Attachment-I

Date: 22/7/99

99-019

(FACESHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: SHAMEEM AHMED
Maria E. Flores

Application No

Title of Study: "Breastfeeding counselling and subclinical mastitis"

Trainee Investigator (if any): _____

Supporting Agency (if Non-ICDDR,B) INSTITUTE OF CHILD HEALTH, LONDON.

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 — 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 — 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 NA

5. Will Signed Consent Form be Required:
   - (a) From subjects — (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:
   - NA Umbrella proposal - Initially submit an with overview (all other requirements will be submitted with individual studies
   - ✓ Protodol (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
   - NA 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.

Shameem Ahmed
Principal Investigator

_____
Trainee

Principal Investigator: Last, first, middle Ahmed Shameem

International Centre for Diarrhoeal Disease Research, Bangladesh

RESEARCH PROTOCOL

FOR OFFICE USE ONLY
Protocol No: 99-019 Date: 22/7/99
RRC Approval: Yes/ No Date: 22/7/99
ERC Approval: Yes/No Date:

1. **Title of Project (Do not exceed 60 characters including spaces and punctuations)**
"Breastfeeding counselling and subclinical mastitis"

2a. Name of the Principal Investigator(s) (Last, Middle, First).	2b. Position / Title	2c. Qualifications
Dr. Ahmed Shameem	Health Scientist	MBBS, MSc, FCPS, PhD
Maria Flores	MSc Student, ICH, London	

3. **Name of the Division/ Branch / Programme of ICDDR,B under which the study will be carried out.**
Operations Research Project

4. **Contact Address of the Principal Investigator**
4a. **Office Location:** ORP, ICDDR,B
4b. **Fax No:**
4c. **E-mail:** shameem@cis.icddrb.org
4d. **Phone / Ext:** (8802) 872531

5. Use of Human Subjects	5a. Use of Live Animal	5b. If Yes, Specify Animal Species
Yes [✓]	Yes [ ]	
No [ ]	No [✓]	

6. **Dates of Proposed Period of Support** *(Day, Month, Year - DD/MM/YY)*
August 1, 1999 to October 10, 1999.

7. **Cost Required for the Budget Period**
7a. 1st Year ($): *2nd Year ($):* *3rd Year:*
7b. Direct Cost ($) Total Cost ($) 3046

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.

BARKAT-E-KHUDA — Name of the Division Director
Signature
5/24/99 — 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**
Shameem Ahmed
Date: 24.6.99

Abstract Summary

Objective: To determine the prevalence of subclinical breast inflammation, in women who have or have not received breast feeding counselling and support by estimating the sodium : potasium ratio of breastmilk.

Methodology: This will be a cross-sectional, matched control study and will be carried out in a rural area of Bangladesh. Three rural hospitals will be selected; one where breastfeeding counselling is offered to women after delivery and two where no specific breastfeeding advice or support are given. Women who give birth to a singleton term baby and agreeing to participate will be included in the study.

A sample of 55 women will be included in each of the two groups (counselled and non-counselled), in order to detect a 20 percent difference in the means of the Na/K ratio. Considering the fact that all mothers may not be available for interview at 6-12 weeks after delivery, 75 women from each group will be enrolled in the study.

Pregnant women are usually advised for breastfeeding during home visits by field workers in the study area. Also, mothers will be counselled and supported for breastfeeding at the hospital when they come for delivery by two trained female counsellors. Mothers will also be requested to come to the hospital for follow-up after 6 weeks of delivery. They will then be interviewed by the trained research assistants to know their source of information and counselling for breastfeeding, breast problems, if any and their infant feeding practices. A sample of foremilk (5ml), separately from both breasts, will be taken. The baby will be weighed both at birth and at the follow-up. A research assistant will watch the mother breastfeed her baby and will assess the technique of feeding. Those who will not come for follow-up will be visited at their homes for the interview and breastmilk sample collection within 7-14 days of the scheduled date. In the comparison area the exact addresses of mothers having delivered at the hospital will be collected from the registers. Mothers will then be visited at their homes at 6 weeks postpartum. A sample of breastmilk will be collected and if breastfeeding, their technique will be observed. An interview will be conducted as well. These mothers will also receive counselling after completion of the interview and breastmilk collection.

Breastmilk will be expressed manually by the women into plastic containers. Appropriate freezing will be done until samples can be transported to Dhaka for storage at -70 ° C. The sodium : potassium ratio will be determined at the Institute of child Health in London, after transporting them there in dry ice.

Confidentiality of all potential participants will be protected, when invited to take part. The study will be clearly explained to them, participation is voluntary and women will be assured that in the case of refusal, her or her child's treatment would not be jeopardised in any manner. The study does not represent any risk to the participating mothers or children. A small milk sample (5 ml) will be expressed by the women themselves and they will be assured that it will not have any detrimental effect on their babies milk intake as it will be naturally replaced.

Possible benefits for the women and their babies will be the counselling received in the counselled group. The uncounselled group will also be advised on and counselled after interviews with them are completed.

Results from this study may show that breastfeeding counselling can prevent subclinical mastitis.

Table of Contents

☑ Check here if appendix is included

Principal Investigator: Last, first, middle Ahmed Shameem

PROJECT SUMMARY: Describe in concise terms, the hypothesis, 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 is required. This summary must be understandable and interpretable when removed from the main application. **(TYPE TEXT WITHIN THE SPACE PROVIDED).**

Principal Investigator

Shameem Ahmed
Maria E. Flores

Project Name "Breastfeeding counselling and subclinical mastitis"

Total Budget Us $ 3046 Beginning Date August 1, 1999 Ending Date October 10, 1999

Hypothesis: Adequate breast feeding counselling reduces the prevalence of subclinical breast inflammation.

Objective: To determine the prevalence of subclinical breast inflammation, in woman who have or have not received breast feeding counselling and support.

Relevant background: Studies in Tanzania and Bangladesh, found a high proportion (13 and 12% respectively) of breast feeding women with elevated milk sodium/potassium ratios (higher than 0.6), between the first and third months of lactation. The fact that this high ratio was associated with increased levels of immune factors involved in mediating or down regulating inflammation such as cytokines; Transforming Growth Factor-β; and interleukin-8 indicate an increased mammary permeability and inflammation. These signs are characteristic of mastitis, but as clinical manifestations were not apprised they are suggestive of the presence of subclinical breast inflammation. Because of its low assay variability Na/K ratio, it is considered the best measure for this phenomenon.

Subclinical breast inflammation, may have detrimental effects on the health of the women's' breasts; on the establishment of adequate breast feeding and on the infants' growth rate. As poor practice of breast-feeding may be an etiologic factor for the development of subclinical breast inflammation, it is important to submit it to further investigation.

Experimental design: Cross-sectional, matched control study.
Three rural hospitals in Bangladesh will be selected; one where breast-feeding counselling is offered to the attending women and two where no specific breast-feeding advice is given.

Inclusion criteria:

- Pregnant women who are willing to breastfeed for at least 6 to 12 weeks postpartum, who gave birth to a singleton and term baby from whom we can obtain its birth weight.
- Exclusively or partially breastfeeding at the moment of participation.
- Agrees to participate in the study by answering a questionnaire about her breast feeding status, practices and type and source of counselling that she received.
- Agrees to give us a milk sample and let us weigh her baby at the moment of the interview.

Research methods:

- Questionnaire, applied to all participating mothers, concerning: source of information and counselling for breastfeeding, breast problems during breastfeeding, breast and infant feeding practices.
- Direct observation by the researcher of the mothers breastfeeding technique.
- Anthropometry; Weighing of the baby at birth and at the moment of questionnaire application.
- Breastmilk sample for sodium and potassium determination.

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

Name		Professional Discipline/ Specialty	Role in the Project
1.	Shameem Ahmed	Health Scientist	Principal Investigator
2.	Ms. Maria E. Flores	Nutrition/Mother and Child Health	Principal Investigator
3.	Dr. Suzanne Filteau	Nutrition	Supervisor

DESCRIPTION OF THE RESEARCH PROJECT

Hypothesis to be tested:

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

Hypothesis: Adequate breast feeding counselling reduces the prevalence of subclinical breast inflammation.

Scientific Basis:

Poor positioning and attachment of the baby to the breast; nipple pain after feeding; use of complementary feeds; rigid schedules; delayed or hurried feeds, etc., are practices that lead to infrequent and ineffective emptying of the breasts, and breast inflammation. Lifestyle factors such as stress have also been identified as indirect risk factors, for milk stasis (Fetherston, 1998). Unhygienic practices have as well been linked to the presence of inflammation, but several studies suggest that until the causal organism has the suitable conditions in static milk to multiply, it will less likely to multiply and invade the tissue (Prentice, 1985).

In its mildest form, breast inflammation may only be detected by increased sodium:potassium ratio, of the breast milk. But even this manifestation may have detrimental effects on the infants weight gain, directly because of the baby's refusal to take the milk (Prentice, 1984), or indirectly as an indicator of inadequacy of breastfeeding practice to meet babies needs (Jane, 1994)

All these factors are susceptible to counselling. Adequate and opportune teaching of good practice techniques and reassurance of the women, should have a positive impact over the overall prevalence of subclinical breast inflammation (Filteau, 1999)

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).

Specific Aims:

1.Obtain data on the level and quality of breastfeeding information and counselling that women receive from three participating rural hospitals in Bangladesh (one that promotes breast feeding and two that do not).

2.Observe breastfeeding techniques of mothers who received counselling and those who did not.

- Baby's position to the breast.
- Baby's attachment to the breast.
- Removal of the baby from the breast.

3.Measure and compare the sodium/potassium ratio in milk samples taken from a group of women who received counselling and one that did not.

4. Measure and compare babies weights at birth and at the day of application of questionnaire, to see if there is any difference in the weight gain of babies whose mothers received counselling for breastfeeding and those who did not; or between babies of mothers with high and normal milk Na/K ratio.

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 hypothesis is 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 hypothesis 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).**

Although Bangladesh is a country with a high prevalence of breastfeeding, the Innocenti Declaration recommendations for adequate practice are not followed (Ahmed, 1999). Previous studies have reported that delayed initiation of breastfeeding is a common practice (Ahmed, 1988); and that the mean duration of exclusive breastfeeding in rural Bangladesh is 1.5 months, with only 20% of the women practising it by five months. (Das, 1992)

These observations might be linked to the pressure from commercial companies and promotion of artificial milk, traditional practices and inadequate counselling. Poor breastfeeding practices could lead to subclinical breast inflammation, as described in a previous study on a rural community in Bangladesh (Filteau, 1999

In its mildest form, breast inflammation may only be detected by increased sodium:potassium ratio (higher than 0.6), in the breast milk. This increased level of ions on mature milk, is a reflection of the opening of the junctional complexes between mammary alveolar cells, that let the access of extracellular space components and fluid through the paracellular pathway (Neville, 1991). An association has been observed between high Na/K ratio with increased levels of immune factors involved in mediating or down regulating inflammation such as cytokines; Transforming Growth Factor-β; and interleukin-8 indicating a systemic response to inflammation (Filteau, in press).

This increase in sodium in the milk has been linked to detrimental effects on the infants weight gain, directly because of the baby's refusal to take the milk (Prentice, 1984), or indirectly as an indicator of inadequacy of breastfeeding practice to meet babies needs (Morton, 1994). This brings the urge to recognise the causes and search for preventive and corrective strategies.

Previous studies have given preliminary data about risk factors for the development of breast inflammation. These can be categorised as follows (Fetherston, 1998):
a) Practices that directly lead to infrequent and ineffective emptying of the breasts or milk stasis: Poor positioning and attachment of the baby to the breast; nipple pain after feeding; use of complementary feeds; rigid schedules; delayed or hurried feeds, etc.
b) Factors that indirectly lead to milk stasis: Lifestyles such as stress
c) Potential sources of infection: Unhygienic practices have as well been linked to the presence of inflammation, but several studies suggest that until the causal organism has the suitable conditions in static milk to multiply, it will less likely and invade the tissue (Prentice, 1985).
d) Other maternal and infant factors: Demographic factors such as maternal age, education, income or parity as well as Maternal or infant illnesses.

Most of the risk factors mentioned above are susceptible to counselling. The improvement of the women's techniques for positioning and attaching her baby, avoidance of practices that would harm the breast or the nipple and encourage emptying of the breast as well as exclusive breastfeeding. As well as the promotion of hygienic practices to avoid infection and personal contact and support would increase the mother's assurance of her capacity to feed her child and strengthen her to look after her baby and herself. This strategies would in turn reduce milk stasis and infection and prevent even the mildest forms of breast inflammation.

The acceptance of this study's hypothesis would be in support of the efforts stated in the "Dhaka Declaration" signed in 1991, pledging to protect, promote and support breastfeeding in Bangladesh. As well as other National and International Initiatives that encourage breastfeeding promotion and counselling (Ahmed, 1999).

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).

This will be a cross-sectional, matched control study. Three rural hospitals in Bangladesh will be selected; one where breast-feeding counseling is offered to the attending women and two where no specific breast-feeding advice is given. Potential participants will be contacted through each one of the hospitals and will be invited to participate when they fulfil the following inclusion criteria (the same will apply for each hospital):

- Women who are willing to breastfeed for at least 6 to 12 weeks postpartum, who gave birth to a singleton and term baby whose birth weight can be taken.
- Exclusively or partially breastfeeding from birth upto follow-up at 6-12 weeks.
- Agrees to participate in the study by answering a questionnaire about her breastfeeding status, practices and type and source of counseling that she received.
- Agrees to give a milk sample (5 ml) and weigh her baby at the time of the interview.

In the study area, pregnant women are usually advised for breastfeeding during home visits by field workers. Also, mothers will be counselled and supported at the hospital when they come for delivery by two trained female counsellors. Mothers will also be requested to come to the hospital for follow-up after 6 weeks of delivery. They will then be interviewed by the trained research assistants. A sample of foremilk, separately from both breasts, will be taken. A research assistant will watch the mother breastfeed her baby and will assess the technique of feeding. Those who will not come for follow-up will be visited at their homes for the interview and breastmilk sample collection within 7-14 days of the scheduled date. In the comparison area the exact addresses of mothers having delivered at the hospital will be collected from the registers. Mothers will then be visited at their homes at 6 weeks postpartum. A sample of breastmilk will be collected and if breastfeeding, their technique will be observed. An interview will be conducted as well. These mothers will also receive counselling after completion of the interview and breastmilk collection.

The counselling package will include:

a) ANTENATAL PREPARATION. During the last two months of pregnancy. This is already on-going in the study area where women are counselled at their homes by field workers.

Content

- Advantages of breastfeeding. The importance of doing it exclusively and on demand.
- Disadvantages and "dangers" of artificial feeding and of supplementing breastfeeding during the early months of life.

- The mechanisms of milk production. The importance of suckling, the differences of the milk (quality and quantity) during different stages of lactation. And the importance of taking time to feed, avoiding hurry feeds.
- Talking with the individual women, to build confidence. Previous experiences, fears, doubts.
- Examine breast.
- Talk about and show adequate techniques. Correct positioning of the mother and the baby to the breast, proper attachment of the baby to the breast, discourage the practice of depressing the breast with the finger for the baby's airway (this should be o.k. with a correct position), discourage the use of tight clothing.

b) EARLY AFTER DELIVERY.
- Encourage breastfeeding shortly (first half-hour) after delivery.
- Help mother establish breastfeeding by supporting her with the techniques. Help her relax and build confidence.
- Make sure breastfeeding is established before the woman is discharged home.
- Tell the mother and family of the importance of rest, and looking after herself.

c) POSTNATAL APPOINTMENT.
- Check breasts, for any early problem.
- Make sure the breastfeeding techniques are adequate.
- Talk about how she is feeling, any problems.
- Keep on encouraging exclusive and on demand feeds. (as well as night feeds)
- Encourage her to look for help from the counselor if she needs it.
- Talk about the baby's normal reactions such as: stools, growth, crying etc.
- Build confidence on what she is doing.

Sample size:
In order to detect a 20% difference on the prevalence of high Na/K ratio between the counseled and non-counseled groups of breast feeding women a very large sample would have been needed. This is logistically impossible due to the short time allocated for the realization of the study.
A sample size of 55 women will be included in both groups (counseled and non-counseled), in order to detect a difference in the means of the Na/K ratio observed in the previous study in Bangladesh of 20%, from: 0.43 to 0.34, with 80% power and 0.05 significance. Although our hypothesis relates to a decrease in the Na/K ratio; we conservatively used a 2-tailed test for differences. Considering the fact that mothers may not be available for interview during or immediately postpartum (6-12 weeks after delivery) and for breastmilk collection, 75 women from each group will be enrolled in the study.

Methods and procedures to accomplish specific aims:
1.The level and quality of breastfeeding information and counselling that woman receive from three participating rural hospitals in Bangladesh, will be assessed using the following procedures:
a) Semi-structured questionnaire applied by the researcher that will cover issues concerning the sources of information and counselling for breastfeeding, breast problems during breastfeeding, breast and infant feeding practices as well as mother's intake of extra salt with meals during the last 24 hours.

b) Observe breastfeeding techniques of mothers who received counselling and those who did not.
Baby's attachment to the breast.
Baby's positioning to the breast.
Removal of the baby from the breast

c) Description of the counseling offered by the hospitals. This will include direct observation of the way breast-feeding is promoted in each hospital, attendance to counseling sessions and interviews with key informants

2. Milk sodium:potassium ratio will be measured to be the indicator of breast inflammation. This is considered the best indicator for this phenomenon because of its low assay variability.
Potassium will be measured to account for:

a) Variations due to the different proportions of aqueous and fat fractions as a result from the sampling methods.

b) The modest parallel decreases in both electrolytes with months of lactation.

Milk samples will be expressed manually by the women from each breast into different plastic containers, and frozen until their analysis. Sodium will be determined by flame atomic absorption spectroscopy (Corning 480 flame Photometer). To determine the degree of mammary epithelial permeability the results will be categorised as Na/K<=0.6; 0.6<na/K<=1.0, or Na/K>1.0 based on previous observed distribution values within a similar population (Filteau, 1999).

3. Measure and compare babies weights at birth and at the day of interview.

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 equipments 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 study will be carried out in a rural district of Bangladesh. Three hospitals will be selected; one where breast-feeding counseling is offered to the attending women and two where no specific breast-feeding advice is given.

The potential participants will be contacted through each one of the hospitals and will be invited to participate when they fulfil the inclusion criteria cited above. Information will be requested as to when is the baby due, where is the birth going to take place and who is going to attend it in order to be able to assure that the baby is weighted at birth. A baby scale will be available.

For the questionnaire appointment (6 to 12 weeks postpartum), an appropriate room in the clinic will be required. The baby scale will also be necessary at this point. The breast milk samples will be expressed manually to plastic containers. Appropriate freezing facilities will be needed, until samples can be transported to Dhaka for the conservation at -70 ° C.

The sodium :potassium ratio will be determined in London, after transporting them there on dry ice.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical softwares 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 gathered in the study will be analysed by the investigators themselves.
- The data will be entered into Epi-info and will be analysed further using SPSS package.
- Standard Statistical tests will be performed. Student t-tests for continuous variables and Chi squared for categorical variables.
- Counselled and uncounselled women will be compared for:
  a) Basic descriptive data analysis to ensure groups are comparable.
  b) Prevalence of increased Na/K.
  c) Mean Na/K

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.

- Requires humans because the intervention is counselling to improve breastfeeding practice in order to determine whether this can improve Na/K ratios.
- All potential participants will be protected, when invited to take part. The study will be clearly explained to them, participation is voluntary and women will be assured that in the case of refusal her or her child's treatment would not be jeopardised in any manner.
- The study does not represent any risk to the participating mothers or children. A small milk sample will be expressed and the mother will be assured that it will not have any detrimental effect on her babies milk intake as it will be naturally replaced.
- Possible benefits for the women and their babies, through the counselling received in the counselled group. The uncounselled group will also be adviced on and counselled after interviews with them are completed.

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.

Not applicable.

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.

Ahmed, S. (1988) "Breastfeeding, weaning and infant growth in rural Chandpur, Bangladesh" PhD Thesis, University of London.

Ahmed, S. (1999) "Infant Feeding Practices in Rural Bangladesh: Policy Implication" Journal of Tropical Pediatrics. 45:37-41.

Das, DK. (1992) "Infant Feeding practices in rural Bangladesh" Indian Journal of Paediatrics. 59:573-577.

Fetherston, C. (1998) "Risk Factors for Lactation Mastitis". Journal of Human Lactation. 14(2):101-205.

Filteau, S. (1999) "Breast milk immune factors in Bangladeshi women supplemented postpartum with retinol or β-carotene". American Journal of Clinical Nutrition. 69:953-958.

Filteau, S. (in press) "Milk Cytokines and Subclinical Breast Inflammation in Tanzanian Women: Effects of Dietary Oil Supplementation" Immunology

Morton, J. (1994) "The Clinical Usefulness of Breast Milk Sodium in the Assessment of Lactogenesis". Paediatrics 93:802-806

Neville M. (1991) "Studies in human lactation:milk volume and nutrient composition during weaning and lactogenesis. American Journal of Clinical Nutrition. 54:81-92

Prentice, a (1984) "Unilateral breast dysfunction in Lactating Gambian women". Annals of Tropical Paediatrics. 4:19-23

Prentice, A. (1985) "Mastitis in rural Gambian mothers and the protection of the breast by milk antimicrobial factors" Transactions of the Royal Society of Tropical Medicine and Hygiene. 79:90-95.

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 findings from this study will be published in an international journal, such as the Journal of Human Lactation.

- The findings will be presented on national meetings.

Collaborative Arrangements

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

This study is the dissertation to obtain the MSc. in Mother and Child Health, by Maria Flores. It is part of a larger ongoing research project conducted by Dr. Tomkins and Dr. Filteau, for which previous research has been done in Bangladesh, Tanzania and South Africa.
Funds for laboratory and computer facilities are received from the Department for International Development Work Programme for Neonatal Health, awarded to Dr. A. Tomkins and Dr. A. Costello.

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
Shameem Ahmed	Health Scientist, ORP, ICDDR,B, Mohakhali, Dhaka	10/12/1951

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

Doctor of Philosophy (PhD) 1988. Institute of Child Health, University of London

Master of Science (M.Sc.) in Mother and Child Health, Institute of Child Health, University of London, December 1984.

Fellow of the College of Physicians and Surgeons of Bangladesh (FCPS) in Paediatrics, Institute of Post-Graduate medicine and Research, Dhaka, July, 1982.

Bachelor of Medicine and Surgery (MBBS), Dhaka Medical College, Dhaka University in 1977. Stood 6th in the University with honors in Pharmacology, Community Medicine, Forensic Medicine and Special Pathology.

RESEARCH AND PROFESSIONAL WORK EXPERIENCE

Health Scientist Operations Research Project, ICDDR,B

Member of the National MCH Task force and ICPD Follow-Up Committee.

Reviewer of research proposals for the Bangladesh Medical Research Council and National Nutrition Council, Dhaka, Bangladesh.

Member of the Health Empowerment Rights Accountability (HERA) group for the ICPD follow up. Coordinated by International Women's Health Coalition, USA.

Member of the South Asia Regional Women's Task Force of IPPF.

PREVIOUS WORK

Associate Professor, Nutrition and Gastroenterology, Department of Paediatrics, IPGM&R since 21.4.1993.

Consultant in Maternal and Child Health (MCH/FH), WHO Eastern Mediterranean Regional Office, Alexandria, Egypt (1990-91).

Consultant in MCH/FH, WHO, Somalia, from 19-06-89 to 20-10-90. Responsible for the Maternal and Child Health Family Health Project.

Assistant Professor (Resident Physician), Department of Paediatrics, Institute of Post-Graduate Medicine and Research, Dhaka.

Medical Officer, Department of Paediatrics, Institute of Post-Graduate Medicine and Research, Dhaka.

Registrar, Department of Paediatrics, Dhaka Medical College Hospital, patient care and training, from 12-11-80 to 22-01-81.

Assistant Registrar, Department of Paediatrics, Dhaka Medical College Hospital, patient care and supervisor of a 40 bedded paediatrics ward, from 01-09-79 to 12-11-80.

Member: South Asia Regional Women's Task Force, IPPF.
Population Association of America.
National MCH Task Force.
National MCH Committee.
National Committee on ICPD follow-up.
Bangladesh National Nutrition Society.
Bangladesh Paediatric Association.
Bangladesh Society of Gastroenterology.
Bangladesh Medical Association.
Bangladesh Child Health Foundation.
Bangladesh Breastfeeding Foundation.
Friends of the Asthma Society of London.
Bangladesh Professional Women's Association.
Health Empowerment Rights Accountability (HERA).

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"Breastfeeding weaning and Infant Growth in rural Chandpur, Bangladesh." PhD dissertation. University of London. 1988.

"Feeding Practices of Children Aged 0-15 Months in a rural area in West Bengal, India. MSc dissertation. University of London, 1984.

Hyperbilirubinaemia in the Newborn." FCPS dissertation Bangladesh College of Physician's and Surgeons. 1982.

Name	**Position**	**Date of Birth**
Dr. Suzanne Filteau	Senior lecturer Centre for International Child Health Institute of Child Health	17/02/57

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

Institution and Location	Degree	Year	Field of Study	
McGill University, Montreal, Canada	BSc	1979	chemistry	
University of Guelph, Guelph, Canada	MSc	1983	nutrition	
University of Guelph, Guelph, Canada	PhD	1987	nutrition	

Research and Professional Experience

June 1997- present	Senior lecturer, Institute of Child Health
September 1990-present	Visiting Research Fellow, London School of Hygiene and Tropical Medicine
May 1995-June 1997	Lecturer, Institute of Child Health
September 1990-April 1995	Research Fellow, Institute of Child Health

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M.C. Jaeger, M Lawson and S. Filteau. The impact of prematurity and neonatal illness on the decision to breast-feed. *J. Advanced Nursing*, 25: 729-737, 1997.

Name	Position	Date of Birth
Maria Eugenia Flores Quijano	MSc. candidate Mother and Child Health Centre for International Child Health Institute of Child Health	11 May, 1971

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

Institution and Location	Degree	Year	Field of Study
Universidad Iberoamericana, Mexico City	BSc	1995	Nutrition

Research and Professional Experience

September 1998-present	MSc. candidate Mother and Child Health
January to September 1998-	Nutrition and breastfeeding consultant. Hospital Angeles del Pedregal, Mexico City
May to October 1997	Assistant for Baby-Friendly Hospital Initiative UNICEF, Mexico City.
June 95 to January 1997	Research Student Unidad de Investigacion Medica en Nutricion Instituto Mexicano del Seguro Social Siglo XXI Mexico City

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Principal Investigator: Last, first, middle Ahmed Shameem

Detailed Budget for New Proposal

Project Title: "Effect of breastfeeding counselling on the prevalence of subclinical breast inflammation ".

Name of PI: Maria E. Flores

Protocol Number: Name of Division:

Funding Source: Amount Funded (direct): U.S. $3046 Total: U.S. $3046 Overhead (%)

Starting Date: 1 August, 1999 Closing Date: 10 October, 1999.

Strategic Plan Priority Code(s):

Sl. No	Account Description	Salary Support			US $ Amount Requested		
	Personnel	Position	Effort%	Salary	1st Yr	2nd Yr	3rd Yr
1	TBA	counsellor	100%	$ 340	$ 1020		
	Sub Total						
	Consultants	------					
	Local Travel	$170			$170		
1	International Travel	$ 1000			$1000		
	Sub Total				**$ 2190**		
	Supplies and Materials (Description of Items)						
240	milk collection tubes ($0.17 each)				$ 40		
240	Na/K Assays ($3.40 each)				$ 816		
	Sub Totals				$856		

	Other Contractual Services (not applicable)			
	Repair and Maintenance			
	Rent, Communications, Utilities			
	Training Workshop, Seminars			
	Printing and Publication			
	Staff Development			
	Sub Total			

	Interdepartmental Services (not applicable)	**1st Yr**	**2nd Yr**	**3rd Yr**
	Computer Charges			
	Pathological Tests			
	Microbiological tests			
	Biochemistry Tests			
	X-Rays			
	Patients Study			
	Research Animals			
	Biochemistry and Nutrition			
	Transport			
	Xerox, Mimeographs etc.			
	Sub Totals			
	Other Operating Costs			
	Capital Expenditure			
TOTAL DIRECT COST		**$ 3046**		

Budget Justifications

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

- Na/K ratios will be analysed in London, for several reasons:
  a) To be comparable with previous studies.
  b) To be run together with U.K. controls.
  c) We have existing arrangements for analysis at the reduced rate of £2.00 (two pounds) equivalent to $3.4.

- The counsellor will be employed, to set up things before the study starts. And to be the translator to overseas researcher.

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)

APPENDIX

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project: "Breastfeeding counselling and subclinical mastitis."

Principal Investigator: Shameem Ahmed, Maria E. Flores

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.

INFORMATION SHEET.
(This information will be read and discussed with the woman in order to get consent for participation.)

We are going to perform a study to determine the prevalence of sub-clinical breast inflammation in women who have or have not received brestfeeding counselling and support. The result of this study will help in reducing the prevention of subclinical breast inflammation through proper breastfeeding counselling and support. You will need to exclusively particularly breastfed your baby for at least 6-12 weeks for the purpose of the study. This study needs to weigh your baby at birth and then again at the time of follow-up at 6-12 weeks. A sample of expressed breastmilk from you after 6-12 weeks of delivery will be required. The amount of milk (5 ml) that you will give would not affect your baby or you. The milk sample will be analysed in the laboratory. We will ask some questions related to this study which needs 15-20 minutes. The information collected for this study will not be used for any other purposes other than this research and will be kept confidential. Your participation in this study is voluntary and you can withdraw from the study at any time. Your participation or withdrawal from the study will in no way hamper in your getting care from this centre or any other centre.

Signature of Investigator: _____ **Signature of Subject:** _____
Date: _____ **Date:** _____

তথ্য পত্র

যে সব মা বাচ্চাদের বুকের দুধ খাওয়ানোর পরামর্শ ও সহায়তা গ্রহণ করেন এবং যারা করেন না, তাদের উভয়ের মধ্যে স্তনের প্রদাহের হার নির্ণয়ের জন্য আমরা একটি গবেষণা প্রকল্প হাতে নিয়েছি। এই গবেষণার ফলাফল মায়েদের বুকের দুধ খাওয়ানোর পরামর্শ ও সহায়তা প্রদানের মাধ্যমে মায়েদের স্তনের প্রদাহের হার কমানোয় ভূমিকা রাখবে। এই গবেষণার জন্য আপনার শিশুকে অবশ্যই কমপক্ষে ৬-১২ সপ্তাহ বুকের দুধ খাওয়াতে হবে। জন্মের সময় এবং ৬-১২ সপ্তাহের মধ্যে ফলো-আপের সময় আপনার শিশুর ওজন নেয়া হবে। আপনার সন্তান জন্ম নেয়ার ৬-১২ সপ্তাহের মধ্যে আপনার কাছ থেকে অল্প পরিমান বুকের দুধ নেয়ার প্রয়োজন হবে, যা আপনি নিজে আমাদের বের করে দেবেন। যে পরিমান দুধ আপনি দেবেন তা আপনার সন্তানের বা আপনার নিজের স্বাস্থ্যের কোন ক্ষতি করবে না। আপনার কাছ থেকে সংগৃহীত দুধ গবেষনাগারে নিয়ে পরীক্ষা করা হবে। গবেষণার প্রয়োজনে আমরা আপনাকে কিছু প্রশ্ন জিজ্ঞেস করবো, এরজন্য ১৫-২০ মিনিট সময় প্রয়োজন হবে। এই গবেষণার জন্য সংগৃহীত তথ্য এই গবেষণা ছাড়া অন্য কোন কাজে ব্যবহার করা হবে না এবং সম্পূর্ণভাবে গোপন রাখা হবে। এই গবেষণায় আপনার অংশগ্রহণ সম্পূর্ণভাবে স্বেচ্ছাপ্রণোদিত এবং যে কোন সময় এই গবেষণা থেকে নিজেকে বাদ দেয়ার অধিকার সব সময় থাকবে। এই গবেষণায় অংশগ্রহণ বা নিজেকে বাদ দেয়া কোনভাবেই আপনাকে এই কেন্দ্র বা অন্য কোন কেন্দ্র থেকে সেবা নেয়ার জন্য বাধা সৃষ্টি করবে না।

গবেষনাকারীর স্বাক্ষর
তারিখ:

অংশগ্রহনকারীর স্বাক্ষর
তারিখ:

Questionnaire.

Name: _____ Participant No._____ Date: _____
Home address: _____
Baby's Date of birth: _____ Hospital: _____
Baby's birth weight: _____ Baby's actual weight; _____

Is this your first baby? YES NO How many children do you have?_____
Did you breast feed the other? YES NO How long?_____

Did you learn from anyone else the way to breast-feed your baby? _____
_____
Did you receive information from any of the following persons: (circle)
your mother mother in-law grand mother

health worker friend other _____

Did you receive counselling about how to breast feed your baby in the hospital?
YES NO
When was the first time you feed your baby after he/she was born? _____

Have you experienced any pain in your breasts in the last week? YES NO
In which breast? RIGHT LEFT BOTH
Have you felt your breasts full and uncomfortable? YES NO
In which breast? RIGHT LEFT BOTH
Do you have any wound on your areolas or nipples? YES NO
In which breast? RIGHT LEFT BOTH
Have you had any problem that has stopped you from breast feeding your baby on the last week? YES NO if yes explain: _____

Has your baby experienced any trouble suckling? YES NO
Does your baby prefer one breast to the other? YES NO

How many times a day does your baby feed? Day: _____ Night: _____
How long is the time period between feeds? <1 hour 2 to 6 hours > 6 hours
How long do you let your baby be sucking from your breast? _____
When do you change your baby to feed from one breast to the other?
_____

Do you think your milk will make your baby grow and be healthy? YES NO
Why? _____
Do you feel your baby gets enough milk every time you feed him? YES NO
Why? _____
Does your baby drink anything different to your milk? YES NO
How do you offer it? BOTTLE CUP OTHER_____
Does your baby eat anything different from your milk? YES NO
How often does he receive something different to you milk? _____
Have you taken extra salt in your meals during the last 24 hours? YES NO
If yes, in how many meals? 1 2 3

Breastfeeding technique evaluation by the researcher:
At this time the researcher will ask the woman to breast-feed her baby. Without the mother noticing , she will asses her technique. At some point the researcher should take a milk sample separately from both breasts.

Position of the baby:		
a) Baby is close to the mother's body	YES	NO
b) Head and shoulders facing the breast and neck extended	YES	NO
c) Nose at same level as the nipple and free	YES	NO
d) Mother is correctly supporting breast with hand	YES	NO
Position of the baby's mouth on the areola and nipple:		
a) Mouth is wide open	YES	NO
b) Lower lip is away from the base of the nipple and curled	YES	NO
c) Jaw action is correct	YES	NO
Removal of the baby from the breast:		
a) Baby comes off the breast spontaneously	YES	NO

Other observations: _____

_____

_____

_____

_____

Mother's age: ___ Occupation: _____ Father's age: ___ Occupation: _____
Number of years you went to school? _____ Your husband? _____
Total monthly expenditure of the family: _____

Check List

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

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

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH BANGLADESH

Office Memorandum

MR. B.K. Saha
ERC

Principal Investigator: Last, first, middle Ahmed Shameem

APPENDIX

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project: "Breastfeeding counselling and subclinical mastitis."

Principal Investigator: Shameem Ahmed, Maria E. Flores

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.

INFORMATION SHEET.
(This information will be read and discussed with the woman in order to get consent for participation.)

We are going to perform a study to determine the prevalence of sub-clinical breast inflammation in women who have or have not received brestfeeding counselling and support. The result of this study will help in reducing the prevention of subclinical breast inflammation through proper breastfeeding counselling and support. You will need to exclusively particularly breastfed your baby for at least 6-12 weeks for the purpose of the study. This study needs to weigh your baby at birth and then again at the time of follow-up at 6-12 weeks. A sample of expressed breastmilk from you after 6-12 weeks of delivery will be required. The amount of milk (5 ml) that you will give would not affect your baby or you. The milk sample will be analysed in the laboratory. We will ask some questions related to this study which needs 15-20 minutes. The information collected for this study will not be used for any other purposes other than this research and will be kept confidential. Your participation in this study is voluntary and you can withdraw from the study at any time. Your participation or withdrawal from the study will in no way hamper in your getting care from this centre or any other centre.

If you agree to participate please sign below

Signature of Investigator: _____
Date: _____

Signature of Subject: _____
Date: _____

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH
Mail : ICDDR,B, GPO Box 128, Dhaka-1000, Bangladesh
Phone : 871751-60, Telex : 675612 ICDD BJ
Fax : 880-2-883116, 886050, 871568, 871686, Cable : Cholera Dhaka

CENTRE
FOR HEALTH AND
POPULATION RESEARCH

July 26, 1999

To: Chairman
Ethical Review Committee
ICDDR,B

From: Dr. A.K.M. Iqbal Kabir
Scientist & member ERC

Subject: Review of the protocol " Breastfeeding counselling and sub-clinical mastitis".

Thank you for considering me to review the above mentioned protocol. I am sorry to mention that I can not be personally present due to my preoccupation with some family program and I need to travel out of town.

The protocol hypothesized that the prevalence of sub-clinical breast inflammation will be reduced in those mothers who are counselled and practices exclusive breastfeeding compared to those who are not counselled. They will determine the ratio of breastmilk Na/K as a proxy indicator of sub-clinical mastitis. The protocol as such is a very simple and investigators will counsel mothers at a community health centre in rural Chittagong and collect breastmilk sample between 6-12 weeks. Lactating mothers will be asked to continue exclusive breastfeeding and asked to provide 5 ml of breastmilk sample at 6-12 weeks.

I don't find any major ethical concern in the protocol. However, my major concern is the investigator in the consent form mentioned that for the study purpose the mothers are asked to continue exclusively breastfeeding their babies for 6-12 weeks which goes against the WHO/UNICEF recommendation for EBF up to six months. This message may be detrimental for promotion of breastfeeding campaign. I would request the investigators to adhere to the national recommendation on breastfeeding message.

There are some minor corrections in the consent form both in English and Bengali versions.

The protocol may be approved subjected to the corrections and suggestions.