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CENTRE
FOR HEALTH AND
POPULATION RESEARCH

PHSD
2001

MEMORANDUM

30 December 2001

To : Professor Japhet Killweo
Head, Reproductive Health Unit
Public Health Sciences Division

From : Professor Mahmudur Rahman
Chairman, Ethical Review Committee (ERC)

Sub : Protocol # 2001-020

Thank you for your memo of 27th November 2001 attaching the modified copy of your protocol # 2001-020 entitled "The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh". The protocol is hereby approved upon your addressing the issues raised by the ERC in its meeting held on 31st October 2001.

Thank you.

cc: Associate Director
Public Health Sciences Division

Attachment 1

Date: 27/11/2001

(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: Professor Japhet Killewo

Application No. 2001 - 020

Title of Study: The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh.

Trainee Investigator (if any): _____

Supporting Agency (if Non-ICDDR,B) USAID

Project Status: _____

[X] 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
   - (e) Benefits to be derived — (Yes) No
   - (f) Right to refuse to participate or to withdraw from study — (Yes) No
   - (g) Confidential handling of data — (Yes) No
   - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure — (Yes) No

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

6. Will precautions be taken to protect anonymity of subjects — (Yes) No

7. Check documents being submitted herewith to Committee:
   - ____ Umbrella proposal - Initially submit an with overview (all other requirements will be submitted with individual studies
   - ✓ Protocol (Required)
   - ✓ Abstract Summary (Required)
   - ✓ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw) (Required
   - ✓ Informed consent form for subjects
   - ____ Informed consent form for parent or guardian
   - ____ Procedure for maintaining confidentiality
   - ____ Questionnaire or interview schedule*

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

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

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

_____ Principal Investigator

_____ Trainee

Modified version (26th Nov. 2001) resubmitted for ERC approval

ICDDRB: Centre for Health & Population Research **RRC APPLICATION FORM**

RESEARCH PROTOCOL

Protocol No.: 2001-020

FOR OFFICE USE ONLY

RRC Approval: Yes/ No Date:

ERC Approval: Yes/No Date:

AEEC Approval: Yes/No Date:

Project Title: The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh

Theme: *(Check all that apply)*

- ☐ Nutrition
- ☐ Emerging and Re-emerging Infectious Diseases
- ☐ Population Dynamics
- ☒ Reproductive Health
- ☐ Vaccine evaluation
- ☐ Environmental Health
- ☐ Health Services
- ☐ Child Health
- ☐ Clinical Case Management
- ☒ Social and Behavioural Sciences

Key words: reproductive health, safe motherhood, maternal mortality

Principal Investigator: Professor Japhet Killewo **Division:** PHSD **Phone:** ex. 2230

Address: ICDDR,B **Email:** japhet@icddr,b

Co-Principal Investigator(s): Dr. Lauren S. Blum
Dr. Carine Ronsmans

Co-Investigator(s): Dr. Greet Dieltiens, Ms. Papreen Nahar and Mr. J. Chakraborty

Student Investigator/Intern:

Collaborating Institute(s):

London School of Hygiene and Tropical Medicine

Population: Inclusion of special groups *(Check all that apply)*:

Gender
- ☐ Male
- ☒ Females

Age
- ☐ 0 – 5 years
- ☐ 5 – 9 years
- ☒ 10 – 19 years
- ☒ 20 +
- ☐ > 65

- ☒ Pregnant Women
- ☐ Fetuses
- ☐ Prisoners
- ☐ Destitutes
- ☒ Service providers
- ☐ Cognitively Impaired
- ☐ CSW
- ☐ Others (specify _____)
- ☐ Animal

Project / study Site *(Check all the apply)*:

- ☐ Dhaka Hospital
- ☐ Matlab Hospital
- ☒ Matlab DSS area
- ☐ Matlab non-DSS area
- ☐ Mirzapur
- ☐ Dhaka Community
- ☐ Chakaria
- ☐ Abhoynagar
- ☐ Mirsarai
- ☐ Patyia
- ☐ Other areas in Bangladesh _____
- ☐ Outside Bangladesh
  name of country: _____
- ☐ Multi centre trial
  (Name other countries involved)
  _____

Type of Study *(Check all that apply)*:

- ☐ Case Control study
- ☐ Community based trial / intervention
- ☐ Program Project (Umbrella)
- ☒ Secondary Data Analysis
- ☐ Clinical Trial (Hospital/Clinic)
- ☐ Family follow-up study
- ☐ Cross sectional survey
- ☐ Longitudinal Study (cohort or follow-up)
- ☒ Record Review
- ☐ Prophylactic trial
- ☐ Surveillance / monitoring
- ☒ Others

Targeted Population *(Check all that apply)*:

- ☒ No ethnic selection (Bangladeshi)
- ☐ Bangalee
- ☐ Tribal groups
- ☐ Expatriates
- ☐ Immigrants
- ☐ Refugee

Consent Process *(Check all that apply)*:

- ☒ Written
- ☐ Oral
- ☐ None
- ☒ Bengali language
- ☐ English language

Proposed Sample size:

Total sample size: _____ ☐

Sub-group _____ ☐

_____ ☐

_____ ☐

_____ ☐

Determination of Risk: Does the Research Involve *(Check all that apply)*:

- ☐ Human exposure to radioactive agents?
- ☐ Fetal tissue or abortus?
- ☐ Investigational new device?
  (specify_____)
- ☐ Existing data available from Co-investigator
- ☐ Human exposure to infectious agents?
- ☐ Investigational new drug
- ☐ Existing data available via public archives/source
- ☐ Pathological or diagnostic clinical specimen only
- ☐ Observation of public behaviour
- ☐ New treatment regime

Yes/No

☒ ☐ Is the information recorded in such a manner that subjects can be identified from information provided directly or through identifiers linked to the subjects?

☐ ☒ Does the research deal with sensitive aspects of the subject's behaviour; sexual behaviour, alcohol use or illegal conduct such as drug use?

Could the information recorded about the individual if it became known outside of the research:

☐ ☒ a. place the subject at risk of criminal or civil liability?

☐ ☒ b. damage the subject's financial standing, reputation or employability; social rejection, lead to stigma, divorce etc

Do you consider this research *(Check one)*:

- ☐ greater than minimal risk
- ☒ no risk
- ☐ no more than minimal risk
- ☐ only part of the diagnostic test

Minimal Risk is "a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as a part of routine physical examination".

Yes/No

☐ ☒ Is the proposal funded?

If yes, sponsor Name: _____Not Applicable_____

Yes/No

☒ ☐ Is the proposal being submitted for funding ?

If yes, name of funding agency: (1) ___USAID Bangladesh_____

(2) _____

Do any of the participating investigators and/or their immediate families have an equity relationship (e.g. stockholder) with the sponsor of the project or manufacturer and/or owner of the test product or device to be studied or serve as a consultant to any of the above?

NO EQUITY RELATIONSHIP

IF YES, submit a written statement of disclosure to the Director.

Dates of Proposed Period of Support	**Cost Required for the Budget Period ($)**
(Day, Month, Year - DD/MM/YY)	*a.* ***Ist Year*** ***2nd Year***
Beginning date 1st January 2002	**US$ 227,823** **US$ 169,700**
End date 31st December 2004	*b.* ***Direct Cost :*** **US$ 315,495** ***Total Cost :*** **US$ 397,523**

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.

Lars Ake Persson — Name of the Assciate Director

SIGNED — Signature

21st October 2001 — Date of Approval

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 administra tive penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the re-quired progress reports if a grant is awarded as a result of this application.

Signature of PI

Date: 26th *November 2001*

Name of Contact Person (if applicable)

Japhet Killewo

Table of Contents

☐ Check here if appendix is included

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 ***Japhet Killewo***

Project Name ***The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh***

Total Budget	Beginning Date	Ending Date
US$ 397,523	***1st January 2002***	***31st December 2004***

Project summary

Over the last 10 years, the Government of Bangladesh (GOB) has undertaken a number of initiatives to try to address the burden of maternal ill health. Activities have mostly concentrated on upgrading referral hospitals to manage emergencies, and little has been done to ensure skilled attendance at birth or effective referral at the community level. To ensure basic obstetric care, a strategy has been adopted to train existing paramedics, but their scope of work and minimum skills have not been clearly defined, nor has a policy been formulated as to where births should take place (i.e. at home or in a health facility). It is often argued that women in Bangladesh will not deliver in a health facility because of the social and cultural barriers that they face in accessing safe motherhood services outside their homes. However, little effort has been made to thoroughly understand the set of conditions responsible for preventing pregnant women from using obstetric services and to determine how best to overcome these barriers. Since the GOB will need to commit scarce resources to ensure that all women in the community receive basic obstetric care, it is crucial to establish whether providing such care in health centres is feasible and possibly more cost-effective than maintaining a system whereby community midwives are to visit women in their homes.

The objectives of this research are to examine the factors that enable women to access obstetric care in a health facility, and to assess whether facility-based basic obstetric care is more cost-effective than home-based delivery care. In addition, we will explore whether the tools currently used to monitor and evaluate safe motherhood strategies adequately measure progress towards a reduction in maternal mortality. This study will build on the unique experience of a maternity care programme in Matlab, where two different approaches to basic obstetric care have been put into place over the last 15 years. These two approaches consist of (1) the training and posting of nurse-midwives in villages to attend home deliveries and (2) the upgrading of health centres to encourage women to give birth in a health facility. We will use existing data sources to assess the cost and effectiveness of these different types of basic obstetric care in reducing perinatal, neonatal and maternal mortality. In addition, qualitative methods will be used to assess the acceptability of different types of birthing care to women.

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

Name	Professional Discipline/ Specialty	Role in the Project
1. Japhet Killewo	Epidemiologist	Principal Investigator
2. Lauren Blum	Medical Anthropologist	Co-Principal Investigator
3. Carine Ronsmans	Epidemiologist	Co-Principal Investigator
4. Greet Dieltiens	Epidemiologist	Co-investigator
5. Papreen Nahar	Social Scientist	Co-Investigator
6. Jyotsnamoy Chakraborty	Manager, Community Research Unit, Matlab	Co-Investigator

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.

This research proposes to address two main questions:

- Is facility-based basic obstetric care acceptable to women and more cost-effective than home-based delivery care, and what are the factors that enable/disable women to access obstetric care in a health facility?
- Do the tools currently used to monitor and evaluate safe motherhood strategies adequately measure progress towards a reduction in maternal mortality?

Specific Aims:

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

The overall objective of this research is to support the GOB in its efforts to design effective strategies to increase access to basic obstetric care for all women and to monitor progress in Safe Motherhood. This study will build on the unique experience of a maternity care programme in Matlab, where two different approaches to basic obstetric care have been put into place. These two approaches consist of (1) the training and posting of nurse-midwives in villages to attend home deliveries and (2) the upgrading of health centres to encourage women to give birth in a health facility. The evaluation of the successes and failures of these contrasting strategies will provide the GOB with invaluable information on the best strategy to improve access to basic obstetric care.

Specific objectives include:

1. To assess the acceptability of home- and facility based maternity care in Matlab, including:
- Examining women's and other household member's needs, demand for and perceptions of home- and facility-based midwifery care
- Examining the constraints women face in accessing skilled birthing care within and outside their homes
- Examining the strategies that may help women overcome major barriers to giving birth outside their homes
- Describing beliefs related to pregnancy and local perceptions of complications and appropriate treatment

2. To assess the effectiveness of different types of basic obstetric care in Matlab, including:
- Describing the extent and trends over time of uptake of services in the two birthing strategies.
- Describing the demographic and socio-economic determinants of use of various types of basic obstetric care
- Assessing the quality of home- and facility-based basic obstetric care using reviews of case notes, interviews and a set of available standards.
- Measuring the impact of different types of basic obstetric care on uptake of comprehensive EOC (i.e "met need" for obstetric care), and on perinatal, neonatal and maternal mortality

3. To assess the cost of different types of basic obstetric care in Matlab

4. To validate the link between processes of care and maternal, perinatal and neonatal mortality in Matlab by assessing the degree of agreement between levels of maternal, neonatal and perinatal mortality at the population level and indicators of access to and use of obstetric services over time and between geographical areas.

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 analyze 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).***

Current issues in Safe Motherhood

Since the launch of the Safe Motherhood initiative in 1987, substantial efforts have been made to reduce the huge burden of maternal mortality in the world. There is more awareness of the extent of maternal ill health, and more knowledge on interventions that can be effective in reducing this burden. The task is now to develop effective and affordable programmes that bring the interventions to women, and in doing so, to monitor whether these strategies are achieving their goals and objectives.

Case studies from countries that have achieved low maternal mortality have shown that delivery care can be organised in a number of ways, from home births with a briefly trained non-professional to institutional deliveries with trained professionals (Koblinsky et al 1999, Van Lerberghe and De Brouwere 1998). Successful programmes have used a variety of strategies, but to achieve success all have required the existence of an effective network of referral to functioning essential obstetric care (EOC) facilities (Maine and Rosenfield 1991). The recognition that many obstetric complications arise without warning signs has shifted the focus from antenatal care to ensuring that emergency obstetric care is accessible to women when they need it. Efforts to upgrade referral hospitals are now underway in many countries, and ensuring quality obstetric care at the referral level has become one of the key components of safe motherhood programmes.

Ensuring access to functioning hospitals is of course not enough. Safe motherhood involves the entire health sector, from community level care for all women to admission in hospitals for the few women who need it. While there is now general agreement that all births should be attended by a skilled attendant, the crucial question of where deliveries should take place and who qualifies as a skilled attendant remains a matter of debate (Koblinsky et al 1999, De Brouwere et al 1998, Walraven and Weeks 1999, Graham et al 2000). Very few developing countries have adopted an approach based on home births with trained midwives, and the circumstances in which such a strategy can be recommended are uncertain. Evidence from an intervention study in Bangladesh that supported the training and deployment of midwives at the village level (Fauveau et al 1991) was later called into question (Maine et al 1996, Ronsmans et al 1997). In Indonesia, a strategy of home births with trained midwives has been adopted, but its effectiveness is still uncertain (Geefhuysen 1999, Ronsmans et al 2001). Organising basic pregnancy and delivery care in health centres might be more efficient, although its effectiveness in reducing maternal and neonatal ill-health is not known.

Reproductive behaviour is also shaped by societal norms, reflecting core values and structural principles within a sociocultural system (Browner and Sargent 1990). The cultural patterning of reproduction includes beliefs and behaviours associated with different types of reproductive processes including maternal roles during pregnancy, prenatal care and the childbirth event. Socially and culturally constructed forces shape the management of obstetrical events, such as the location where the birth should take place, preferences for obstetrical care providers, appropriate procedures during delivery, the circumstances under which an intervention is warranted and the form an intervention may take. The hierarchy of authority during labour and delivery and the processes of decision-making during childbirth can also provide insights into the broader patterns of stratification and illuminate gender roles within the domestic group and larger society.

Measuring change resulting from safe motherhood programmes presents its own challenges (Campbell et al 1997). Not only are the desired outcomes of mortality and morbidity difficult to ascertain

(Graham et al 1996, Campbell et al 1997), even the measurement of more proximate endpoints such as service utilisation or quality of care is far from straightforward (De Brouwere and Van Lerberghe 1998, Ronsmans 2001, Pittroff and Campbell 2000). Indicators such as the proportion of births attended by skilled health personnel or of births by caesarean section have gained credence but whether they adequately measure progress in safe motherhood remains uncertain (WHO 1997, Graham et al 2000, Ronsmans 2001). The recognition that some women need specialist obstetric care to prevent maternal death has led to the search for indicators measuring the met (or unmet) need for obstetric care (UNICEF et al 1997, De Brouwere and Van Lerberghe 1998). These aim to identify both users and non-users of obstetric services among pregnant women thought to require such care. Obstetric service is measured among a sub-group with maternal complications, assuming the need can be met by the stated obstetric service. Concrete experiences with such indicators have been limited however, and empirical evidence that they are sensitive markers for improvements in maternal health services is not yet available (Ronsmans 2001).

Safe Motherhood in Bangladesh

As part of its effort to reduce maternal mortality, the Government of Bangladesh (GOB) has been implementing a programme of upgrading health facilities and services to make emergency obstetric care available to all women. The programme has involved the upgrading of EOC facilities in a phased manner with a target to ultimately provide comprehensive EOC services in all District Hospitals (DHs), all Maternal and Child Welfare Centres (MCWCs) and selected Thana Health Complexes (THCs). In its first phase of implementation, the programme has included some MCWCs, some DHs and some THCs, and has involved infra-structural renovation of existing facilities, provision of equipment and transport, development of appropriate human resources and development of linkages and referral strategies for complicated cases

The programme started in 1994 and within five years a marked expansion of EOC services has been observed, with 60 of the 90 MCWCs and 38 of the 59 district hospitals having been upgraded. In addition, of the 40 THCs designated for upgrading to provide comprehensive EOC services, three have so far been upgraded. Despite these encouraging improvements, the progress so far, in terms of utilisation of these services, has been rather slow. Less than one third of pregnant women use antenatal services once while about 40% have less than two doses of tetanus toxoid. More importantly, over 90% of deliveries are still taking place at home without any skilled assistance.

While comprehensive strategies have been developed to strengthen emergency obstetric care at the referral level, no clear policies have been formulated towards ensuring basic obstetric care at the community level. Furthermore, it is unclear whether the strategy that has been adopted by the government to train existing paramedics (Family Welfare Visitors (FWV)) to become community midwives is effective and appropriate. The scope of work and minimum skills of community midwives have not been clearly defined, nor has a policy been formulated as to where women should give birth (i.e. at home or in a health facility).

It is often argued that women in Bangladesh will not deliver in a health facility because of the social and cultural barriers that they face in accessing safe motherhood services outside their homes. Some studies have given detailed descriptions of beliefs related to pregnancy and birthing practices in Bangladesh (Afsana and Rashid 2000; Blanchet 1984; Goodburn et al 1994; Rozario 1993). For instance, Blanchet (1984) gives an account of birthing practices in a village setting where all women delivered in the home setting with a dai or other unskilled attendant. More recently, Afsana and Rashid (2000) conducted a study examining the utilisation of medical care during childbirth in a health centre. However, little effort has been made to identify and thoroughly understand the set of conditions responsible for preventing pregnant women from using safe motherhood services and to determine how best to overcome these barriers and thus enable women to seek obstetric care from a midwife in a health facility. To date no studies have adequately identified the most critical factors that affect the acceptability of skilled and unskilled birthing attendants.

The GOB is using a number of indicators, such as the proportion of births with a skilled attendant, the proportion of births with a caesarean section, and the proportion of births with a complication that take place in an EOC facility, to monitor the success of its programme. Whether any of these processes of care,

alone or in combination, correlate with a reduction in maternal mortality, however, is not known. The definition of a skilled attendant, for example, is equivocal and the mere labeling of a person as a professional does not necessarily guarantee skills or competence (Graham et al 2001). It is now widely accepted that skilled *attendance* requires a skilled *attendant* as well as an enabling environment that will make it possible for the skilled worker to apply his or her expertise effectively. This environment includes drugs, supplies and equipment, but also supervision, a clear career structure and other mechanisms that will ensure sustained high quality of care. Similarly, while population-based caesarean section rates may be adequate indicators of progress where access to services is very low, this may not be the case once services improve, as the indications for caesarean sections will broaden. It is thus essential for the GOB to determine whether the indicators selected do indeed reflect progress towards improving maternal health.

Safe Motherhood in Matlab

Basic EOC services were introduced in the Matlab Maternal and Child Health and Family Planning (MCH/FP) area in 1987 and are still operating today (Fauveau et al 1991, Ronsmans et al 1997, Vanneste et al 2000). In 1987, four nurse-midwives were posted in two of four health centres and were asked to provide basic obstetric care in women's homes during pregnancy, labour and delivery or after delivery. Women requiring higher levels of care were referred to the Matlab clinic, which had been upgraded as a basic EOC facility, and, when the need arose, to hospitals in Chandpur providing comprehensive EOC services. This programme was expanded to cover the entire MCH/FP area in 1990. Beginning in 1996, the strategy of home births with a midwife was progressively shifted to a strategy of births in basic EOC facilities. During this time, one of the four health centres was gradually upgraded to become a basic EOC facility and by the end of 2000, one more health centre had been upgraded and women were encouraged to give birth in the centres rather than at home. Women living relatively close to the Matlab clinic were also encouraged to deliver in that clinic.

The programme has been successful in that uptake of basic EOC was remarkably prompt. Between 1987 and 1993, 56% of pregnant women sought care from a midwife in their homes either for a routine antenatal visit or during labour and delivery (Vanneste et al 2000). In that same period, 27% of all women who gave birth at home did so in the presence of a midwife. The response to the introduction of basic EOC care in health centres in 1996 was equally impressive. One year after upgrading one of the health centres nearly one third of pregnant women were giving birth there. We know of no other such experience in Bangladesh, and it is thus important to understand what contributed to the success of this strategy, including what its effect might be on the need for specialised obstetric care and on the women and the new-born's health.

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).

Research design

This is a detailed case study using a variety of quantitative and qualitative methods to evaluate the acceptability, effectiveness and cost of two contrasting strategies to ensure access to basic obstetric care at the community level. A research strategy including both quantitative and qualitative methods strengthens

the research design by enhancing the understanding and interpretation of the results. The study will consist of the following components:

1) The effectiveness of different delivery strategies will be assessed by describing their uptake in different annual periods between 1987 and 2001 in the MCH-FP area.
2) The impact of different delivery strategies on "met need" for obstetric care and on perinatal, neonatal and maternal mortality will be assessed in a cohort of women who gave birth between 1987 and 2001 in the MCH/FP area.
3) The assessment of the quality of home- and facility-based care will be based on a knowledge and skills test of health providers, record reviews, and women's interviews. Observations of birthing events will also be carried out in the health facilities and in homes where unskilled attendants are assisting births.
4) The acceptability of services will be assessed using a variety of qualitative methods including interviews with key informants, health providers (midwives and traditional birth attendants) and users and non-users of basic obstetric care offered by trained midwives, as well as through observations.
5) The cost of services will be determined through record reviews, interviews with providers and observations of births.
6) The validation of the link between processes of care and perinatal, maternal and neonatal mortality will be assessed in a cohort of women who gave birth between 1976 and 2001 in the MCH/FP and Comparison areas of Matlab.

The Research Site

The research will be carried out in the Matlab field station of the ICDDR,B. Matlab is an upazilla (sub-district), which is the lowest level administrative unit in the health system. ICDDR,B's activities in Matlab include both service delivery and data collection. A Health and Demographic Surveillance System (HDSS), which tracks over 220,000 residents in 140 villages, has been in operation since 1966. Using a unique identifying system that follows every individual in the surveillance area, demographic data are routinely collected on such vital events as births, deaths, cause of deaths, and migration. ICDDR,B provides community based reproductive health services to half of the Matlab area and the HDSS also collects data through these services on morbidity and service utilisation.

In 1998, 109,598 people were residing in the area where ICDDR,B provides services including 28,352 married women, and the total fertility rate is 3.0, with 2,287 births annually. The area is divided into four blocks, each with a health sub-centre servicing about 25,000-30,000 people. Each sub-centre is staffed by two medical assistants, one family welfare visitor and one nurse-midwife.

Study components:

1. Effectiveness study

data sources for this component will be the HDSS of ICDDR,B. To assess the effectiveness of different birthing strategies at the community level on their uptake, all births between 1987 and 2001 recorded in the HDSS will be classified yearly according to the type of first level care received. The relevant categories include: (1) basic obstetric care at home with a midwife, (2) basic obstetric care in a health centre and (3) home birth with a relative, traditional birth attendant or other non-skilled birth attendant. Trends over time in the uptake of these categories of services will be examined for annual percentage of all births receiving care over the period between 1987 and 2001 and compared. In addition, the demographic and socio-economic profile of users of the different types of care will be described using information available from the HDSS and census data. In order to assess accessibility of skilled midwifery services in the three birthing strategies, the average distance of all the women delivering during 1987 and 2001 to the nearest health Centre or midwife will be compared. The HDSS data sources for this component will have the

- necessary information regarding births, place of delivery, type of attendant, age, parity, marital status, educational status, occupation etc. Trend tests will be performed to determine the direction of change in the uptake for the different birthing strategies.

2. Impact study

To assess the impact of the three types of care on uptake of comprehensive EOC, a number of indicators will be defined and their frequency compared among the three groups. These indicators include: (1) the % of births in a comprehensive EOC facility, (2) the % of births with a caesarean section, (3) the % of births with a major obstetric complication treated in an EOC facility (UNICEF et al 1997) and (4) the % of births with a major obstetric intervention for a major obstetric complication (De Brouwere and Van Lerberghe 1998). The three groups will also be compared for levels of perinatal, neonatal, and maternal mortality. For each birthing strategy, information about the defined indicators will be obtained from a combination of data sources. These include the DHSS, special studies on maternal mortality, midwife records, midwife registers, Matlab clinic registers, unmet obstetric need study and census data. Each outcome (service use or health outcome) of interest will be the subject of a separate analysis, using the birthing strategies as exposure variables, controlling for time trends and socio-economic variables.

Between 1987 and 2001, approximately 40,000 births have taken place in the MCH/FP area. Of these, about 10,000 took place at home with a midwife, and an estimated 4000 births will have taken place in a health centre with a midwife by 2001. The table provides estimates of the minimum detectable relative risk in a number of outcomes comparing home and health centre births, assuming a level of confidence of 95% and 80% power:

Table: Minimum detectable relative risks comparing midwife-led home- and facility-based births

Indicator	**Estimated prevalence in unexposed**	**Minimum detectable relative risk**
% of births in comprehensive EOC facility	1.5%	2.00
% of births with caesarean section	1%	2.50
% of births with a major obstetric complication treated in an EOC facility	30%	1.30
% of births with a major obstetric intervention for an absolute maternal indications	0.5%	3.00
Neonatal mortality	4%	1.50
Perinatal mortality	6%	1.50

The number of births is not sufficient to compare levels of maternal mortality. Maternal deaths in the three groups will be compared using a qualitative investigation of the circumstances leading to death (in particular the care seeking pattern prior to death).

3. Quality of care

The quality of obstetric care in the three birthing strategies (health facilities and at home) will be assessed against international and national standards of obstetric care. Methods to evaluate the quality of care include the following:

- Using the WHO needs assessment tools, we will describe the availability of drugs, equipment and supplies for home and health centre based delivery care and will compare these to the standards set for basic obstetric care in Bangladesh. Efforts will also be made to describe the 'enabling' environment (e.g. provision for transport, supervision, in-service training, feedback from the Matlab clinic etc.). Additional data sources will be obtained from service providers in the three birthing strategies.

- The knowledge and skills of midwives will be tested against the set of minimum skills for a skilled attendant as defined by the Safe Motherhood Interagency Group (SMIAG 1998) and against the curriculum for midwives as specified in Bangladesh. Attention will be paid to the management of normal labour and delivery as well as life-saving interventions. Knowledge and skills will be assessed through a written test, observations of basic skills and a review of selected records.
- Observations of obstetric care will be conducted both in the home setting and health care facility and will include antenatal care and deliveries. Direct observations will provide an opportunity to assess interactions between the health provider and the pregnant woman and to evaluate practices utilised by skilled and non-skilled birthing attendants, including management of labour and delivery.
- Finally, unstructured interviews will be carried out with women having received different types of care to review their perceptions of the quality of the care received.

4. Acceptability of services

In order to assess the acceptability of services, a variety of methods will be used to facilitate the use of triangulation to verify the information and to enhance the interpretation of the data results. Key informants will provide baseline information on beliefs related to pregnancy and childbirth; perceptions of complications associated with pregnancy and appropriate treatment; household decision-making related to choice of maternity care; perceptions of the advantages and disadvantages of accessing home- and facility-based maternity care; birthing practices administered by different health providers; and perceptions of the quality of care provided by different practitioners. Key informant interviews will also be used to assess the extent and ways in which community involvement has influenced the rapid uptake of obstetric services in Matlab. The interviewers will work with eight to ten key informants including health providers (midwives and traditional birth attendants), mothers of reproductive age, fathers and grandmothers, and interviews should continue throughout the duration of this phase of the research project. Regular interactions with key informants will provide the opportunity to review information gathered during previous interviews, verify data collected through other methods and, in the later phases of information gathering, test hypotheses.

In-depth interviewing of "cases" of childbirth should provide concrete and credible data to assess perceptions of the quality of maternity care offered and constraints women confront in accessing skilled birthing care. The goal is to collect a detailed description of the history of the pregnancy, focusing on factors that influenced decisions on the place of delivery, and the childbirth event from approximately 50 households from each category (home delivery with an unskilled attendant, home delivery with a midwife, and delivery in a health care facility with a midwife) in which childbirth took place. The sample will include recent childbirth events, with an attempt to match samples so that cases representing the three categories are similar in age and live in close proximity. The framework of the narrative will be given by the woman herself, with in-depth interviewing of her mother, mother-in-law and other attending persons who can provide information to complete the description of events at different stages of pregnancy, labour and childbirth. Questioning on decision-making on the place of delivery will concentrate on who participated in key discussions from which actions emerged and how each participant contributed. While delivery with the midwives in the home setting is presently being phased out, other anthropologists studying the management of obstetrical events have demonstrated that because childbirth is a highly intense physical and emotional experience, women and others involved in the birthing process retain a vivid recollection of the birth history and the interaction with the birthing attendant (see Sargent and Bascope, 1996).

It is hypothesized that socio-demographic and cultural factors that potentially affect the utilisation of services offered by midwives to women in Matlab include: i) age and parity, ii) prior pregnancy experience, iii) type of family structure, iv) education of the woman and other family members, v) perceptions of pregnancy complications and appropriate care, and vi) cultural beliefs concerning how to ensure a safe delivery and positive outcome for the child. As cultural beliefs and social expectations interact to produce

behaviours, it is expected that the interface of a variety of factors will account for differences in utilisation of the services. Husbands will also be interviewed to identify their degree of participation in the planning of the childbirth event and other aspects of the male role.

Finally, observations of home deliveries with non-skilled attendants and deliveries with midwives in the health facility will provide firsthand information on the delivery process. These encounters are essential for understanding the intricacies of maternity care and the social context of childbirth, such as the role of family members in the birthing process, and they will allow us to differentiate between practices elucidated through interviews and actual behaviours. The observations will be carried out by female, non-clinicians, with extensive field experience using qualitative research methods, including conducting direct observations and recording textual data. The women identified to carry out this segment of the research will receive additional training to prepare them specifically to administer observations of labor and delivery.

Observations will only take place if the family permits to attend the delivery sequence both in the facility and in the household. If at any time a family member objects to the presence of the research officer, the observation will be terminated. While the research officers are not qualified to determine whether someone is in need of higher levels of care, if the woman experiences an emergency and clearly needs medical assistance the interviewer should assist the pregnant woman to access appropriate health care.

5. Cost and cost-effectiveness of services

The cost of home- and facility-based care will be assessed by estimating the cost of different major components within the two different birthing strategies and by measuring the incremental or additional cost of strengthening the facility based delivery care system. Since maternal death is a rare event, it would not be feasible to look at cost saved per maternal death averted. However the following cost-effectiveness ratios can be measured and compared for different types of strategies: the cost per service delivered through different strategies, the cost per neonatal death averted and the cost per birth related complications averted.

By using data from the ICDDR,B reporting systems (financial data as well as data on service activities), we will estimate the capital and recurrent costs of setting up and maintaining facility- and home-based midwifery care. In addition, midwives will be interviewed and observed for two weeks to determine their detailed activity patterns. Capital inputs will include furniture and fittings, equipment, machinery, vehicles, and building. Recurrent cost will include personnel cost (salaries and benefits), training, rent and utilities, supplies (operation and maintenance), building (operation and maintenance), vehicle (operation and maintenance), and management and quality control support from the head office.

In order to allocate cost proportionally to all different categories, a time motion study will also be conducted. This will be done through observing the midwives at the facility and at home and documenting detailed activity patterns. In addition, midwives will be interviewed to capture the activities that might be missed during observation. To determine the time needed for the midwives to travel to client's households, a number of midwives will be interviewed to ascertain the average time they spend on travelling to reach a client at home. Average costs of both services will be calculated using the number of women opting for different strategies as outcome measures.

6. Validation of the link between process and outcome indicators

In this analysis we will consider associations in the aggregate, i.e. between the maternal mortality ratio of the entire population and the proportion of deliveries in the same population who have received certain types of skilled obstetric care. The indicators that will be considered include those that are currently used by the GOB (e.g. the % of births with a skilled attendant, in an EOC facility, with a caesarean section, and indicators of met need for obstetric care) and other indicators of met need suggested in the literature (De

- Brouwere and Van Lerberghe 1998, Ronsmans 2001). For most indicators we will be able to assess trends over a period of 25 years (1976-2001) in the MCH/FP and Comparison areas. Indicators of met need for obstetric care will only cover ten years (1990-2000).

  Multiple sources of data from the MCH/FP and Comparison areas between 1976 and 2001 will be used for this purpose, including midwife records, HDSS and MHSS data and data from the efforts to measure met need for obstetric care.

Data Analysis

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

Data analysis

Data analysis for the quantitative component of the study will utilize a number of statistical software packages including SAS, SPSS and EPIINFO depending on the software used for the originally intended purpose. Different relevant variables will be extracted from the data sets, recoded, and new ones created from existing ones as composite variables for the purpose of answering specific research questions. Statistical procedures to be used in the study will include descriptive statistics as well as relevant statistical tests of significance like student's t-test or chi-squared test. Multivariate analysis will be done to take into account the effect of confounders as well as effect modifiers in order to develop a predictive model of utilization of obstetric care.

Statistical analysis of key variables collected through the in-depth interviews will include chi-square, Mann-Whitney U and other non-parametric measures.

Data sources - Qualitative

Ethnographic and qualitative data analyses is an iterative process, involving ongoing data collection and analyses (Agar 1996). For this project, that translates into possible modifications of questions based on preliminary findings, data will be collected through key informant interviewing and semi-structured interviews. As data is collected, a coding system will be developed by the investigators for the qualitative data analyses. The coding system will be based on the initial research questions and objectives, theoretical concepts, as well as emergent themes both within and across sites.

Qualitative interview data will be entered into a word processing program compatible with use in Atlas.ti, a text-organizing program and texts will be coded in Atlas.ti. In order to ensure the validity of the coding, a sample of texts will be double coded by two individuals. Clippings of codes will be analysed by the investigators always with the broader research objectives in mind.

Data sources - Quantitative

The quantitative component of this study will largely build on an existing database. A number of data sources will be used:

- HDSS, which provides information on births, deaths (i.e. neonatal and perinatal deaths), marriages and migration in the MCH/FP and Comparison areas.
- Special studies on maternal mortality: Maternal deaths have been the subject of special studies covering the period 1976-93 (Fauveau et al 1991, Ronsmans et al 1997, 1998). For deaths of women in the reproductive age range, cause of death was assigned by physicians based on the information on the events preceding the death provided by the relatives of the deceased (verbal autopsy). A maternal death has been defined as a death in women aged 15-44 years while pregnant or within 90 days of delivery, regardless of the cause. Further studies are currently ongoing to assess maternal deaths and their causes between 1994 and 2001
- Midwife records: Midwives keep standard records for each pregnant woman, whether the birth takes place at home or in a health centre. During antenatal visits demographic, anthropometric and medical factors are recorded. Recorded variables include parity, age, previous obstetric history, height, presence

of tibial oedema, anaemia and jaundice, blood pressure, protein in urine, reported symptoms of fever or vaginal bleeding, position of the foetus, the presence of twins and the measurement of fundal height. When midwives attend labour and delivery they note the timing of the delivery and the nature of the complications. The midwives have been trained extensively in the recognition of complications and we rely on their clinical expertise for case definitions.

- Midwife registers: For all activities the midwives keep a register in which the timing and purpose of the visit is noted, and whether or not the woman is transferred to higher levels of care
- Register in Matlab clinic: This register includes information on the nature of the complications for women admitted to the Matlab maternity clinic, and place and time of referral to higher levels of care (if any)
- Matlab health and socio-economic survey (MHSS): This survey includes information on the place of birth and mode of delivery on all births to a sample of married women age 15 and older in the MCH/FP and Comparison areas in 1996.
- Census: The 1982 and 1993 census provides information on socio-economic characteristics of the households
- Unmet obstetric need study: An ongoing study is assessing uptake of obstetric services in the Matlab area (MCH/FP and comparison areas) between 1990 and 2000. Indicators recorded in this study include: the proportion of births attended by skilled health personnel, the proportion of births with a caesarean section, and met need for obstetric care (UNICEF et al 1997, De Brouwere and Van Lerberghe 1998).

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.

Women and the larger society in general will benefit from the longer term goal of the study, which is to identify effective strategies to increase access to basic obstetric care for all women and to monitor the progress of Safe Motherhood. While much of the study involves the analysis of secondary data, respondents interviewed to assess acceptability of services will be enrolled in the study after giving informed consent (see consent form, Appendix I). Any respondent may withdraw from the study or any component of the study at any time. Confidentiality of information will be strictly followed, and restrictions on access to data forms will be enforced. Ethical approval for this study will be sought from the institutional review board at ICDDR,B.

Use of Animals

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

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

Literature Cited

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

1. Afsana, K. and S. F. Rashid 2000. Discoursing Birthing Care: Experiences from Bangladesh. Dhaka: The University Press Limited.
2. Agar, M. 1996. The Professional Stranger: An Informal Introduction to Ethnography. San Diego: Academic Press.
3. Blanchet, T. 1984. Meanings and Rituals of Birth in Rural Bangladesh. Dhaka: University Press Limited.
4. Browner, C. and C. Sargent 1990. Anthropology and Studies of Human Reproduction. In: Johnson T. and C. Sargent, eds. Medical Anthropology: Contemporary Theory and Method. New York: Praeger.
5. Campbell O, Filippi V, Koblinsky M, Marshall T, Mortimer J, Pittrof R, Ronsmans C, Williams L (1997). Lessons learnt. A decade of measuring the impact of safe motherhood programmes. London School of Hygiene and Tropical Medicine, London.
6. De Brouwere V and Van Lerberghe W(1998). Les besoins obstetricaux non couverts. Paris: L'Harmattan.
7. De Brouwere V, Tonglet R, Van Lerberghe W. Strategies for reducing maternal mortality in developing countries: what can we learn from the history of the industrialised West? *Trop Med Intern Health* 1998,3:771-782.
8. Fauveau V, Stewart K, Khan SA, Chakraborty J. Effect on mortality of community-based maternity-care programme in rural Bangladesh. *Lancet* 1991,338:1183-1186.
9. Geefhuysen CJ. Safe motherhood in Indonesia: A task for the next century. In: Berer M, Ravindran TKS (eds). Safe Motherhood initiatives: Critical issues. *Reproductive Health Matters* 1999:62-72
10. Graham W, Filippi V, Ronsmans C. Demonstrating impact using maternal mortality: an impossible dream? *Health Policy and Planning* 1996;11:16-20.
11. Graham WJ, Bell JS, Bullough CHW (2000). Can skilled attendance at delivery reduce maternal mortality in developing countries? Paper prepared for EU round table on 'Mother's health and health services', Brussels 27-28 November 2000
12. Koblinsky MA, Campbell O, Heichelheim J. Organising delivery care: what works for safe motherhood? *Bulletin of the World Health Organization* 1999, 77:399-406
13. Maine D, Rosenfield A, McCarthy J, Kamara A, Luca AO (1991). Safe Motherhood: options and issues. Columbia University, New York
14. Maine D, Akalin MZ, Chakraborty J, de Francisco A, Strong M. Why did maternal mortality decline in Matlab? Studies in Family Planning 1996,27:179-187.
15. Pittrof R and Campbell O (2000). Quality of maternity care. Silver bullet or red herring? London: Maternal Health Programme, London School of Hygiene and Tropical Medicine.
16. Ronsmans C, Vanneste A-M., Chakraborty J, Van Ginneken JV. A comparison of three verbal autopsy methods to ascertain levels and causes of maternal deaths in Matlab, Bangladesh. *International Journal of Epidemiology* 1998;27:660-666.
17. Ronsmans C, Vanneste AM, Chakraborty J, Van Ginneken J. Maternal mortality decline in Matlab, Bangladesh: a cautionary tale. *Lancet* 1997,350:1810-4.
18. Ronsmans C. How can we monitor progress towards improved maternal health goals? *Studies in Health Services Organisation & Policy*, 2001,17: 317-342
19. Ronsmans C, Achadi E, Supratikto G, Zazri A, McDermott J, Koblinsky M, Marshall T. Evaluation of a comprehensive home-based midwifery programme in South Kalimantan, Indonesia. *Tropical Medicine and International Health* 2001,6:1-12.
20. Rozario, S. 1993. The Dai and the Doctor: Discourses on Women's Reproductive Health in Rural Bangladesh. In: Ram K. and M. Jolly, eds. Maternities and Modernities: Colonial and Post Colonial Experiences in Asia and Pacific. London: Cambridge University Press.
21. Safe Motherhood Inter-Agency Group (1998). Report on the Safe Motherhood Technical Consultation 18-23 October 1997. Colombo, Sri Lanka. New York: Family Care International.

22. UNICEF, WHO and UNFPA (1997). Guidelines for monitoring the availability and use of obstetric services. New York, UNFPA.
23. Van Lerberghe and De Brouwere (2000). Of blind alleys and things that have worked: history's lessons on reducing maternal mortality. Paper prepared for EU round table on 'Mother's health and health services', Brussels 27-28 November 2000
24. Vanneste AM, Ronsmans C, Chakraborty J, de Francisco A. Prenatal screening in rural Bangladesh: from prediction to care. *Health Policy and Planning,* 2000,15:1-10
25. Walraven G, Weeks A. The role of (traditional) birth attendants with midwifery skills in the reduction of maternal mortality. *Trop Med Intern Health* 1999,4:527-529.
26. World Health Organization (1997). Monitoring reproductive health: selecting a short list of national and global indicators. WHO/RHT/HRP/97.26

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.

Regular meetings of investigators will be held to discuss findings, analyse data, write reports and manuscripts and prepare presentations for conferences. Important results and conclusions will be disseminated through working papers, journal articles and presentations at national and international conferences and meetings. A dissemination workshop will be carried out at the conclusion of the study.

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)***

The ICDDR,B will collaborate with the Maternal and Child Epidemiology Unit, London School of Hygiene and Tropical Medicine, London, UK on the study design and implementation, data analysis and preparation of reports. In addition, the investigators will collaborate with members of the GOB working in Safe Motherhood as well as NGOs.

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.

Biography of Japhet Killewo

1. **Name:** Prof. J.Z.J. Killewo
2. **First Names:** Japhet Zebadiah Joseph
3. **Address:** International Centre for Diarrhoeal Disease Research (ICDDR,B)
   GPO Box 128 Dhaka-1000, Bangladesh

4. **Date of Birth:** 22 April, 1948
5. **Place of Birth:** Uru, Moshi, Tanzania
6. **Qualifications:**

PHD PROGRAMME at the University of Umea in Sweden 1992-1994 PhD (Umea) 1994. Topic of study, "Epidemiology towards the control of HIV infection in the Kagera region of Tanzania"

MASTER OF SCIENCE IN EPIDEMIOLOGY at the London School of Hygiene and Tropical Medicine in London 1981-1982. MSc. Epidemiology (London). Topic of study, Aetiology of infertility in Tanzania (Phase 2 of the National Infertility Survey of Tanzania);

DIPLOMA IN PUBLIC HEALTH at the University of Dar es Salaam, Tanzania. DPH (DAR) 1989-1980; Topic of study, "Evaluation of acceptability of community compost latrines in peri-urban areas"

BACHELOR OF MEDICINE AND BACHELOR OF SURGERY at the Makerere University of Kampala, Uganda 1971-1976. MBChB (Makerere) 1976; Doctor of Medicine degree.

7. **Appointments:**

1. Programme Head, Reproductive Health Programme, ICDDR, B, Dhaka, Bangladesh	October 1999 to date
2. Program Manager, Muhimbili University College of Health Sciences (MUCHS) Programme Management Unit, Dar es Salaam, Tanzania	April 1997 to September 1999
3. Head, Department of Epidemiology and Biostatistics, MUCHS	July 1986 to July 1997
4. Associate Professor in Epidemiology, University of Dar es Salaam	July, 1996 to date
5. Senior lecturer in Epidemiology, University of Dar es Salaam	July 1991 to June, 1996
6. Visiting senior research fellow, at the Department of Social Medicine, Harvard Medical School, Boston, USA.	Sept. 1991 to June, 1992.
7. Lecturer in Epidemiology, University of Dar es Salaam	July 1983 to June, 1991
8. Assistant lecturer in Epidemiology, University of Dar es Salaam	July, 1980 to June, 1983

8. **Other professional Qualifications:**

(i) Certificate of attendance in advanced methods of Epidemiology: New England Inc., Tufts University Cambridge, MA USA. 12-30 July 1992
(ii) Certificate of attendance in advanced methods of Epidemiology: London School of Hygiene and Tropical Medicine, England. 11-23 September, 1989
(iii) Certificate in an interdisciplinary research and development course on Epidemiology and field research methodology, May 23 - June 3, 1988, Umea,Sweden
(iv) Certificate in Tuberculosis Control, June to October, 1984, at the Research Institute of Tuberculosis, Japan
(v) Certificate in Health Planning and Development October/November 1983. Sussex University, England.

9. **Working Experiences since 1977:**

i. General Medical Officer's duties for two years, District Medical Officer for one year.

ii. Member of a team in the investigation and control of a Cholera epidemic April, May and June 1978
iii. Teaching Epidemiology and Biostatistics to regular Medical Undergraduates and Postgraduates.
iv. Conducting quantitative and qualitative research in the following areas: Community acceptability of compost latrines, infertility, Traditional healers and Birth attendants, Health and Environment, operations research, protective effect of measles vaccine, HIV/AIDS, Plague and Nutrition.
v. Independent expert and consultant in proposal review and to facilitate in "Writer's Workshops"
vi. Organized local and International Scientific Conferences and research methodology training workshops.
vii. Participated and organized Strategic Planning workshops.

10. Publications:

Published widely in local as well as in international journals and books. There are more than 42 published articles in journals, 18 of which I am the first author. Topics of articles range from infectious disease epidemiology, environmental health, reproductive health, STDs and HIV/AIDS to review articles and book chapters.

The following are publications in the last three years and representative earlier publications pertinent to this application.

1. Killewo, J.Z.J.; Mtimavalye, L.A.R; Remme, J; Leshabari,M.T; Van Praag, E and Massawe, F.M. **The Risk of repeated abortions**. Journal of Obstetrics and Gynaecology of Eastern and Central Africa 1985; **4:** 69-72.

2. Van Praag, E.; Mtimavalye, L.A.R.; Massawe, F.M.; Killewo, J.Z.J.; Remme J.; and Leshabari M.T. **The Epidemiology of infertility and pregnancy wastage in Tanzania. A pilot study.** Journal of Obstetrics and Gynaecology of Eastern and Central Africa. 1985; **4**: 61-66.

3. Mtimavalye, L.A.R.; Massawe. F.M.; Remme, J; Killewo, J.Z.J.; Van Praag, E and Leshabari M.T. (1984). **Infertility among women in five rural and Two Urban District of Tanzania**. Journal of Obstetrics and Gynaecology of Eastern and Central Africa 1984; **3:** 125-129.

4. Nicoll, A., Killewo, J.Z.J., and Mgone, C. **HIV and infant feeding practices: Epidemiology implications for Sub-Saharan African countries** (1990) AIDS, 4 (7): 661-665

5. Killewo, J. And Urassa, E.
Epidemiology of maternal mortality in Africa
In: Contemporary issues in maternal health care in Africa pp 1-10
Eds. Nasah, BT. Mati, JKG. Kasonde, JM.
Harwood Academic Publishers GmbH. Australia 1994

6. Kwesigabo G, Killewo J, Sandström A et al. Decline in the prevalence of HIV-1 infection in young women in the Kagera Region of Tanzania. **Journal of Acquired Immune Deficiency Syndromes & Human Retrovirology** 1998;**17**: 262-268

7. Killewo J, Kwesigabo G, Sandström A et al. Acceptability of voluntary HIV testing with counselling in a rural village in Kagera, Tanzania. **AIDS CARE – Psychological and Socio-medical Aspects of AIDS/HIV** 1998; **10:** 431-439

8. Kwesigabo G, Killewo J, Sandström A et al. Prevalence of HIV infection among hospital patients in North West Tanzania. **AIDS CARE CARE – Psychological and Socio-medical Aspects of AIDS/HIV** 1998; **11:** 87-93

9. Urassa W, Godoy K, Killewo J, Kwesigabo G, Mbakileki A, Mhalu F, Biberfeld G. The Accuracy of alternative confirmatory strategy for detection of antibodies to HIV-1: Experiences from a regional laboratory in Kagera, Tanzania. **Journal of Clinical Virology** 1999; **14:** 25-29

10. Lugalla JPL, Emmelin MAC, Mutembei AK, Comoro CJ, Killewo JZJ, Kwesigabo G, Sandstrom AIM, Dahlgren LG. The social and cultural contexts of HIV/AIDS transmission in the Kagera region, Tanzania. Journal of Asian and African Studies 1999; XXXIV(4) 377-402.

11. The voluntary HIV-1 counseling and testing efficacy study group (2000). The voluntary HIV-1 counseling and testing efficacy study: design and methods. AIDS and Behavior 4 (1): 5-14. Members of the study group are: M. Claudes Kamenga, Michael D. Sweat, Isabelle De Zoysa, Gina Dallabetta, Thomas J. Coates, Olga A. Grinstead, Steven E. Gregorich, David C. Heilbron, William P. Wolf, Kyung-Hee Choi, Julius Schachter, Donald Balmer, Francis Kihuho, Stephen Moses, Frank Plummer, M. Gloria Sangiwa, Margaret Hogan, ***Japhet Killewo***, Davis Mwakagile, Colin Furlonge, Kevin R. O'Reilly, Samuel Kalibala, Ben Nkowane, and Eric van Praag.

12. M. Gloria Sangiwa, Olga A. Grinstead, Margaret Hogan, Davis Mwakagile, ***Japhet Z. J. Killewo***, Steven E. Gregorich, M. Claudes Kamenga, Michael D. Sweat, Kevin R. O'Reilly, Samuel Kalibala, Eric van Praag and Thomas J. Coates (2000). Characteristics of individuals and couples seeking HIV –1 prevention services in Dar es Salaam, Tanzania. The voluntary HIV-1 counseling and testing efficacy study. AIDS and Behavior 4 (1): 25-34

13. M. Gloria Sangiwa, Ariane van der Straten, Olga A. Grinstead and the voluntary HIV-1 counseling and testing efficacy study group (2000). Clients'perspective of the role of voluntary counseling and testing in HIV/AIDS prevention and care in Dar es Salaam, Tanzania. The voluntary HIV-1 counseling and testing efficacy study. AIDS and Behavior 4 (1): 35-48. Members of the study group are: M. Claudes Kamenga, Michael D. Sweat, Isabelle De Zoysa, Gina Dallabetta, Thomas J. Coates, Olga A. Grinstead, Steven E. Gregorich, David C. Heilbron, William P. Wolf, Kyung-Hee Choi, Julius Schachter, Donald Balmer, Francis Kihuho, Stephen Moses, Frank Plummer, M. Gloria Sangiwa, Margaret Hogan, ***Japhet Killewo***, Davis Mwakagile, Colin Furlonge, Kevin R. O'Reilly, Samuel Kalibala, Ben Nkowane, and Eric van Praag.

14. Kwesigabo G, ***Killewo JZJ,*** Urassa W, Mbena E, Mhalu F, Lugalla JLP, Godoy C, Biberfeld G, Emmelin M, Wall S Sandstrom A. Monitoring of HIV infection prevalence and trends in the general population using pregnant women as a sentinel population: 9 years experience from the Kagera region of Tanzania. Journal of Acquired Immune Deficiency Syndromes 2000; 23:410-417

15. Nicoll A, ***Killewo J***. Science, Sense and Nonsence about HIV in Africa. Communicable Disease and public Health 2000; 3: 78-79

Biography of Lauren S. Blum

Name: Lauren S. Blum
Position: Medical Anthropologist
Date of Birth: 02/02/60

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

Ph.D. in Medical/Nutritional Anthropology, University of Connecticut (1999)

MPH in International Health, Columbia University (1988)

B.A. in English Literature, University of Colorado (1983)

Research and Professional Experience

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

2000-Current: Medical Anthropologist, Social & Behavioural Sciences Programme, Public Health Sciences Division, ICDDR,B.

1992-1993: Graduate Research Assistant, Department of Anthropology, University of Connecticut.

Conducted research on sociocultural factors influencing alcohol and drug use among White Mountain Apache.

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

1988-1991: Manager Education, Training and Publications, Helen Keller International. Provided technical assistance to government and NGO representatives on the development of policies and integration of vitamin A nutrition activities in child health programs. Assessed sociocultural factors affecting health-related practices and designed interventions to improve child health and nutritional outcomes. Created training programs and organized workshops on health and nutrition for health workers located in Africa and Asia. Developed educational materials on practical measures to prevent nutritional deficiency and management of child illness episodes.

1987-1988: Public Health Technical Trainer, Institute Superieur Pedagogique, D. R. Congo. Evaluated training needs in western, southern and eastern Congo and designed a training curriculum. Co-ordinated all training activities all training activities and led sessions on public health and nutrition-related topics for health workers living in rural communities in Congo.

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

1986: Nutrition Researcher, International Red Cross, Niger. Conducted research to assess household economic resources and to evaluate the health and nutritional status of women and children in a northern region of Niger. Analyzed the data to determine Community needs for food distribution program.

1985: Nutrition Technical Training Program Co-ordinator, Peace Corps, Niger. Trained a group of Peace Crops volunteers on public health and health and nutrition education strategies, with an emphasis on maternal and child health.

1983-1985: Nutrition Educator, Peace Corps, Niger. Worked in maternal/child health clinic assisting with prenatal consultations and well-baby weighing. Conducted nutrition education sessions in the clinic setting and at the community level on child feeding practices and management of child illness.

- Short-term consultant:

1997: Basics, Niger, March – July: Worked as a member of an interdisciplinary research team on the qualitative research protocol included in a study designed to identify socio-economic factors affecting caretaker compliance to medical treatments in rural Niger. Analyzed the study results and developed recommendations to improve caretaker's adoption of treatment strategies.

1996: October OMNI: Wrote technical paper on vitamin A capsule supplementation strategies for public health officials working to control vitamin A deficiency.

1995: September Peace Corps, Mali: Based on a rural assessment, designed training on public health and nutrition for development workers living in rural communities. Delivered sessions on preventive and curative health care strategies, micronutrient deficiency and measures to control nutritional deficiency.

1995: March, CARE International, Niger,: Examined aspects of the sociocultural system affecting the nutritional status of women and children. Developed programmatic recommendations designed to enhance women's involvement in household decision-making related to health seeking practices, food purchasing and intrahousehold food distribution.

1994: August Peace Corps, Niger: Evaluated and redesigned research objectives for first-year volunteers. Trained volunteers in qualitative research methods.

1994: May, Peace Corps, Niger: Co-ordinated in-service training for health and nutrition education volunteers.

1993: Helen Keller International: Co-author video script on factors affecting vitamin A nutriture and methods to control deficiency.

Publications

Blum L. and G. Pelto 2001. Coping with a Nutrient Defiency: Explanatory models of vitamin A defcieincy signs and symptoms in a northern Niger community. Submitted for publication to Medical Anthropology.

Blum L. and G. Pelto 2001. Perceptions of vitamin A deficiency in a West African village. Submitted for publication to Ecology of Food and Nutrition.

Biography of Carine Ronsmans

Name: Carine Ronsmans
Position: Senior Lecturer
Date of Birth: 12/04/58

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

DOCTORATE IN PUBLIC HEALTH , Department of Population Sciences and International Health at the Harvard School of Public Health, Boston, USA (1990-1993). Subject of research: Clustering of child deaths in rural Senegalese families

MASTER IN PUBLIC HEALTH Harvard School of Public Health, Boston, USA (1989-1990)

DIPLOMA IN TROPICAL MEDICINE Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium (1982-1983)

MEDICAL DOCTOR Catholic University of Leuven, Belgium (1975-1982)

Research and Professional Experience

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

1998- : Clinical Senior Lecturer at the **London School of Hygiene and Tropical Medicine, Maternal and Child Epidemiology Unit**

I am currently involved in 4 studies: (1) to explore the role of audits into near-miss obstetric events as a means of improving quality of care in hospitals in Benin, Cote d'Ivoire, Ghana and Morocco (principal investigator with Veronique Filippi), (2) to conduct audits into the causes of maternal death in Senegal, Mali, The Gambia and Guinea Bissau (co-investigator), (3) to examine the contribution of indirect obstetric causes to maternal mortality in developing countries (principal investigator) and (4) to evaluate a Safe Motherhood programme in Indonesia (co-investigator). I am the course organiser for an introductory course in epidemiology and teach on an advanced study design course, a reproductive health course and a course on Safe Motherhood in developing countries. I supervise two PhD students and am the Unit representative for PhD students.

1997-1998: Professor in Epidemiology, Prince **Leopold Institute of Tropical Medicine, Epidemiology Unit, Department of Clinical Sciences**

1993-1998: Clinical Lecturer at the **London School of Hygiene and Tropical Medicine, Maternal and Child Epidemiology Unit**

I was involved with an ongoing maternal health project entitled 'Effective Maternal Health Services', principal investigator of a study to look at the effectiveness of antenatal care in preventing maternal morbidity and mortality in Bangladesh, and co-investigator for a study evaluating the use of near misses as a tool for

evaluating safe motherhood programmes in Benin. Course organiser for an MSc course on epidemiological study design and for a short course (three weeks) on epidemiological methods.

1987-1989: Researcher at the **International Centre for Diarrhoeal Diseases Research, Bangladesh (ICDDR'B)**

I was part of a research team addressing questions on how to improve maternal and child health within the context of an MCH-FP program in rural Bangladesh (Matlab). I was the principal investigator for two research projects: 1. evaluating an intervention using home treatment for dysentery by community health workers. 2. describing health seeking behaviour for diarrhoea in rural Bangladesh.

1985-1986: **Medecins sans Frontieres-Belgium(MSF-B), ICDDR'B, Bangladesh**: Adviser to the Government for the organisation of epidemic control of diarrheal diseases.

Principal investigator for a research project aimed at developing an algorithm for treatment of dysentery in an area endemic for shigellosis.

1984-1985: Co-ordinator for **MSF-B, Tchad** for the nutritional and medical surveillance in two refugee camps.

1983-1984: Intern in Surgery and Internal Medicine at **St.Jozef hospital, Mechelen, Belgium**

Publications

1. Ronsmans C, Campbell O. Verbal autopsies for maternal deaths. Report of a WHO workshop. WHO/FHE/MSM/95.15 Geneva: WHO
2. Ronsmans C. Maternal Health and the World Bank (letter). *Lancet* 1995,346:1711.
3. Graham W, Filippi V, Ronsmans C. Demonstrating impact using maternal mortality: an impossible dream? *Health Policy and Planning* 1996;11:16-20.
4. Filippi V, Graham W, Ronsmans C. The relevance of mortality as an outcome measure of evaluation studies: Illustration using Safe Motherhood Programmes. In: Khlat M (ed.) Demographic evaluation of health programmes. Proceedings of a seminar in Paris February 26-28, 1996. Committee for International Cooperation in National Research in Demography (CICRED), United Nations Population Fund (UNFPA), French Ministry of Cooperation (1996)
5. Filippi V, Gandaho T, Ronsmans C, Graham W, Alihonou E. The 'near-misses': are life-threatening complications practical indicators for Safe Motherhood programmes? Accepted for publication in : 'Innovative approaches to the assessment of reproductive health' International Union for the Scientific Study of Population (1997).
6. Campbell O, Filippi V, Koblinsky M, Marshall T, Mortimer J, Pittrof R, Ronsmans C, Williams L. Lessons learnt.(1997) A decade of measuring the impact of safe motherhood programmes. London: London School of Hygiene and Tropical Medicine
7. Ronsmans C, Vanneste AM, Chakraborty J, Van Ginneken J. Maternal mortality decline in Matlab, Bangladesh: a cautionary tale. *Lancet* 1997,350:1810-4.
8. Ronsmans C, Vanneste AM (eds)(1997). Safe Motherhood research and new challenges in the maternity care programme. Proceedings of a workshop for dissemination of findings. Dhaka: International Centre for Diarrhoeal Diseases Research
9. Filippi V, Alihonou E, Mukantaganda S, Graham WJ, Ronsmans C. Near misses: maternal morbidity and mortality (letter) *Lancet* 1998,351:145-6
10. Ronsmans C, Vanneste AM, Chakraborty J, Van Ginneken J. A comparison of three verbal autopsy methods to ascertain levels and causes of maternal deaths in Matlab, Bangladesh. *International Journal of Epidemiology* 1998, 27:660-666
11. Ronsmans C, Campbell OMR. Short birth intervals don't kill women: evidence from Matlab, Bangladesh. *Studies in Family Planning* 1998,29: 282-290

12. Ronsmans C, Achadi E, Sutratikto G, Zazri A, McDermott J. Use of hospital data for Safe Motherhood Programmes in South Kalimantan, Indonesia. *Tropical Medicine and International Health* 1999,4:514-521.
13. Campbell OMR, Ronsmans C, Collumbien M. What birth interval is best. *IPPF Medical Bulletin* 1999,33:3-4.
14. Ronsmans C and Khlat M. Adolescence and risk of violent death during pregnancy in Matlab, Bangladesh. *The Lancet* 1999,354:1448
15. Ronsmans C, Campbell O and Collumbien M. Effect of supplementation with vitamin A or beta-carotene on mortality related to pregnancy. Slight modifications in definitions could alter interpretation of results (letter) *British Medical Journal* 1999,319:1201
16. Ronsmans C (1999). Complications of pregnancy and delivery. In: Reducing perinatal and neonatal mortality. Report of a meeting Baltimore, Maryland May10-12,1999. Child Health Research Project Special Report Volume 3 Number 1
17. Khlat M and Ronsmans C. Deaths attributable to childbearing in Matlab, Bangladesh: indirect causes of maternal mortality questioned. *American Journal of Epidemiology* 2000,151(3): 300-306
18. Vanneste AM, Ronsmans C, Chakraborty J, de Francisco A. Prenatal screening in rural Bangladesh: from prediction to care. *Health Policy and Planning,* 2000,15:1-10
19. Ronsmans C (2000). Maternal mortality. In: Nutrition and Health in developing countries. Semba R, Bloem M (eds).The Humana Press.
20. Kusiako T, Ronsmans C, Van der Paal L. The contribution of complications of childbirth to perinatal mortality in Matlab, Bangladesh. *Bulletin of the World Health Organization* 200,78:621-627
21. Walraven G, Telfer M, Rowley J, Ronsmans C. Levels of maternal mortality, its causes and contributing factors in rural Gambia. *Bulletin of the World Health Organization* 2000,78:603-613
22. Filippi V, Ronsmans C, Gandaho T, Graham W, Allihonou E, Santos P. Women's report of severe (near-miss) obstetric complications in Benin. *Studies in Family Planning* 2000,31:309-324.
23. Campbell O, Ronsmans C. Vitamin A and ß carotene supplements reduce mortality related to pregnancy in rural malnourished populations: Commentary. *Journal of Evidence-Based Healthcare* 2000; 4 (2): 40
24. Ronsmans C, Filippi V. Improving obstetric care through near-miss audit. *Child Health Dialogue* 2000,18:9
25. Ronsmans C, Campbell O. Dietary Supplementation with Vitamin A and ß-Carotene Reduced Pregnancy-related Maternal Mortality: Commentary. *Evidence Based Obstetrics & Gynecology* 2000; 2: 35
26. Ronsmans C, Khlat M, Belco K, Ba M, de Bernis L, Etard J-F. Evidence for a "healthy pregnant woman effect" in Niakhar, Senegal? *International Journal of Epidemiology* 2001,30:467 - 474.
27. Kodio B, de Bernis L, Ba M, Ronsmans C, Pison G, Etard JF. Levels and causes of maternal mortality in rural areas in Senegal. *Tropical Medicine and International Health* 2001 (in press)
28. Ronsmans C, Filippi V. Severe obstetric morbidity. In: Qualitative approaches for investigating maternal deaths. Geneva: World Health Organisation (In press)
29. Ronsmans C, Walraven G, Etard JF. Verbal autopsies. In: Qualitative approaches for investigating maternal deaths. Geneva: World Health Organisation (In press)
30. Ronsmans C. How can we monitor progress towards improved maternal health goals? *Studies in Health Services Organisation & Policy*, 2001,17: (in press)
31. Ronsmans C. What is the evidence of the role of audits to improve the quality of obstetric care? *Studies in Health Services Organisation & Policy*, 2001,17: (in press)
32. Ronsmans C, Achadi E, Supratikto G, Zazri A, McDermott J, Koblinsky M, Marshall T. Evaluation of a comprehensive home-based midwifery programme in South Kalimantan, Indonesia. *Tropical Medicine and International Health* (in press).
33. Supratikto G, Wirth ME, Achadi E, Cohen S, Ronsmans C. A district-based audit into the causes and circumstances of maternal death in South Kalimantan, Indonesia. *Bulletin of the World Health Organisation* (in press).

Biography of Greet Dieltiens

Name: Greet DIELTIENS
Position: RHP/PHSD/ICDDRB
Date of Birth: 30 August 1965

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

MASTER IN PUBLIC HEALTH, Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium (1999-2000)

MASTER IN EPIDEMIOLOGY, London School of Hygiene and Tropical Medicine, London, United Kingdom (1997-1998)

DIPLOMA IN TROPICAL MEDICINE, Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium (1991-1992)

MEDICAL DOCTOR, Catholic University of Leuven, Belgium (1991)

Research and Professional Experience

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

2001: Technical advisor for the Unmet Obstetric Needs Project, Reproductive Health Program, Public Health Sciences Division, ICDDRB

Oct-Nov-Dec 2000: interim-teacher epidemiology for the MPH (International Course in Health Development), Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium

1998-1999 (11 months): General Practitioner, head of a practice in the National Health System in Central London, United Kingdom.

1995-1997: WHO-consultant to the National Tuberculosis Program in Bolivia

1992-1995: District Medical Officer for the Province Moxos, Department Beni, Bolivia

1992: Replacing General Practitioners in Belgium

Biography of Papreen Nahar

1. **Name:** Ms. Papreen Nahar
2. **Last Name:** Ms. Nahar
3. **Address:** SBSP/ PHSD, Center for Health and Population Research Bangladesh/ ICDDR,B
4. **Date of Birth:** 21st February, 1968
5. **Place of Birth:** Dhaka, Bangladesh
6. **Academic Qualifications:** MS (University of Amsterdam)
   MSc. (University of Dhaka)
   Honors Graduation (University of Dhaka)

7. Current Appointment:

SRO (Medical Anthropologist) ICDDR, B Social and Behavioral Sciences Program, Public Health Sciences Division, Duration: Since 1st November, 1994 to present

8. Other professional Qualifications:

1. Training on "Epidemiology and Biostatistics" Center for Health and Population Research; ICDDR,B, Feb.-Mar. 1998
2. Short course on "Reproductive Health Research" Department of Epidemiology & Population Sciences. London School of Hygiene & Tropical Medicine, University of London, UK. June-July, 1996
3. Training on "Exceptional Children"Bangladesh Institute of Mentally Retarded, Dhaka, Bangladesh Aug-Oct 1992

9. Basic Training:

Master's in Medical Anthropology, from the University of Amsterdam, The Netherlands 1999
Master's in Child Development & Family Relations from the University of Dhaka, 1993
Graduation with Honors in Child Development & Family Relations from the University of Dhaka -1991

10. Working Experiences:

Co-Researcher: Research title "Industrial Diseases" under IEDCR (Institute of Epidemiology and Disease Control Research). Intensive research was carried out on illnesses of employed workers experienced in garment factories of Dhaka City. Duration: September to October 1994.

Research Assistant: worked with 3 Ph.D. candidates from the University of Cambridge, UK, Department of Biological Anthropology. "Anthropometry and Breast feeding Investigation Techniques by Structured Observation" Duration: December 1993 to August 1994.

Co-writer: "Teacher's Guide Book" Formulated a guideline on non-formal Education for "Polly Progoty Shahayok Shongstha" . Duration: March to August 1992.

Research Assistant: With an Associate Professor of the Department of History from the University of Dhaka, collected information from different library relevant to her Doctoral thesis called "The World of Muslim Women in Colonial Bengal' - 1876-1939" Duration: March 1991 to February 1992.

11. Publications:

I. EPICADEC NEWS: (Biannual newsletter of the foundation care developing countries) No.16, October 2000 "***Reproductive Life of Dutch Women with Epilepsy***"

II. Reproductive Health Matters; Vol. – 8, No. – 15, May-2000 Pg. 33-44. "*Living with Infertility*: Experiences Among Urban Slum Populations in Bangladesh.

III. HEALTH: The SAGE publication, London. Vol.2, No.1, January 1998. P..P.91-110 "*Women's Health Priorities: Cultural Perspectives on Illnesses in a Rural Bangladesh*".

IV. Social Science and Medicine (accepted for review) "*An Explanatory Model of Vaginal Discharge: Experiences from Rural Bangladesh*".

V. Bangla Academy Publishers (accepted for publication). Translated Dr. Sonia Nishat in's book, [English to Begali], **"The World of Muslim Women in Colonial Bengal".**

Abstracts Published:

1. Abstract published in a conference manual –'Interpreting infertility' from Amsterdam, The Netherlands. "An Explanatory model of infertility in urban slum population of Dhaka city". November 1999
2. "Socio Cultural and Behavioral Factors in STD Prevalence in Urban Slum Population Dhaka". Published at the Sixth Scientific Conference (ASCON VI) March 1997.
3. An explanatory Model of Vaginal Discharge Among Women in Rural Bangladesh" published in the Fifth Annual Scientific Conference (ASCON-V) January 1996.
4. "Reproductive Health Care Seeking Behavior in a Rural Community" Published in the Fifth Annual Scientific Conference (ASCON V) January 1996.

Masters thesis in Medical Anthropology:

"The wings of butterfly: Reproductive life and self-image of Dutch women with epilepsy" (Conducted in The Netherlands) 1999

Other thesis conducted on the Following Topics:

- The Discriminatory Status of 'Adolescent girls' of Middle Class families in Dhaka city.(In Masters course of Child Development and family Relations)
- Women in Higher Education and their choice of Selecting life Partners: Dhaka city Exclusively. (In Honors Course)

Biography of Jyotsnamoy Chakraborty

Name: Jyotsnamoy Chakraborty
Position: Senior Manager
Date of Birth: 31/01/1943

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

Postgraduate Diploma in Food Science and Nutrition, Agricultural University, Wageningen, The Netherlands (1983)

Diploma in Sanitary Inspector-ship Course, Institute of Public Health, Dhaka, Bangladesh (1962)

Matriculate from the Board of Intermediate and Secondary Education, Dhaka (1961)

Research and Professional Experience

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

1999 – to date: Senior Manager, Community Health Research Unit, Matlab Health Research Centre, Public Health Sciences Division, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)

1984-1999: Manager, Health Services, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B).

1980-84: Senior Field Research Officer, Matlab Field Station, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B).

1980-1980: Field Research Officer, Grade-1, Matlab Field Station, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B).

1974-1980: Supervisor, Matlab Field Station, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B).

1972-1072: Supervisor, National Nutrition Survey, United Nation Relief Operation in Dhaka, Bangladesh.

1971-1972: Supervisor, In-charge Supplementary Feeding Centre (Mothers and Child), Indian Red Cross Society, India.
1968-1971: Field Surveillance Assistant, Cholera Research Laboratory, Dhaka, Bangladesh.

1964-1968: Senior Sanitary Inspector, Cholera Research Laboratory, Dhaka, Bangladesh.

1963-1964: Sanitary Inspector, Cholera Research Laboratory, Dhaka, Bangladesh.

1963: Assistant Malaria Inspector, Malaria Eradication Program (under WHO), Dhaka, Bangladesh.

Publication:

1. Anne Maria Vanneste, Carine Ronsmans, Jyotsnamoy Chakraborty and Andres de Francisco. 'Prenatal Screening of Rural Bangladesh: from prediction of care'. Health Policy Planning: 1999 15(1): 1-10.

2. BA Hoque, J Chakraborty, JTA Chowdhury, UK Chowdhury, M Ali, SE Arifeen and RB Sack. 'Effects of Environmental Factors on Child Survival in Bangladesh'. Public Health (1999) 113, 57-64.

3. Amy Rice, Rebeca J Stolzfus, Andres de Francisco, J Chakraborty, Chris L Kjolhede, and MA Wahed. 'Maternal Vitamin A or B-Carotine Supplementation in Lactating Bangladeshi Women Benefits Mothers and Infants but does not protect Sub-clinical Deficiency'. American Society for Nutritional Science 0022/3166 (1999).

4. Mohammad Ali, Andres de Francisco, M Mahmud Khan, Jyotsnamoy Chakraborty, and Jacques Myaux. 'Factors Affecting the Performance of Family Planning workers: Importance of Geographical Information Systems in Empirical Analysis'. Int. Journal of Population Geography 5, 19-29 (1999).

5. Rebeca J. Stolsfus, Jyotsnamoy Chakraborty, Amy Rice, Binidicte de la Brievi and Andres de Francisco. 'Plausible evidence of effectiveness of an Iron-Supplementation Programme for pregnant and post-partum women in rural Bangladesh'. Food and Nutrition, Vol. 19, No. 3, (C) (1998).

6. Carine Ronsmans, Anne Maria Vanneste, Jyotsnamoy Chakraborty, and Jeroen Van Ginniken. 'A comparison of three verbal autopsy methods to ascertain levels and causes of maternal deaths in Matlab, Bangladesh'. International Journal of Epidemiology (1998): 27:660-66.

7. A de Francisco, A.J. Hall, L. Unicomb, J. Chakraborty, Md. Yunus and R.B. Sack. 'Maternal measles antibody decay in rural Bangladeshi infants – Implications for Vaccination Schedules'. Vaccine Vol. 16, No. 6 (564-68) 1998.

Detailed Budget (USAID Format)

Project Title: The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh

Name of PI: Prof. Japhet Killewo

Protocol Number: Name of Division: PHSD

Funding Source: USAID Amount Funded (direct): Total: 315,495 Overhead (%) 26 82,028

Starting Date: January 2002 Closing Date: December 2004

Strategic Plan Priority Code(s):

Sl. No	Account Description	Salary Support				US $ Amount Requested	
1	Payroll and Benefits	Position	Effort% 1st Yr	2nd Yr	Salary	1st Yr	2nd Yr
	International staff						
	One Researcher / Lauren Blum	P4/2	15	15	111,384	16,708	17,543
	One Researcher / Japhet Killewo	P5	15	15	136,044	20,407	21,427
	One Researcher / Carine Ronsmans		15	15	101,940	15,291	16,056
	Local staff						
	One Senior Research Officer	NOB	100	100	9,552	9,552	10,030
	One Senior Research Officer	NOA	100	50	7,908	7,908	4,152
	One Administrative Manager	NOB	20	20	9,552	1,910	2,006
	Four Interviewers / Social Sciences	GS5	100	-	4,212	16,848	-
	One Interviewer / MHSS data	GS4	100	-	3,228	3,228	-
	Four Interviewers/Health Economics	GS4	50	-	3,228	6,456	-
	One Data Entry Personnel	GS4	80	20	3,228	2,582	678
	One Data Entry Personnel	GS4	50	100	3,228	1,614	3,389
	One Field Supervisor	GS6	10	10	5,472	547	575
	One Senior Manager	NOC	10	10	12,192	1,219	1,280
	One Data Processing Supervisor	GS6	10	10	5,472	547	575
	One Analyst Programmer	NOB	70	70	9,552	6,686	7,021
	One Data Manager / DSS	NOA	20	20	7,908	1,582	1,661
	Sub-Total :					**113,086**	**86,391**

2	**Travel and Transport (of Internatinal and local Staff)**		1st Yr	2nd Yr
	International Travel (four) :	London-Dhaka-London : Ticket cost	2,000	2,000
		Perdiem	3,000	3,250
	Local Travel	Matlab accommodation	1,220	1,000
	Transport:	Dhaka -Matlab -Dhaka	8,500	3,500
		Matlab Transport	2,500	1,000
	Sub-Total :		**17,220**	**10,750**

3	General Operating Cost					1st Yr	2nd Yr
	Cost towards use of HDSS data					6,500	6,500
	Rent, Communications, Utilities					1,500	1,500
	Repairs and Maintenance					1,000	1,000
	Office supplies (Stock/Non-stock/other misc.)					3,000	1,500
	Sub-Total :					**12,000**	**10,500**
4	**Training**					**1st Yr**	**2nd Yr**
	Local : Training of field workers	(social sciences)				700	-
	International : Short course in London					6,000	-
	Sub-Total :					**6,700**	**-**
5	**Capital Purchases**					**1st Yr**	**2nd Yr**
	Computer, Printer, UPS					3,000	-
	Laptop computer					2,200	-
	Software, accessories and others					2,000	-
	Sub-Total :					**7,200**	**-**
6	**Consultants :**	**Position**	**Effort**	**%**	**Salary**	**1st Yr**	**2nd Yr**
			1st Yr	**2nd Yr**			
	One Health Economist	P4/2	10	10	111,384	11,138	11,695
	One Obstetrician & gynaecologist	NOD	25	10	15,936	3,984	1,673
	One Physician	NOD	25	10	15,936	3,984	1,673
	International Travel					1,000	1,000
	Sub Total					**20,106**	**16,042**
7	**Other Direct Costs**					**1st Yr**	**2nd Yr**
	Dissemination :						
	International Conference					-	5,100
	Matlab dissemination workshop					-	1,000
	Dhaka dissemination workshop					-	2,000
	Printing & publication					1,000	400
	Meeting Expenses					1,500	1,000
	Service Charges					2,000	1,500
	Sub Total					**4,500**	**11,000**
						1st Yr	**2nd Yr**
	Total :					**180,812**	**134,683**
	Overhead (26%)					**47,011**	**35,017**
	Overall Total					**227,823**	**169,700**
	Grand Total						**397,523**
	TOTAL DIRECT COST :						**315,495**

Budget Justification

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

1. International and Local Staff:

The project proposes to utilize three international level project staff on a part-time basis. These scientists were responsible for the development of the project objectives and will subsequently be engaged in its implementation and conclusion. They will conduct the required analysis (both qualitative and quantitative) and make the relevant scientific interpretations. They will then be responsible for dissemination of results in scientific forums.

The project also proposes to hire the services of one senior research officer who will be responsible for the day-to-day running of the project, with close supervision by the principal investigator. For continuous monitoring of the project this staff will be utilized 100% of the time over the two years period. Other senior researchers and administrative staff will be employed part time. As most interview work and data management tasks will be implemented during the first year, the budget has reflected this accordingly. This means that the project will utilize these personnel part-time as indicated in the budget.

2. Travel and Transport:

The project proposes four international trips that will require air tickets and per diems for the collaborating international staff and consultants. These scientists will have to travel several times to Dhaka and to the field for project-related tasks and for scientific discussions. According to the project proposal, a number of project staff, particularly the researchers, will need to travel regularly to the project site in Matlab to implement the study. Local transport to and from Matlab requires both road and water transport. Matlab is a riverine rural area where speedboat transport is the most convenient one for research work but, unfortunately, costly. Other means of transportation like public transport and country boats are very unreliable.

3. General Operating Cost:

The project will need to pay for the cost of using the HDSS data-base which is continuously being updated and linked to ongoing studies and services throughout the intervention and comparison areas of Matlab. The cost is based on two of the six study components which directly depend on using the HDSS database to answer the research questions. In addition, the project will need to communicate by phone, fax, e-mail and sometimes by ordinary mail to contact collaborators or other related persons. These services cost money but are not project-specific. Hence, the project intends to contribute to the bills through a sharing mechanism. The project will also need to maintain and repair equipment and other materials to be purchased.

In addition, most consumables like stationery and field-related gear will be needed in the first year of the project, hence, the higher budget than in the second year.

4. Training:

As part of the collaboration with the LSHTM in London and in order to strengthen research capacity in maternal health issues, the project is proposing to train one of its local junior project staff for a short period in London. In addition, successful implementation of this project in the field largely depends on well-trained field workers. The project proposes to conduct training for all its field workers to perform their tasks well. Funds to be expended will cover their training materials plus cost of venue and allowances.

5. Capital purchases:

Major purchases include one desktop computer for data entry cleaning and analysis and for keeping the various databases that the project intends to acquire and use. A laptop will also be required to facilitate data processing and report writing and especially the writing of reports and development of manuscripts during field time and while on transit. Other equipment and material such as printers, software, UPS and diskettes will also be needed to maintain the data and to complete reports and manuscripts.

6. **Consultants:**
Due to its diverse nature of involving different research disciplines, the project will require the services of persons working in specific relevant health fields as short-term consultants. These include a health economist, an obstetrician and gynaecologist as well as a general physician. These individuals will be hired to address issues in the project that are linked to their expertise. International travel of one consultant (P-level) is also included once in a year.

7. **Other direct costs:**
These relate to the cost of attending scientific conferences to present findings from the study. The project also proposes to hold dissemination workshops at various levels in order to influence policy. The project sees these activities as essential for achieving its objectives.

Printing of questionnaires and other materials will be required.

During the project period meetings will take place both in Dhaka and Matlab for which an estimated amount is included in the budget.

The project will need to pay for the services of office attendants, clerks, translators, labourers on a daily-wage / contractual service agreement basis. Charges for other inter-departmental services, which the project may incur, is also included here.

Overhead:
An overhead item of 26% has been added as stipulated in the Centre's policy. This indirect cost to the project covers the cost of administration and utilities that are not being covered by the project. The direct cost of the project has therefore excluded this budget line.

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)

Other Support is detailed below:

Safe Motherhood : Essential Obstetric Care Project
Funding Source: The Commission of the European Communities
Amount : US$1,636,348
Duration: Three years
Grant No: BGD/B7-300/0038-01
ALA/97/0038

Male Involvement in Reproductive Health
Funding Source: The Commission of the European Communities
Amount : US$1,107,765
Duration: Three years
Grant No: BGD/B7-300/0038-01
ALA/97/0038

APPENDIX

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project: The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh

Principal Investigator: Japhet Killewo

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.

Consent form for the acceptability component
Identification Number:

Assalamualaikum/Adab. We work at the Cholera Hospital in Matlab and we are presently conducting a study on beliefs related to pregnancy and childbirth and household decision-making affecting maternity care. Through this and other research presently being conducted, we aim to improve access to safe obstetric care. We would like to spend about an hour with you to learn more about your experiences and views. If you agree to participate in the study we will ask you a number of questions today. We may also need to return to ask additional questions sometime in the future. During the interview, you may refuse to answer questions or terminate the session at any time. We should also let you know that you will not be paid. Your participation is completely voluntary.

While we will be taking notes during our talk, we want to assure you that all of your answers will be kept strictly confidential. The information that we record will be kept in a secure location and only scientists will have access to this data.

Do you have any questions for us?

Are you willing to engage in this exercise?

[ ] Does not agree to be interviewed (Thank the individual for her time)

[ ] Agrees to be interviewed

Signature of the literate respondent: Date:

Thumb impression of illiterate respondent: Date:

To be completed by the interviewer

The information in the consent form was read out loud in the presence of the witness and the respondent clearly understood the contents of the consent form.

Signature of the interviewer: Date:

For illiterate respondents, signature of a witness: Date:

Are you available to talk now? Thank you

গবেষণার গ্রহনযোগ্যতা নিয়ে সম্মতিপত্র

পরিচয় সূচক সংখ্যা:
আসসালামুআলাইকুম/আদাব,

আমরা মতলবের কলেরা হাসপাতালে কাজ করি। এখন আমরা, গর্ভাবস্থা ও বাচ্চা হওয়া নিয়ে যে ধরনের প্রচলিত বিশ্বাস আছে তা নিয়ে গবেষণা করতে যাচ্ছি। একইসাথে আমরা পরিবারের অন্যান্য সদস্যদের সিদ্ধান্ত কিভাবে মায়েদের শরীর স্বাস্থ্যের যত্নের উপর প্রভাব ফেলে সে বিষয়গুলো নিয়েও গবেষণা করছি। বর্তমান গবেষণা এবং অন্যান্য যে সব গবেষনা আমরা করছি সেগুলোর মধ্যদিয়ে সবাই যেন সহজে নিরাপদ সন্তান ধারন,প্রসব ও প্রসূতিকালীন যত্ন পায় সে ব্যবস্থা করতে চাচ্ছি। আমরা আপনার অভিজ্ঞতা ও মতামত জানার জন্য ঘন্টাখানেক সময় আপনার সাথে কাটাতে চাচ্ছি। যদি আপনি আমাদের এই গবেষণায় অংশ নিতে চান তাহলে আমরা আপনার কাছে বেশ কিছু বিষয়ে জানতে চাইবো। আগামীতে আরো কিছু প্রশ্ন করার জন্য আমাদের ফিরে আসার দরকার হতে পারে। আমাদের সাথে কথাবার্তা বলার সময় আপনি যে কোন প্রশ্নের উত্তর দিতে না চাইতে পারেন অথবা কথাবার্তা বলার এই পুরো আয়োজনটাকে বাতিল করে দিতে পারেন। আমরা আপনাকে আরো জানাচ্ছি যে, এর জন্য আপনাকে কোন টাকা পয়সা দেয়া হবেনা। আপনার অংশ গ্রহন পুরোপুরি আপনার ইচ্ছামাফিক।

কথাবার্তা বলতে বলতে আমরা অনেক কিছু টুকে/লিখে নিব কিন্তু আমরা আপনাকে নিশ্চয়তা দিচ্ছি আপনি আমাদেরকে যা বলবেন সবই আমরা গোপন রাখবো। আমরা যে সকল তথ্য আপনার কাছ থেকে নেব তা নিরাপদ জায়গায় রাখা হবে এবং একমাত্র আমাদের দলের গবেষকরাই এগুলো ব্যবহার করবেন।

আমাদের কাছে কি আপনার কিছু জানার আছে?

আপনি কি আমাদের সাথে কথাবার্তা বলবেন?

( ) সাক্ষাৎকার দিতে বা কথাবার্তা বলতে রাজি নন (যে সময়টুকু দিলেন সে সময়টুকর জন্য তাকে ধন্যবাদ দিন)

( ) সাক্ষাৎকার দিতে অথবা কথাবার্তা বলতে রাজি।

লেখাপড়া জানা উত্তরদাতার স্বাক্ষর তারিখ:

লেখাপড়া না জানা উত্তরদাতার টিপসই তারিখ:

সাক্ষাৎকার গ্রহনকারী এটি পূরনকরবেন।

তিনি যাতে স্পষ্টভাবে শুনতে পান সেভাবে তাকে সম্মতিপত্রটি একজন সাক্ষীর সামনে পড়ে শুনানো হয়েছে এবং আমার মনে হয় উত্তরদাতা সম্মতিপত্রটি স্পষ্টভাবে বুঝেছেন।

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স্বাক্ষাৎকারগ্রহনকারীর সাক্ষর : তারিখ

- লেখাপড়া জানেন না এমন উত্তরদাতার ক্ষেত্রে সাক্ষীর স্বাক্ষর তারিখ:

আপনি কি এখনই আমাদের সাথে কথা বলবেন?
ধন্যবাদ

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project: The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh

Principal Investigator: Japhet Killewo

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.

Consent form for the observation of deliveries
Identification Number:

Assalamualaikum/Adab. We work at the Cholera Hospital in Matlab and we are presently conducting a study on beliefs related to pregnancy and childbirth and household decision-making affecting maternity care. Through this and other research presently being conducted, we aim to improve access to safe obstetric care. Ultimately, our goal is to improve delivery services to ensure the safety and health of women during childbirth.

In order to learn more about how birthing attendants and trained midwives handle deliveries and the kind of postpartum care they provide to mothers and newborns, we would like to request you to allow one of our female research officers to remain present during the time of delivery. This will enable us to observe actual processes and practices during labor and childbirth. Only selected pregnant mothers in your area are being requested to participate in this part of the study. We should also inform you that the person carrying out the observations is not a trained clinician and therefore is unable to give medical assistance or make any medical decisions.

Your participation in this study is completely voluntary and you have the right to withdraw from the study at any time. Furthermore, we want to assure you that all of the information that we record will be kept in a secure location and only our team of researchers will have access to this data.

Do you have any questions for us?

Are you willing to engage in this exercise?

[ ] Does not agree to be interviewed (Thank the individual for her time)

[ ] Agrees to be interviewed

Signature of the literate respondent: Date:

Thumb impression of illiterate respondent: Date:

To be completed by the interviewer

The information in the consent form was read out loud in the presence of the witness and the respondent clearly understood the contents of the consent form.

Signature of the interviewer: Date:

For illiterate respondents, signature of a witness: Date:

Are you available to talk now? Thank you

বাচ্চা প্রসব প্রক্রিয়া পর্যবেক্ষনের সম্মতিপত্র

পরিচয় সূচক সংখ্যা:
আসসালামুআলাইকুম/আদাব,

আমরা মতলবের কলেরা হাসপাতালে কাজ করি। এখন আমরা, গর্ভাবস্থা ও বাচ্চা হওয়া নিয়ে যে ধরনের প্রচলিত বিশ্বাস আছে তা নিয়ে গবেষনা করতে যাচ্ছি। এবং সাথে সাথে আমরা পরিবারের অন্যান্য সদস্যদের সিদ্ধান্ত কিভাবে মায়েদের শরীর স্বাস্থ্যের যত্নের উপর প্রভাব ফেলে সে বিষয়গুলো নিয়েও গবেষণা করছি। বর্তমান গবেষণা এবং অন্যান্য যে সব গবেষনা আমরা করছি সেগুলোর মধ্যদিয়ে সবাই যেন সহজে নিরাপদ সন্তান ধারন,প্রসব ও প্রসূতিকালীন যত্ন পায় সে ব্যবস্থা করতে চাচ্ছি।

সর্বপরি আমাদের এই গবেষণার উদ্দেশ্য হচ্ছে কিভাবে বাচ্চা হওয়ার সময় মায়েদের সেবা/যত্ন আরও উন্নত করা যায় যাতে করে মার এবং বাচ্চার স্বাস্থ্য এবং জীবন নিশ্চিত হয়।

আপনারা যদি অনুমতি দেন তবে আমাদের একজন গবেষক (মেয়ে), বাচ্চা প্রসবের সময় দাই এবং অন্যান্য মহিলা যারা প্রসবের সময় এবং প্রসবের পরে মায়েদের যে সব সেবা দিয়ে থাকেন সে বিষয়গুলো দেখার জন্য সেসময় সেখানে থাকতে চান। আমাদের গবেষক আরও দেখতে চান যে, কিভাবে নতুন বাচ্চাকে দাই বা বাড়ির অন্যান্য মহিলারা জন্মেরপর যত্ন নিয়ে থাকেন। গবেষনার জন্য করা এই কাজটি আমাদের বুঝতে সাহায্য করবে কিভাবে আমাদের দেশে বাচ্চা প্রসব করা হয় এবং কি উপায়ে বাচ্চা প্রসব করানো হয়। এই এলাকার বাছাই করা অল্প কিছু মায়েদের গবেষণার এই অংশে অংশ গ্রহন করার জন্য অনুরোধ করা হয়েছে। আমরা আপনাকে আরো জানাচ্ছি যে, যিনি এই পর্যবেক্ষন করবেন তিনি কোন প্রশিক্ষনপ্রাপ্ত ডাক্তার বা চিকিৎসক নন এবং এ কারনে তিনি কোন চিকিৎসা সহায়তা বা চিকিৎসা সংক্রান্ত কোন সিদ্ধান্ত নিতে অক্ষম/ পারবেন না।

আপনার এই অংশ গ্রহন সম্পূর্ণ আপনার ইচ্ছার উপর এবং আপনি যে কোন মুহূর্তে এই আয়োজন বাতিল করতে পারেন। আমরা আপনাকে এইবলে নিশ্চিত করতে চাই যে এই সমস্ত তথ্য গোপন এবং নিরাপদ রাখা হবে এবং শুধুমাত্র আমাদের গবেষকরাই এগুলো ব্যবহার করবেন।

আমাদের কাছে কি আপনার কিছু জানার আছে?

আপনি কি আমাদের সাথে কথাবার্তা বলবেন?

( ) সাক্ষাৎকার দিতে বা কথাবার্তা বলতে রাজি নন (যে সময়টুকু দিলেন সে সময়টুকর জন্য তাকে ধন্যবাদ দিন)

( ) সাক্ষাৎকার দিতে অথবা কথাবার্তা বলতে রাজি।

লেখাপড়া জানা উত্তরদাতার স্বাক্ষর তারিখ:

লেখাপড়া না জানা উত্তরদাতার টিপসই তারিখ:

সাক্ষাৎকার গ্রহনকারী এটি পূরনকরবেন।

তিনি যাতে স্পষ্টভাবে শুনতে পান সেভাবে তাকে সম্মতিপত্রটি একজন সাক্ষীর সামনে পড়ে শুনানো হয়েছে এবং আমার মনে হয় উত্তর দাতা সম্মতিপত্রটি স্পষ্টভাবে বুঝেছেন।

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স্বাক্ষাৎকারগ্রহনকারীর সাক্ষর : তারিখ

লেখাপড়া জানেন না এমন উত্তরদাতার ক্ষেত্রে সাক্ষীর স্বাক্ষর তারিখ:

আপনি কি এখনই আমাদের সাথে কথা বলবেন?
ধন্যবাদ

Check List

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

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

Instructions for Observations During Labor and Delivery

Environment During Labor and Delivery

1. Describe where the delivery will take place (e.g. in the room of a household or the health care facility) and record in detail the actual surroundings.

2. Describe the level of cleanliness in the environment; include any information that may raise or allay concerns related to sanitary conditions including the appearance of the attendant (clothing, indications of cleanliness (nails, etc.)

3. Indicate whether natural light is used or if the room is lit in some way.

4. Describe the materials or instruments, which are available for the delivery, and their apparent condition. Also, indicate when the materials were brought to the room and what preparation (such as sterilization of instruments) was made of the materials for the delivery.

5. Indicate whether any special clothes or materials are prepared or available for the woman and the baby.

6. Describe the place where the woman remains during contractions (e.g. on the bed, on the ground) and how she is positioned (lying on her back or side, squatting, etc.).

People Attending the Birthing Process

1. Describe the people in the room. As this will be a dynamic process, the observations should reflect changes in the individuals in the room and indicate how long individuals remain.

2. Describe the roles the various people in the room play related to decision making around her care. Make a record when any sort of assistance is provided to the pregnant woman.

3. Record interactions between other people in the room and the pregnant woman, including verbal and/or physical contact.

4. Record interactions that take place between the health care provider and the other people in the room. This can involve verbal discussions or ways in which the other people may physically assist the birthing attendant.

Condition of the Pregnant Woman

1. Describe apparent physical changes in the woman's condition that occur during labor and delivery. For instance, how severe are the contractions and what are the

mechanisms she uses (screaming, talking to somebody, breathing exercises, crying) to cope with severe pain? Record in detail observations during the pushing phase. How easy or difficult is it for her to push? How long does it take for the baby's head to crown?

2. Record how she seems to cope with the intense emotions that come with labor and delivery. To what extent is she able and willing to express her emotions or does she seem to make an effort to suppress her feelings?

Patient/Health Provider Relations

1. Describe the way in which the patient and health provider communicate with each other and how this changes during the different phases of labor and delivery. Based on the observations, record the type of relationship that seems to exist between them. For instance, is the health provider compassionate, firm, caring, austere with the pregnant woman? Does this change over time?

2. Record any encouragement the birthing attendant may give the pregnant women during the labor and delivery process. For instance, does the birthing attendant give her support during the most painful contractions or encourage her in any during the pushing phase.

3. Describe how the woman in labor is able to express herself during labor and delivery. Is she able to make specific demands (e.g. ask for some sort of physical contact such as a massage or to hold a hand during labor, ask for a drink, ask the birthing attendant for assistance with pushing, etc.) based on her particular needs during the different phases of labor and delivery.

4. Record how the birthing attendant responds to the pregnant woman's needs. Is she willing to give her physical or emotional assistance when the pregnant woman is in apparent need of help or experiencing extreme pain.

Procedures Used During Labor and Delivery

1. Describe how the birthing attendant prepares herself for the delivery. For instance, does she wash her hands, wear gloves, etc.

2. Indicate techniques used at different phases of labor or delivery. For instance, does the birthing attendant check the fetal heartbeat, measure the blood pressure, conduct a pv assessment of the progress of labor? In may parts of the world if the pregnant woman does not seem to be making adequate progress during the pushing phase the birthing attendant may apply physical pressure to her abdomen or tie clothes tightly around the abdomen. What is done when the head of the baby crowns? Is a perineal gauge used during delivery? Are any procedures used (episiotomy, massage of the vagina) to prevent tearing?

3. Make records of any medications used during labor. For instance, are any pain relievers administered or is medication such as oxytocin or indigenous medicines (e.g. moriam) used to speed up delivery.

4. Record the use of any instruments employed during labor and particularly during the delivery of the baby.

5. Indicate if anybody else attending the delivery is involved in administering techniques or medications.

Post Delivery

1. What is done with the newborn after the delivery? Who is responsible for tending to the care of the newborn?

2. Who is responsible for cutting the umbilical cord? How quickly is it done, by whom and with what instrument is the cord cut?

3. How soon following the delivery is the mother able to have physical contact with the baby? Describe the contact between the mother and child? Does the mother offer the breast to the child? If so, when?

4. Record how soon after the delivery of the baby the placenta is delivered. Indicate who is responsible for overseeing the delivery of the placenta and whether any techniques or procedures are used to facilitate the delivery of the placenta.

5. Record what is done with the placenta and other bloody materials. Who is responsible for cleaning up and taking care of these materials?

6. Describe how the mother is treated after the delivery. Is she congratulated or soothed in any way? Record verbal interactions or physical contact that takes place after the delivery. Is she offered any food or drink? If so, how soon after delivery?

7. Describe how the mother reacts to the arrival of her baby. What if any questions (e.g. the sex or size of the baby) does she ask the attendant or others in the room? Is she interested in seeing or holding the newborn?

8. Are any procedures used to repair tears she may have experienced during the delivery?

9. Indicate whether you observe any exchange that appears to be conducted to compensate the birthing attendant for her work.

Guidelines for Observations of Labor and Childbirth

Environment During Labor and Delivery			
1.Describe the location			
2.Level of cleanliness			
3. Lighting in the room			
4. Materials or instruments available for the delivery			
5. Clothing or other materials available for mother and newborn			
6. Place where the woman is located and position she is in during the different phases of labor and delivery.	Contractions/Dilation of Cervix/Transitional phase	Pushing and Delivery of the Baby	Delivery of the Placenta

People Attending the Labor and Birth	
1. Actual observers	a.
	b.
	c.
	d.
	e.
	f.
2. Apparent roles of the other people in the room	a.
	b.
	c.
	d.
	e.
	f.
3. Interactions that occur with the woman in labor	a.
	b.
	c.
	d.
	e.
	f.
4. Interactions with the health provider	a.
	b.
	c.
	d.
	e.

Condition of the Pregnant Woman			
1. Signs of physical changes during the different phases of labor and delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
2. Signs of emotional changes during different phases of the delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta

Patient/Provider Relations			
1. Interactions during the different phases of delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
2. Level of encouragement or nurturing	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
3. Extent to which the woman can express her needs to the health provider	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
4. Response of the birthing attendant to the woman's needs	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta

Procedures used during labor and delivery			
1. Preparations the birthing attendant makes for the delivery			
2. Techniques used by the birthing attendant during different phases of delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
3. Medications used by the attendant during different phases of the delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
4.Instruments used by the attendant during different phases of the delivery	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta
5.Procedures used on the pregnant woman by anybody else in the room	Contractions/Dilation of Cervix/transitional phase	Pushing and Delivery of the Baby	Delivery of the placenta

Post Delivery	
1. What is done with the newborn	
2. Cutting of the umbilical cord	
3. Mother/newborn contact	
4. Delivery of the placenta	
5. Removal of the placenta and other bloody materials	
6. Treatment of the mother	
7. Reaction of the mother to the newborn	
8. Procedures used to repair tears	
9. Compensation for the work of the birthing attendant	

Centre for Health and Population Research

ETHICAL REVIEW COMMITTEE

Annual/Completion Report
For Research Protocol Involving Human Subjects

1	Protocol Number ***2001-020***	Protocol Title ***The acceptability, effectiveness and cost of strategies designed to improve access to basic obstetric care in rural Bangladesh.***		
2	RRC approval date ***15 Oct. 2001***	ERC approval date ***30 Dec. 2001***	Actual start date ***7 Mar. 2002***	Planned end date (per actual start date) ***Mar. 2004***
3	Reporting Period	From (date) ***7 Mar. 2002***	To (date) ***6 Mar. 2003***	
4	Principal Investigator	***Prof. Japhet Killewo***		
5	Program/Division	***Reproductive Health Unit / PHSD***		
6	Was/were any proposal(s) for addendum to/ modification of the protocol submitted after the approval of the protocol, for ERC approval? Yes ☐ No ☐√	RRC Approval date	ERC approval date	
7	Protocol Objectives ***Component 1: Effectiveness, Impact and Validation*** *1.1 To determine the effectiveness of each of three delivery strategies viz. a) home deliveries with a TBA/TTBA, b) home deliveries with a midwife, c) facility deliveries in addressing the intended goal of meeting the unmet obstetric need in Matlab* *1.2 To assess the impact of the above three strategies on uptake of comprehensive EOC services* *1.3 To validate the link between process indicators and outcome* ***Component 2: Costing*** *2.1 To estimate and compare the average cost of maternity care for the three different strategies* ***Component 3: Acceptability*** *3.1 Describe beliefs related to pregnancy and local perceptions of complications and appropriate treatment* *3.2 Examine women's and other household members demand for and perception of home- and facility-based midwifery care* *3.3 Understand the constraints women face in accessing skilled birthing care* *3.4 Identify strategies that may help women overcome barriers to delivering outside the home*			

8	Activities planned during the preceding 12 months (quantifiable)	Activities accomplished during the preceding 12 months
	1. Effectiveness, impact & validation component	
	a) Recruitment of staff	*a) Two Sr. Res. Investigators (NOB), one Sr. Res. Officer (NOA), and five Social Scientists (1 GS6 + 4 GS5) have been recruited. Salaries of other supporting staff including one Health Economist are being charged from the budget according to their respective involvement.*
	b) Obtain relevant data from HDSS	*b) We had placed a request to the HDSS to provide data on selected variables in the ICDDR,B service area during 1987-2000 classified in three sections 1)Identification 2) Pregnancy and delivery characteristics 3) Survival status of live births including socio-economic status. As the HDSS do not collect the socio-economic data through its surveillance system ,it was planned to pool this information from Matlab Health and Socioeconomic Survey of 1996 and Population Census in 1982. So far, we have received data in section 1 and 2 from the HDSS. Currently HDSS is processing data in section 3 to provide.*
	c) Obtain Green Card data, Pictorial Card data and Maternity Records in Matlab.	*c) In order to produce trends of % of all births receiving care, in addition to HDSS data we needed information on pregnancy complications and care seeking patterns of those women in the intervention area during (1987-2001). For this we have obtained Green Card data (1987-1993), Pictorial Card data (1996-2001and Maternity Registry records in Matlab Clinic and ICDDR,B Sub Centers (1996-2001).*
	d) Conduct a special survey to collect ANC, delivery and PNC data during 1994-97 for completeness of pregnancy related data during 1987-2001 in HDSS area.	*d) As there were no Pictorial Cards issued to the pregnant women in the HDSS area during 1994-96, a special survey was conducted to collect retrospective information on pregnancy complications and care seeking patterns of those women during this Gap Period in the ICDDR,B treatment area. A total of 9133 deliveries (live and still birth in 9092 mothers) have been identified form the HDSS to conduct this Gap Period Survey.*
	e) Designing instruments	*e) Instruments were developed for the Gap Period Survey*
	f) Recruitment & training of the interviewers	*f) Ten interviewers were recruited in Dec. 2002 for a period of 3 months. They were trained on how to use the instruments to collect the data.*
	g) Data collection and data entry	*g) Out of 9092 mothers, information could have been collected of 8730. There were 73 absentees and 289 migration-outs. Data collection completed on 30, March 2003.*

	h) Verbal autopsy for validation component	*h) Collecting verbal autopsy data from all women who died during the period 1990-2001 is an essential component of validating the process indicators in our study. But for the current study, this activity did not get funding through USAID. However, data from several other sources including the one - Unmet Obstetric Need (UON) project of ICDDR,B will be used to implement this activity. From the existing works of these studies, necessary information about the maternal death cases in women aged 12-49 during 1990-1999 will be available for HDSS area. In addition, to cover the year 2000-2001, through the UON project, four interviewers have been recruited and trained to perform the verbal autopsies to identify maternal deaths in the HDSS area. The interviewers also field tested the relevant instruments. So far a total of 170 female deaths aged 12-49 have been identified to conduct verbal autopsies.*
	i) Data entry, cleaning and linking	*i) By the end of 1st year all the data have been entered. Work is ongoing for cleaning of the Green Card , Gap Period, Pictorial Card and Maternity Register data as well as linking with the HDSS data.*
	2. Costing component	
	a) Designing instruments	*a) To estimate and compare the average cost of maternity care 9 sets of data collection instruments have been developed, 5 sets for interviewing clients at home and 4 sets for providers and linkage personnel.*
	b) Recruitment & training of the interviewers	*b) Four health economists has been recruited as interviewers in Nov. 2002. Training of the interviewers and field test of the questionnaire were completed on 22, Jan. 2003.*
	c) Data collection for household cost	*c) Data collection started on 23 Jan. 2003. The first year target in data collection has been completed.*
	d) Coding, and editing	*d) Coding and editing of the collected data is ongoing.*
	3. Acceptability of services (Qualitative component)	
	a) Designing instruments	*a) Three sets of data collection instruments have been developed for 1) in-depth interview in households in which a recent childbirth took place 2) interview with birthing attendants including trained midwives and unskilled attendants 2) direct observations of home- and facility-based deliveries*
	b) Hiring and training of social scientists	*b) Five social scientists have been recruited and trained in collecting qualitative data.*
	c) Data collection	*c) The target in first year data collection has been completed.*
	d) Coding	*d) Coding of the qualitative data is in progress*
	e) Data analysis	e) *Some preliminary analysis has been done*

9	Do you have any information from this study or from other studies that significantly changes the risk/benefit ratio for the participants enrolled in this study or likely to affect the consent of prospective participants?	Yes ☐	No ☐√
	If Yes, describe		
10	*How many participants were planned to be enrolled?*	*Since start*	*Last 12 months*
	Component 1: Effectiveness, impact & validation		
	- HDSS data for 1987-2001	*All*	*All*
	- Green Card for 1987-1993	*All*	*All*
	-Pictorial Card 1997-2001	*All*	*All*
	- Maternity records1997-2001	*All*	*All*
	Gap Period data collection for 1994-1997	*All*	*All*
	Validation (verbal autopsy)		
	- From other studies + UON for 1990-1999	*1053*	*All*
	- From UON study for 2000-2001	*170*	*none*
	Component 2: Costing		
	Interview of clients	*300*	*60*
	Interview of providers	*68*	*none*
	Component 3: Acceptability		
	Household representative	*150*	*75*
	Birth attendant	*Not specified*	*15*
	Observation of delivery	*10*	*5*
11	*How many participants have been enrolled?*	*Since start*	*Last 12 months*
	Component 1: Effectiveness, impact & validation		
	- HDSS data for 1987-2001	*92991**	*All**
	- Green Card for 1987-1993	*9825*	*All*
	-Pictorial Card 1997-2001	*12221*	*All*
	- Maternity records1997-2001	*2270*	*All*
	Gap Period data collection for 1994-1997	*8730*	*All*
	Validation (verbal autopsy)		
	- From other studies + UON for 1990-1999	*1053*	*All*
	- From UON study for 2000-2001	*none*	*none*
	Component 2: Costing		
	Interview of clients	*60*	*60*
	Interview of providers	*none*	*none*
	Component 3: Acceptability		
	In-depth interview	*75*	*75*
	Birth attendant	*15*	*15*
	Observation of delivery	*5*	*5*
	If the target is not achieved, please give reasons for not achieving the enrolment target		
	j) *For the HDSS data during 1987-2001 among the requested data in 3 sections viz. *1) Identification and 2) Pregnancy and delivery characteristics 3) Survival status of live births including socio-economic status, we have received section 1 and 2. At the time of writing this report HDSS was processing data in section 3 to provide.*		

12	Have subjects been enrolled strictly per inclusion criteria specified in the protocol?	Yes ☑ No ☐ NA ☐
	If No, provide reasons for deviation	
13	Whether principles of 'informed consent' were followed in enrolling participants?	Yes ☐ ☑ No ☐ NA ☐
	If No, please provide reason(s)	
14	Have samples been collected as specified in the protocol?	Yes ☐ ☑ No ☐ NA ☐
	If No, please provide reason(s)	
15	Was/were any unanticipated problem(s) encountered involving risks to the participant(s)?	Yes ☐ No ☐ ☑ NA ☐
	If Yes, please describe	
16	Was there any adverse events associated with the study?	Yes ☐ No ☑ NA ☐
	If Yes, give the number and symptom of adverse event(s)	
17	Has any enrolled participant(s) been withdrawn from the study because of the adverse event?	Yes ☐ No ☐ NA ☐ ☑
	If Yes, please briefly describe	
18	Was there any serious adverse events* or death associated with the study?	Yes ☐ No ☐ NA ☐ ☑
	If Yes, please briefly describe	
19	Was any difficulty encountered in collecting data (applicable for behavioral science related protocol)	Yes ☐ ☑ No ☐ NA ☐
	If Yes, provide probable reasons In qualitative component, initially we experienced delay due to difficulty in locating households.	
20	Whether the control group was provided with medical care as specified in the protocol?	Yes ☐ No ☐ NA ☐ ☑
	If No, please provide reason(s)	
21	Is the confidentiality of the information collected being maintained?	Yes ☐ ☑ No ☐
	If No, please provide the reason(s)	

22	Have you undertaken preliminary / final analysis of the data?	Yes ☐√ No ☐
	If Yes, please briefly describe the findings *From the qualitative component – the preliminary analysis suggests that three were major barriers in receiving care from skilled attendants. These are 'cultural,' 'structural' and 'care related barriers.' Among the 'cultural barriers' minimal advance planning, lack of involvement of the pregnant woman herself in decision making process, reluctance for women to share that they are in labor until the advance stages, shame "shorom" attached to delivering in a hospital setting are the main. Distance, cost and problem of household responsibilities were the major 'structural barriers.' Delivery position, breaking "purdah," misconceptions about episiotomies, inappropriate behavior of midwives, distinguish between 'rich' and poor patients, concerns about instruments and procedures used, lack of privacy in the sub-centre, lack of emotional support, cleaning/discarding of afterbirth and forcing women to accept permanent method were the 'care related barriers.'*	
23	What are the major findings? See preliminary findings above.	
24	Any other remarks *After linking the HDSS data with the other maternity care related data sources in Matlab, 94% of the Green Card data, 98% of the Pictorial Card data and 84% of the Maternity Records matched properly. One of the most important reasons for lack of matching is wrong RID typing. The other reason is date of outcome is incomplete. To solve these problems of matching work on this is in good progress in Matlab. We have printed out the un-matching pictorial cards and Matlab staff will start working on them soon. We are almost certain that the gap-period linking will be perfect except that we have only achieved 96% response rate in the field.*	

Date 20/5/ 2003 Signature of PI _____

Date 21/5/2003 Signature of Associate Director/Program Head _____

*NOTE: All serious adverse events should be reported to the Chairman, Ethical Review Committee, within 24 hours of occurrence of the event(s).

* The following symptoms constitute serious adverse events:

a) Any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/ incapacity, or a congenital anomaly/birth defect.
b) More than one reason for seriousness can be entered
c) Each hospitalization (also planned or elective) fulfills the criterion of "serious".

IMPORTANT MEDICAL EVENT
Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in patient hospitalization; or the development of drug dependency or drug abuse.

LIFE-THREATENING
Any adverse experience, in the opinion of the initial reporter, which places the participant at immediate risk of death and it excludes an adverse experience that, in a more severe from, might have caused death.

DISABILITY
A substantial disruption of a person's ability to conduct normal life functions.

DEGREES OF EVENTS

Mild: usually transient in nature and generally not interfering with normal activities.
Moderate: sufficiently discomforting to interfere with normal activities.
Severe: prevents normal activities.