স্বয়ং কিস্তি প্রদ শর্তক  
 পছন্দ করছেন প্রকৃ তা হাট কিস্তিদের খাদ্য প্রশ্নন  
 সমুদয় করছে কিনা। আনার আনা করছি আগনি এই  
 উঁটা খেয়ে উদ্যোগ ও বিদ্যু উঁটা বাঁধীতে নিজে  
 এবং পরবর্তীতে আনার উন্নতি আগনি এই উঁটা  
 বিক্রয় ব্যবহার করছেন ও আগনার কিস্তি পছন্দ  
 করছে কিনা। আনার খাদ্যমানে আগনার এই  
 উঁটা কিস্তি আবারের সাহায্য মিসাতে উন্নতি  
 তা উদ্যোগ এবং কিস্তি পছন্দ উঁটা বাঁধীতে  
 নিজে যেতে দিবে। পরবর্তীতে দুই সপ্তাহ পর  
 আগনার বাঁধীতে আগনার অধিকতর জানতে যাওয়া।  
 আগনি যদি প্রথমে গবেষণায় অক্ষম প্রশ্নন করতে না  
 চান, তাহলেও খাদ্যমানে কর্তৃক আগনার অধিকতর  
 প্রশ্নমাগিতা করতে দ্বিধা দ্বিধা করবেন না।

আগনি যদি স্ব-ইচ্ছায় এই গবেষণায় অক্ষম  
 প্রশ্ন করতে চান তবে, নিজে আগনি দিন।

ARQC Study

এই গবেষণার উদ্দেশ্য হলো বাংলাদেশের মিস্ত্রীদের  
 পুষ্টির মান উন্নয়ন করা। আন্তর্জাতিক উদ্যোগের গবেষণাগুলি  
 গবেষণার মাধ্যমে বাংলাদেশের জল সঞ্চয়নের মাধ্যমে  
 পরিবারের বয়স্কদের সদস্যদের জন্য রান্না করা যায়, তারা  
 খাবার বুনে কিছুকে আঁকমাঝারি গ্রহণযোগ্যতা উপলব্ধি  
 করতে চায়। আঁকমাঝারি জলতে চাওয়া যাও কিছু এই সকল  
 খাবারের স্বাদ সহন্য করতে পারেন কিনা এবং কোন খাবার  
 কিছুকে আঁকমাঝারি স্নায়ুর জন্য সহজতর, আঁকমাঝারি আঁকমাঝারি  
 কনুও আপনি জানেন রান্না করে রান্না খাবার থেকে  
 দেখবেন এবং বাতীতে আপনিদের সকলের জন্য তৈরি  
 খাবার কিছুকে আঁকমাঝারি, আঁকমাঝারি আঁকমাঝারি আপনি  
 আঁকমাঝারি রান্না করা খাবারের স্বাদ সর্জনকে শুধি আপনি  
 কিছুতে সহন্য করতে পারেন কিনা এবং সর্জনকে বলবেন।  
 ছাত্র মাঝারে আঁকমাঝারি আপনিদের কিছু রান্না করা খাবার  
 থেকে দিও এবং সহন্যতে চুই সর্জন পুর আপনি  
 বাতীতে আপনিদের অভিজ্ঞত জানতে যাও, আপনি যদি ...  
 এই গবেষণায় অংশ গ্রহণ করতে না চান, তাহলেও  
 ছাত্রমাঝারি বর্ধমান আপনিকে সর্জনকে সহন্যযোগ্যতা করতে  
 দ্বিগুণ চেষ্টা করতে পারেন না।

আপনি যদি স্ব-ইচ্ছায় এই গবেষণায় অংশগ্রহণ  
 করতে চান, তবে নিম্নে স্বাক্ষর দিন।

*Barbara*

Title: An ethnographic study of acceptability of ARGC fortified weaning food

Summary of Referee's Opinions: Please see 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.

	Rank Score		
	High	Medium	Low
Quality of Project			
Adequacy of Project Design		X	
Suitability of Methodology		X	
Feasibility within time period		X	
Appropriateness of budget	X		
Potential value of field of knowledge	X		
	X		

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 (Rasmuson 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 would 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 appended). 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 complete 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 would be helpful to demonstrate feasibility of conducting the study within time period. I think, though, that it is feasible.

My major comment has to do with the design of the study. 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 - behavioral 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:

4

basic question acceptability looking at baseline behavior  
looking at intro of product  
how much does it change behavior.

COMMENTS ON PROJECT PROPOSAL: AN ETHNOGRAPHIC STUDY ON  
ACCEPTABILITY OF ARGC 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.

The 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 ARGC 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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Without any question about other study protocols, I am

