International Centre for Diarrhoeal Disease Research, Bangladesh
CENTRE FOR HEALTH AND POPULATION RESEARCH
Mail : ICDDR, B, GPO Box 128, Dhaka-1000, Bangladesh
Phone: 880-2-8811751-60, Telex : 642486 ICDD BJ
Fax : 880-2-8823116, 8812530, 8811568, 8826050, 9885657, 8811686, 8812529
Cable : Cholera Dhaka

Memorandum

P/H SD 2000

29 April 2003

To : Dr. Shams El Arifeen
Principal Investigator of protocol # 2000-037
Public Health Sciences Division

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

Sub : Approval for the second phase of the research protocol # 2000-037

This is in reference to your undated memo in response to my memo dated 3rd March 2003 communicating you the observations of the ERC on your request seeking ERC's approval for implementation of the second phase of your research protocol # 2000-037 entitled "Community-based interventions to reduce neonatal mortality in Bangladesh". Approval for conducting the second phase of the above mentioned study is hereby accorded upon your satisfactory addressing of the issues raised by the ERC in its meeting held on 26th February 2003.

You shall conduct the study in accordance with the ERC-approved protocol; and shall be responsible for protecting the rights and welfare of the subjects and compliance with the applicable provisions of ERC Guidelines. You shall also submit report(s) as required under ERC Guidelines. Relevant excerpt of ERC Guidelines and '*Annual/Completion Report for Research Protocol involving Human Subjects*' are attached for your information and guidance.

Thank you and I wish you all success in running the above-mentioned study.

copy: Acting Head, Public Health Sciences Division

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Cable : Cholera Dhaka

Memorandum

3 March 2003

To : Dr. Shams El Arifeen
Principal Investigator of protocol # 2000-037
Public Health Sciences Division

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

Sub : Request for approval of the second phase of the research protocol # 2000-037

Thank you for your memo dated 19th February 2003 submitting a report on the first phase and requesting ERC's approval for implementation of the second phase of your research protocol # 2000-037 entitled "Community-based interventions to reduce neonatal mortality in Bangladesh". The report and your request were considered by the ERC in its meeting held on 26th February 2003. After review and discussion, the Committee made the following observations:

a) The PI should get the minutes of the meeting attached to the proposal authenticated by the Sr. Assistant Secretary, MOFW, GoB, who forwarded the minutes.

b) The Committee suggested random checking of the assessment made by the CHWs to ensure its quality.

c) The PI's plan about involvement in the study of the CHWs who failed in hospital-based evaluation was not clear to the Committee

You are, therefore, advised to address the above issues, and submit the modified version of the proposal for consideration of the Chair.

Thank you.

Copy: Acting Associate Director
Public Health Sciences Division

International Centre for Diarrhoeal Disease Research, Bangladesh
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19 February 2003

To Professor Mahmudur Rahman
Chairman, Ethical Review Committee

From Shams El Arifeen for
Local PI, Protocol # 2000-37

Subject Protocol # 2000-37 (Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh)

This is in reference to your memo dated 14 August 2001 and to the study proposal, which necessitate an approval from ERC for second phase of the study. Your letter says that consideration of the approval of the phase II of the proposal will be subject to (a) satisfactory evaluation of the capacity of the community health workers of the project to correctly assess and manage the sick new born (b) a written GoB approval for the administration of antibiotic injection by the CHWs.

It is our pleasure to inform you and the members of the ERC that we conducted a vigorous evaluation exercise to assess the adequacy of the training and the ability of the CHWs to perform their activities especially assessing and managing sick newborn. All the CHWs, as individual and as group performed very well in the assessment. The report on the evaluation exercise is attached with this letter for your consideration towards approval to continue with the study as proposed.

As per requirement, we obtained a written GoB approval from the Ministry of Health and Family Welfare for administration of injectable antibiotics by the CHWs. The copy of the letter is attached.

So, we expect that you and members of the committee would find these satisfactory and approve implementation of second phase of this important research initiative.

Thank you.

cc.

Chairman, Research Review Committee

Associate Director, Public Health Sciences Division

Abdullah H Baqui, Johns Hopkins University

Community-Based Intervention to Reduce Neonatal Mortality in Bangladesh

Report on CHWs' Post-Training Evaluation of adequacy to determine and manage sick neonates

Report to ERC, ICDDR,B in compliance with ERC requirements

(ref: ERC Memo dated: 14 August 2001)

February 18th, 2003

1. Introduction

The primary objectives of the research project entitled "Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh" are:

1. To improve newborn care and recognition and management of infections in neonates by mothers and trained, skilled and supervised first-line health workers.
2. To evaluate the impact of packages of obstetric and neonatal care practices including community health education, provision of clean delivery, essential newborn care, and management of neonatal infections by first-line health workers, either in the home or at community clinics, on neonatal mortality rates.

The Home Care model of the study involves community health workers (CHWs) who will be able to recognize ill neonates based on a clinical algorithm and to refer them to the nearest health facility. For those mothers/families who are unable to comply with the referral, CHWs will manage cases in the community which will include injectable antibiotics. The clinical algorithm is adapted from the GoB IMCI algorithm and also draws on the findings of the WHO Young Infants study and other available information. The Ethical Review Committee (ERC) of ICDDR,B approved this protocol but asked the research team to submit a report on the assessment of the skills of the CHWs to undertake this responsibility after training. The ERC also asked the research team to obtain approval from the Ministry of Health and Family Welfare for the administration of injectable antibiotics by the CHWs.

2. Evaluation of adequacy of training of CHWs

CHWs were assessed in two phases. First phase was conducted during the training and the second was a formal evaluation (based on the methodology in the proposal). We expanded this to include two components, hospital-based and community-based evaluations.

2.1. CHW Training and ongoing evaluation

The CHWs have gone through a set of trainings including basic and advanced modules. As part of the training they underwent ongoing evaluation of their performance through written examinations and clinical assessment sessions in hospital. This was done in a systematic way to assess the performance and skills of individual CHWs. The CHWs were trained on how to use the algorithm and chart booklet through didactic sessions, videos and actual practice on sick newborns and healthy newborn babies in Sylhet M A G Osmani Medical College Hospital. Every CHW was required to successfully complete a minimum of three clinical

assessment record forms during training, which were directly evaluated by physician trainers. Detailed records of performance were kept for every CHW.

CHW were also trained on safe intra-muscular injection practice. They were trained on cleaning injection site, cutting the ampoule, mixing/preparing antibiotics, calculating and drawing correct dose. They also practiced intra-muscular injection using vaccines on babies and women visiting vaccination sites.

2.2. Post-Training Formal Evaluation:

After the completion of training the CHWs underwent a rigorous evaluation process in real-to-life settings and as outlined in the proposal. We felt that if we only did a skill assessment in the community, as proposed in the protocol, then the CHWs may not see enough sick newborns. So the whole exercise was re-designed so that every CHW would do 10 assessments of sick neonates. We thus added a hospital-based component to the evaluation exercise, followed by community-based evaluation. Only the CHWs who successfully completed in the hospital part were sent for the community component where they had to assess eight more newborns.

Thus, each CHW assessed a total of 18 neonates, ten in the hospital, where most were sick neonates and eight in the community which included mostly healthy newborns. In the study proposal we had proposed only eight assessments by each CHW. In both settings, trained physicians independently evaluated every newborn, and the assessment by the CHWs was compared with that of the physician who was considered gold standard. The skills of the CHWs were assessed on 3 aspects: clinical assessment, classification, and management of the sick newborn. The assessment procedure and scoring system are explained in the charts at the end of this report.

2.2.1. Hospital-based evaluation:

The Hospital Based evaluation took place on 2nd Feb 2003 in the neonatal ward of Sylhet MAG Osmani Medical College Hospital. Any CHW who achieved less than 80% accuracy rate (less than 8 successful assessments out of 10 sick newborns) accuracy rate was disqualified. The CHWs were rated for their ability to assess clinically, classify and manage the sick newborns. Since the management reflects the outcome of all 3 steps, the score obtained by the CHWs on management was used to decide on the performance of the CHWs. Five unsuccessful CHWs underwent retraining and re-evaluation to be eligible for the community component (please see Chart-1 at the end of this report).

As mentioned, each of the individual assessments was scored based on the accuracy compared to the gold standard- the assessments done by the physicians. Taking all the 400 cases (40 CHWS times 10 each) into account, the achieved score ranged from 87% to 100%. Thirty-eight of the 40 CHWs had an accuracy score of 95% to 100%. An assessment was considered to be correct if the score was 80 or more. Out of forty CHWs, thirty five achieved 80% or higher competency in 8 out of 10 sick neonates on their initial evaluation at the hospital with regards to all the three steps of the evaluation: assessment, classification and management of sick newborn. The accuracy among these 35 CHWs ranged from 80% to 100%, with an average of 99% for all the cases they assessed (ten by each CHW, giving a total of 350). Detailed, CHW-specific scores are given below in Table 1. The unsuccessful five CHWs with an initial average of less than 80% were retrained and they then went

through a second evaluation in the hospital. In the second evaluation all of them achieved accuracy of more than 85% in all the cases they assessed. Thus all of 40 CHWs ultimately were able to demonstrate satisfactory use of the clinical algorithm.

2.2.2. Community-based evaluation:

All 40 CHWS who qualified in the hospital evaluation exercise were sent for the community component. The community based evaluation took place in the community setting of Beanibazar and Zakigonj upazilas of Sylhet from 4th Feb 2003 to 8th Feb 2003. The CHWs were assessed in a way similar to hospital component to have eight assessments at community (who were previously identified by surveyors). Here also the physicians' assessment was used as gold standard. Table-2 presents the results of the performance of the CHWs in the community component. It shows that, all 40 CHWs could achieve the desired level of 80% accuracy. In the total of 320 assessments, taking all the assessments into account, the score ranged from 99%-100%. The cut-off for passing this evaluation was set at 7 correct assessments out of eight cases. Out of forty CHWs, all achieved the required accuracy to pass the test, that is, all of them achieved 80% or more accuracy in at least seven of the eight test cases (please see Chart-2 at the end of this report).

The findings from this evaluation of the skills of the CHWs show that they are ready to perform their role as community based health workers and will be able to clinically assess the newborns to identify any danger sign needing referral to a higher level medical care. This also shows that they have the skills to manage these cases, if needed.

Table 1: Summary of assessment by CHWs in hospital-based evaluation

S.N.	CHW with Code	10 sick newborn assessment per CHW						Result**
		Clinical Assessment		Classification		Management		
		# of correct assessment*	Average of ten scores	# of correct classification*	Average of ten scores	# of correct management*	Average of ten scores	(>8 correct=Pass, 2 or more incorrect= Fail)
1	CHW 01	10	98	10	99	10	99	Passed
2	CHW 02	10	99	10	99	10	100	Passed
3	CHW 03	10	97	10	98	10	100	Passed
4	CHW 04	10	100	10	100	10	100	Passed
5	CHW 05	10	99	10	100	10	100	Passed
6	CHW 06	10	100	10	100	10	100	Passed
7	CHW 07	10	99	10	100	10	100	Passed
8	CHW 08	10	94	10	98	9	95	Passed
9	CHW 09	10	98	10	99	10	100	Passed
10	CHW 10	10	96	10	99	10	99	Passed
11	CHW 11	10	93	9	93	8	87	Failed
12	CHW 12	10	92	10	98	9	93	Passed
13	CHW 13	10	98	10	99	10	99	Passed
14	CHW 14	10	98	10	100	9	95	Passed
15	CHW 15	10	94	10	100	10	100	Passed
16	CHW 16	10	99	10	98	9	94	Passed
17	CHW 17	10	98	10	100	10	97	Passed
18	CHW 18	10	99	10	100	10	100	Passed
19	CHW 19	10	97	10	98	10	99	Passed
20	CHW 20	10	98	10	98	7	87	Failed
21	CHW 31	10	97	10	98	9	97	Passed
22	CHW 32	10	100	10	100	10	98	Passed
23	CHW 33	10	98	10	98	10	99	Passed
24	CHW 34	10	99	10	99	10	99	Passed
25	CHW 35	10	95	9	97	9	97	Passed
26	CHW 36	10	99	10	100	10	98	Passed
27	CHW 37	10	98	10	98	10	100	Passed
28	CHW 38	10	97	10	98	8	85	Failed
29	CHW 39	10	100	10	98	10	100	Passed
30	CHW 40	10	96	10	98	10	99	Passed
31	CHW 41	10	98	10	98	9	100	Passed
32	CHW 42	10	99	10	99	10	99	Passed
33	CHW 43	10	96	10	97	7	87	Failed
34	CHW 44	10	99	10	100	10	100	Passed
35	CHW 45	10	98	10	99	10	100	Passed
36	CHW 46	10	96	10	98	10	97	Passed
37	CHW 47	10	97	9	96	9	93	Passed
38	CHW 48	10	97	10	98	8	89	Failed
39	CHW 49	10	96	10	100	10	95	Passed
40	CHW 51	10	99	10	100	10	100	Passed
All			95		96		95	

* CHW's score is 80% or more for each of the individual sick newborn she assessed

** these are first evaluation results

Table 2: Summary of assessment by CHWs in community-based evaluation

		8 assessment per CHW						Result
S.N.	CHW with Code	Clinical Assessment		Classification		Management		
		# of correct assessment*	Average of ten scores	# of correct classification*	Average of ten scores	# of correct management*	Average of ten scores	(>8 correct=Pass, 2 or more incorrect= Fail)
1	CHW 01	8	99	8	100	8	99	Passed
2	CHW 02	8	100	8	100	8	100	Passed
3	CHW 03	8	100	8	100	8	100	Passed
4	CHW 04	8	100	8	100	8	100	Passed
5	CHW 05	8	100	8	100	8	99	Passed
6	CHW 06	8	100	8	100	8	100	Passed
7	CHW 07	8	100	8	100	8	100	Passed
8	CHW 08	8	100	8	100	8	100	Passed
9	CHW 09	8	100	8	100	8	100	Passed
10	CHW 10	8	100	8	100	8	100	Passed
11	CHW 11	8	100	8	100	8	100	Passed
12	CHW 12	8	100	8	100	8	100	Passed
13	CHW 13	8	99	8	99	8	99	Passed
14	CHW 14	8	100	8	100	8	99	Passed
15	CHW 15	8	100	8	100	8	100	Passed
16	CHW 16	8	100	8	100	8	99	Passed
17	CHW 17	8	100	8	100	8	100	Passed
18	CHW 18	8	100	8	100	8	99	Passed
19	CHW 19	8	100	8	100	8	100	Passed
20	CHW 20	8	100	8	100	8	100	Passed
21	CHW 31	8	99	8	100	8	100	Passed
22	CHW 32	8	100	8	100	8	100	Passed
23	CHW 33	8	100	8	100	8	100	Passed
24	CHW 34	8	100	8	100	8	100	Passed
25	CHW 35	8	100	8	100	8	100	Passed
26	CHW 36	8	100	8	100	8	100	Passed
27	CHW 37	8	100	8	100	8	100	Passed
28	CHW 38	8	100	8	100	8	100	Passed
29	CHW 39	8	100	8	100	8	100	Passed
30	CHW 40	8	100	8	100	8	100	Passed
31	CHW 41	8	100	8	100	8	100	Passed
32	CHW 42	8	100	8	100	8	100	Passed
33	CHW 43	8	100	8	100	8	100	Passed
34	CHW 44	8	100	8	100	8	99	Passed
35	CHW 45	8	100	8	100	8	100	Passed
36	CHW 46	8	98	8	100	8	100	Passed
37	CHW 47	8	100	8	100	8	100	Passed
38	CHW 48	8	100	8	100	8	100	Passed
39	CHW 49	8	100	8	100	8	100	Passed
40	CHW 51	8	100	8	100	8	100	Passed
All			97		98		97	

* CHW's score is 80% or more for each of the individual newborn she assessed

Assessment procedure and scoring system

Chart-1: Hospital-based evaluation

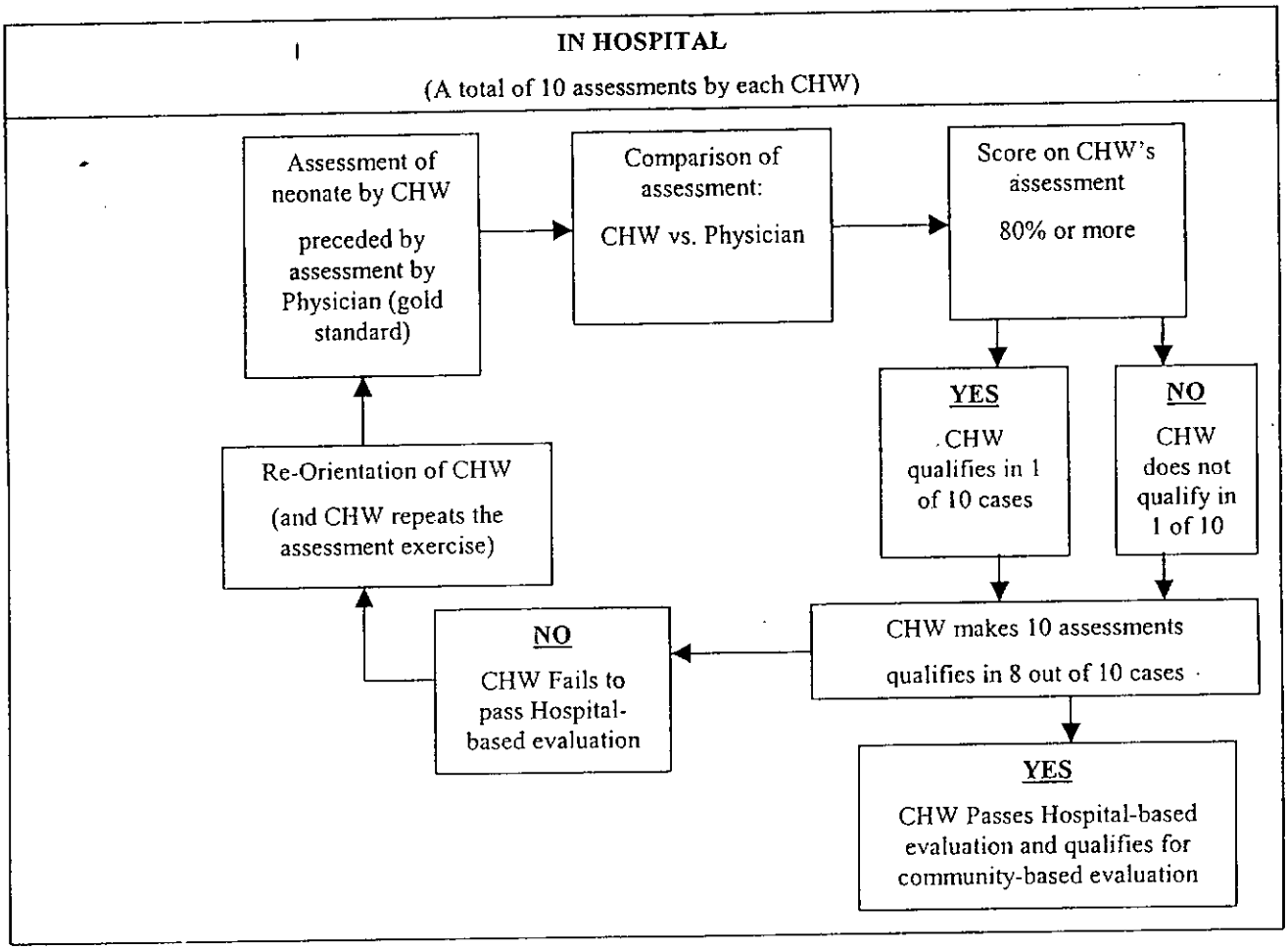
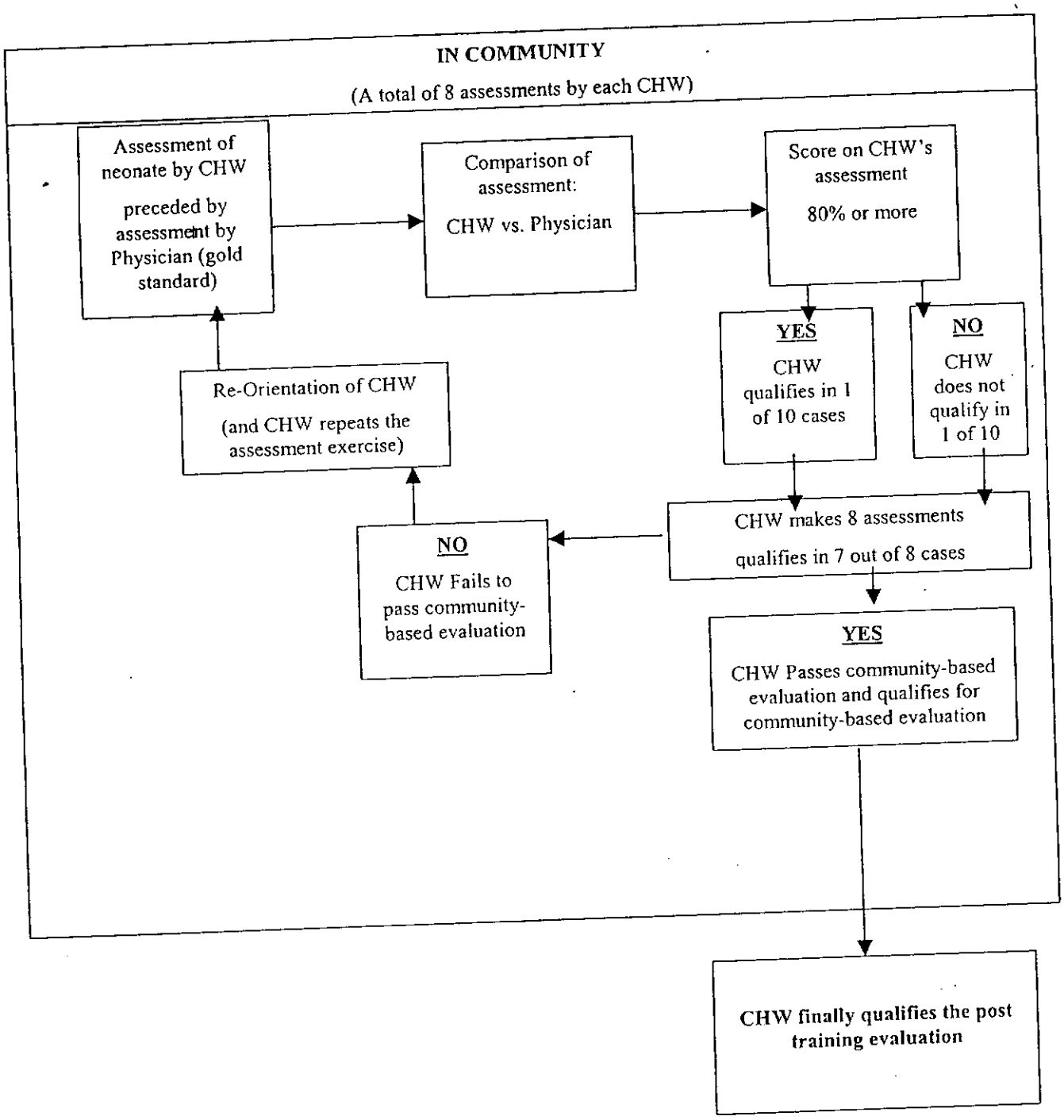


Chart-2: Community-based evaluation



Government of the People's Republic of Bangladesh
Ministry of Health and Family Welfare
(Development-1 Section)

No-FWD-1/Medicine/37/2001/

Dated: 24 September 2002

Subject : Minutes of the meeting on the use of antibiotic by community based Health workers.

Date: 18:9.2002
Time : 2.00 P.M.
Venue: Conference Room, MOHFW.
Chairperson: Mr. M. Fazlur Rahman, Secretary, Ministry of Health & Family Welfare.

List of participants enclosed in Annex-A

Chairperson welcomed the members and initiated the discussion. He then invited the members to give their views on the issue.

Dr. M. Habib Seraji of ICDDR'B informed the meeting that Infant Mortality Rate (IMR) is unacceptably high in our country .ICDDR'B decided to conduct a community based Intervention Study to reduce Neonatal Mortality in Bangfadesh under a project entitled "**Community Based Intervention to reduce Neonatal Mortality in Bangladesh**". Study will be conducted in Sylhet region. Under the project Health & Family Planning workers will be trained to identify and refer serious infections to Upazila Health Complex, to treat at home or Community Clinic if referral fails and they will also use antibiotic.

Prof.(Rtd)A.B.Bhuyian, Prof. Latifa Shamsuddin and Dr. Atiqur Rahaman Khan said that as per decision of the 47th National Technical Committee meeting they reviewed the Research Protocol. They recommended that the proposed **Research Project** including the use of injectable antibiotic by the community based Health & Family Planning workers may be approved. Director General of Health Services and Director General of Family Planning also endorsed the views of the experts on the issue. Director (MCH) of Family Panning Directorate said that the **National Technical Committee in its 48th meeting approved the proposal of use of antibiotic (with injectable) one time in 24(twenty four)hours by trained Health and Family Planning workers.**

Decision:

- **Pilot study in Sylhet Region to use of antibiotic (with injectable) one time in 24(twenty four) hours by trained community based Health & Family Planning workers for reducing Neonatal Mortality is approved.**
- **It must be linked with referral.**

The meeting ended with vote of thanks to and from the Chair.

Sd/-
24.9.2002
(M. Fazlur Rahman)
Secretary

Government of the People's of the Republic of Bangladesh
Ministry of Health and Family welfare
(Development –1 Section)

No FWD-1/Medicine/37/2001/1126(9)

Dated : 28th September 2002

Subject: Minutes of the meeting held on 18th September 2002 at MOHFW on the use of antibiotic by community based Health workers.

Minutes of the meeting held on 18th September at the Ministry of Health and Family Welfare on the use of antibiotic by community based Health workers is hereby forwarded for kind information and necessary action.

(A. H. M. Towhidul Islam)
Senior Assistant Secretary

Distribution:

1. Director General of Health Services, Mohakhali, Dhaka.
2. Joint Secretary (FW), Ministry of Health & Family Welfare
3. Director General of Family Planning Azimpur, Dhaka .
4. Prof. Latifa Shamsuddin, Chairman, Deptt. of Obse & Gynae, BSMMU, Shahbag, Dhaka .
5. Deputy Secretary, (DEV- FW), MOHFW.
6. Director (MCH Services), Azimpur, Dahaka .
7. Prof. (Rtd), Abdul Bayes Bhuiyan, Obstetrics and Gynaecology Society of Bangladesh, Dhaka .
8. Dr. Atiqur Rahman Khan, Director, Research & Policy, IPH Building, Mohakhali Dhaka .
9. Dr. M Habib Shiraji, Project Coordinator, ICDDR'B, Dhaka .

Copy :

1. P S to the Secretary, Ministry of Health and Family Welfare.

International Centre for Diarrhoeal Disease Research, Bangladesh
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April 21, 2003

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

From: Shams El Arifeen
Principal investigator (Protocol # 2000-37)

To: Prof. M. Rahman
I have gone through the response by PI and found them have been incorporated in the 2nd phase (revised) may be considered for approval.
Thanks
Dr. Kabir

Subject: Request for approval of the second phase of the research protocol # 2000-37

Thank you for considering our request for approval of the second phase of our research protocol entitled 'Community-Based Intervention to Reduce Neonatal Mortality in Bangladesh'. We thank you for the valuable comments on the report from the first phases regarding the assessment of the CHWs of the project. Our responses to the issues raised/suggestions made by the committee are as follows:

a) The PI should get the minutes of the meeting attached to the proposal authenticated by the Sr. Assistant Secretary, MOHFW, GoB, who forwarded the minutes.

Response: The minutes of the meeting has been authenticated by the Sr, Assistant Secretary, MOHFW, GoB and the authenticated copy is attached.

b) The committee suggested random checking of the assessment made by the CHWs to ensure its quality.

Response: The committee has rightly emphasized on continued monitoring of quality of the assessment to be made by the CHWs. We also consider this as an important aspect of the community-based intervention and have made definite plans to ensure the quality of CHWs' assessments and management. CHWs will have intensive supportive supervision from the project Medical Officers and Clinical Supervisors (nurses) on a regular basis. The supervisors will routinely review CHW records, observe actual assessments of neonates by the CHWs and will perform systematic

random checking of the neonatal cases assessed by the CHWs. In addition, continuing education sessions will be organized monthly and refreshers training will be organized periodically during their tenure with the project.

c) The PI's plan about involvement in the study of the CHWs who failed in the hospital-based evaluation was not clear to the committee.

Response: We regret that we had not been very clear on this issue in our previous submission. We had trained all our 40 CHWs on the clinical assessment and management. After completion of training, all the CHWs underwent an assessment of their skills first in a hospital setting. In hospital-based test, 35 out of 40 CHWs passed our very strict criteria. The five-CHWs who had failed this test underwent further training/review on the clinical assessment and management of sick neonates. These five CHWs were tested again in the hospital and this time all five CHWs passed the test. So in fact, all of 40 CHWs eventually qualified the hospital-based test, the first 35 passed the test in one attempt and the remaining 5 had to take another round to qualify. After qualifying the hospital test, all 40 CHWs had to go for a community-based evaluation of their skills, in which all the forty CHWs passed. As, all the CHW could qualify in the both the hospital and community based components we plan to engage all of them in the fieldwork.

We have enclosed a revised version of the protocol describing the quality monitoring and random checking of the CHWs in the revised section 4.16. We hope the committee find these responses satisfactory and allow us to proceed with the second phase of the project.

Thank you.

Government of the People's of the Republic of Bangladesh
Ministry of Health and Family welfare
(Development –1 Section)

No FWD-1/Medicine/37/2001/112(9) Dated : 28th September 2002

Subject: Minutes of the meeting held on 18th September 2002 at MOHFW on the use of antibiotic by community based Health workers.

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(A. H. M. Towhidul Islam)
Senior Assistant Secretary

Distribution:

1. Director General of Health Services, Mohakhali, Dhaka.
2. Joint Secretary (FW), Ministry of Health & Family Welfare
3. Director General of Family Planning Azimpur, Dhaka .
4. Prof. Latifa Shamsuddin, Chairman, Deptt. of Obse & Gynae, BSMMU, Shahbag, Dhaka .
5. Deputy Secretary, (DEV- FW), MOHFW.
6. Director (MCH Services), Azimpur, Dahaka .
7. Prof. (Rtd), Abdul Bayes Bhuiyan, Obstetrics and Gynaecology Society of Bangladesh, Dhaka .
8. Dr. Atiqur Rahman Khan, Director, Research & Policy, IPH Building, Mohakhali Dhaka .
9. Dr. M Habib Shiraji, Project Coordinator, ICDDR'B, Dhaka .

Copy :

1. P S to the Secretary, Ministry of Health and Family Welfare.

MD. SHAHARUL ISLAM
Senior Assistant Secretary
Ministry of Health & Family Welfare
Government of the People's Republic of Bangladesh

Government of the People's Republic of Bangladesh
Ministry of Health and Family Welfare
(Development-1 Section)

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Decision:

- **Pilot study in Sylhet Region to use of antibiotic (with injectable) one time in 24(twenty four) hours by trained community based Health & Family Planning workers for reducing Neonatal Mortality is approved.**
- **It must be linked with referral.**

The meeting ended with vote of thanks to and from the Chair.

Sd/-
24.9.2002
(M. Fazlur Rahman)
Secretary

Resubmitted on Apr 21, 2003

Attachment 1

Date: August 8, 2001

(Revised)

(FACE SHEET) ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: Shams El Arifeen (Local) Trainee Investigator (if any): _____

Application No. 2000 - 037 Supporting Agency (if Non-ICDDR,B) _____

Title of Study: Project Status: _____

Community-based interventions to reduce neonatal mortality in Bangladesh

[✓] 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
     Nasal swab

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
   - (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

RESEARCH PROTOCOL

Protocol No.:
2000 - 037

FOR OFFICE USE ONLY

RRC Approval: Yes/ No Date:
ERC Approval: Yes/No Date:
AEEC Approval: Yes/No Date:

Project Title:
Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

Theme: *(Check all that apply)*

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

Key words: Neonates, neonatal mortality, community-based intervention, community clinic, Bangladesh

Principal Investigator: Mathuram Santosham **Division:** **Phone:**

Address: Division of Community Health and Health Systems, Johns Hopkins University School of Hygiene and Public Health, USA

Email: msantosh@jhsph.edu

Co-Principal Investigator(s): Robert E Black, Abdullah H Baqui, Shams El Arifeen, Gary L Darmstadt

Co-Investigator(s):

JHU:	Peter Winch, Hugh Waters, Paul Law, Saifuddin Ahmed
ICDDR,B:	Lars Ake Persson, K Zaman
Shishu Hospital:	Samir K Saha
ICMH:	Sameena Chowdhury, Khurshid Talukder
BRAC:	Mustaq Raja Chowdhury
Shimantik:	Sahela Khatun
Save the Children:	Md Enamul Kabir
SEARCH:	Abhay Bang

Student Investigator/Intern: None

Collaborating Institute(s):

i) Division of Community Health and Health Systems, Department of International Health, Johns Hopkins University School of Hygiene and Public Health, USA
ii) International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR)
iii) Dhaka Shishu Hospital, Dhaka, Bangladesh
iv) Institute of Child and Mother Health (ICMH)
v) Shimantik - A national NGO funded by Pathfinder International and USAID/ Bangladesh
vi) BRAC, Bangladesh
vii) Save the Children, Bangladesh and USA
viii) Society for Education, Action and Research in Community Health (SEARCH)

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

Gender
- X Male
- X Females

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

- X 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
- X Other areas in Bangladesh ---- Sylhet
- ☐ 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 surve *Revised on: 17 October 2000*
- X Longitudinal Study
- ☐ Record Review
- ☐ Prophylactic trial
- X Surveillance / monitoring
- ☐ Others

Targeted Population *(Check all that apply)*:

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

Consent Process *(Check all that apply)*:

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

Proposed Sample size:

Total sample size: 9624 newborns

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
- X Pathological or diagnostic clinical specimen only
- X Observation of public behaviour
- ☐ New treatment regime

Yes/No

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

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

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

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

☐ X 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
X 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

☐ X Is the proposal funded?

If yes, sponsor Name: _____

Yes/No

X ☐ Is the proposal being submitted for funding ?

If yes, name of funding agency: (1) USAID _____

(2) SCF, USA _____

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?

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

Dates of Proposed Period of Support	Cost Required for the Budget Period ($)				
(Day, Month, Year - DD/MM/YY)	*a.*	*Ist Year*	*2nd Year*	*3rd Year*	*Other years*
Beginning date 1-3-2001		*$ 582,836*	*$ 573,272*	*$ 372,196*	
End date 28-2-2004	*b.*	*Direct Cost :*		*Total Cost :* $ 1, 528, 304	

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.

LA PERSSON — Name of the Assoc. Director

Signature

11/12/2000 — 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 administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Signature of PI

Date: Nov. 29, 2000

Name of Contact Person (if applicable)

Shams El Arifeen

RESEARCH PROTOCOL

1. Title of Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

2. Investigators :

2a. Principal Investigator:

JHU:	Mathuram Santosham

2b. Co-Principal Investigators:

JHU:	Robert E Black
	Abdullah H Baqui
ICDDR,B:	Shams El Arifeen (Local PI)
Save the Children:	Gary L Darmstadt

2c. Co-Investigators:

JHU:	Peter Winch, Hugh Waters, Paul Law, Saifuddin Ahmed
ICDDR,B:	Lars Ake Persson, K Zaman
Shishu Hospital:	Samir K Saha
ICMH:	Sameena Chowdhury, Khurshid Talukder
BRAC:	Mustaq Raja Chowdhury, Rep from Program Division
Shimantik:	Sahela Khatun
Save the Children:	Md Enamul Kabir
Government of Bangladesh:	Jahir Uddin (former Director, MCH and Line Director, ESP)
	Ahmad Al Sabir (Research Director, NIPORT)

3. Name of Collaborating institutions:
   i. Division of Community Health and Health Systems, Department of International Health, Johns Hopkins University School of Hygiene and Public Health, USA,
   ii. International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)
   iii. Dhaka Shishu Hospital, Dhaka, Bangladesh
   iv. Institute of Child and Mother Health (ICMH)
   v. Shimantik - A national NGO funded by Pathfinder International and USAID/ Bangladesh
   vi. BRAC, Bangladesh
   vii. Save the Children Federation (SC)/ USA and Bangladesh Field Office
   viii. Society for Education, Action and Research in Community Health (SEARCH)
   ix. Ministry of Health and Family Welfare, Government of Bangladesh

4. Dates of Proposed Period of Support
   (Day, Month, Year - DD/MM/YY): 01/05/2001 to 30/04/2004

5. In-Country Cost Required for the Budget Period: $

6. Sponsor(s): USAID/Washington
   USAID/Dhaka and
   Saving Newborn Live Initiative (SNL), Save the Children Federation, USA

REVISED: April 21, 2003

Abbreviations

ARI	Acute respiratory infection
CC	Community-Clinic
CHW	Community Health Worker
ERC	Ethical Review Committee
ESP	Essential service package
FW	Field Worker
FWA	Family Welfare Assistant
FWV	Family Welfare Visitor
GoB	Government of Bangladesh
HA	Health Assistant
HC	Home-based Care
HPSP	Health and Population Sector Program
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
LBW	Low birth weight
MOH	Ministry of Health and Family Welfare
NGO	Non-governmental organization
NMR	Neonatal mortality rate
NP	Nasal
ORS	Oral Rehydration Solution
Spn,	*Streptococcus pneumoniae*
SS	Sample size
TBA	Tradtitional birth attendant
THC	Thana Health Complex
TT	Tetanus toxoide
UHFWC	Union Health and Family Centre
WHO	World Health Organization

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.

In many developing countries, neonatal death rates are unacceptably high. About 98% of an estimated 5 million annual neonatal deaths occur in developing countries, mainly in Asia and Africa. Many countries in these regions have a neonatal mortality rate of more than 40/1,000 live births and several countries have a rate of more than 60/1,000 live births.

We propose to evaluate the impact of a package of obstetric and neonatal care that includes community health education, provision of clean delivery, essential newborn care, and management of neonatal infections on neonatal mortality in Bangladesh. This package will be developed based on formative research, which will include both qualitative and epidemiological studies of the study population and expert inputs. The services will be provided by first-line community-based health workers. We plan to evaluate two different strategies for delivery of services known as: 1) Community Clinic (CC) model involving delivery of services through a community clinic infrastructure like that, and in conjunction with that proposed by the Health and Population Sector Program (HPSP) of the Government of Bangladesh, and, 2) Home-based Care (HC) model in which services are delivered at home. In addition we will train and evaluate the skills of the first line health workers.

Individual-level allocation of these interventions will not be feasible, thus clusters will be the units of randomization. Clusters will consist of a group of geographically associated villages. Selected communities will be randomly assigned to one of the two intervention arms, or to continue current practices as the comparison arm. Mothers and first-line health workers will be trained in routine pregnancy and newborn care and in recognition of emergency obstetric signs and signs of neonatal infections and the management of the sick newborn. Clinic-based and home-based health workers will be trained on the management of serious neonatal infections and evaluated before commencement of Phase II of study, i.e., intervention evaluation.

Functional community clinics will be established in the CC clusters with the assistance of the GoB. Clinic health workers will offer selected essential health and family planning services from these clinics as outlined in the HPSP, and will manage neonates with serious bacterial infections who attend the clinics. Since it is not known if the CC intervention will be adequate to significantly impact neonatal mortality, we will evaluate a more intensive, Home-based Care (HC) package of services which includes active surveillance through home visits to identify and manage serious neonatal bacterial infections.

The primary outcome measure will be changes in neonatal mortality rates in the intervention and comparison communities from the beginning to the end of the study period. Cause-specific neonatal mortality rates will be measured using a standardized verbal autopsy instrument administered by trained data collectors and confirmed by physicians upon review of the records. The proportion of neonatal mortality attributable to each cause will be compared between the intervention and comparison communities after controlling for the baseline rates.

The proportion of 1-month-old infants colonized with antibiotic-resistant bacteria will be compared in a sample of infants from the two intervention and comparison areas. Colonization with antibiotic-resistant bacteria at 1 month of age will be defined as nasal colonization with penicillin-resistant *Streptococcus pneumoniae.*

The cost of providing the intervention services will be determined per neonate, per neonatal sepsis case treated, and per neonatal death averted separately for the two intervention areas. Cost information on the current services will be collected for comparison.

If the CC model proves to be successful, the findings will be disseminated widely and technical assistance will be provided to scale-up the intervention in the HPSP of Bangladesh. If only the HC model is found to be adequately efficacious, further operational research will be conducted to evaluate the feasibility and impact of incorporating essential features of this intervention into the HPSP of Bangladesh.

DESCRIPTION OF THE RESEARCH PROJECT

1. Hypothesis to be Tested:

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

Neonatal mortality rates will be at least 40 percent lower in communities in which trained, skilled, and supervised community-based health workers provide packages of essential obstetric and neonatal care, including community health education, provision of clean delivery, essential newborn care, as well as management of serious neonatal infections compared to communities in which such training and services are not provided.

2. 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).**

2.1. Primary Aim

2.1.1. To improve newborn care and recognition and management of infections in neonates by mothers and trained, skilled and supervised first-line health workers.

2.1.2. To evaluate the impact of packages of obstetric and neonatal care practices including community health education, provision of clean delivery, essential newborn care, and management of neonatal infections by first-line health workers, either in the home or at community clinics, on neonatal mortality rates.

2.2. Secondary Aims

2.2.1. Evaluate the impact on cause-specific neonatal mortality rates, particularly on deaths due to serious neonatal infections, as determined using verbal autopsy, of packages of obstetric and neonatal care practices to be provided by first-line health workers.

2.2.2. Evaluate the impact of administration of antibiotics at the community level by skilled health workers on colonization of neonates with antibiotic-resistant bacteria.

2.2.3. Evaluate the relative cost-effectiveness of the interventions to provide enhanced obstetric and neonatal care at the community level by skilled health workers, including home or community clinic-based provision of community health education, clean delivery care, essential newborn care, and management of serious neonatal bacterial infections.

3. 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).**

Despite significant declines in infant and child mortality rates in recent decades, neonatal mortality rates remain unacceptably high. Of the 8 million infant deaths that occur worldwide each year, approximately 5 million occur in the neonatal period and many more deaths occur during the second and third months of life (1-2). In many developing countries, neonatal deaths are systematically under-reported because of cultural reluctance to report (2). Nevertheless, an estimated 98% of the neonatal deaths occur in developing countries, mainly in Asia and Africa where many countries have a neonatal mortality rate of more than 40 per 1000 live births and several countries have a rate of more than 60 per 1000 live births (1).

Most of the deliveries and neonatal deaths in developing countries occur at home (3) and, consequently, very few neonatal illnesses and deaths are attended by medically qualified persons. In Bangladesh, only about 4.0% of the deliveries take place in a health facility and only about 8.0% of the deliveries are attended by a doctor or a nurse/trained midwife (3). Very few population-based studies in developing countries have examined the risk factors of neonatal or perinatal mortality. Using case-control methodology, a community-based study in a rural area of Bangladesh compared the characteristics of women who requested medically trained birth attendants at home with those who did not, in order to identify constraints to service delivery and suggest program changes to increase service utilization (4). Prior contact with medical professionals were much more common among cases than controls, with the greatest differences observed in the frequency of antenatal visits. At least one antenatal visit was the strongest predictor that a woman or her family will call a medically trained birth attendant. Primi-parity, proximity to the provider, and education both of the mother and her spouse were also predictive. Recommendations included increasing contact through antenatal visits and extending midwife coverage through training and supervision of traditional birth attendants. A community-based study conducted in Matlab, Bangladesh observed that complications during labour and delivery – such as prolonged or obstructed labour, abnormal fetal position, and hypertensive diseases of pregnancy increases the risk of perinatal mortality five-fold and accounted for 30% of prenatal deaths (5).

Given the paucity of community-based data from developing countries, little is known about the causes of neonatal deaths in the community. Limited understanding of causes of neonatal mortality in developing countries is based on studies of hospitalized neonates. Hospital-based data, however, may not reflect causes of neonatal mortality in the community. It is believed that neonatal infections, along with birth asphyxia and complications of pre-maturity are the principal causes of death in neonates worldwide (6).

Data from Bangladesh on causes of neonatal deaths are limited. Two recent nationwide verbal autopsy studies (8, 50) provide data on causes less than 5-year-old deaths in Bangladesh. Because of the difficulty of assigning a cause of death in very early neonatal period (0-2 days), these studies categorised all deaths that occurred in the first 3 days of life as 'early neonatal or pregnancy and delivery related' deaths. About 50% of the neonatal deaths occurred in the first 3 days of life. Neonatal tetanus accounted for 17% and ALRI and diarrhea together accounted for about 19% of the deaths. That means, about 36% of all neonatal deaths or about 72% of deaths in

babies 3-28 days old were due to infection. It is safe to assume that many deaths in the first three days of life (where a cause of death could not be assigned) were also due to infection although birth asphyxia, birth injury, birth defects, low birth weight, and prematurity are also likely to be important causes of deaths in the first three days of life. These estimates are not far from the global estimate by Barbara Stoll (2). Stoll estimated that globally, 30% to 40% of neonatal deaths are associated with infections.

The World Health Organization (WHO) has developed a case management strategy to reduce case-fatality from acute respiratory infections (ARI) in children in developing countries (7). The cornerstone of this strategy is a simple clinical algorithm that can be taught to minimally educated Community Health Workers (CHWs) so that they can identify pneumonia cases in children using simple clinical signs (e.g., rapid breathing, lower chest wall in-drawing). In the first 2 months of life, when an estimated one-third of all childhood deaths and two-thirds of infants deaths occur, the ARI case management strategy has been broadened to include sepsis and meningitis, in addition to pneumonia, because of the difficulty in clinically distinguishing these entities from one another. The WHO ARI case management strategy has been shown to significantly reduce ARI-related childhood mortality in many settings. A recently completed study in Bangladesh documented an impressive decline in ARI-related mortality throughout the country after the phased introduction of an ARI case management strategy in the National Health Program. This reduction of ARI deaths, however, was almost entirely limited to 1- to 4-year-old children. There was virtually no decline in ARI-related deaths in neonates and very little decline in the post-neonatal period (8,9). Success of ARI case management is largely dependent on early recognition of pneumonia cases and appropriate care-seeking by the parents as well as provision of quality care by the providers (10-16). For neonates, illness recognition, timely care-seeking, and availability of quality care can all be problematic. Recent developments in qualitative research, however, may lead to improvements in illness recognition and timely care-seeking, and, in turn, result in significant reductions in ARI-related deaths. The focused ethnographic study method provides an excellent framework for analysis and better understanding of cultural patterns and related behaviours allowing design of culturally appropriate interventions to improve care-seeking for both preventive and curative care (17).

For children age 2 months to 4 years, the importance of bacteria as causes of pneumonia in developing countries is well documented. *Streptococcus pneumoniae* and *Haemophilus influenzae* cause most of the severe cases (18-20). In contrast, data on clinical signs and aetiologic agents of serious infections in infants less than 2 months of age are scarce. Bacterial infections can very rapidly lead to death in this age group. Prevention of these deaths requires early recognition based on simple clinical signs by family members or first-line health workers and immediate case management.

To improve management of illness in young infants less than age 3 months in outpatient and inpatient settings, WHO sponsored a multi-center study in four developing countries: Ethiopia, The Gambia, Papua New Guinea and The Philippines (21). One of the objectives of this study was to develop a simple clinical algorithm that would enable health workers in developing countries to identify young infants with severe disease or sepsis. The result of a careful, structured analysis of the data led to a relatively simple model involving weight, age, temperature, respiratory rate, and seven specific clinical findings (inability to suck, crepitations, cyanosis, history of convulsions, definite lower chest wall in-drawing, failure to arouse with minimal stimulation, history of change in activity) which was predictive of the presence of serious illness with a high degree of accuracy (22). This study also compared the accuracy of the 12-item, simplified, 3-diagnostic-category model with that of the 12 clinical signs in the WHO guidelines for the management of sick infants. These latter signs include: temperature >37.5° C or <36.5° C, baby feels cold to touch, presence of

convulsions, fast breathing (>60 per minute), severe chest in-drawing, nasal flaring, grunting, bulging fontanel, pus draining from the ear, red umbilical stump, skin pustules, lethargy/unconsciousness and less than normal movement. After the WHO young infant study, the WHO algorithm for the assessment of infants less than age 2 months was modified to include inability to attach well to the breast, inability to suckle and inability to feed as indicators of possible serious infection, resulting in improved predictive power of the algorithm. Among the infants with clinical signs of infection, the rate of positive blood culture ranged from 4% in The Philippines to 11% in The Gambia. The lower culture positivity rate likely is the result of a high rate of antibiotic use in the community, although this is unproven. At the time when this study was carried out, published studies from developing countries suggested that *Klebsiella* spp. and *Staphylococcus aureus* were the most important neonatal pathogens in developing countries (2, 21). The main causes of serious infections in the four study sites of WHO young infant study were the classical Gram-positive pathogens, Staphylococcus aureus, *Steptococcus pneumoniae*, and *Streptococcus pyogenes* (23).

In a recent study in Gadchiroli District, Maharashtra, India, SEARCH, led by Dr. Abhay Bang, trained Female Health Workers in the intervention areas to provide a package of home-based neonatal care, including health education to pregnant women, diagnosis and management of birth asphyxia, identification of high-risk [premature and low birth weight (LBW)] neonates for more intensive surveillance, temperature maintenance, promotion of breastfeeding, administration of vitamin K, treatment of skin infections, and identification of sick newborns suspected of having septicemia, meningitis and/or pneumonia using a simple algorithm, and administration of antibiotics [oral cotrimoxazole and intramuscular gentamicin] in the home (24). The net percent reduction in neonatal mortality due to sepsis was 76% and neonatal mortality declined by 62% compared to the control, non-intervention areas at an estimated cost of $5.30 per neonate. Although promising, the findings of this study should be treated with caution for the following reasons: a) the study lacked the proper number of randomization units, having been conducted in only two areas which already had been serving as "control" and "action" (intervention) areas for many years prior to introduction of the newborn care package; b) neonatal mortality rates in the control area varied year-to-year from 50 to 65 per 1000, rendering statistical inference and precise calculation of the effect-size problematic; c) there might also have been a strong pre-existing secular trend in the intervention area, which might have been obscured in the reported data by the grouping of data for 2 years in the baseline results and therefore, the impact observed may have been a combination of effects due to the intervention and the secular trend; and d) finally, the principal investigators of this study had lived and worked in the study community for a decade prior to introducing the intervention, and the contribution of their presence to the impact of the intervention is difficult to assess. Furthermore, the intervention evaluated by Bang et al. was very intensive and large-scale implementation of this intervention is unlikely to be feasible. Thus, the impact of less intensive packages of delivery and newborn care interventions on neonatal mortality in the community needs to be demonstrated in other settings.

We propose to evaluate the impact of packages of obstetric and neonatal care interventions similar to the one Bang *et al.* introduced in India. The packages will be adapted with the assistance of the GoB, however, to make them more feasible for large-scale implementation within the governmental health system in Bangladesh. The health program in Bangladesh has recently undergone a major reform. Until recently, two-monthly home visits to every household by health workers to deliver selected health and family planning services at the door-step of clients were the norms. Based on the experiences of the past, the Government of Bangladesh (GoB) has developed a new Health and Population Sector Program (HPSP); this program is currently being implemented. The goal of HPSP is to offer a package of essential health and family welfare services, known as essential service package (ESP) to the entire population, particularly to women, children and the

poor. ESP was designed taking into consideration the needs of the population as well as the feasibility of implementation of the services and sustainability of the program. The key aspect of ESP is to deliver the essential health services through one-stop service delivery points. Under the HPSP, the plan is to deliver ESP in the rural areas through the following three tiers:

1) Thana Health Complex (THC) with in- and out-patient facilities and staffed by physicians and paramedics – each THC on average serves 270,000 population,
2) Union Health and Family Welfare Centre (UHFWC) with out-patient facilities only and staffed by paramedics (Family Welfare Visitors, Medical Assistants) and occasionally by a physician – each on average serves 27,000 population, and,
3) Community Clinic staffed by a Family Welfare Assistant (FWA) and a Health Assistant (HA) which is equivalent to a CHW – on average each clinic serves about 6,000 population.

The lowest tier of health facility under HPSP will be the community clinics. Providing ESP through community clinics is a recent strategic approach of the GoB, and the clinics have yet to be established. GoB plans to establish a total of 18,000 community clinics throughout the country to bring the essential services to the villagers, although these services will be largely provided at the clinics to self-referred patients rather than within homes. Each clinic will be staffed by a team of 2-3 existing FWAs and HAs. These workers will be re-trained and possibly be re-designated (probably to Community Clinic Worker). The GoB-managed community clinics will provide the following services:

- antenatal, basic delivery, postnatal and essential newborn care;
- immunization against six diseases for all children and tetanus toxoid (TT) immunization for 14-49 year-old women;
- symptomatic treatment or treatment according to prescription from higher facilities of iodine deficiency, acute respiratory infection, tuberculosis, leprosy, malaria, fungal infections of the skin;
- management of diarrhoea with oral rehydration solution (ORS) and education on home management of diarrhoea, preparation and feeding of ORS;
- distribution of temporary contraceptive methods;
- insertion of intrauterine device, first-dose depo-provera injection, management of contraceptive side effects by Family Welfare Visitors during their scheduled visit to UHFWCs;
- symptomatic treatment of minor injury, fever, pain, burn, poisoning, asthma, skin diseases and minor diseases of eyes, teeth and ear; and
- referral of complicated cases to higher facilities.

HPSP does not anticipate that all the couples in the catchment area of a clinic will come to the clinic at the outset of the program to receive reproductive health services including family planning services. As a result, these women of child-bearing age will have to be reached and other issues will have to be addressed through selected home visits. HPSP, however, does not have any provision for regular home visits.

We plan to evaluate the impact of delivering a package of essential obstetric and newborn care, including community health education, clean delivery care, essential newborn care, and management of serious neonatal bacterial infections through the community clinics. This delivery model, which includes some but not all of the services which the GoB proposes to deliver through the community clinics, is further described in a later section and will be known as the Community Clinic (CC) model. As already mentioned, the clinics have yet to be established and for the purpose of this study, the Ministry of Health and Family Welfare (MOHFW) of the GoB has agreed to set up the clinics in the study clusters allocated to the CC intervention area in a timely manner. If however, MOHFW is unable to establish clinics in all the CC clusters, the NGO partners will

establish CCs in the remaining clusters which will be comparable to GoB CCs. If the CC intervention proves to be effective, then efforts will be made to scale-up this intervention. Since it is not known if the CC package of services will be adequate to have a significant impact, we will evaluate a more intensive Home-based Care (HC) model for delivery of services which will include scheduled home visits to identify ill neonates, including those with possible serious neonatal bacterial infections, particularly in the first week of life. Pregnant women and newborns in the third, control study arm will receive care as currently available in this area and will serve as the comparison group.

In addition to assessing effectiveness, we will conduct cost-effectiveness analysis. A clear demonstration of the cost-effectiveness of interventions to reduce neonatal mortality can have profound effects on policy and, ultimately, on additional interventions and mortality rates. There are very few studies in the existing literature that provide cost-effectiveness estimates for interventions to reduce neonatal mortality. Joyce *et al.* (47) found that the early initiation of prenatal care is the most cost-effective intervention for the reduction of neonatal mortality, and that neonatal intensive care – although effective – is one of the least cost-effective approaches. The few existing studies of the cost-effectiveness of community-level interventions have shown that TBAs are less cost-effective than facility-based services in reducing maternal mortality (48, 49). Cost-effectiveness studies for community neonatal mortality interventions may show different results – since many of these interventions require less facility-based care than the treatment of maternal complications arising from pregnancy and delivery. Bang *et al.*, cited above, found that the cost of home-based neonatal care in rural India cost $5.30 per neonate treated, resulting in one death averted for 18 neonates treated.

4. 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).**

4.1. Overall Study Design

The purpose of this study is to develop feasible and cost-effective packages of obstetric and newborn care, including management of serious neonatal bacterial infections, using focused qualitative studies and an epidemiological analysis of the health problems; and to evaluate the impact of two different strategies to deliver the packages on neonatal mortality. The study will have the following three arms:

1) Community Clinic (CC) model
2) Home-based Care (HC) model
3) Comparison arm

Individual level allocation of these interventions will not be feasible; therefore, communities will be the units of randomization. Communities or clusters will consist of a group of geographically associated villages. Selected communities will be randomly assigned to one of the two intervention areas or to continue current practices as comparison area. The primary outcome measure will be changes in neonatal mortality rates in the intervention and comparison communities from the beginning to the end of the study period. Neonatal mortality is defined as death of a live-born infant within 28 days of life. A live-born infant is defined as birth of a live infant after 28 weeks of gestation.

Cause-specific neonatal mortality rates will be measured using a standardized structured verbal autopsy instrument administered by trained Field Workers. We recognize the difficulty of assigning causes of deaths in neonates. A study in Bangladesh attempted to validate the caregiver's interview to diagnose common causes of severe neonatal illness (51). We will adopt this instrument, and concurrent with this study we propose to further develop and validate a neonatal verbal autopsy instrument in another study site in Bangladesh . The proportion of neonatal mortality attributable to each cause will be compared between the intervention and comparison communities before and after the study period.

The proportion of 1-month-old infants colonized with antibiotic-resistant bacteria will be compared in a sample of infants from the HC intervention and comparison areas. Colonization with antibiotic-resistant bacteria at 1 month of age will be defined as nasal colonization with penicillin-resistant *Streptococcus pneumoniae.*

The cost of providing the intervention services will be determined for care of each newborn in the first month of life, per neonatal sepsis case treated, and per neonatal death averted separately for the two intervention areas. Cost information on the current services will be collected for comparison.

If the CC intervention proves to be successful, the findings will be disseminated widely and technical assistance will be provided to scale-up the intervention in the HPSP of Bangladesh. If only the HC is found to be adequately efficacious, further operational research will be conducted to evaluate the feasibility and impact of incorporating essential features of this intervention into the HPSP of Bangladesh.

4.2. Study Population

The study will be carried out in two rural sub-districts of Sylhet division of Bangladesh in partnership with Bangladeshi institutions, International Centre for Diarrheal Disease Research, Bangladesh (ICDDR,B), Dhaka Shishu Hospital, and Institute of Child and Mother Health; the NGOs Shimantik and BRAC funded by USAID/ Bangladesh, and with Save the Children Federation Bangladesh and USA.

Sylhet division is considered as low-performing in terms of health and family planning program when compared with other regions within the country. The proposed study will be conducted in Bianibazar and Golapganj sub-districts of Sylhet division. The estimated population of these two sub-districts is about 450,000. According to Bangladesh Demographic and Health Survey (BDHS) 1996-97, the Crude Birth Rate (CBR) in Bangladesh was 29.4/1,000 population and the Neonatal Mortality Rate (NMR) was 48.4/1,000 live births. NMR of Sylhet division was about 60/1,000 live births, much higher than the national average. BDHS doesn't provide a separate estimate of CBR Sylhet division but presumably the CBR of Sylhet was much higher than the rest of the country because the TFR of Sylhet was 4.2 and the national average TFR was 3.27. Site selection was based on high rates of neonatal and infant mortality and home delivery, poor access to health care, and a minimum of 12,000 live births per year. Additional consideration was the presence of NGO partners with the ability to scale-up the intervention if it proves to be effective.

Compared to the national average, proportion of women who receives at least one dose of TT during pregnancy is slightly lower in Sylhet Division where the study will be carried out. According to Bangladesh Demographic and Health Survey (BDHS) 1996-1997, TT coverage was 62% in Sylhet compared to 75% nationally. According to BDHS 1999-2000, the coverages were 67% and 81% respectively in Sylhet and in the country as a whole. A verbal autopsy study was conducted in the BDHS 1996-1997 sample. Nationally, about 17% of all neonatal deaths were attributable to neonatal tetanus. The sample size was not large enough to calculate neonatal tetanus specific mortality rates by division. However, presumably the rate was higher in Sylhet. However, we don't think that these differences will confound the study findings. The primary aim of this project is to evaluate the impact of a package of obstetric and neonatal care practices including management of serious neonatal infections by first-line health workers, either in the home or at community clinics, on neonatal mortality rates. The package includes tetanus toxoid immunization to pregnant women. We plan to conduct verbal autopsies to assign causes of neonatal deaths. Therefore, we will have cause-specific neonatal mortality rates and we will know what proportion of the reduction in neonatal mortality is due to reduction in neonatal tetanus.

4.3 Baseline Studies and Design of Intervention

4.3.1. Baseline Qualitative Research

Baseline qualitative studies will be conducted in the study communities to assess knowledge, attitudes and practices regarding routine obstetric and neonatal care and the care of sick neonates. The qualitative studies will address the following issues (also see annex 1):

4.3.1.1. Routine Pregnancy and Obstetric Care

a) Antenatal care: tetanus immunization; recognition and management of anemia, urinary tract infections, pre-eclampsia, and sexually transmitted diseases.
b) Hygienic practices: clean hands, clean delivery surface, sterile instruments, minimal vaginal examinations, sterile suturing of vaginal tears/episiotomy sites, and avoidance of application of foreign substances to the vagina.
c) Recognition and management (and referral) of complications: hemorrhage, puerperal sepsis, eclampsia, prolonged labor, premature/prolonged rupture of membranes, and chorioamnionitis.
d) Local terms used to describe maternal care practices and illnesses.
e) Traditional maternal care practices.
f) Care-seeking behaviour and socio-cultural factors that impact seeking and receiving maternal care.

4.3.1.2. Routine Neonatal Care

a) Routine care provided to all newborn infants, including umbilical cord and skin care, thermal control, breastfeeding practices, and eye prophylaxis.
b) Traditional neonatal care practices.
c) Identification of preterm and LBW neonates.
d) Advice given to the mother, and by whom, regarding routine neonatal care.
e) Period of time after birth during which neonates traditionally are kept at home.

4.3.1.3. Recognition of Sick Neonates

a) Signs and symptoms used to identify sick neonates.
b) Terms used to describe and categorize sick neonates.

4.3.1.4. Health-seeking Behavior for Neonatal Care

a) Options available for the care of sick neonates.
b) Reasons for when and why care is sought from a particular provider.
c) Barriers to obtaining health care.
d) Family and community attitudes, beliefs and dynamics involved in the decision of whether or not to seek care.

4.3.1.5. Care of Sick Neonates

a) Family acceptance of home visits by health workers to provide neonatal care.
b) Family willingness to attend community clinics to receive care for sick neonates.
c) Family willingness to pay for a home visit by health workers or a clinic visit for neonatal care.

4.3.1.6 Methods

The following methods will be used:

a) twenty semi-structured interviews in the home with women who have recently delivered, and with mother-in laws, focusing on routine newborn care. These interviews if possible will include structured observations of newborn care practices such as bathing and feeding;
b) twenty semi-structured interviews with pregnant women;
c) ten semi-structured interviews with traditional birth attendants;
d) ten observations of deliveries and postpartum care by traditional birth attendants;
e) three focus-group discussions with pregnant women;
f) three focus group discussions with mothers-in-law of pregnant women; and
g) three focus group discussions with husbands of pregnant women.

Each of these data collection activities will include the following question formats:

a) direct questions;
b) free-listing for a variety of domains such as illnesses of young children, sources of care, treatments, reasons to give or not give colostrum;
c) presentation of a scenario, followed by questions about what the respondent would do in such as situation. The scenarios will describe problems/symptoms mothers typically encounter in caring for newborn infants;
d) rating and ranking exercises to examine perceptions of the seriousness of different symptoms and the perceived appropriateness of different sources of care.

Interview and focus group guides, as well as structured observation instruments, will be developed based on: 1) available data from other studies, 2) the MotherCare qualitative research manual on maternal and neonatal care, 3) data collection instruments on neonatal care used in the Healthy Mother/Healthy Child project in Egypt, and 4) other data collection instruments used in other studies of newborn care practices in the community.

4.3.1.7 Data Analysis

Data from semi-structured interviews and structured observations will be coded and entered into a data-base such as EPI-INFO. Textual data will be coded using Nud*ist Version 4.0.

4.3.2. Final Design of Interventions

The analyzed qualitative data will then be used in:
a) the design of baseline and post-intervention survey instruments measuring a change in the degree of exposure to the intervention, as well as a change in the obstetric and neonatal care practices applied. The ethnographic information will help in terms of content as well as appropriate local terms to use in the instruments.
b) the design of the improved obstetric and neonatal care intervention package to be applied in the subsequent phase.
d) the design of training and health education materials to be used in subsequent training sessions of mothers and providers.

Specific decisions to be made based on the qualitative and observational data will be:
a) who (what class of provider) should be responsible for providing care to the newborn immediately after delivery? Do TBAs and/or CHWs have a role? Does a new cadre of health worker need to be recruited and trained? Are there cadres of governmental health workers that could provide the needed services?
b) what steps need to be taken to encourage exclusive breastfeeding from the time of birth?
c) what danger signs in newborns will be stressed in health education, and what will mothers/caretakers be told to do in response to these danger signs?
d) where and how will treatment of newborns with danger signs take place?

4.3.3 Meeting to Finalize Intervention Strategy

The proposed interventions will be presented in a workshop in Dhaka, Bangladesh attended by program managers, neonatologists, obstetricians, epidemiologists, and social scientists. The interventions will be finalized with inputs from these expert panels.

4.3.4 Development of Training and Educational Materials

Building upon our initial study design, site visits to SEARCH, and based on results of qualitative studies and consultations (i.e., intervention trial meetings, see 4.3.3), and utilizing training manuals developed other groups (e.g., WHO, JHPEIGO, SEARCH) and in consultation with Save the Children, training manuals and educational material for the mothers and first-line health workers will be finalized.

4.3.5 Field-testing of Training and Educational Materials

The training and educational materials will be initially implemented in field tests in 2-3 selected communities to determine their utility and to finalize their content based on feedback from the mothers, health care workers, supervisors, trainers, study physicians and other study personnel.

4.4 Census, Mapping and Household Survey

A baseline census of the study areas will be conducted by enumerators to map and characterize the population. A baseline household survey also will be conducted following the census in the entire study population to identify the expectant mothers and to estimate birth and infant and neonatal death rates. The survey will be used to obtain retrospective pregnancy, birth and death information in the previous 2 years using a Demographic and Health Survey-type instrument. Information on socio-economic and demographic variables, water and sanitation conditions, health knowledge, health care seeking behaviour and other possible confounders or correlates of mortality also will be collected in the baseline module so that any group differences can be adjusted for during data analysis. The baseline census data and community maps will serve as the foundation for the collection of data on live births, neonatal deaths and infant deaths.

4.5 Study Clusters and Randomization

Adjacent villages having about 6,000-7,000 population will be demarcated as study clusters. About 60 such clusters will be selected for the study to ensure adequate sample size. To minimize baseline differences in neonatal mortality rates and other characteristics between the intervention and comparison areas, the clusters will be stratified by baseline neonatal mortality rates and according to their geographic proximity and clusters within each stratum will be randomly allocated to the two intervention areas and the comparison area. All pregnant women and newborn babies in the comparison clusters will receive usual obstetric and newborn care provided by the existing providers. The mothers and first-line health workers in the intervention clusters will receive comprehensive training in obstetric care, newborn care and identification of serious neonatal bacterial infection.

4.6. Outcome Variables and Definitions Used

The primary outcome measure will be changes in neonatal mortality rates in the intervention and control communities from the beginning to the end of the study period. Neonatal mortality is defined as death of a live-born child within 28 days of life. A live-born child is defined as birth of a live infant after 28 weeks of gestation, still-birth is defined as birth of a dead foetus with a gestation period of 28 weeks or more, and miscarriage is defined as birth of a dead foetus with a gestational age of less than 28 weeks.

Secondary outcome measures will be cause-specific neonatal mortality rates as measured by verbal autopsy method, rates of colonization with antibiotic-resistant bacteria in 1-month-old infants, maternal outcomes, knowledge and behavior change outcomes and cost-effectiveness of the packages of obstetric and neonatal care (please see annex 2). Cause-specific neonatal mortality rates will be measured using a standardized verbal autopsy administered by trained, skilled health workers. The proportion of neonatal mortality attributable to each cause, particularly due to serious neonatal infection ("sepsis") will be compared between the intervention and comparison communities before and after the study period. The term neonatal sepsis is collectively used for septicemia, meningitis, or severe pneumonia, diagnosed using a clinical algorithm (25,26).

Treatment of serious neonatal infections based in a clinical algorithm could lead to considerable over-treatment, which could contribute to increasing antimicrobial resistance of common organisms. To assess the effect of use of antibiotics on the resistance pattern of common organism to antimicrobials, the proportion of 1-month-old infants colonized with antibiotic-resistant bacteria will be determined in samples of infants from the both the intervention areas and comparison area and will be compared. Colonization with antibiotic-resistant bacteria at 1 month of age will be defined as nasal colonization with penicillin-resistant *Streptococcus pneumoniae.*

4.7. Sample Size Estimations

When interventions are allocated to communities or clusters but individuals within the communities are the subject of the intervention, sample size determination can be done in one of two ways. One option is to consider communities as the unit of observation. However, for calculating the required number of communities, community-level incidence rates (or proportions or means) and variance estimates are required and such data are often not available. The baseline survey we plan to conduct will provide these data and we will check the validity of our sample size calculation when the survey data become available.

For now, sample size has been calculated assuming individual level randomization or a simple random sampling method and the estimated sample size has been multiplied by an appropriate design effect. The design effect is 1 if there is no heterogeneity between communities in the outcomes of interest, in the sense that the variation between the community-specific rates or means is no more than would be expected to occur by chance due to sampling variations. For most outcomes, however, there are real differences between communities (i.e., the design effect will be >1), and in these circumstances the required study size will be greater than with individual allocation.

4.7.1 Sample Size for Impact on Neonatal Mortality

Sample sizes were calculated to detect assumed differences in neonatal mortality rates between the treatment and comparison groups. The rates were assumed based on review of available literature. Sample size required was calculated with 80% power, 95% significance level, and an estimated design effect of 2 (design effect equals cluster size*intra-cluster correlation; we estimated that the average cluster size will be about 200 newborns and we assumed a intra-cluster correlation of 0.01). The following table provides sample size requirements for different levels of baseline neonatal mortality rates (NMR) and different assumed levels of reduction in neonatal mortality rates:

Baseline NMR per 1000 live births	**Percent reduction**	**SS required in each study arm for individually randomized study**	**Total SS required for cluster randomized study assuming a design effect of 2 (n_{srs}*design effect*number of study arms)**
60	40	1,326	7,956
50	60	653	3,918
50	50	984	5,904
50	40	1,604	9,624
40	60	822	4,932
40	50	1,239	7,434
40	40	2,022	12,132

With a baseline neonatal mortality rate of 50 per 1,000, an individually randomized study with 1,604 newborns in each group would be sufficient to detect a reduction of 40% in the intervention arms. If 50% of the neonatal deaths are due to sepsis and the intervention reduces sepsis related deaths by 70%, then this sample size will also be adequate to measure the impact of the intervention on sepsis-related death with 95% significance level and 80% power. We assumed that doubling the sample size should be sufficient to account for between-community variability. Thus, we anticipate enlisting about 20 communities, and 3,208 newborns in each study arm or a total of about 60 clusters and 9,624 newborns in the study.

4.7.2 Sample size for pneumococcal nasal colonization

The nose and the nasopharynx are the principal reservoir in the body for *S. pneumoniae* (Spn), and the strains present there in healthy children reflect those that circulate in the community and cause respiratory infections (27-31). A newly colonizing strain causes disease approximately 15% of the time and most often within a month of acquisition (27). We found previously that 54% of young infants in South India had nasal (NP) colonization at age 2 months (32). Other investigators have reported that 13% of South Indian infants below age 6 weeks were colonized (33), and in Sub-Saharan Africa up to 80% of children were colonized at age 2 months (34-35). We assumed that 10% of the 1-month-old babies in our population will be colonized. We further assumed that 10% of the Spn isolates from babies in the intervention communities will be penicillin resistant as opposed to 2% of the Spn stains isolated from infants in the comparison clusters. The following table provides the required sample sizes to detect the assumed differences between the treatment and comparison groups with 80% power and 95% significance level.

Study Group	NP colonization with Spn (%)	Spn isolates resistant to penicillin (%)	Babies colonized with penicillin-resistant Spn (%)	Sample size required in each study arm
Infants from CC and HC model communities	10%	10%	.01	1703
Infants from Comparison communities	10%	2%	.002	

Therefore, we will be required to enroll 1,703 one month old babies from each study arm or a total of 5,109 babies in this component of the study.

4.8. Intervention Description

We plan to develop a package of obstetric and newborn care intervention including management of serious neonatal infection and to evaluate the efficacy of two different strategies for delivery of the services. The two delivery strategies are known as: 1) Community Clinic (CC) model, and, 2) Home-based Care (HC) model. In this section, we provide a general description of the interventions, although the specifics of the package will be further developed based on the findings of baseline qualitative and epidemiological studies. Both intervention arms will involve community health education and education in the provision of safe-delivery and essential newborn care, in the recognition of maternal and neonatal danger signs, and in recognition and management of serious neonatal infections. Mothers and newborn babies in the comparison arm will continue to receive the current care (see Appendix 3).

4.8.1 Package of interventions

4.8.1.1 Community health education

Community health education targeted toward pregnant women and their families (see also Appendix 3) will be conducted in both intervention communities using a variety of media. To-date, the health education to illiterate and semi-literate women in Bangladesh has largely relied on inter-personal communication with some visual materials. However, to effect practice, we will be required to target other groups e.g., husbands, community leaders. These groups will be reached through group meetings. The partners of this project (Shimantik, BRAC, ICDDR,B) have extensive experience in providing health education to rural women in Bangladesh. We will develop the health education strategies building on the experiences of the partners. Specific health messages will address the importance of:

1. prenatal care including TT immunization and adequate nutrition during pregnancy,
2. hygienic delivery practices,
3. identification of signs of emergency obstetric care and indications for self-referral,
4. signs of birth asphyxia and importance of resuscitation,
5 early and exclusive breastfeeding,
6. neonatal temperature maintenance,
7. hygiene for preventing neonatal infections,
8. monitoring of newborn weight gain,
9. recognition of danger signs and symptoms in pregnant women and neonates, and
10. appropriate health-seeking behavior for sick mothers and neonates.

4.8.1.2 Provision of essential safe-delivery and newborn care

Mothers and first-line health workers (TBAs, FWAs and HAs in the CC model; TBAs and CHWs in the HC model) will be provided education in the performance of essential practices to improve obstetric and newborn care (see also Appendix 3). Obstetric and newborn care practices which mothers and first-line health workers in both intervention areas will be trained in will include:

1. use of neonatal care kits;
2. hygienic maternal and neonatal care, including hand-washing, clean delivery, and neonatal umbilical cord and skin care (including bathing);
3. recognition of maternal and newborn danger signs and referral of complicated pregnancies or obstetric emergencies to the nearest THC and referral of sick newborns to the nearest THC.
4. thermal control, including drying the newborn with warm, clean towels immediately after birth, wrapping the newborn in layers of cloth and dressing the neonate as appropriate for the season, covering the newborn's head, promoting skin-to-skin contact with the mother, and utilizing skin-to-skin contact and/or sleeping bags designed for re-warming hypothermic neonates;
5. early, exclusive breastfeeding, including feeding of colostrum and avoidance of pre-lacteal feeds. If the neonate sucks poorly, first-line health workers will be trained to teach mothers how to feed expressed breast milk with a spoon. The health workers also will be trained in the recognition and management of common breast problems during lactation (e.g., inverted nipples, mastitis, breast abscess);
6. ocular prophylaxis for ophthalmia neonatorum;

4.8.1.3 Education in recognition and management of serious neonatal infections

Mothers, TBAs and first-line health workers in both intervention models (FWAs and HAs in the CC model, CHWs in the HC model) will be trained to recognize, refer and treat neonates with

suspected serious infection, including pneumonia, meningitis and sepsis. Similar to the approach used (20) and validated recently (personnal communication) by Bang *et al.*, if two or more of the following signs are simultaneously present in a neonate, then the case will be denoted as potential serious bacterial infection:

1. inability to feed adequately, or poor suck;
2. weak or abnormal cry or cessation of crying;
3. lethargic, drowsy, unconscious, or loss of tone;
4. erythema, tenderness, and/or discharge around the umbilicus; or localized skin infection (pyoderma);
5. diarrhoea, vomiting and/or abdominal distention;
6. respiratory distress: respiratory rate > 60/min, severe chest in-drawing, grunting;
7. axillary temperature >99° F or <95°F or neonate feels cold to the mother in the absence of an otherwise identifiable reason for hypothermia;
8. seizures.

Although we provided a list of eight referral criteria and proposed that if two or more of these signs are simultaneously present in a neonate, then the case will be denoted as serious neonatal infection and referred, we realize that using two signs decreases sensitivity. It is important to balance between missing cases and over treating with 10 days of parenteral antibiotics. To achieve the right balance we perhaps should have two groups of signs e.g., temperature >100 degree, seizures, rapid breathing and drowsy/unconscious which would require one sign whereas, signs such as jaundice, diarrhea, abdominal distension would require two signs. Bang et al. in India is in the process of analyzing their data on use of signs by Village Health Workers to predict neonatal sepsis. Moreover, a multicenter study has been proposed with the aim of further developing and validating an algorithm for identifying seriously ill young infants, which may be completed in time to inform the algorithm we choose. We will have the opportunity to modify the algorithm based on those results and our own initial experience. We will revise and validate the algorithm while we conduct the baseline studies.

In the CC model, there will not be surveillance for ill neonates in the community; rather management of sick neonates depends upon self-presentation to the clinic. In the HC model, scheduled home visits and surveillance will facilitate identification, and subsequent antibiotic treatment of neonates with potential serious bacterial infection. Parents of infants with potential serious bacterial infection will be encouraged to take the child to the nearest THC. If the parents are not able or are unwilling to take the child to the THC, the first –line health worker (HA or FWA in CC areas; CHW in HC areas) will obtain consent and administer antibiotics either at the clinic (CC model) or in the home (HC model).

The antibiotic regimen will be once-daily intramuscular procaine penicillin (50,000 units/kg) and gentamicin (5 mg/kg for neonates < 7 days of age, 7.5 mg/kg for those ≥ 7 days of age) for 10 days. Currently, it is recommended by the WHO that empirical management of serious bacterial infections in young infants up to age 2 months include use of benzylpenicillin or ampicillin plus an aminoglycoside such as gentamicin administered parenterally (36, 37). The American Academy of Pediatrics approves use of penicillin G procaine at 50,000 units/kg daily for moderately severe infections in the neonate, although not for severe infections due to limitations to serum and CSF penetration; on the other hand, cotrimoxazole is not recommended for infants less than 2 months of age. Studies in neonates < 7 days of age given penicillin G procaine at 50,000

units/kg have shown serum levels of 7.4-8.8 ug/ml 2-12 hrs after the dose; levels in neonates > 7 days of age were 5-6 ug/ml during the first 4 hr after administration (38). Another study reported peak serum concentrations of 7.7-41.9 ug/ml 4 hr after a single dose of penicillin G procaine at 50,000 units/kg (38). These levels would be expected to be sufficient to treat group A streptococcus, and penicillin-sensitive pneumococci, major pathogens found to cause infections in young infants in the WHO Young Infant Study (39). Recent data from Bangladesh demonstrated that 10.5% of pneumococci isolated from children at Shishu (Children) Hospital had intermediate resistance to penicillin (MIC 0.1 to 1.0 ug/ml); no instances of total resistance were found (40). In contrast, 61.9% and 15.2% of isolates had intermediate and total resistance, respectively, to cotrimoxazole. We feel that oral administration of antibiotics is not prudent for treatment of neonatal infections, injection of antibiotics in the home more than once daily is not feasible in developing countries, and the third-generation cephalosporins are too costly and have associated concerns regarding increased risk for emergence of resistant strains with widespread use. Consequently, we feel that procaine penicillin in combination with gentamicin given intramuscularly once daily is a rational choice for treatment of the common agents of neonatal infections in the community.

In addition to antibiotic treatment, mothers of neonates with suspected serious bacterial infection will be encouraged to continue breastfeeding and will be taught to maintain their neonate's temperature. Parents of neonates with suspected sepsis who refuse referral to the THC will be instructed to bring their baby to the clinic daily for 10 days (CC model) or the neonate will be visited in the home for 10 days by the CHW (HC model) for assessment of the clinical condition of the baby and administration of antibiotics. If the condition of the baby deteriorates, the parents again will be encouraged to take the child to the nearest THC. If the parents are not able to comply with the referral, treatment will continue as before at the clinic or in the home. Hospitalized neonates will be kept in a health center/hospital until clinically stable (i.e., normal feeding, stable body temperature); thereafter, consideration will be given to continuing treatment in the community (at the clinic or in the home).

All health workers will receive appropriate and adequate training about the safe use of injectable antibiotics (details in section 4.13). The skills of the health workers will be formally evaluated and the report of that evaluation will be submitted to the Ethical Review Committee for review and approval to proceed with the evaluation of the actual intervention. Details of this has been given in section 4.14.

4.8.2 Delivery Strategies

4.8.2.1 Community Clinic (CC) model

Functional community clinics will be established by the Ministry of Health and Family Welfare (MOHFW) and the partner NGO. These clinics will serve as the focal point for delivery of maternal and newborn care. TBAs in the CC clusters will be trained and supervised in the provision of safe delivery and basic newborn care (as outlined above). The mothers, TBAs, FWAs and HAs will be trained in routine newborn care and in recognition of danger signs indicating the need for emergency obstetric or neonatal care, and the importance of timely care-seeking (see Appendix 3). The CC health workers (FWAs and HAs) will offer ESP services including antenatal, postnatal and newborn care from the CC, and will manage ill neonates who present to the clinic, including those with potential serious neonatal infection (see 4.8.1.3).

4.8.2.2 Home-based Care (HC) model

There will be no CC in the HC clusters. We are working closely with the MOHFW. Two MOHFW Directors are participating in this project as investigators. MOHFW is phasing in CCs,

and indicated that they do not plan to build CCs in those areas during the time of the intervention. In these clusters the mothers, and first-line health workers (in this case, community-based TBAs and CHWs providing services in the homes) will be trained and supervised in routine newborn care and in the recognition of maternal and neonatal danger signs and the importance of promptly seeking care (as outlined above). In contrast to the CC model, however, CHWs will provide antenatal care in the home, will assist with delivery care, and after birth of the neonate will make scheduled home visits to provide essential newborn care and, if necessary, manage serious neonatal bacterial infections in the home. CHWs will be from the communities themselves, and will be available to provide assistance at any time in-between visits. TBAs will be instructed to attend all deliveries in their village and will be given a small financial incentive for reporting each birth. The CHWs will be primarily responsible for providing newborn care but the TBAs will also be trained in newborn care so that they can work with the CHWs as a team or can provide this care in the absence of the CHW. CHWs also will be instructed to attend all deliveries and assist the TBAs as needed. The CHWs will follow the neonates regularly through the neonatal period as part of their surveillance activities. The CHWs in the intervention communities will be instructed to visit all newborns on the first, third, and seventh days, and then weekly until the baby is 28 days old.

Due to the presence of CHWs in the homes, additional services that can be provided as part of this intervention package include:

1. neonatal resuscitation, including recognition of birth asphyxia within 1 minute of birth, clearance of mucus with an oral mucus sucker/trap, provision of tactile stimulation and, when necessary, artificial breathing with mouth-to-mask or tube-and-mask techniques;
2. growth monitoring (e.g., PATH, TALC scales);
3. recognition and management of skin and umbilical infections;
4. active surveillance for danger signs, particularly potentially serious bacterial infections.

4.9. Record keeping

In both intervention models, first-line health workers (FWAs and HAs in CC areas; CHWs in HC areas) will record detailed clinical information including outcome for infants in their care, either at the clinic or in the home, respectively, using a standardized data collection form.

4.10. Data Collection for Assessing the Impact of the Intervention

4.10.1 Vital statistics, verbal autopsies and other outcome measures

The primary outcome, changes in neonatal mortality rates in the intervention and control communities from the beginning to the end of the study period, will be based on accurate measurement of mortality rates. Trained Data Collectors (DCs) will be responsible for a) counting pregnancies, live births, neonatal and infant deaths, and b) conducting verbal autopsies in reported neonatal deaths. The DCs, however, will not have any training on neonatal care, and their work will be independent of the intervention. The DCs will collect demographic data from both the intervention and control communities on a 3-monthly basis. The first-line health workers will provide a record of every known birth and neonatal death in the community care intervention clusters, but we may not know about all births and deaths, particularly in the comparison clusters. To minimize potential bias, the DCs will ascertain and record the outcome of all reported pregnancies (stillborn, live-born, miscarriage) within the control and intervention communities. In addition, we will compare the records of the health workers to those of the DCs on births and deaths in the intervention clusters on an ongoing basis to estimate whether these events are undercounted

by the DCs. If an undercounting is found, we will attempt to determine the reasons for such undercounting and will use this information to retrain the DCs.

Verbal autopsies will be performed to determine the cause of death for all neonatal deaths in both the intervention and control communities. Verbal autopsies will be conducted using a structured and validated instrument. Cause of death will be determined independently by 2 pediatricians/neonatologists who will review the verbal autopsy records. In addition, we will develop a computer algorithm to assign causes of death. Death will be categorized as follows: prematurity, sepsis/meningitis/ pneumonia, diarrhea, asphyxia, tetanus, hypothermia, birth trauma, congenital anomalies and unknown.

Data on antenatal care, TT immunization, iron/ folate supplementation, place of delivery, birth attendants, post-partum care and complications, neonatal preventive care, breast-feeding and neonatal hypothermia will be collected during the 3-monthly visits from recently delivered mothers.

4.10.2. Colonization with antibiotic-resistant bacteria

Colonization with antibiotic-resistant bacteria will be assessed in sub-samples of one-month old infants during the period when the interventions will be implemented. Nasal swabs will be obtained from the infants and cultured for penicillin-resistant *Streptococcus pneumoniae* by standard techniques (28,29,32,33).

4.10.2.1. Sampling of children for bacterial culture

Comparison will be made of the proportions colonized with antibiotic-resistant pneumococci of samples of children from the two intervention areas and the comparison area. The samples will be selected every week from all three areas from a list of one-month old infants using a simple random sampling method. The sampling fraction will be determined by dividing the numbers of infants required to be sampled each week by the numbers of infants available for sampling in that week.

4.10.2.2. Specimen collection and transport

Nasal culture swabs will be obtained by trained laboratory assistant when the infant is 1 month old. Swabs will be collected by standard methods using a small flexible rayon-tipped swab (Difco CultureSwab Transport Medium with Amies Medium) inserted into one nare to the level of the anterior nasopharynx, attempting to saturate the swab by leaving it in place for 5 seconds or rotating it 180 degrees before removal. Swabs will be placed in transport media, labeled by the laboratory assistant and transported to Dhaka Shishu Hospital within 24 hours.

4.10.2.3. Microbiology and antibiotic-susceptibility testing

Bacterial culture of the nasal swab for *S. pneumoniae* will be performed at the Shishu Hospital microbiology laboratory using standard methods and interpreted as described previously (32,33). Pneumococcal serotype/group determination will be performed by the capsular swelling procedure (quelling reaction) with type-specific anti-pneumococcal pool, type or group, and factor sera (Statens Seruminstitute, Copenhagen, Denmark) as we have described previously (41). All pneumococcal isolates will be tested for antimicrobial susceptibility against penicillin as we have described previously (41).

4.11. Determination of Costs and Cost-Effectiveness

The study will track costs and make estimates of the cost-effectiveness of the CC and HC intervention models, compared to the control area and compared to other estimates in the literature.

4.11.1 Calculating Costs

In order to effectively estimate the costs that are related to the interventions themselves, costs will be divided into the following groups: program intervention costs, users' intervention costs, and research and evaluation costs. *Program intervention costs*, which can be directly compared to changes in outcome measures in cost-effectiveness analysis, will be collected by program staff and will include:

- Payments to first-line health workers.
- Training courses for health workers.
- Drugs, supplies, and neonatal care kits used in the course of the intervention.
- The cost of renting clinic buildings
- Amortized capital costs (equipment, vehicles, buildings)

We will track and include capital costs, using depreciation techniques to calculate the portion of the investment cost that is appropriate to include in the cost-effectiveness calculation.

Research and evaluation costs, which are not counted when calculating cost-effectiveness, include survey implementation and analysis and verbal autopsies. *Users' intervention costs* will be measured through the baseline and follow-up demographic household surveys. These costs include any direct financial payments for services, as well as transportation costs and the amount of time that individuals spend to use the services of the intervention. Questions about each of these items will be included in the baseline and follow-up demographic household surveys. Time costs will be translated into financial costs based on the economic level of the household, as measured by the household survey (see Section 4.13, below). The costs of any pre-existing (baseline) services will be considered when calculating the true costs of the intervention for users.

The study will follow recommended costing and accounting techniques for the allocation of indirect costs and calculation of depreciation (42, 43). We will use time-allocation interview procedures to further assist in attributing indirect costs to the interventions' outcomes, based on Activity-Based Costing techniques (44, 45). An additional option is to use a WHO costing spreadsheet specifically designed to cost out interventions to reduce maternal and neonatal mortality in developing countries (46).

4.11.2 Measuring Cost-effectiveness

We will use the following effectiveness measures as denominators for cost-effectiveness ratios: (1) neonate treated; (2) neonate death averted – all causes; (3) neonate sepsis death averted; and (4) neonate asphyxia death averted. Deaths averted will be measured by the demographic household surveys. Cost-effectiveness ratios will be calculated for each of these measures and compared across the CC Intervention, HC Intervention, and comparison areas – and compared to estimates in the existing literature. In calculating separate cost-effectiveness ratios, we will separately calculate both the outcomes and the costs for the prevention of neonatal sepsis and neonatal asphyxia deaths – so the costs included in the numerators for these two cost-effectiveness ratios will be mutually exclusive. The division of the costs between the two causes of death will be based on the allocation of workers' time and supplies for specific tasks directly related to the cause of death in question, and a general allocation of remaining time and supplies that cannot be directly traced. In calculating the time and input costs related to the neonatal intervention, we will separate out those costs that are relevant to maternal interventions. However, at this point we do not plan to calculate separate cost-effectiveness ratios for maternal health care, since mothers are not the principal target of the intervention.

4.12 Equity Analysis for Program Beneficiaries

The baseline and follow-up demographic household surveys will include questions on respondents' economic status, gender, and area of residence. The study will analyze the distribution of the interventions' benefits by each of these characteristics – to determine which groups are benefiting the most from the intervention. This analysis will be done both for neonates treated and also deaths averted, so it will be possible to determine if economic status, gender, or area of residence is a predictor of positive response to treatment. Economic status will be measured using a series of variables reflecting household ownership (housing, appliances, animals, vehicles) and the state of the household's dwelling.

4.13. Training

TBAs and first-line health workers (FWAs and HAs in the CC areas; CHWs in the HC areas) in the intervention communities will receive training on different components of the obstetric and neonatal care intervention.. All health workers (HA, FWA and CHW) will receive appropriate and adequate training on identification of neonates with health problems using a clinical algorithm, correct diagnosis, and management including the safe use of injectable antibiotics. Section 4.3.4 describes how the training package will be developed. The health workers will receive 6 week training with 36 working days. The draft training programme is given in Appendix 5. The clinical component of the training will be conducted in a reputed and established health training institute with attached clinical facilities. This training will be provided by clinicians of the training institute, trained project staff and will be supervised by the pediatricians in the team of investigators. The training will be preceded by a 5-day training of trainers, who will be trained by experienced neonatologists/paediatricians and obstetricians. The skill development of the health workers will be continuously monitored during training based on the IMCI clinical course training methodology. Health workers facing problems with the correct assessment and management of the neonates will be identified and individualy guided.

The Physicians, Medical Assistants and Family Welfare Visitors working in the THC and Union Health and Family Welfare Centres (UH&FWC) will also receive a short training on management of emergency obstetric cases and neonatal sepsis cases as these cases will be referred to them from the communities. These trainings will be provided by trained project staff and supervised by the pediatricians in the team of investigators.

4.14. Evaluation Of Health Worker Training

At the end of the training, the 40 trained health workers will spend 2 weeks in one of the two study upazilas for field assessment of their ability to perform assigned tasks with respect to the management of sick neonates. This will include identification of sick neonates, classification of the condition, and management. The field assessment will be done in 2 batches with 20 health workers in each batch, that is over 4 weeks total.

The area along with the households will already be mapped and listed during the baseline census. The health workers being trained will visit the listed households looking for neonates. We expect each health worker to be able to visit 50 households each day and to identify 4 neonates every 6 days on average. In 12 days, they will identify about 320 neonates. For each neonate, they will ask the mother whether the baby has any problem and if there is a reported problem then the health worker will conduct a full clinical assessment, classify the condition and prescribe the appropriate treatment which will be referral for those classified as having a severe infection (without giving any antibiotic, but recording on the evaluation form the dosage of the injectable that

the child should be receiving). For each identified neonate, the health worker will also fill out a small form indicating the address of the neonate. The neonate address form will be sent immediately by a local messenger to the trained physician waiting at one of 8 selected locations. The physician will visit all the neonates immediately (within 2-3 hours of notification) and conduct their own assessment of the neonate's condition. Each physician will need to visit no more than 2-3 neonates everyday. We will compare the assessment and management of health workers against the physicians as gold standard. An agreement of 80% will be considered as acceptable agreement.

A report of this evaluation will be submitted to the Ethical Review Committee for review and for approval to proceed with the evaluation of the actual intervention as designed.

4.15. Implementation of the Intervention

The interventions will be initially implemented in 2-3 selected communities to determine the training and other support system needs for the implementation of the intervention. In the CC intervention communities, clinics will be established. At the commencement of the study, the drug and other supply needs of the health workers will be assessed. Supply utilization will be monitored and the requirements will be periodically reviewed and appropriate changes will be made as needed.

A simple record keeping and reporting system will be designed and implemented. This will mainly assist the service providers in conducting a comprehensive assessment of the sick neonates. The THCs in respective sub-districts will serve as the referral facilities.

A system will be established to carefully monitor and ensure the performance standard of the health workers and other intervention staff on an ongoing basis. The activities of the health workers in both models will be monitored on an ongoing basis by field supervisors who will visit each clinic (CC model) or each health worker (HC model) once every fortnight and by the study physicians. Technical review sessions will also be organized as part of the routine management meetings. These sessions will be designed to address common and/or persistent problems with service delivery and quality of service. The health workers will receive refresher training every two months.

4.16. Quality Assurance

To ensure proper implementation of the intervention and to ensure the quality of CHWs' assessments and management, the project Medical Officers and Clinical Supervisors (nurses) will undertake intensive supportive supervision of the CHWs on a regular basis. They will observe actual assessments of neonates by the CHWs and will make systematic random checking of the neonatal cases assessed by the CHWs. Bi-monthly refresher training will be arranged for the CHWs and other project field staff in which the problems encountered will be discussed and resolved. To ensure the quality of the data collected, the study supervisors and investigators will make spot checks. In addition, a 5% sample of study mothers will be re-interviewed within two days of the original interview.

4.17. Data Management and Analysis

4.17.1 Data management

All questionnaires and data forms will be reviewed by the investigators for accuracy, consistency and completeness. Whenever necessary, the CHWs/DCs will make additional field visits to clarify inconsistencies or collect missing information. After editing, the data will be entered in databases using on-line custom-designed data entry programs. Necessary range and consistency

checks will be in-built. Data will be periodically checked by running and reviewing frequency distributions and cross-tabulations.

4.17.2. Data analysis

Baseline characteristics of the treatment and control groups will be examined for group comparability. Any significant baseline differences will be controlled for during data analysis. The frequency distribution will be examined to assess the distribution of data. If the data is not normally distributed, decisions about need for data transformation and the appropriateness of statistical tests will be made. To account for the clustered nature of the data, techniques such as Generalized Estimating Equation and multi-level modeling will be used.

Efficacy evaluation will be done by comparing the primary and secondary outcome measures in the two intervention areas and the comparison area after controlling for the baseline rates. The baseline rates will be calculated using the baseline survey data. Annual mortality rates during the intervention phase will be calculated using the three monthly demographic data. For calculation of mortality rates, all births and deaths that occur in the study area will be included irrespective of whether or not they received the treatment.

To detect statistical differences in neonatal mortality changes in the study arms, a t-test will be performed at the cluster levels. T-tests will examine the differences in the mean of neonatal mortality changes between baseline and at completion (NNM_b-NNM_c) among the study arms. Because of multiple comparisons among the study arms, Bonferroni and Scheffe adjustment procedures will be used to adjust p-values.

Because of variability in the characteristics of the population in the study arms, the t-test will also take into account the differentials in the characteristics of the population in which the observed rates will be weighted by the expected rates in the clusters.

In addition, at an individual level, the logit of probability of NNM will be modeled as:

$$\text{Logit}(p_{ij}) = \alpha_j + \beta X_{ij} + \delta Z_{ij} + \gamma M_j + \nu_j,$$

where, X is a categorical variable for the study arms, Z is the matrix of characteristics of the infants/mothers, and M_j is the baseline NNM rate at cluster j; and ν is the stochastic parameter for unobserved heterogeneity at the cluster levels. The model will be fitted as a random-effects GLM with logistic link. The differentials in NNM by study arms will be tested by null hypotheses: $\beta_1=0$, $\beta_2=0$, and $\beta_1=\beta_2$.

Same statistical procedures will be used for other outcome variables.

5. Ethical Assurance for Protection of Human Rights

5.1. Ethical Review Committee (ERC)

The Investigators will be responsible for ERC approval for the study. Before the study commences, the appropriate documents (which may include the Protocol, Informed Consent form, and information sheets) will be submitted to the ERC by the Investigator. A copy of the study approval, including informed consent approval, is to be kept with the Investigator's study documents.

Appropriate reports on the progress and termination of the study will be made to the ERC by the Investigator in accordance with ERC guidelines and governmental regulations

5.2. Informed Consent

In obtaining and documenting informed consent, the Investigators must comply with the applicable regulatory requirement(s), Good Clinical Practice, and ethical principles. The Informed Consent form must be approved by an ERC prior to its use.

The Informed Consent forms describe that participation is voluntary and can be terminated at any time without reason. The scope of the trial is explained. In addition, the parent/guardian will receive information on alternate sources of care. By agreeing (by signing, when appropriate) to the Informed Consent form, the parent/guardian confirms the child's voluntary participation and their intention to follow the study protocol and the instructions of the Investigator.

The Investigator is responsible for obtaining verbal/written informed consent, as appropriate, from the parents/guardians for each subject enrolled.

This is a large project in an estimated 80,000 households. The study will involve formative research (both qualitative and quantitative), design and implementation of a package of interventions, on-going collection of data to assess the adequacy of the implementation of the intervention and to measure various outcomes. We plan to obtain verbal consent when we employ data collection methods that are neither sensitive nor invasive. Written consent will be obtained when sensitive/invasive procedures are applied. The table below summarizes the types of consent that we plan to obtain by study methods.

Summary of Consent Procedures

Study methods	Estimated Sample size	Verbal consent	Written consent
Phase I: Formative Research and Development			
Baseline qualitative studies			
Semi-structured interviews	50-60	✔	
Observation of deliveries	10	✔	
Focus group discussions	6 (estimated number of participants: 60-72)	✔	
Baseline census and household surveys	80,000 households	✔	
Worker skill evaluation	80,000 households	✔	
Phase II: Intervention Evaluation			
Initial consent for inclusion in the Home Care Arm of the Study	30,000 women of child bearing age and about 3,300 newborn babies	✔	
Initial consent for inclusion in the Community Clinic Arm of the Study	30,000 women of child bearing age and about 3,300 newborn babies	✔	
Initial consent for inclusion in the Comparison Arm of the Study	30,000 women of child bearing age and about 3,300 newborn babies	✔	

Study methods	Estimated Sample size	Verbal consent	Written consent
Management of serious infection in neonates at home or CCs if referral fails	500-600 newborn babies		✔
Collection of nasal swab	5,200		✔
Community education	80,000 households	Only routine recommended care will be provided. Therefore no consent will be obtained.	
Provision of safe delivery and newborn care	6,600 pregnant women and newborn babies		

When written consent is obtained, signed copies of this consent form must be a) retained on file by the Principal Investigator, b) given to the participant and c) put in the babies file. The written informed consent form must be signed and dated by the parent/guardian prior to the specific study procedure.

6. Resources, Coordination, Collaboration, and Project Management

6.1 Personnel and responsibilities

6.1.1 Principal Investigator, Dr. Mathuram Santosham, is responsible for:

1. protocol development, modifications, and submission to review committees;
2. study oversight, including subject recruitment, screening, and monitoring; recruitment of personnel, training and oversight; submission of timely reports as needed, local budget management; and study integrity and quality;
3. data compilation, analysis, interpretation and security;
4. manuscript preparation and submission to scientific journals.

6.1.2 Co- Principal Investigator(s), Drs. Robert Black, Abdullah Baqui, Shams El Arifeen, Gary Darmstadt, are responsible for:

1. implementation of the project and quality collection of data;
2. submission of timely reports;
3. data compilation, analysis, interpretation and security;
4. manuscript preparation and submission to scientific journals.

6.1.3 Co-investigators, are responsible for:

1. recruitment of subjects, randomization, supervision of field activities, laboratory testing, study monitoring, data compilation and analysis.

6.2 Study Site and Role of Partners:

The Project will be carried out in two rural sub-districts of Sylhet division of Bangladesh in collaboration with the Ministry of Health and Family welfare (MOHFW) of the Government of Bangladesh (GoB), ICDDR,B, Dhaka Shishu Hospital, Institute of Child and Mother Health, Save the Children Federation (local Bangladesh field office and Washington D.C.-based Saving Newborn Lives Initiative team), and two national NGOs – Shimantik and BRAC, BangladeshThe following section identifies the main responsibilities of each partner.

The responsibilities of partners are explicitly outlined in Matrix 4. General areas of responsibility include:

Johns Hopkins University will be responsible for the following activities:

a) proposal development
b) fund raising
c) IRB/ERC approvals
d) development of training and educational materials
d) overall design, coordination and supervision of field implementation
d) data analysis and preparation of reports
e) dissemination, policy recommendation, advocacy

Child Health Program of ICDDR,B will be responsible for the following activities:

a) recruit management and field staff
b) implement baseline studies
c) participate in the design and pre-testing of intervention
d) assist with training and implementation of the intervention
e) responsible for collection and management of data for evaluation purposes
f) monitor implementation of intervention
g) participate in data analysis and report preparation
h) participate in dissemination, policy formulation, and advocacy

Dhaka Shishu Hospital in Dhaka, Bangladesh will provide laboratory support for collection and processing nasal swabs.

Save the Children will assist with proposal development, identifying resources to aid in the design of baseline ethnographic studies and in the design of instruments and training manuals, design of the interventions, including community education, neonatal care and treatment protocols, data interpretation, preparation of manuscripts, dissemination of results, policy formulation and advocacy.

Institute of Child and Mother Health, Dhaka will assist with design of training manuals and training of first-line health workers, and design of the interventions.

BRAC will assist with design of baseline studies, design and implementation of the intervention.

Shimantik will be jointly responsible with JHU and ICDDR,B for the implementation of the intervention. The study will be conducted in the field area of Shimantik in Sylhet. TBAs, CHWs and DCs will be recruited from the HC villages so that they can relate to and communicate with mothers and other members of the study community in the local dialect. Shimantik will be specifically responsible for the following activities:

a) assist with field staff recruitment
b) baseline studies
c) participate in the design and pre-testing of intervention
d) working closely with GoB and other partners, responsible for training and implementation of the intervention
e) collect and manage data for evaluation purposes
f) monitor implementation of intervention
g) participate in data analysis and preparation of report
h) participate in dissemination, policy recommendation, advocacy

SEARCH will provide on-site exposure to home-based neonatal care in its Gadchiroli project area.

6.3. Project Management

The Neonatal Intervention Project is an initiative of the Johns Hopkins University (JHU), USA. To ensure relevance and proper implementation, JHU has established partnership with the following Bangladeshi institutions:1) Government of Bangladesh (Director/MCH, Director/PHC, Research Director/NIPORT) , 2) ICDDR,B, 3) SCF/BFO, 4) Shimantik, 5) BRAC, 6) Shishu Hospital and 7) ICMH. It is anticipated that the project will be funded through four different funding mechanisms; 1) USAID/Global funding to JHU, 2) SNL/SCF funding to JHU which will in turn subcontract with the Bangladeshi institutions Shimantik, BRAC, Shishu Hospital and ICMH to support the implementation of the intervention, 3) USAID/Bangladesh funds to ICDDR,B to cover the research and evaluation costs and 4) GoB 's contribution in-terms of use of staff time and facilities.

The broad-based partnership of institutions and multiple sources of funding are major strengths of the project. This will ensure the relevance of the project and will increase the likelihood of scaling-up and sustaining the intervention The different project partners bring diverse, rich, and unique experiences and expertise. However, the partnership and multiple sources of funding also make the project management complex and challenging.

For proper management, the following project structure and guiding principles are envisioned:

1) Project Coordination Committee (PMC) comprised of Investigators and the Project Coordinator will be responsible for overall design and coordination of project activities. The Principal Investigator or his designee will retain the authority to make final decisions regarding the design and implementation of the project. The PMC will be responsible for timely implementation of the project and submission of technical reports to all donors periodically. However, each partner institutions will remain responsible for maintaining accounts, submission of financial reports to donors and to deal with financial audits as required by the donors.
2) A national level Technical Review Committee (TRC) will be formed to provide expert inputs in to the design of the intervention, evaluation plans and formulation of policy statements regarding implementation and future scaling up of the intervention. The TRC will comprise of representatives from GoB, USAID, SCF, local UN agencies (e.g., WHO, UNICEF, World Bank), major health NGOs (e.g., RSDP, UFHP, BRAC, BPHC), professional associations (e.g., Perinatal Society, Neonatology Forum, Ob/Gyn Society).
3) The Project Management Team headed by the Project Coordinator will be responsible for the implementation of the project. Although, staff members will be recruited through different mechanisms, all full time project staff will be reporting to the Project Coordinator. There will be two project teams: 1) Research and Evaluation Team and 2) Implementation Team.

Local staff will be recruited primarily through two mechanisms: 1) ICDDR,B and 2) Shimantik. The organization of the project was thoroughly discussed with senior management of ICDDR,B and Shimantik. Both institutions endorsed the proposed organization of the project.

7. Project Completion and Sustainability

Upon completion of the project, health workers in the comparison clusters will be trained in the provision of routine obstetric and neonatal care, recognition of danger signs in mothers and

neonates, and, possibly, in the management of neonatal sepsis. The active participation of the MOHFW officials, ICDDR,B and local NGOs will help to facilitate communication with MOHFW/GoB and local NGO networks. This, in turn, will aid in dissemination of information about the trial results and the translation of the results into policy statements and sustainment of the intervention activities at the community level.

The NGO-partners Shimantik and BRAC are part of a network of NGOs supported by USAID/Bangladesh through a cooperative agreement with Pathfinder International and BRAC. Save the Children has an active presence throughout the Indian subcontinent, and SEARCH is currently planning to expand their intervention areas in partnership with local NGOs in Maharashtra, India. ICDDR,B has a proven track record of conducting health research and providing policy assistance/guidance in Bangladesh. Thus, if the intervention proves to be successful, we will have established partnerships in place that will facilitate scaling-up of the intervention.

Health services in Bangladesh are provided by the Ministry of Health and Family welfare (MOHFW) and NGOs. MOHFW has one HA and one FWA in each electoral ward with an estimated population of about 6000. MOHFW/GoB is planning to establish one CC in each ward. As mentioned earlier, if the CC model proves to be effective, the findings will be disseminated widely and technical assistance will be provided to scale-up the intervention in the HPSP of Bangladesh and elsewhere. If only the HC model is found to be adequately effective, further operational research will be conducted to incorporate this model into the HPSP of Bangladesh. As an interim strategy, home visits may be required to effectively deliver newborn care and to identify neonatal sepsis cases. The estimated number of annual births in a ward with a HA and a FWA will be about 150. To implement the CC model as described, an estimated 900 visits annually will be required by HAs/FWAs per ward. If this additional workload is divided between the two workers, each worker will be required to make about 2 additional visits per working day. This should be possible as an interim strategy. Moreover, as the education received by mothers about maternal and newborn care during a first pregnancy may have lasting positive impact during subsequent pregnancies, and as more mothers in the community have benefited form the intervention and may act as a resource pool, it may be possible in the future to target the intervention to only newly-wed couples or, perhaps, first-time mothers), thus making the program less costly and more sustainable.

In addition, critical evaluation of the HC model may identify certain visits that are critical and others not. Thus the number of visits may be reduced in a subsequent strategy. Once the community clinics become fully functional in the HPSP of Bangladesh, parents who are not able to take their sick baby to a distant THC due to resource constraints or social or family factors, may well be willing and able to seek care from clinics. Thus, if either of the proposed intervention models proves to be efficacious, then it will be of great benefit to Bangladeshi children.

8. Time Line

Administrative and Ethical Approval:.....Before the commencement of the Project

Phase I:

Hiring of personnel: .....Months 1-2
Training of baseline study personnel: .....Months 3
Qualitative study: .....Months 4-9
Census, mapping and baseline survey: .....Months 4-9
Design of Intervention: .....Months 6-10
Design of educational material:.....Months 6-10
Pre-testing of the intervention: .....Months 10-12
Training of first-line health workers: .....Months 11-13

Phase II:

Begin and continue neonatal care intervention: .....Months 14-28
Begin and continue home management of serious bacterial infections: .Months 14-28
Begin and continue collection of vital statistics: .....Months 14-31
Data quality assurance: .....ongoing
Data management: .....ongoing

Phase III:

Data analysis and report writing: .....Months 32-36

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Appendix 1

Information needed to develop behavior change communications

Type of intervention	Behaviors to be promoted through the intervention	Information needed to develop behavior change strategies
GROUP: MOTHERS AND OTHER FAMILY MEMBERS		
Both interventions	-Seek antenatal care (ANC) -Take TT immunization -Take measures for clean delivery -Identify signs of EOC and self-refer to Thana Health Centre (THC) -Dry and keep newborn warm -Cord care - Avoid pre-lacteal feeds -Immediate, exclusive breast-feeding -Bathing and skin care -Maintain appropriate hygiene	-Current practices with ANC and TT -Reasons for not seeking ANC and TT -Current delivery care practices: what is done to ensure clean delivery; what signs are used to identify high-risk deliveries and what actions are taken -Current newborn care: what routine care is provided to newborn infants including umbilical cord and skin care, thermal control, eye prophylaxis? Is there a period when the newborn is kept separated from the mother? -Is birth asphyxia recognized as a problem and what is done to manage it? -Current feeding practices including pre-lacteal feeds, exclusive breast-feeding -Gender issues: Are male and female babies cared for differently? If yes, what things are done differently and why? - Recognition and management of pre-term and LBW: do families recognize them; how; do they do anything different for these babies; if yes, what?
Home-based Care Intervention	Identify danger signs in the newborn and contact the CHW or take to the nearest THC	-Recognition and management of sepsis: What signs and symptoms are used to identify sick neonates; what terms are used to describe and categorize sick neonates; what types of care are available for sick neonates; when and why care is sought from a particular provider; what are the barriers to obtaining care; decision making process
Community Clinic Intervention	- Identify danger signs in the newborn and take the baby to the CC or to the nearest THC	
GROUP: TRADITIONAL BIRTH ATTENDANTS		
Both Interventions	-Promote use of ANC and TT immunization -Attend deliveries and take measures for clean delivery -Identify signs of EOC and refer to Thana Health Centre (THC) - Identify and manage birth asphyxia -Dry and keep the newborn warm -Cord care - Educate mothers to avoid pre-lacteal feeds and continue exclusive breast-feeding until the baby is 5 mo old -Bathing and skin care -Identify signs of sepsis in the newborn and refer to the CC (CC model), the CHW (HC model) or to the nearest THC (both models)	-Current practices of TBAs in regard to ANC and TT -Current delivery care practices of TBAs: what they currently do to ensure clean delivery; what signs they use to identify high risk deliveries and what actions they take - Current newborn care practices by TBAs: what routine care are provided by TBAs to newborn infants including umbilical cord and skin care, thermal control, eye prophylaxis? -Can TBAs recognize birth asphyxia? What signs are used to diagnose birth asphyxia? What terms are used to describe birth asphyxia? What they do to manage birth asphyxia? Are they trained to resuscitate? -Current role of TBAs re feeding practices including pre-lacteal feeds, exclusive breast-feeding -Recognition and management of pre-term and LBW infants: do TBAs recognize them; how; do they do anything different for these babies; if yes, what? -Recognition and management of sepsis: Do TBAs currently play any role to identify and manage sick neonates? What signs and symptoms they use to identify sick neonates; what terms they use to describe and categorize sick neonates; what types of care they provide?

Type of intervention	Behaviors to be promoted through the intervention	Information needed to develop behavior change strategies
Group: FIRST-LINE Health Workers		
Home-based Care Intervention (CHWs)	- Home visit to promote use of ANC and TT immunization - Attend deliveries and take measures to ensure clean delivery-Identify signs of EOC and refer to Thana Health Centre (THC) -Identify and manage birth asphyxia-Drying and keeping the newborn warm-Cord care-Eye prophylaxis - Educate mothers to avoid pre-lacteal feed and continue exclusive breast-feeding until the baby is 5 mo old-Bathing and skin care - Monitor growth - Make scheduled home visits to identify skin/umbilical infections - Identify and treat skin and umbilical infections --- Identify signs of sepsis in the newborn and refer to the nearest THC - Treat sepsis cases at home if the parents are unable to take their baby to the THC	-Current practices of health workers in regard to ANC and TT -Current delivery care practices of health workers if any: what they currently do to ensure clean delivery; what signs they use to identify high risk deliveries and what actions they take - Current newborn care practices: what routine care is provided to newborn infants including umbilical cord and skin care, thermal control, eye prophylaxis? -Can the workers recognize birth asphyxia? What signs are used to diagnose birth asphyxia? What terms are used to describe birth asphyxia? What they do to manage birth asphyxia? Are they trained to resuscitate? -Current role re feeding practices including pre-lacteal feeds, exclusive breast-feeding - Recognition and management of pre-term and very LBW: do recognize them; how; do they do anything different for these babies; if yes, what? -Recognition and management of sepsis: Do CHWs currently play any role to identify and manage sick neonates? What signs and symptoms they use to identify sick neonates; what terms they use to describe and categorize sick neonates; what types of care they provide?
Community Clinic Intervention (FWAs and HAs)	Educate mothers on delivery and newborn care including signs of EOC and neonatal sepsis during ANC visits to clinic. If a women reported by a TBA to be pregnant does not come to the community clinic for ANC visit she will be visited at home once during the third trimester and the education will be provided during this visit - Recognize and treat skin and umbilical infections in neonates attending the clinics -Evaluate suspected sepsis cases attending the clinics -Refer sepsis cases to THC - Treat sepsis cases at the clinics if the parents are unable to take their baby to the THC	

Appendix 2
Indicators and data sources

Time	Interventions	Indicators	Data Sources
Before & during pregnancy	- Family planning - STD/HIV prevention & management - Tetanus toxoid immunization - Antenatal care - Advice re nutrition - Iron/folate supplem. - Recognition, early detection & manage-ment of complications (eclampsia, bleeding, abortion, anaemia)	-Proportion of women received at least two antenatal check-ups by trained personnel -Proportion of women received at least two doses of TT during pregnancy -Proportion of women received iron/folate during pregnancy - Proportion of women with correct knowledge of pregnancy complications requiring self referral to a health facility - Proportion of women with correct knowledge of routine neonatal care (breast-feeding, warmth, hygiene, skin and cord care and recognition of neonatal danger signs)	- Data on antenatal care, TT immunization and iron/folate suppl. and knowledge of pregnancy complications and newborn care will be collected from a sample of mothers by DCs when the baby is one month old
During delivery	- Clean & safe (atraumatic) delivery - Recognition, early detection & manage-ment of complications at health center or hospital (hemorrhage, eclampsia, prolonged / obstructed labor	-Proportion of births attended by trained health personnel -Proportion of women with correct knowledge of delivery related complications requiring self referral to a health facility - Proportion of women experienced delivery complications	-Data on place of delivery, birth attendants and delivery complications will be collected from a sample of mothers by DCs when the baby is one mo old
After delivery: mother	- Recognition, early detection & management of postpartum complications at health center or hospital - Postpartum care (promotion & support to breast-feeding and management of breast complications) - Family planning - STD/HIV prevention & management - Tetanus toxoid	-Proportion of women received post-partum care -Proportion of women with correct knowledge of post-partum complications requiring self referral to a health facility - Proportion of women experienced post-partum complications (e.g., hemorrhage, retained placenta, sepsis)	- Data on post-partum care and complications will be collected from a sample of mothers by DCs when the baby is one mo old
Immediately after delivery: newborn	- Resuscitation - Prevention & management of hypothermia - Early & exclusive breast-feeding - Prevention & management of infections including ophthalmia neo-natorum and cord infections	-Proportion of newborn received preventive care for eye, skin, cord infections and thermal control - Proportion of babies received resuscitation for birth asphyxia	- Data on neonatal preventive care and resuscitation will be collected from a sample of mothers by DCs when the baby is one month old
First month of	- Early & exclusive breast-feeding	**- Neonatal Mortality Rate**	- Data on pregnancy, pregnancy outcome, death and causes

Time	Interventions	Indicators	Data Sources
life: newborn	-Prevention & management of infections including cord infections - Identification and management of serious neonatal infections	- **Perinatal Mortality Eate** -Cause specific neonatal mortality rate - Proportion of neonates colonized with antibiotic resistant bacteria - Proportion of neonates exclusively breast-fed on day 1 and at 1 month of age -Incidence of neonatal infections -Proportion of newborn received preventive care for eye, skin, cord infections and thermal control -Proportion of babies received care for hypothermia (e.g., skin to skin contact) - Incidence rates of selected morbidity e.g., umbilical cord and skin infections, diarrhoea and ARI during the first month of life - Number of serious neonatal infections seen in the health facilities and how many of them truly have serious infections - Number of serious neonatal infection cases managed at home or CC	of death (by VA) will be collected by DCs during 3 monthly home visits - Data on on breast-feeding, hypothermia and other neonatal morbidies will be collected by DCs when the baby is one mo old. - Data on referred cases will be collected from health facilities - Data on serious infections treated at home or CC from CHWs record and CC records

- The bold faced ones are primary indicators and the remaining ones are secondary indicators. .
- The shaded indicators can only be used for descriptive purposes.

Appendix 3

Table 1: Summary of interventions in the three study arms (Adapted from the WHO Mother-Baby Package)

	Interventions	Study Arm #1: Home-based Care Model (HC)	Study Arm #2: Community Clinic Model (HC)	Study Arm #3: Comparison communities
Before & during pregnancy	-Family planning -STD/HIV prevention & management -Tetanus toxoid immunization -Antenatal care -Advice re: nutrition -Iron/folate supplem. -Recognition, early detection & management of complications (eclampsia, bleeding, abortion, anaemia)	-Community health education on maternal and neonatal health using a variety of media -**CHWs based in villages** educate mothers on the importance of adequate nutrition, TT immunization, antenatal care, iron-folate supplementation and refer to existing GoB/NGO clinics for these essential services; -insertion of IUDs, 1st dose depo-provera injections etc. by FWVs at UHFW Cs -management of complications by physicians & paramedics at THCs	-Community health education on maternal and neonatal health using a variety of media -**FWAs and HAs operating out of Community Clinics** conduct immunization, antenatal care, iron-folate supplementation -insertion of IUDs, 1st dose depo-provera injections etc. by FWVs at UHFW Cs -management of complications by physicians & paramedics at THCs	-**FW As and HAs based in villages** provide immunization & FP services during monthly outreach (satellite) clinics -antenatal care, iron-folate supplementation by health workers at UHFWC -insertion of IUDs, 1st dose depo-provera injections etc. by FWVs at UHFW Cs -management of complications by physicians & paramedics at THCs
During delivery	-Clean & safe (atraumatic) delivery -Recognition, early detection & management of complica tions at health center or hospital (hemorrhage, eclampsia, prolonged/obstructed labor)	-Deliveries conducted in the home by trained TBAs assisted by CHWs -Complicated deliveries & management of complications by physicians & paramedics at THCs	-Deliveries conducted in the home by trained TBAs -Complicated deliveries & management of complications by physicians & paramedics at THCs	-Deliveries conducted in the home by trained TBAs -Complicated deliveries & management of complications by physicians & paramedics at THCs
After delivery: mother	-Recognition, early detection & management of postpartum complications at health center or hospital -Postpartum care (promotion & support to breastfeeding and management of breast complications) -Family planning -STD/HIV prevention & management -Tetanus toxoid	-Basic management in the home and referral of complications by TTBAs -Management of complications by physicians & paramedics at THCs -Promotion of exclusive breastfeeding by CHWs	-Basic management in the home and referral of complications by TTBAs and HA/FWAs operating out of CCs -Management of complications by physicians & paramedics at THCs -Promotion of exclusive breastfeeding by FWAs & HAs operating out of Community Clinics	-Basic management in the home and referral of complications by TBAs -Management of complications by physicians & paramedics at THCs
Immediately after delivery. newborn	-Resuscitation -Prevention & management of hypothermia -Early & exclusive breastfeeding -Prevention & management of infections including ophthalmia neonatorum and cord infections	-Early management of newborn by mothers, CHWs and TBAs -Recognition and management of birth asphyxia by CHWs -Identification and management of hypothermia by CHWs	-Early management of newborn by mothers and TBAs -Recognition and management of birth asphyxia by TTBAs -Identification and management of hypothermia by TTBAs	-Current practices

	Interventions	Study Arm #1: Home-based Care Model (HC)	Study Arm #2: Community Clinic Model (HC)	Study Arm #3: Comparison communities
First month of life: newborn	-Early & exclusive breastfeeding -Prevention & management of infections including cord infections	-Promotion of exclusive breastfeeding by CHWs -Management of cord and skin infection by CHW s at home -Recognition (during home visits) and referral to UHFWCs and THCs of sick neonates by CHWs -Treatment of sick neonates referred by CHWs at UHFWCs and THCs -Treatment of sick neonates at home by CHW s if the parents are not able to comply with referral	-Promotion of exclusive breast feeding by FWAs & HAs operating out of Community Clinics -Management of cord and skin infection by FWAs operating out of CCs -Recognition, referral and treatment of sick neonates by FWAs & HAs operating out of Community Clinics -Treatment of sick neonates referred by FWAs & HAs at THCs -Treatment of sick neonates at CCs by HAs if the parents are not able to comply with referral	Current practices of families, TBAs and FWA/HAs and other providers

Table 2: Types of intervention related workers and their training, tasks and supervision by study arms

Type of worker	Intervention Arm		
	HC Model	**CC Model**	**Comparison**
HA/FWA	**Number:** These are existing GoB workers. There are usually 1-2 workers per 6,000-7,000 population. About 40% of the positions are currently vacant in the proposed study site. **Training:** These workers have on the job training on selected health and family planning services. The services include maternal health but almost no neonatal health care. No additional training will be provided **Tasks:** These workers currently organize satellite clinics to immunize mothers and children, distribute contraceptives and provide limited curative care (e.g., ORT for diarrhea and co-trimoxazole for pneumonia). **Supervision**: These workers are supervised and supported by GoB Sanitary Inspectors, Family Planning Inspectors and paramedics working out of UHFWC	**Number:** Same as HC Model. The NGO-partner will recruit similar workers to fill up the vacant positions **Training:** Same as HC Model. Project will provide one month training and periodic refresher training in the following areas: -Community health education focusing on neonatal and maternal health -WHO's Mother-Baby package interventions -Identification and management of serious neonatal infections -Functioning of Community Clinics -Establishing referral linkages with higher level health facilities -Monitoring and supporting TBAs -Record-keeping and collection **Tasks**: operating out of Community Clinics: -conduct BCC, immunization, antenatal care, iron/ folate supplementation - distribute temporary contraceptive methods -Symptomatic treatment of minor illnesses and injury -Identify and refer mothers with pregnancy/ delivery/post-partum complications to higher level facilities -Refer neonates with serious infections to THC -Treat neonates with serious infections with parenteral antibiotics at CC if referral fails **Supervision**: The supervision and support for workers operating CCs will be consistent with the level of supervision that will be provided by MOH when the CCs will be functional. The system will be worked out in consultation with GoB officials. Project paramedics will provide the needed support if a GoB personnel is not available	**Number:** Same as HC Model **Training:** Same as HC Model **Tasks:** Same as HC Model **Supervision**: Same as HC Model

Appendix 4
PROJECT DOCUMENTS TO BE DEVELOPED

Operations Manuals

Baseline Ethnographic Study
Census and Mapping
Vital Statistics
Verbal Autopsy
Obstetric and Neonatal Care
Home Management of Neonatal Sepsis
Colonization with Antibiotic-Resistant Bacteria
Cost-Effectiveness Analysis

Data Collection Instruments

Baseline Ethnographic Study
Census and Mapping
Vital Statistics
Verbal Autopsies
Obstetric and Neonatal Care
Home Management of Neonatal Sepsis
Colonization with Antibiotic-Resistant Bacteria
Cost-Effectiveness Analysis

Personnel Requirements

The following personnel will be required:

Task	**Qualification of professional staff**	**Qualifications of field staff**
Baseline ethnographic study	Anthropologist	Data Collectors with at least a 10^{th} grade education
Design and field testing of intervention	Communication Specialist, Pediatrician/Neonatologist, Obstetrician, Epidemiologist	Community Health Workers with at least 10th grade of education
Census, mapping, and baseline survey	Epidemiologist/Demographer	Data Collectors with at least a 10^{th} grade education
3-monthly demographic data and verbal autopsy	Epidemiologist/ Public Health Physician/Pediatrician	Data Collectors with at least a 10^{th} grade education
Neonatal care, home or CC management of infection	Epidemiologist, Public Health Physician, Pediatrician/\Neonatologist	Community health workers with at least a 10^{th} grade education
Data quality assurance and validation of verbal autopsies	Epidemiologist/ Public Health Physician/Pediatrician	Field supervisors with at least Bachelor's Degree and field experience Project physician
Data management and analysis	Data Manager/Programmer	Data management assistant

	HC Model	CC Model	Comparison
CHW	**Number**: One/6000-7000 population. **Training:** The CHWs will receive one month training and regular refresher training on the following areas: -Community health education focusing on neonatal and maternal health -WHO's Mother-Baby package interventions -Identification and management of serious neonatal infections -Establishing referral linkages with health facilities -Monitoring and supporting TBAs. -Record keeping and data collection **Tasks: -** Conduct behavior change communication (BCC) on WHO mother-baby package intervention -Refer pregnant mothers to health facilities for TT immunization, antenatal care, and pregnancy/ delivery/post-partum complications -Attend deliveries to assist TBAs and to provide newborn care including resuscitation of asphyxiated babies -Make scheduled home visits to identify and manage sick neonates -Refer neonates with serious infections to THC - Treat neonates with serious infections with parenteral antibiotics at home if referral fails **Supervision:** The HC clusters will be divided into 4 blocks. A project nurse/paramedic will be responsible to supervise/ support 1 block. Each CHW will be visited at least once in a month. The project nurse/paramedics will arrange fortnightly meetings to discuss and resolve problems and to replenish supplies.	None	None
TBAs	**Number**: One TBA per 1,000 population will be identified and trained. **Training:** The TBAs will receive 21 days training over a 6 months period on the following topics: -Community health education focusing on neonatal and maternal health -WHO's Mother-Baby package interventions including clean and safe delivery and identification and referral of pregnancy, delivery and post-partum complications - Identification and management of birth asphyxia -Identification and referral of serious neonatal infections -Establishing referral linkages with health facilities		Families will continue to seek usual care from existing TBAs and other service providers
Paramedics/ FWV at UHFWC	**Number:** one per 25,000 pop based in the UHFWC. **Training:** These workers have 18 months training on family planning and maternal care and on the job training on essential services. Project will provide additional one week training on: - Identification and management of pregnancy, delivery and post-partum complications -Identification and management of serious neonatal infections -Establishing referral linkages with the field -Monitoring and supervision of field activities **Tasks:** Provide preventive (e.g., antenatal care, TT immunization) and limited curative care - Organize satellite clinics - Support FWAs - Manage pregnancy, delivery and post-partum complications and refer cases requiring blood transfusion, C-section etc to THC/District Hospital -Identification of serious neonatal infections and refer them to THC -Establishing referral linkages with the field -Monitoring and supervision of field activities		
Doctors at THC	**Number**: 8-9 doctors per 250,000 pop based in the THC **Training:** They have a 5 year medical degree. However, most of them are not trained to do C-section . Project will organize one week refresher training in ICMH and Shishu Hospital on: - Identification and management of pregnancy, delivery and post-partum complications -Identification and management of serious neonatal infections		

Training Requirements

Training of the following personnel is required:

Title	Training
Enumerators	accurate determination and recording of all live births, neonatal deaths and infant deaths in assigned communities
	accurate performance of verbal autopsy
Village health workers	provision of neonatal care hygiene during delivery and the post-partum period neonatal resuscitation newborn warming and skin care early institution of breast feeding ocular prophylaxis for ophthalmia neonatorum measurement of birth weight identification of high risk neonates management of superficial skin infections recognition of neonates with sepsis administration of oral and parenteral antibiotics record keeping
Field supervisors	quality control
Project physician	quality control validation of verbal autopsies

Appendix 5
DRAFT TRAINING METHODOLOGY AND CURRICULUM

Topic	Methods	Duration
Community health education	Theoretical Video exercise Role plays Field practice	6 half days=3 days
Essential safe-delivery	Theoretical Video exercise Role plays Clinical practice	18 half days=9 days
Essential newborn care: - use of neonatal care kits - hygienic neonatal care, including hand-washing and neonatal umbilical cord and skin care - thermal control of newborn - early, exclusive breastfeeding - ocular prophylaxis	Theoretical Video exercise Role plays Clinical practice	18 half days=9 days
Recognition and management of serious neonatal infections: - Recognition of serious neonatal infections - Classification of neonatal condition - Identification of treatment - Measurement of correct antibiotic dose - Practicing injections under supervision - Counseling the mother - Feeding counseling - Management of cases	Theoretical Video exercise Role plays Clinical practice	30 half days=15 days
		Total=36 days

Appendix 6

Draft Guides for data collection activities in the formative research phase of the study "Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh"

A. Semi-structured interviews with women who have recently delivered

I Identity of the care-providers

Who provides newborn care during the first week of life?

1) The grandmother? Y/N
   i) Which days? Day 1,2,3,4,5,6,7
   ii) Which tasks? Describe
   iii) What percent of the time?
2) The mother? Y/N
   i) Which days? Day 1,2,3,4,5,6,7
   ii) Which tasks?
   iii) What percent of the time?
3) Others? Y/N
   i) Whom?
   ii) Which days? Day 1,2,3,4,5,6,7
   iii) Which tasks?
   iv) What percent of the time?
4) Are there particular tasks performed by the mother, the grandmother, the traditional birth attendant, etc? Describe:_____
5) Who assisted with delivering the baby?
   (a) Midwife
   (b) Traditional birth attendant
   (c) Physician (OB)
   (d) Other physician: _____
   (e) Grandmother
   (f) Other family member _____
   (g) No one
6) Was the delivery prolonged (took an usually long time)? Y/N
7) Was the delivery complicated? Y/N
8) Were medications given to speed up the delivery? Y/N

II Identity of those providing advice about newborn care during pregnancy and during the first week of life

9) Who provided advice to you during pregnancy and during the first week after delivery about newborn care
   a) Physician (OB)
   b) Physician (pediatric)
   c) Traditional birth attendant
   d) Nurse
   e) Grandmother
   f) Other relative: _____
   g) Other: _____
10) I received advice from a health care provider about:
   a) importance of tetanus immunization during pregnancy Y/N
   b) the importance of breastfeeding Y/N
   c) the importance of giving the first milk (colostrum)
   d) the importance of starting breastfeeding within an hour of birth Y/N
   e) the importance of exclusive breastfeeding, i.e., giving nothing else such as sugar water or bottle feeding Y/N
   f) I was discouraged from giving sugar water or other feeds besides breastmilk such as formula Y/N
   g) how to breastfeed Y/N
      attachment of the baby Y/N
      position of the baby Y/N
      other Y/N
   h) how to address breastfeeding problems such as

breast engorgement Y/N
sore nipples Y/N
fissuring of nipples Y/N
other Y/N

i) the importance of handwashing after diaper changes Y/N
j) the importance of keeping the baby warm Y/N
i) drying the baby immediately after birth Y/N
ii) wrapping the baby immediately after birth Y/N
iii) putting a hat on the baby to help him/her stay warm Y/N
k) care of the umbilical cord Y/N
i) cleaning the umbilical cord Y/N
ii) putting a dressing on the umbilical cord Y/N
iii) What else?
l) bathing practices Y/N
i) frequency of bathing Y/N
ii) whether or not to use soap Y/N
iii) whether to immerse the baby or pour water over the baby
iv) drying immediately after the bath
m) skin care
i) were you advised to apply anything to the skin Y/N
ii) what were you advised to apply? _____
n) recognition of danger signs Y/N
i) how to recognize diarrhea Y/N
ii) how to recognize pneumonia or breathing difficulties Y/N
iii) how to recognize infection of the umbilical cord Y/N
iv) how to recognize skin infection
v) other danger signs: _____
o) were you encouraged to seek help if your baby developed danger signs? Y/N
p) from whom were you encouraged to seek help if your baby has danger signs
i) traditional birth attendant
ii) nurse/midwife
iii) healer
iv) private physician
v) government physician
vi) other: _____
q) where were you told to go if the baby has danger signs
i) stay at home and call the traditional birth attendant
ii) stay at home and call the nurse/midwife
iii) private clinic or hospital
iv) government clinic
v) other: _____
r) were you advised to seek routine postnatal care on:
i) day 2
ii) day 4
iii) day 6
iv) other: _____

III Recognition of birth asphyxia

11) Did the baby have a problem with not breathing or getting enough oxygen at birth? Y/N
12) Was the baby blue after birth? Y/N
(a) All over
(b) Hands and feet only

13) Was the baby very pale after delivery? Y/N
14) Did the baby have any spontaneous movements after birth? Y/N
15) Did the baby cry on its own/spontaneously within the first few seconds after birth? Y/N
16) Did the baby need assistance with breathing immediately after birth? Y/N
17) What assistance was given?
(a) Smelled an onion or garlic
(b) Tap on the back
(c) Head position was changed
(d) Suctioned from the mouth and/or nose
(e) Mouth-to-mouth resuscitation

18) Was the baby capable or not of suckling immediately after birth? Y/N
19) How did the baby suckle?
    (a) Fed well
    (b) Fed poorly
    (c) Could not feed

IV Feeding practices

20) How soon after birth did you first breastfeed the baby?
    (a) Within 1 hour
    (b) Within 4 hours
    (c) Within 12 hours
    (d) Within 24 hours
    (e) Longer than 24 hours
21) Did you have any trouble breastfeeding? Y/N
22) What breastfeeding problems did you have?
    a) Baby could not latch
    b) Baby could not get enough milk
    c) Breasts were too sore to feed
    d) Breasts became engorged
    e) Breasts became infected (abscess/mastitis)
23) Did you seek advice regarding this problem with breastfeeding? Y/N
24) From whom did you seek advice:
    a) Grandmother
    b) Traditional birth attendant
    c) Nurse/midwife
    d) Physician
    e) Sister
    f) Neighbor
    g) Other: _____
25) Were you referred to a health care provider for this problem? Y/N
26) To whom were you referred?
    a) Traditional birth attendant
    b) Nurse/midwife
    c) Private physician
    d) Government doctor
    e) Other
27) Did you give anything besides breastmilk during the first week of life?
28) If yes, what else did you give?
    (a) Sugar water
    (b) Honey
    (c) Oil
    (d) Other
29) How often/how many times?
    (a) Only once
    (b) 2-3 times
    (c) 4-6 times
    (d) 7 or more times
30) For how many days was it given?
    (a) 1 day
    (b) 2 days
    (c) 3-4 days
    (d) 5-7 days
31) How was it given?
    (a) Spoon
    (b) Bottle
32) Baby fed colostrum (the first milk)? Y/N

V Thermal control

33) Did you dry the baby immediately after delivery? Y/N
34) When (how long after birth)?
    (a) Within 1 min
    (b) Within 5 min

(c) Within 15 min
(d) Within 1 hour
(e) Longer than 1 hour

35) By whom?
(a) Physician
(b) Midwife
(c) Traditional birth attendant
(d) Mother
(e) Grandmother
(f) Sister
(g) Other relative

36) What was used to dry the baby?
a) Clean towels
b) A cloth
c) Other: _____

37) Did you warm the room for the delivery? Y/N
38) Did you warm the room at other times for the baby's sake during the first week of life? Y/N
39) When?
40) For what reason?
(a) The baby was cold
(b) To prevent the baby from becoming cold
(c) Other

41) Did you or anyone else wrap the baby in clothes immediately after delivery? Y/N
42) If yes, what was used to wrap the baby?
(a) Blanket
(b) etc

43) Were the clothes used to wrap the baby clean? Y/N
44) Who wrapped the baby?
(a) Physician
(b) Midwife
(c) Traditional birth attendant
(d) Grandmother
(e) Sister
(f) Other relative

45) How soon after delivery was the baby wrapped?
(a) Within 1 min
(b) Within 5 min
(c) Within 15 min
(d) Within 1 hour
(e) Longer than 1 hour

46) Was a hat placed on the baby after delivery? Y/N
47) How often was a hat worn during the first week of life?
a) Every day
b) Only the day of delivery
c) Just now and then

48) How long after birth did the first hug of the baby occur?
(a) Within 1 min
(b) Within 5 min
(c) Within 15 min
(d) Within 1 hour
(e) Longer than 1 hour

49) If longer than 5 min, why?
(a) The baby was sick
(b) Mother was sick
(c) Others were hugging the baby

50) Did you have skin-to-skin contact with the baby (i.e., the baby was still naked and was placed on the mother's chest/abdomen) immediately after birth or any time during the first week? Y/N
51) When? Immediately after birth? Y/N
52) What other times?_____
53) Did the baby ever feel cold to you? Y/N
54) If yes, how did you tell?
(a) Baby felt cold to the touch
(b) Someone else told me the baby was cold
(c) Temperature was measured

55) What did you do about it?
   (a) Wrapped the baby in more clothes/blankets
   (b) Heated the room
   (c) Breastfed the baby
   (d) Skin-to-skin contact

VI Hygienic practices

56) Do you wash your hands before handling the baby?
   (a) Always
   (b) Sometimes
   (c) No
57) Do you wash your hands after diaper changes?
   (a) Always
   (b) Sometimes
   (c) No
58) What do you use to clean your hands?
   (a) Water
   (b) Soap
   (c) Spirit (alcohol)
   (d) Other disinfectant: name_____
   (e) Other

VII Umbilical cord care

59) Did you clean the umbilical cord? Y/N
60) How often?
   (a) Once daily
   (b) Twice daily
   (c) Three times daily
   (d) Every other day
   (e) Twice during the first week
   (f) Once during the first week
61) With what?
   (a) Water
   (b) Soap and water
   (c) Spirit (alcohol)
   (d) Other
62) What did you apply the cleanser with?
   a) hands
   b) cotton ball
   c) clean cloth
   d) other_____
63) Did you apply anything to the umbilical cord? Y/N
64) What?
   (a) Antiseptic? Name the antiseptic
      1. Gentian violet
      2. Triple dye
      3. Chlorhexidine
      4. Spirit (alcohol)
      5. Other antiseptic
   (b) Dust?
   (c) Other?
65) How often/how many times?
   (a) Once daily
   (b) Twice daily
   (c) Three times daily
   (d) Every other day
   (e) Twice during the first week
   (f) Once during the first week
66) Did you keep the umbilical cord covered? Y/N
67) With what?
   (a) Sterile dressing
   (b) Cloth

(c) Other

68) Did the diaper cover the umbilical cord? Y/N
69) Were any problems with the cord encountered? Y/N
70) What?
(a) Redness
(b) Tenderness
(c) Pus
(d) Oozing
(e) Other
71) How did you deal with the problem?
(a) Went to see the government doctor
(b) Went to a private clinic
(c) Went to see a healer
(d) The midwife/nurse was summoned
(e) The traditional birth attendant was summoned
(f) Took care of it myself
(g) Cleaned the umbilicus more frequently
(h) Other

VIII Bathing practices

72) Did you bathe the baby during the first week? Y/N
73) How old was the baby when the first bath was given?
(a) Less than 6 hours
(b) 7-24 hours
(c) 1-2 days
(d) 3-4 days
(e) 5-7 days
74) Did you use anything to clean the baby? Y/N
75) Soap? Y/N
76) What kind of soap?
77) Was anything else used to bathe/clean the baby? Y/N
78) What?
79) Did you immerse the baby in water or did you mainly pour water over the baby?
(a) Immersed the baby except for the head
(b) Immersed just part of the baby
(c) Just poured water over the baby
(d) Used a cloth to wipe off the baby only
(e) Other
80) Did you warm the room before the bath? Y/N
81) Was the bath water heated? Y/N
82) Was the baby dried after the bath? Y/N
83) With what?
(a) Clean towel
(b) Other
84) How many times did you bath the baby during the first week of life?
(a) Once
(b) 2-3 times
(c) 3-4 times
(d) 5-6 times
(e) Every day
(f) More than once a day
85) If more than once a day, why?
86) How long did the typical bath take?
(a) Less than 1 min
(b) 1 to 5 min
(c) 6 to 15 min
(d) 16 to 30 min
(e) More than 30 min

IX Clothing/diapering

87) Did you change the baby's clothes after the bath? Y/N
88) Did you change the baby's clothes at times other than the bath? Y/N

89) How frequently?
   (a) More than once each day
   (b) Once daily
   (c) Every other day
   (d) Every 3 to 4 days
   (e) Every 5 to 7 days
90) What kind of diapers did you use?
   (a) Nappy
   (b) Other:
91) How many times per day did you change the diaper?
   (a) Whenever the baby had a bowel movement
   (b) Before each feeding
   (c) After each feeding
   (d) 3 or less
   (e) 4-6
   (f) 7-9
   (g) 10-12
   (h) More than 12

X Skin care practices

92) Did you see white substance (i.e., vernix) on the baby at birth? Y/N
93) Did you or anyone else attempt to wipe off the white substance (i.e., vernix) present on the skin at birth? Y/N
94) How?
95) Did you rub it off with clothes?
96) Did you attempt to remove it during bathing?
97) Did you apply anything (e.g., oil, lotion) to the baby's skin during the first week of life?Y/N
98) When was it applied for the first time?
   (a) Within 6 hours of birth
   (b) 7-24 hours of birth
   (c) 1-2 days of birth
   (d) 3-4 days of birth
   (e) 5-7 days of birth
99) What was applied?
   (a) Oil
   (b) Lotion
   (c) Cream
   (d) Talcum powder
100) How often/how many times was it applied?
   (a) Once daily
   (b) 2 to 3 times daily
   (c) More than 3 times daily
   (d) Once every other day
   (e) Once or twice in the week
101) Did you apply it to the skin after the bath? Y/N
102) Did you apply if to the skin at other times besides after bathing?Y/N
   (a) Each morning
   (b) Each evening
   (c) With diaper changes
   (d) Other
103) For how long do you plan to apply it?
   (a) For 1 day
   (b) For 2-7 days
   (c) For 1-2 weeks
   (d) For 3-4 weeks
   (e) For 1-2 months
   (f) For more than 2 months
104) What was the reason for applying it?
   (a) To keep the baby well
   (b) To prevent cough and cold
   (c) To prevent serious infection
   (d) To keep the baby warm
   (e) To prevent skin infection
   (f) To make the skin more smooth (improve the appearance of the skin)

(g) As a traditional practice

105) Who instructed you to apply it?
- (a) Physician
- (b) Midwife
- (c) Traditional birth attendant
- (d) Grandmother
- (e) Other relative
  1. Who?
- (f) Neighbor

106) If you were given an oil by the doctor that might help your baby and would not be harmful, would you be willing to apply it? (i.e., would they be willing to participate in an emollient trial)? Y/N

107) If no, why not?

108) Did your baby develop any infection or injury on the skin? Y/N

109) If yes, what was it?
- (a) Burn
- (b) Abrasion
- (c) Cut
- (d) Scabies
- (e) Impetigo
- (f) Other

110) How did you treat it?
- (a) Washed the area
- (b) Other_____

111) What did you use to wash the area?
- (a) Water
- (b) Soap
- (c) Spirit (alcohol)
- (d) Other disinfectant _____
- (e) Other

112) Did you apply anything to the area of injured/infected skin? Y/N

113) What?
- (a) Ointment
- (b) Oil
- (c) Lotion
- (d) Cream
- (e) Antibiotic
- (f) Which one?

114) Did you cover the area? Y/N

115) With what?
- (a) Bandage
- (b) Cloth
- (c) Other

116) Did you take any special precautions to avoid injury to the baby's skin? Y/N

117) What did you do?
- (a) Kept the skin covered
- (b) Applied an ointment/cream/lotion
- (c) Handled the baby as little as possible
- (d) Other

118) Did your baby develop a diaper rash during the first week of life? Y/N

119) What did you do about it?
- (a) More frequent changing of the diaper
- (b) Leave the diaper off
- (c) Applied something to the skin in the diaper area? Y/N

120) What did you apply to the skin in the diaper area?
- (a) Oil
- (b) Lotion
- (c) Cream
- (d) Powder
- (e) Diaper rash medicine (name)

XI Recognition of danger signs

121) Did your baby have any danger signs during the first week of life? Y/N

122) When did you see the sign(s)?

a) At birth
b) First day of life
c) Day 2
d) Day 3
e) Day 4 or 5
f) Day 6 or 7

123) Did the baby have swelling of the scalp after birth (i.e., caput)? Y/N
124) Did the baby have discharge from the eyes? Y/N
125) Describe the discharge from the eyes:
    (a) Watery
    (b) Pus
    (c) Bloody
126) Did the baby have red conjunctivae? Y/N
127) Did the baby have bleeding in the white of the eyes (i.e., conjunctival hemorrhage)? Y/N
128) Did the baby have marks on the face or head after birth? Y/N
129) Where?
130) Did the baby have any bruises on the body after birth? Y/N
131) Where?
132) Did the baby have decreased movement of abnormal position of an arm (e.g., Erb's palsy)? Y/N
133) Did the baby develop a distended belly? Y/N
134) Describe (what did it look like?).
135) Did the baby develop vomiting? Y/N
136) How many times did the baby vomit?
    (a) Once per day
    (b) 2 to 3 times per day
    (c) 4 or more times per day
137) What did it look like?
    (a) Curdled milk
    (b) Greenish (i.e., bile)
    (c) Bloody
    (d) Other
138) Did the baby develop diarrhea? Y/N
139) Describe the diarrhea:
    (a) Watery
    (b) Bloody
    (c) Mucous present
    (d) Other
140) When did you first notice the diarrhea?
    (a) First day
    (b) Day 2-3
    (c) Day 4-5
    (d) Day 6-7
141) How many days did the diarrhea last?
a) 1 day
b) 2-3 days
c) 4 to 7 days

142) Did the baby develop any breathing difficulties? Y/N
143) Did the baby have periods of not breathing? Y/N
144) How long?
    (a) Less than 15 seconds
    (b) More than 15 seconds
145) Breathing fast? Y/N (i.e., more than 60/min)
146) Was the baby grunting? Y/N
147) Chest indrawing? Y/N
148) Cough? Y/N
149) Did you feel that the baby was hot (i.e., had fever)? Y/N
150) How could you tell?
    (a) The baby felt warm to the touch
    (b) Measured the temperature
    (c) Baby was sweating a lot
151) Did the baby stop or decrease breastfeeding after a good start? Y/N
152) When?
    (a) First day
    (b) Days 2 to 3 of life

(c) Days 4 to 5
(d) Days 6 to 7

153) Did the baby's crying stop or become weak and decreased? Y/N
154) When?
(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7
155) Did the baby's crying increase a lot; i.e., did the baby become irritable? Y/N
156) When?
(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7
157) Did the baby become very sluggish, have decreased movements, become unusually sleepy or difficult to wake up? Y/N
158) When?
(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7
159) Did the baby's body become rigid? Y/N
160) Did the baby have fits or convulsions?
161) Did his color change to blue/cyanotic?
162) Did the baby develop jaundice? Y/N
163) When was the jaundice first noticed?
(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7
164) Was there any bleeding anywhere in the baby's body? Y/N
165) Where?
166) Did the umbilical stump have any oozing or pus? Y/N
167) Did the umbilical stump have any tenderness? Y/N
168) Did the umbilical stump have any bleeding?
169) Did the umbilical stump have any redness?
170) When was this first noticed?
(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7
171) Did the baby have any pustules on the skin? Y/N
172) Where? (Mark all that apply)
(a) Head
(b) Trunk
(c) Arms/legs
173) Other rash on the skin? Y/N
174) Describe location
(a) Head
(b) Trunk
(c) Arms/legs
175) What did it look like? _____
176) Is your baby now
a) healthy
b) sick
c) dead
177) If you baby died, where did he/she die:
a) at home
b) at the government health facility
c) at a private clinic
d) at a private hospital
e) other
178) If you baby developed danger signs (answer the following):
a) Sign/problem:

b) What was done:

i) Nothing, I did not think it was important

ii) Nothing, a relative told me it was not important

Who told you this?

Grandmother
Sister
Neighbor
Other?_____

iii) The traditional birth attendant was summoned

iv) The nurse/midwife was summoned

v) The baby was taken to be evaluated by a health care provider. Y/N

vi) To whom did you go for help?

Private physician
Government facility
Traditional birth attendant
Nurse/midwife
Healer
Other person in the community

vii) When did you seek help?

i. On the first day the sign was noticed
ii. Days 2 to 3 after the sign was noticed
iii. Days 4 to 5
iv. Days 6 to 7

viii) Did you follow the advice given? Y/N

If not, why not?

Against tradition or customs.
Against beliefs
Too expensive
Too difficult to do
I didn't think it would help
I didn't have any confidence in the health care provider.

179) Did you take the baby for routine evaluation by a health care professional during the first week of life? Y/N

180) When?

(a) First day
(b) Days 2 to 3 of life
(c) Days 4 to 5
(d) Days 6 to 7

181) To whom?

(a) Private physician
(b) Governmental physician
(c) Traditional birth attendant
(d) Midwife
(e) Healer
(f) Other person in the community.
1. Who?

182) Was a problem discovered? Y/N

183) What problem?

184) What advice was given about the problem?

185) What did you do for the problem?

B. Example of a scenario to be presented to pregnant or recently delivered women

Salma has 2 boys and just had a baby girl, Farida, in August. The Traditional birth attendant attended her delivery and said every thing was OK, and advised her not to nurse the baby before next day, and to start giving him sugar water. In the next day, Salma was changing Farida's diaper and noticed a few yellowish discharge around the umbilicus. She started breast feeding her as advised. She was happy nursing the baby about every couple of hours. On the third day, she noticed more yellow discharge around the baby's umbilicus. The baby was sleepy almost all day long and didn't even cry as usual and didn't want to suckle when given the breast. At around sunset, Salma tried again to breast feed her and carried her. She felt the baby is hot. Her mother in law told her not to worry, it's just too hot outside and this is the reason why the baby feels hot and that she just needs to sleep that is why she doesn't want to suckle on her breast.

1. What do you think about the traditional birth attendant's advice?

2. Why do you think it is bad advice?

3. Is there anything worrying about the baby?

4. Is there anything specific about the baby's condition that concerns you?

5. What would you do in this situation?

C. Observation of delivery practices of traditional birth attendants in the home

This questionnaire is given to the mother and any birth attendant identified. The individual administering the questionnaire will also observe and make notes on care practices and danger signs observed.

I Preparation for delivery

1) Did the birth attendant wash her/his hands with soap before delivery? Y/N
2) Did she/he use a disinfectant (e.g., spirit) on her/his hands before delivery? Y/N
3) Did she/he sterilize the equipment used for delivery by
    a. Washing with soap and water
    b. Boiling in water
    c. Neither

II During delivery: maternal care

4) Who was the birth attendant during labor and delivery of the baby?
    a. Midwife
    b. Daya
    c. Physician (OB)
    d. Other physician: _____
    e. Grandmother
    f. Other family member _____
5) At what stage was the birth attendant summoned?
    a. When contractions first began
    b. When strong contractions began
    c. When the water broke
    d. When a problem developed
    e. What problem developed?
    f. Other_____
6) Where did the delivery occur?
    a. Home
    b. Private clinic
    c. Private hospital
    d. Governmental clinic
    e. Governmental hospital
7) Did the birth attendant wash the perineum with disinfectant solution? Y/N
8) Instruments used during delivery included:
9) Forceps
10) Ventouse
11) Was a Caesarian section performed (in the home)? Y/N
12) Were drugs or injections given during delivery?Y/N
    a) To speed labor
    b) Pain killers
    c) Others:
13) Was anesthesia given during delivery (i.e., ether inhalation) Y/N
14) Was an episiotomy performed?Y/N
15) Did a perineal tear occur? Y/N
16) Where was the perineal tear/episiotomy repaired?
    a. In the home by the birth attendant
    b. In the home by a physician who was summoned
    c. At a health care facility to which the mother was referred
17) Did the birth attendant pull on the umbilical cord to help get the placenta out?
    a. Yes
    b. No
    c. Don't know
18) Did the birth attendant milk the cord to get more blood into the baby?
    a. Yes
    b. No
    c. Don't know

III During delivery: neonatal care

19) Did the baby need assistance with breathing immediately after birth

a. No assistance was needed
b. The baby was given an onion to smell. Received a tap on the back
c. Immersed in water
d. Held upside down
e. The baby was laid down and the head was positioned to allow for breathing
f. Suctioned the mouth and nose
g. Mouth-to-mouth resuscitation
h. Other

20) How was the umbilical cord cut?
a. Sterile scissors
b. Non-sterile scissors
c. New razor blade
d. Used razor blade
e. Other_____

21) How was the umbilical cord tied?
a. Umbilical cord clamp
b. Sterile thread
c. Non-sterile thread
d. Leaves
e. Other

22) Was anything else applied to the umbilical cord after being cut? Y/N
a. Gentian violet antiseptic
b. Triple dye antiseptic
c. Chlorhexidine antiseptic
d. Alcohol (spirit) antiseptic
e. Other antiseptic
f. Dust
g. Other

23) Was the baby dried immediately after delivery?
a) Face and/or head only
b) Whole body
c) No

24) What was used to dry the baby?
a. Clean towels designated for drying the baby
b. A cloth was found and used (not specially designated for the baby)
c. Other: _____

25) Was the baby wrapped immediately after delivery?
a) Yes
b) No, but the baby was placed on the mother's chest/abdomen naked immediately after delivery
c) No

26) Were the clothes used to wrap the baby clean? Y/N
27) Was a hat placed on the baby after delivery? Y/N
28) Did the birth attendant encourage the mother to breastfeed? Y/N
a) Immediately after birth
b) Within the first hour
c) Within the first 2-4 hours
d) Within the first 5-12 hours
e) Within the first 13-24 hours

29) Did anyone attempt to wipe off the white substance (i.e., vernix) present on the skin at birth? Y/N
30) Was anything applied to the baby's eyes after birth?
a) Nothing
b) Antibiotic
c) Don't know
d) Other _____

31) Was the baby given an injection after birth? Y/N
a) No
b) Vitamin K
c) Antibiotic
d) Other
e) Don't know

32) Was anything applied to the baby's skin after delivery?
a. No
b. Oil
c. Ointment

d. Powder
e. Other _____

33) Was the baby examined by the birth attendant? Y/N
34) Was the baby weighed? Y/N
35) The baby was
a) usual size
b) very small
c) small
d) large
e) very large
36) The baby was premature
a) less than 6 months
b) between 6 to 7 months
c) between 7 to 8 months
d) between 8 to 9 months
e) don't know
37) What was the actual weight of the baby in grams?_____
38) If the baby was small/very small or large/very large, or born premature, did the birth attendant advise the mother to have the baby seen by a health care provider? Y/N
39) If answer to question above is yes, where was the mother advised to take the baby?
a) Private office
b) Private hospital
c) Government clinic
d) Government hospital
e) Other:_____
40) Did the newborn have any injuries (birth trauma)? Y/N (SHOW ME)
41) Were there any noticeable congenital anomalies? Y/N (SHOW ME)

IV Postnatal care: maternal care

42) Did the birth attendant educate the mother about danger signs during the week after delivery:
a) Fever Y/N
b) Uterus not decreasing toward normal size Y/N
c) Uterus not becoming hard Y/N
d) Bleeding Y/N
e) Expect normal lochia (some bloody vaginal discharge is normal) Y/N
f) Abnormal bleeding (e.g., more than 1 pad per hour) Y/N
g) Foul smelling vaginal discharge Y/N
h) Dysuria Y/N
i) Other _____

43) Did the birth attendant provide advice about breastfeeding
a) Attachment of the baby Y/N
b) Position of the baby Y/N
c) How to address breast engorgement Y/N
d) How to address sore nipples Y/N
e) How to address fissuring of nipples Y/N
f) Other Y/N
44) Did the birth attendant visit again to see the mother during the first week after delivery? Y/N
a. On the first day after delivery
b. On the second day after delivery
c. On the third day after delivery
d. On the fourth day after delivery
e. On the fifth day after delivery
f. On the sixth day after delivery
g. On the seventh day after delivery
45) Did the birth attendant examine the mother during the follow-up visit? (if more than one visit, was the mother examined on any of the visits?) Y/N
a. Breasts Y/N
b. AbdomenY/N
c. Perineum Y/N
d. Other _____
46) Did the mother have any problems after delivery? Y/N
47) What was the problem? _____

48) Did the birth attendant take care of the problem?
   a) Yes, the birth attendant took care of the problem in the home by him/herself
   b) Yes, the birth attendant referred the baby appropriately for care
   c) No, the birth attendant attempted to address the problem but the remedies did not work
   d) No, the birth attendant did not notice the problem
   e) No, the birth attendant knew of the problem but did nothing about it
   f) No, the birth attendant was not called
   g) Other
49) What did the birth attendant do about the problem?_____
   a. Did the observer confirm the problem? Y/N
   b. Did the observer discover a problem missed by the caretakers and the birth attendant? Y/N
   c. If so, what was discovered?

V **Postnatal care: neonatal care**

50) The birth attendant provided advice about:
   a) The importance of breastfeeding Y/N
   b) The importance of giving the first milk (colostrum)
   c) The importance of exclusive breastfeeding, i.e., giving nothing else such as sugar water or bottle feeding Y/N
   d) The importance of handwashing after diaper changes Y/N
   e) The importance of keeping the baby clean Y/N
   f) The importance of keeping the baby warm Y/N
   g) Cleaning the umbilical cord Y/N
   h) Putting a dressing on the umbilical cord Y/N
   i) Frequency of bathing Y/N
   j) Whether or not to use soap during bathing Y/N
   k) Whether to immerse the baby or pour water over the baby during bathing?
   l) Drying the baby immediately after the bath Y/N
   m) Were you advised to apply anything to the skin Y/N
   n) What were you advised to apply to the skin? _____
   o) How to recognize diarrhea Y/N
   p) How to recognize pneumonia or breathing difficulties Y/N
   q) How to recognize infection of the umbilical cord Y/N
   r) How to recognize skin infection
   s) Other danger signs: _____

51) Did the birth attendant visit again to see the baby during the first week after delivery? Y/N
   a. On the first day after delivery
   b. On the second day after delivery
   c. On the third day after delivery
   d. On the fourth day after delivery
   e. On the fifth day after delivery
   f. On the sixth day after delivery
   g. On the seventh day after delivery
52) Did the birth attendant examine the baby during the follow-up visit? (if more than one visit, was the mother examined on any of the visits?) Y/N
53) Was the baby's weight measured at the follow-up visit? Y/N
54) Was the umbilical cord examined? Y/N
55) Was the baby's breathing evaluated? Y/N
56) Did the baby have any problems after delivery? Y/N (The observer should look for the presence of these signs/symptoms in the baby
   a. Umbilical cord problem? Y/N, if no skip to next question.
   b. Umbilical cord redness?
   c. Umbilical cord tenderness?
   d. Umbilical cord pus
   e. Umbilical cord oozing?
57) Diarrhea? Y/N, if no skip to next question
   a. Was the diarrhea bloody?
   b. When did the diarrhea start?
   c. What was the frequency of the diarrhea
58) Vomiting? Y/N, if no skip to next question
   a. Describe the vomiting (what did it look like? Curdled milk?) _____
   b. How many times did the baby vomit?
59) Was the baby dehydrated? Y/N/I don't know

60) Unusually distended belly?
61) Skin infection (e.g., impetigo)?
62) Stopped breastfeeding after a good start?
63) Fever, Measured _____
64) Fever, tactile (felt warm)?
65) Hypothermia (baby was cold)?
66) Failure to pass urine within 36 hours of birth?
67) Failure to pass stool within 36 hours of birth? (Look for imperforate anus)
68) Breathing too fast?
69) Grunting?
70) Cough?
71) Chest indrawing?
72) Copious sputum?
73) The baby stopped crying?
74) The baby became very irritable/increased crying?
75) The baby became sleepy all the time and was difficult to wake up?
76) The baby's body became rigid all over?
77) There were fits/convulsions?
78) The baby's color changed to blue/cyanotic?
79) The baby's skin color turned yellow (jaundice)?
80) The baby had bleeding?
81) Where did the baby have bleeding?_____
82) Did the birth attendant take care of the problem?
    a) Yes, the birth attendant took care of the problem in the home by him/herself
    b) Yes, the birth attendant referred the baby appropriately for care
    c) No, the birth attendant attempted to address the problem but the remedies did not work
    d) No, the birth attendant did not notice the problem
    e) No, the birth attendant knew of the problem but did nothing about it
    f) No, the birth attendant was not called
    g) Other
83) What did the birth attendant do about the problem?_____
84) Did the observer confirm the problem? Y/N
85) Did the observer discover a problem missed by the caretakers and the birth attendant? Y/N
86) If so, what was discovered?

Community-based Interventions to Reduce Neonatal Mortality in Bangladesh
Summary Budget

	Year 1	Year 2	Year 3	Total
	US$	US$	US$	US$
ICDDR,B Including Shishu Hospital and ICMH*	303,717	261,148	181,985	746,850
Simantik	234,119	272,124	150,211	656,454
BRAC	15,000	15,000	15,000	45,000
SEARCH	10,000	10,000	10,000	30,000
SCF/Bangladesh	20,000	15,000	15,000	50,000
Total	582,836	573,272	372,196	1,528,304

* Shishu Hospital budget = US$ 52,370
ICMH budget = US$21,000

Shimantyk Budget

Personnel	Effort %	Duration (mos)	#	Rate Tk.	Rate US$	Year 1 PMs	Year 1 Amount	Year 2 PMs	Year 2 Amount	Year 3 PMs	Year 3 Amount	Total	USAID Part	SCF Part		Total
Prof.Sahela Khatun	50%	36	1		1500	12	$9,000	12	$9,450	12	$9,923	$28,373	28,373			28,373
Bazlur Rahman (Proj. Director)	10%	36	1	23,833	441	12	$530	12	$556	12	$584	$1,670	1,670			1,670
Project Officer		36	1	16,250	301	12	$3,611	12	$3,792	12	$3,981	$11,384	11,384			11,384
Accountant (Sylhet)		36	1	16,250	301	12	$3,611	12	$3,792	12	$3,981	$11,384	11,384			11,384
Liaison Officer (Dhaka)		36	1	10,833	201	12	$2,407	12	$2,528	12	$2,654	$7,589	7,589			7,589
Intervention Staff:																
Field Supervisor/Paramedics/Nurse		18	8	5,850	108	0	$0	96	$10,920	48	$5,733	$16,653	16,653			16,653
Community Health Worker		18	50	2,925	54	0	$0	600	$34,125	300	$17,916	$52,041		52,041		52,041
Porter/Messenger		30	20	2,925	54	240	$13,000	240	$13,650	120	$7,166	$33,816	33,816			33,816
Evaluation Field Staff																
Demogr. Field Worker (Baseline)		7	85		65	595	$38,675	0	$0	0	$0	$38,675		38,675		38,675
Demogr. Field Worker (Surveil)		17	50		65	0	$0	500	$34,125	350	$25,082	$59,207		59,207		59,207
Expert Co-investigator (Honararium)					400	12	$4,800	12	$5,040	12	$5,292	$15,132	15,132			
							$75,634		$117,977		$82,312	$275,923	126,001	149,923	275,923	
Local Travel																
Dhaka Sylhet Train Travel				800	15	24	$356	24	$373	12	$196	$925		925		925
Dhaka Sylhet Air Travel				4000	74	10	$741	10	$778	6	$490	$2,009		2,009		2,009
Per-diem				500	9	100	$926	100	$972	60	$613	$2,511		2,511		2,511
Within Sylhet:																
CHW (CCL Model)			25	250	5	0	$0	300	$1,458	150	$766	$2,224	2,224			2,224
CHW (CCR Model)			25	500	9	0	$0	300	$2,917	150	$1,531	$4,448	4,448			4,448
Field Workers				625	12	595	$6,887	500	$6,076	350	$4,466	$17,429	17,429			17,429
Vehicle rental (including driver)				20000	370	12	$4,444	12	$4,667	12	$4,900	$14,011	14,011			14,011
Fuel costs				12500	231	12	$2,778	12	$6,417	12	$5,063	$14,257	14,257			14,257
							$16,131		$23,658		$18,024	$57,813	52,369	5,444	57,813	57,813
Office-cum-Guest House costs (Sylhet)					500	12	$6,000	12	$6,300	12	$6,615	$18,915		18,915		18,915
(includes: furnishings, ACs, cook, guard, etc.)																
							$6,000		$6,300		$6,615	$18,915	-	18,915	18,915	18,915

Other Costs													
Training of field staff					$30,000				$30,000	30,000			30,000
TBA Training Costs					$16,667				$16,667	16,667			16,667
Incentives to TBAs to report births	births: 6,667		4		$0		$24,000		$2,667	$26,667		26,667	26,667
BCC costs					$1,000		$1,000		$1,000	$3,000	3,000		3,000
Printing costs					$2,000		$1,000		$500	$3,500	3,500		3,500
Communication charges					$2,105		$2,105		$2,105	$6,315	6,315		6,315
Stationary					$1,000		$1,000		$1,000	$3,000	3,000		3,000
Other supplies					$2,000		$2,000		$2,000	$6,000	6,000		6,000
Neonatal care kit given to village health workers					$16,239		$32,478		$0	$48,718		48,718	48,718
Other drug costs					$2,000		$1,000		$0	$3,000		3,000	3,000
Referral costs		2000	37	0	$0	12	$444	6	$222	$667		667	667
Bicycle			110	20	$2,200		$0		$0	$2,200		2,200	2,200
Motor cycle			2000	8	$16,000		$0		$0	$16,000		16,000	16,000
Computer/printer/UPS & accessories etc			1500	3	$4,500		$0		$0	$4,500		4,500	4,500
Photocopier			2500	1	$2,500		$0		$0	$2,500		2,500	2,500
Umbrella/bag (50 sets)					$400		$0		$0	$400	400		400
Community Clinic set up	25		80	0	$0	300	$24,000	150	$12,000	$36,000	27,000	9,000	36,000
Office Space Rental - Dhaka			150	12	$1,800	12	$1,800	12	$1,800	$5,400	5,400		5,400
Office Space Rental - Sylhet/Upazilas			200	12	$2,400	12	$2,400	6	$1,200	$6,000		6,000	6,000
Utilities		10000	185	12	$2,222	12	$2,222	6	$1,111	$5,556	5,556		5,556
Office furniture and small office equipment		10000	185	11	$2,037	0	$0	0	$0	$2,037		2,037	2,037
Audit costs					$1,000		$1,000		$1,000	$3,000	3,000		3,000
Contractual services and unforseen costs					$3,000		$3,000		$3,000	$9,000	9,000		9,000
Pretesting (staff, supplies, community clinics)					$4,000		$0		$0	$4,000		4,000	4,000
					$115,070		$99,450		$29,605	$244,125	118,837	125,288	244,125	244,125
Total Direct Costs					$212,835		$247,385		$136,556	$596,777	297,207	299,570	596,777	596,777
Simantyk Overhead 10%					$21,284		$24,739		$13,656	$59,678	29,721	29,957	59,678	59,678
Total Symantyk Budget					$234,119		$272,124		$150,211	$656,454	326,928	329,526	656,454	656,454

Contents of neonatal care kit given to village health workers:

	Rate (Tk)		Number of CHWs		
Brush for cleaning nails and hands	60		50		$56
Torch	100		50		$93
Wristwatch	500		50		$463
Mucus sucker	120		50		$111
Tube and mask for resuscitation	650		50		$602
Spring balance for weighing	1500		50		$1,389
Thermometer	15		50		$14
Photo album with reference pictures	500		50		$463
		Per Child	No of Children	% needing	
Baby clothes and head cover	100		6600	100%	$12,222
Blanket	150		6600	100%	$18,333
Sleeping bag	Not needed				
Breast pump for inverted nipples	35		6600	15%	$642
Spoon	25		6600	100%	$3,056
Records and file	10		6600	100%	$1,222
Soap	15		6600	100%	$1,833
Cotton - 400 gm	55	10	6600	100%	$672
Spirit - lb	70	20	6600	100%	$428
Sodium hypochloride solution	450	50	6600	100%	$1,100
Gentian violet 1%	50	50	6600	100%	$122
Tetracycline eye ointment	15		6600	100%	$1,833
			6600		
Disposable insulin syringes and needles	6		6600	25%	$183
Gentamicin vials (40 mg/ml)	10	5 doses	6600	25%	$306
Cotrimoxazole syrup	22		6600	25%	$672
Paracetamol (acetaminophen) Syrup	15		6600	25%	$458
Vitamin K (1 mg ampoules)	20		6600	100%	$2,444
					$48,718

Shishu Budget

30-Nov-00

Personnel	Effort	#	Rate US$	Year 1 PMs	Year 1 Amount	Year 2 PMs	Year 2 Amount	Year 3 PMs	Year 3 Amount	Total
Samir K Saha	10	1	2500	12	$3,000	12	$3,000	12	$3,000	$9,000
Manzoor Hussain	3	1	2917	6	$525	12	$1,050	6	$525	$2,100
Lab Manager	20	1	400	4	$320	12	$960	8	$640	$1,920
Research officer	35	1	375	0	$0	12	$1,575	8	$1,050	$2,625
Lab Assistant	100	1	100	0	$0	12	$1,200	8	$800	$2,000
Porter 1	100	1	125	0	$0	12	$1,500	8	$1,000	$2,500
Porter 2	100	1	125	0	$0	12	$1,500	8	$1,000	$2,500
					$3,845		$10,785		$8,015	$22,645
Local Travel										
Dhaka Sylhet Train Travel	600	11	0		$0	120	$1,333	60	$667	$2,000
Dhaka Sylhet Air Travel	4000	74	4		$296	6	$444	3	$222	$963
Per-diem	500	9	20		$185	250	$2,315	125	$1,157	$3,657
Within Sylhet	2000	37	12		$444	12	$444	6	$222	$1,111
					$926		$4,537		$2,269	$7,731
Other Costs										
Media					$3,000					$3,000
Disposbles Glasswares etc.					$6,000					$6,000
Antisera					$6,000					$6,000
E-strips					$1,500					$1,500
Miscellaneous and unforseen costs					$1,000		$1,000		$1,000	$3,000
					$17,500		$1,000		$1,000	$19,500
Total Direct Costs					$22,271		$16,322		$11,284	$49,876
Shishu Overhead 5%					$1,114		$816		$564	$2,494
Total Shishu Budget					$23,384		$17,138		$11,848	$52,370

CDDR,B Budget

'ersonnel	Duration (mos)	Level	#	Effort	Rate US$	Year 1 PMs	Year 1 Amount	Year 2 PMs	Year 2 Amount	Year 3 PMs	Year 3 Amount	Total	USAID Part	SCF Part	
INVESTIGATORS															
Dr. Shams El Arifeen	36	P3/6	1	30%	6,808	12	$24,509	12	$25,734	12	$27,021	$77,264	$77,264		
Dr. K. Zaman	36	NO-C/11	1	20%	1,411	12	$3,386	12	$3,556	12	$3,734	$10,676		$10,676	
MANAGEMENT															
Study Coordinator	36	NO-C/5	1	100%	1,185	12	$14,216	12	$14,926	12	$15,673	$44,815		$44,815	
Training Specialist	24	NO-B/1	1	100%	790	6	$4,740	12	$9,954	6	$5,226	$19,920		$19,920	
Anthropologists/Comm. specialist	12	NO-A/1	1	100%	677	12	$8,124	0	$0	0	$0	$8,124		$8,124	
Office Manager	36	NO-A/3	1	25%	694	12	$2,082	12	$2,186	12	$2,295	$6,564		$6,564	
Data Manager	36	NO-A/5	1	25%	776	12	$2,328	12	$2,444	12	$2,567	$7,339		$7,339	
Programmer	36	GS-6/1	1	100%	473	12	$5,676	12	$5,960	12	$6,258	$17,894		$17,894	
Admin Assistant	36	GS-4/1	1	100%	280	12	$3,360	12	$3,528	12	$3,704	$10,592	$10,592		
Data Management Assistant	28	GS-3/1	4	100%	237	36	$8,525	48	$11,935	28	$7,310	$27,770	$27,770		
Office Attendant/Xerox Operator	36		1	50%	171	12	$1,026	12	$1,077	12	$1,131	$3,234		$3,234	
FIELD STAFF															
Field Research Manager	28	NO-A/1	2	100%	677	20	$13,540	24	$17,060	12	$8,957	$39,557	$39,557		
Medical Officer	18	NO-A/1	4	100%	677	8	$5,416	48	$34,121	16	$11,942	$51,479		$51,479	
Demographic Surveys															
Field Research Officer	28	GS-5/1	2	100%	361	20	$7,220	24	$9,097	14	$5,572	$21,889		$21,889	
Sr. Field Research Assistants	28	GS-4/1	8	100%	280	80	$22,400	96	$28,224	56	$17,287	$67,911	$67,911		
Baseline Qualitatative Survey Staff															
Sr. Field Research Assistants	8	GS-4/1	6	100%	280	48	$13,440	0		0		$13,440		$13,440	
Consultant							$5,000		$3,000			$8,000		$8,000	
otal Personnel Costs							$144,988		$172,803		$118,677	$436,468	$223,094	$213,373	$436,468
ocal Travel															
for Investigator and mgt. Staff			Tk.	US$	#										
Dhaka Sylhet Train Travel			800	15	24		$356	24	$373	8	$131	$860		$860	
Dhaka Sylhet Air Travel			4000	74	34		$2,519	23	$1,789	15	$1,225	$5,532	$5,532		
Per-diem (for air/train travel)			500	9	150		$1,389	150	$1,458	75	$766	$3,613		$3,613	
for field staff															
Within Sylhet							$1,000	0	$1,000	0	$500	$2,500	$2,500		
							$5,263		$4,621		$2,621	$12,505	$8,032	$4,472	$12,505

CDDR,B Supplies and Other Operating Costs								
Computer/notebook/Printers/UPS & accessories, etc.		$15,850	$0	$0	$15,850		$15,850	
Motor Cycle	8	$16,000			$16,000		$16,000	
Bicycle	10	$1,200			$1,200		$1,200	
Projector		$6,000	$0	$0	$6,000		$6,000	
Audio cassette recorder and etc.		$500	$0	$0	$500	$500		
Umbrella/clipboard/field bag		$200	$0	$0	$200	$200		
Start up cost of satellite offices (furniture etc.)		$1,481	$0	$0	$1,481		$1,481	
Rental, utilities and etc. of satellite offices		$148	$148	$49	$346	$346		
Other Supplies		$2,000	$2,000	$1,000	$5,000	$5,000		
Printing (forms/cards/others) and photocopy costs		$5,000	$2,000	$750	$7,750	$7,750		
Communications Charges		$500	$500	$500	$1,500	$1,500		
Training/workshops and dissemination		$4,500	$1,000	$2,500	$8,000		$8,000	
Fuel		$3,500	$3,500	$1,800	$8,800	$8,800		
Stationary		$1,105	$1,105	$1,105	$3,315	$3,315		
Sub-contract with BCC firm (development of training/education materials)		$8,000	$0	$0	$8,000	$8,000		
otal Supplies and Other Costs		$65,985	$10,253	$7,704	$83,942	$35,411	$48,531	$83,942
otal Direct Costs		$216,235	$187,677	$129,002	$532,915	$266,537	$266,377	$532,915
CDDR,B overhead 25%		$54,059	$46,919	$32,251	$133,229	$66,634	$66,594	$133,229
otal ICDDR,B Budget		$270,294	$234,596	$161,253	$666,143	$333,172	$332,971	$666,143
echnical Assistance sub-contract with ICMH		$7,000	$7,000	$7,000	$21,000	$10,500	$10,500	
echnical Assistance sub-contract with Dhaka Shishu Hospital		$23,384	$17,138	$11,848	$52,370	$26,185	$26,185	
otal Sub-contract		$30,384	$24,138	$18,848	$73,370	$36,685	$36,685	
CDDR,B Processing Fee	10%	$3,038	$2,414	$1,885	$7,337	$3,669	$3,669	
RAND TOTAL FOR ICDDR,B		$303,717	$261,148	$181,985	$746,850	$373,525	$373,325	$746,850

Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh
Abstract Summary for Ethical Review Committee

Despite significant declines in infant and child mortality rates in recent decades, neonatal mortality rates remain unacceptably high. Of the 8 million infant deaths that occur worldwide each year, approximately 5 million occur in the neonatal period and many more deaths occur during the second and third months of life. In many developing countries, neonatal deaths are systematically under-reported because of cultural reluctance to report. Nevertheless, an estimated 98% of the neonatal deaths occur in developing countries, mainly in Asia and Africa where many countries have a neonatal mortality rate of more than 40 per 1000 live births and several countries have rate of more than 60 per 1000 live births. Therefore, interventions need to be designed to reduce mortality in the neonatal period.

In a recent study in India, SEARCH, led by Dr. Abhay Bang, trained village health workers (VHWs) in intervention areas to provide a package of home-based neonatal care, including diagnosis and management of birth asphyxia and sepsis. Sick newborns suspected of having septicemia, meningitis and/or pneumonia received antibiotics in the home. The net percent reduction in neonatal mortality due to sepsis was 76% and neonatal mortality declined 62% compared to the control area at an estimated cost of $5.30 per neonate. Although promising, this study lacked the proper number of randomization units, having been conducted in only two areas which already had been serving as "control" and "action" areas for many years prior to introduction of the newborn care package. Moreover, mortality rates in the control area varied year-to-year from 50 to 65 per 1000, rendering statistical inference and precise calculation of the effect-size problematic. There may also have been a strong pre-existing secular trend in the intervention area, which may have been obscured in the reported data by the grouping of data for 2 years in the baseline results. Therefore, the impact observed may have been a combination of effects due to the intervention and the secular trend. Furthermore, the intervention offered was too elaborate making large scale implementation extremely difficult. Thus, the impact of a simplified package of newborn care interventions on neonatal mortality in the community must be demonstrated in other setting. The proposed research aims to evaluate the impact of a package of obstetric and neonatal care practices, including management of infections in neonates to be provided either in the Thana Health Centre (THC) or at homes or at the community clinics by trained health workers on neonatal mortality rates in a rural area of Bangladesh. The additional aims are to evaluate the impact on cause-specific neonatal mortality rates, particularly on deaths due to neonatal sepsis, using verbal autopsies; to evaluate the impact of home administration of antibiotics on colonization of neonates with antibiotic-resistant bacteria; and to evaluate the cost-effectiveness of the proposed intervention.

The purpose of this study is to develop a simple, feasible and cost-effective package of obstetric and neonatal care interventions, including management of serious bacterial infections in neonates using focused ethnographic and epidemiologic studies and to evaluate the impact of this intervention on neonatal mortality. The services will be provided by first-line community-based health workers. We plan to evaluate two different strategies for delivery of services known as: 1) Community Clinic (CC) model involving delivery of services through a community clinic infrastructure like that proposed by the Health and Population Sector Programme (HPSP) of the Government of Bangladesh, and, 2) Home-based Care (HC) model in which services are delivered at the door-step.

The study will be carried out in two rural sub-districts of Sylhet division of Bangladesh. Site selection was based on high rates of neonatal and infant mortality and home delivery, poor access to health care, and a minimum of 10,000 live births per year. Sample sizes were calculated to detect assumed differences between the treatment and comparison groups with 80% power and 95% significance level. With a baseline neonatal mortality rate of 50 per 1,000, an individually randomized study having 1604 newborns in each group would be sufficient to detect a reduction of 40% in the intervention arm. If 50% of the neonatal deaths are due to sepsis and the intervention reduces sepsis related deaths by 70%, then this sample size will also be adequate to measure the impact of the intervention on sepsis-related death. Since we plan to randomize communities, rather than individuals, we will double the sample size to account for between-community variability. We anticipate enlisting about 20 communities, and 3,208 newborns in each study arm or a total of 60 clusters and 9,624 newborns in the study.

Baseline ethnographic studies will be conducted in the study communities to assess knowledge, attitudes and practices regarding routine obstetric and neonatal care and the care of sick neonates. The findings of the ethnographic studies will be used to design the intervention as well as to design all baseline and post- intervention survey instruments. A baseline census and household survey will be conducted to map and characterize the population. The baseline census data and community maps will serve as the foundation for the collection of data on live births, neonatal deaths and infant deaths.

Individual-level allocation of these interventions will not be feasible, thus clusters will be the units of randomization. Clusters will consist of a group of geographically associated villages. Selected communities will be randomly assigned to one of the two intervention arms, or to continue current practices as the comparison arm. Mothers and first-line health workers will be trained in routine pregnancy and newborn care and in recognition of emergency obstetric signs and signs of neonatal infection. Clinic- and home-based health workers also will be trained on the management of serious neonatal infections. A formal evaluation of the skills of these workers in assessing and managing sick newborns will be conducted after the training and the report of this evalution will be submitted to ERC before phase II of study, i.e., intervention evaluation.

Functional community clinics will be established in the CC clusters. Clinic health workers will offer essential health and family planning services from these clinics as outlined in the HPSP, and will manage neonates with serious bacterial infections who attend the clinics. Since it is not known if the CC intervention will be adequate to significantly impact neonatal mortality, we will evaluate a more intensive, home-based package of services (HC) which includes active surveillance through home visits to identify and manage serious neonatal bacterial infections.

The primary outcome measure will be changes in neonatal mortality rates in the intervention and comparison communities from the beginning to the end of the study period. Cause-specific neonatal mortality rates will be measured using a standardized verbal autopsy instrument administered by trained Field Workers and confirmed by physicians upon review of the records. The proportion of neonatal mortality attributable to each cause will be compared between the intervention and comparison communities after controlling for the baseline rates.

The proportion of 1-month-old infants colonized with antibiotic-resistant bacteria will be compared in a sample of infants from the intervention and comparison areas. Colonization with antibiotic-resistant bacteria at 1 month of age will be defined as nasopharyngeal colonization with penicillin-resistant Streptococcus pneumoniae.

The cost of providing the intervention services will be determined per neonate, per neonatal sepsis case treated, and per neonatal death averted separately for the two intervention areas. Cost information on the current services will be collected for comparison.

If the CC model proves to be successful, the findings will be disseminated widely and technical assistance will be provided to scale-up the intervention in the HPSP of Bangladesh. If only the HC model is found to be adequately efficacious, further operational research will be conducted to incorporate essential features of this intervention into the HPSP of Bangladesh.

Strategies to address ethical issues:

1. The purpose of this project is to develop an intervention to reduce neonatal mortality. Therefore, it is necessary to include neonates in the study.

2. Neonates with clinically suspected serious infections, whose parents are not willing or able to take their babies to the local hospital, will receive injectable antibiotics at home or at the community clinic after obtaining consent from the parents. There can be minor risk of injury or infection at the injection site. Many of these neonates may die if the treatment is not provided. Therefore, the benefits of the intervention will out weight the risk.

3. All necessary precautions will be taken to minimize this risk. The health workers will be adequately trained and their performance will be regularly monitored by project physicians.

4. Identity of all study participants will remain confidential. Records will be used by study staff only in connection with carrying out their obligations relating to the clinical trial and every effort will be made to keep the records as confidential as possible. Data will be analyzed and published using subjects' identification number only.

5. Verbal and written informed consent will be obtained, as appropriate, from all households participating in the study. The consent forms/information sheets are attached. No information will be withheld.

6. The baseline studies, sepsis surveillance in the intervention area, and the 3-monthly surveillance will create some burden to the study families. A research staff will visit all household every three months to collect pregnancy, birth and death information. Each visit will take approximately 15 minutes.

7. The households in the intervention clusters will directly benefit from health education and provision of obstetric and neonatal care. The households in the comparison clusters will not directly benefit from their participation. However, if the intervention proves to be beneficial, the society at large will be benefited.

8. Records from Thana Health Centres, Family Welfare Centres and Community Clinics will be used. Other than nasal swab, no other specimens from study subjects will be used.

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **semi-structured interview**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to learn about the problems, perception, and care seeking patterns for delivery and newborn care services in your community. Based on that we plan to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. Only selected mothers/birth attendants in your area are being requested to participate in this study. If you agree to participate in this study, a field worker will visit your house once or twice and ask you some questions about pregnancy and delivery care, newborn care, how you recognize sick newborn, and what type of care you seek for normal and sick babies. Each home visit will take about one hour.

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **focus group interview**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to learn about the problems, perception, and care seeking patterns for delivery and newborn care services in your community. Based on that we plan to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. Only selected pregnant mothers/husbands of pregnant mothers in your area are being requested to participate in this study. If you agree to participate, you will be invited to participate in a discussion session with another 10-12 mothers/fathers in your area. We will discuss how your community takes care of pregnancy, delivery, newborn babies, and how you recognize sick newborn, and what type of care you seek for normal and sick babies. The discussion session will take about 2-4 hours.

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

(Information sheet to obtain ***verbal consent*** *from participants* ***to allow observation of deliveries)***

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to learn about the problems, perception, and care seeking patterns for delivery and newborn care services in your community. Based on that we plan to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. Only selected pregnant mothers in your area are being requested to participate in this study. We are requesting you will allow one of our female health workers to remain present during the time of delivery so that we can learn how the local birth attendants handle deliveries and what kind of post-partum care they provide to mothers and newborn babies.

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **baseline household survey**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to learn about the problems, perception and care seeking patterns for delivery and newborn care services in your community. Based on that we plan to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. All mothers in your area are being requested to participate in this study. If you agree to participate in this study, a field worker will visit your house once or twice and ask you some questions about your household, how you or your family take care of delivering babies and how you would take care of the baby after s/he is born. Each home visit will take about 30 minutes.

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **consent** from participants in the **home-based care** model area)*
ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to train mothers, birth attendants and community-based health workers in the provision of improved delivery care, newborn care, and management of serious neonatal bacterial infections to reduce deaths in the first month of life. All mothers in your area who expect to deliver in the next year are requested to participate in this study. If you agree to participate, a field worker will visit your house before the baby is born and ask you some questions about how you or your family take care of delivery and the baby after the baby is born. If you agree to participate, one of our workers will visit your house every three months for 15 months to collect information on pregnancies, births and deaths. If any of the babies in the study die, our worker will visit the home to ask questions to find out the causes of death. We understand that there is an emotional risk involved since you will be requested to discuss about your deceased child. You can refuse to participate in this part of the study or may ask the worker to come back on another day. Each home visit will take about 20 minutes.

We will send a trained health worker to your home to assist the person who is delivering your baby . She will also come to your house every few days to find out if your baby is sick. If your child gets a serious infection, the health worker will advise you to go to the nearest *thana* (sub-district) health center. If for some reason you are not able to attend the *thana* health center or another hospital, the health worker will treat your baby at home by giving antibiotic injections if you agree to such treatment. There may be pain and occasionally an infection may develop at the injection site. The health worker will take all possible precautions to reduce this risk. In addition, the health worker may collect a swab from the nose of your baby with a cotton tip applicator to examine for presence of bacteria when the baby is one month old. Your baby may or may not be selected for this component of the study. If your baby is selected for the swab or if we have to give him/her antibiotic injections at home we will seek your written consent before the procedures.

Your participation in this research project is completely voluntary. You have the right to withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. All necessary medical care resulting from your participation in this research study will be provided to you without cost. Other than medical care, you will not receive any compensation for the participation of your baby in this research project. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You should report any medical problems or concerns you may have as soon as possible to this doctor. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is an investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

(Information sheet to obtain ***consent*** *from participants in the* ***community clinic care*** *model area)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to train mothers, birth attendants and community-based health workers in the provision of improved delivery care, newborn care, and management of serious neonatal bacterial infections to reduce deaths in the first month of life. All mothers in your area who expect to deliver in the next year are being requested to participate in this study. If you agree to participate, a field worker will visit your house before the baby is born and ask you some questions about how you or your family take care of delivering babies and how you would take care of the baby after s/he is born. Thereafter, one of our workers will visit your house every three months for 15 months to collect information on pregnancies, births and deaths. If any of the babies in the study die, our field worker will visit the home to ask questions to find out the causes of death. We understand that there is an emotional risk involved since you will be requested to discuss about your deceased child. You can refuse to participate in this part of the study or may ask the worker to come back on another day. Each home visit will take about 20 minutes.

A Community-based Health Worker trained in basic delivery and newborn care and management of infections in newborn will be available in the community clinic (CC) in your area. You will be expected to attend the CC for ante-natal and newborn care. If your baby gets sick, you will be expected to attend the CC for evaluation of your baby by the health worker. If your child gets a serious infection, the health worker will advise you to go to the nearest *thana* (sub-district) health center. If for some reason you are not able to attend the *thana* health center or another hospital, the health worker will treat your baby at the CC by giving antibiotic injections if you agree to such treatment. There may be pain and occasionally an infection may develop at the injection site. The health worker will take all possible precautions to reduce this risk. In addition, the health worker may collect a swab from the nose of your baby with a cotton tip applicator to examine for presence of bacteria when the baby is one month old. Your baby may or may not be selected for this component of the study. If your baby is selected for the swab or if we have to give him/her antibiotic injections at the clinic we will seek your written consent before the procedures.

Your participation in this research project is completely voluntary. You have the right to withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. All necessary medical care resulting from your participation in this research study will be provided to you without cost. Other than medical care, you will not receive any compensation for the participation of your baby in this research. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, the forms may also be reviewed by staff members from organizations who are funding this study. By giving consent, you agree to such inspection and disclosure.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You should report any medical problems or concerns you may have as soon as possible to this doctor. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is an investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **consent** from participants in the **comparison area**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. All mothers in your area who expect to deliver in the next year are being requested to participate in this study. If you agree to participate in this study, a field worker will visit your house before the baby is born and ask you some questions about how you or your family take care of delivering babies and how you would take care of the baby after s/he is born. Thereafter, one of our workers will visit your house every three months for 15 months to collect information on pregnancies, births and deaths. If any of the babies in the study die, our field worker will visit the home to ask questions to find out the causes of death. We understand that there is an emotional risk involved since you will be requested to discuss about your deceased child. You can refuse to participate in this part of the study or may ask the worker to come back on another day. Each home visit will take about 20 minutes. In addition, the health worker may collect a swab from the nose of your baby with a cotton tip applicator to examine for presence of bacteria when the baby is one month old. Your baby may or may not be selected for this component of the study. If your baby is selected we will seek your written consent before the procedure.

Your participation in this research project is completely voluntary. You have the right to withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is an investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Form to obtain **written consent** from participants **to treat babies with serious infection at home or community clinic with injectable antibiotics**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

As you know, we are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. You also know that the purpose of this study is to train mothers, birth attendants and community-based health workers in the provision of improved delivery care, newborn care, and management of serious neonatal bacterial infections to reduce deaths in the first month of life. You and your newborn baby are currently participating in this study.

In our judgment, your baby has developed a serious infection and we advise you to go to the nearest *Thana* (sub-district) Health Center (THC). However, we understand you are either unable or unwilling to take your child to the THC or another hospital. We can treat your baby at home/ community clinic by giving antibiotic injections if you agree to such treatment. There may be pain and occasionally an infection may develop at the injection site. We will take all possible precautions to reduce this risk.

Your permission to treat your baby at home/community clinic is completely voluntary. You will be always encouraged to take your child to the THC if you decide to do so. All necessary medical care resulting from your participation in this study will be provided to you without cost. Other than medical care, you will not receive any compensation for the participation of your baby in this research project.

If you agree to allow your child to be treated at home/community clinic, please sign this form. Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By signing this form, you agree to such inspection and disclosure.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You should report any medical problems or concerns you may have as soon as possible to this doctor. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is an investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions? Yes No

Do you provide permission to treat your child at home/community clinic? Yes No

If you agree to these procedures please sign your name below.

Signature of Parent or Guardian

Witness to Consent Procedures*

Signature of Investigator

Date

**Optional, unless subject is illiterate, or unable to sign*

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION

Void One Year From Above Date
CHR #._____

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Form to obtain **written consent** from participants **for collection of nasal swab**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

As you know, we are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. You also know that the purpose of this study is to train mothers, birth attendants and community-based health workers in the provision of improved delivery care, newborn care, and management of serious neonatal bacterial infections to reduce deaths in the first month of life. You and your newborn baby are currently participating in this study.

During initial enrollment we mentioned that your baby may be selected for collection of a nasal swab to examine for presence of bacteria when the baby is one month old. Your baby has now been selected for collection of a nasal swab and we are requesting your permission to collect the swab. If you provide permission, a health worker will collect a swab from the nose of your baby with a cotton tip applicator. There is no risk in this procedure other than slight discomfort to your baby.

Your permission to collect the swab is completely voluntary. If you provide permission to collect the swab from your child, please sign this form. Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By signing this form, you agree to such inspection and disclosure.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You should report any medical problems or concerns you may have as soon as possible to this doctor. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is an investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you provide permission to collect the nasal swab from your child?	Yes	No

If you agree to these procedures please sign your name below.

Signature of Parent or Guardian

Witness to Consent Procedures*

Signature of Investigator

Date

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION

Void One Year From Above Date
CHR #._____

**Optional, unless subject is illiterate, or unable to sign*

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **worker skill evaluation**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

Explanation of Research Project:

We are from a local non-governmental organization (NGO) known as Shimantik. We are doing a study on the health of young children. We are working with the Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR,B. We would like to ask for your permission to participate in this study. The purpose of this study is to learn about the problems, perception and care seeking patterns for delivery and newborn care services in your community. Based on that we plan to develop delivery and newborn care services that can be provided by birth attendants and community health workers to ensure that the babies are delivered as safely as possible and to provide proper treatment for babies in the first month of life if they get sick. As part of this study, we have received extensive training on the assessment of the newborn and management of sick newborns. All mothers in your area are being requested to participate in this study. If you agree to participate, I will examine your newborn and ask you a few questions to determine the health of the baby. This will take about 15 minutes. In a few hours a doctor will come and also examine your baby to see if he/she is all right and to provide treatment if the baby has an illness.

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time. Even if you do not want to join the study, or if you withdraw from the study, you will still receive the same quality of medical care available to you at Shimantik health facilities and the *thana* health center. You may find some questions of sensitive nature. You may decide not to respond to those questions.

Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By giving consent, you agree to such inspection and disclosure.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR,B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR,B at 2-8810117.

Do you have any questions?	Yes	No
Do you agree to participate in this research project?	Yes	No

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **semi-structured interview**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের-জন্য আপনার অনুমতি চাইছি। সন্তান প্রসব এবং নবজাতকের স্বাস্থ্য সম্পর্কে আপনাদের ধারনা, আপনারা কি ধরনের অসুবিধার সম্মুখীন হন ও কি ধরনের সেবা গ্রহণ করে থাকেন সেটা জানাই এই গবেষনার উদ্দেশ্য। এর উপর ভিত্তি করেই আমরা নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা পরিকল্পনা করব যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথাসম্ভব নিশ্চিত করা যাবে। আপনার এলাকার কিছু সংখ্যক গর্ভবতী মায়েদের/ ধাত্রীদেরই এই গবেষনায় অংশ গ্রহনের জন্য অনুরোধ করা হচ্ছে। আপনি যদি এই গবেষনায় অংশগ্রহণে সম্মত হন তবে একজন মাঠকর্মী আপনার বাড়ী এক-দুই বার যাবেন এবং এ সকল বিষয়ে প্রশ্ন করবেন: গর্ভাবস্থা ও প্রসবকালীন সেবা, নবজাত শিশুর সেবা, নবজাত শিশু কখনও অসুস্থ হলে কি ভাবে তা আপনারা বোঝেন, এবং সুস্থ ও অসুস্থ নবজাত শিশুর জন্য আপনারা কি ধরণের সেবা গ্রহণ করেন। এ সকল প্রশ্নের উত্তর দিতে প্রতিবার প্রায় ১ ঘন্টার মত সময় লাগবে।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন?	হ্যাঁ	না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **focus group interview**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। সন্তান প্রসব এবং নবজাতকের স্বাস্থ্য সম্পর্কে আপনাদের ধারনা, আপনারা কি ধরনের অসুবিধার সম্মুখীন হন ও কি ধরনের সেবা গ্রহণ করে থাকেন সেটা জানাই এই গবেষনার উদ্দেশ্য। এর উপর ভিত্তি করেই আমরা নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা পরিকল্পনা করব যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথাসম্ভব নিশ্চিত করা যাবে। আপনার এলাকার কিছু সংখ্যক গর্ভবতী মায়েদের/ গর্ভবতী মহিলার স্বামীদেরই এই গবেষনায় অংশ গ্রহনের জন্য অনুরোধ করা হচ্ছে। আপনি যদি এই গবেষনায় অংশগ্রহণে সম্মত হন তবে আপনাকে ১০-১২ জন মা/বাবাদের সংগে একাটি আলোচনা সভায় অংশগ্রহণের জন্য অনুরোধ করা হবে। এই সভায় আমরা আলোচনা করব আপনি কিংবা আপনার এলাকার লোকজন গর্ভবতী মহিলা, সন্তান প্রসব এবং নবজাত শিশুর কিভাবে পরিচর্যা করেন; নবজাত শিশু কখনও অসুস্থ হলে কি ভাবে বোঝেন এবং আপনারা সুস্থ ও অসুস্থ নবজাত শিশুর কি ভাবে সেবা করেন। এ ধরণের আলোচনায় ২ থেকে ৪ ঘন্টা সময় লাগতে পারে।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন?	হ্যাঁ	না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants **to allow observation of deliveries**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। সন্তান প্রসব এবং নবজাতকের স্বাস্থ্য সম্পর্কে আপনাদের ধারনা, আপনারা কি ধরনের অসুবিধার সম্মুখীন হন ও কি ধরনের সেবা গ্রহণ করে থাকেন সেটা জানাই এই গবেষনার উদ্দেশ্য। এর উপর ভিত্তি করেই আমরা নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা পরিকল্পনা করব যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথা সম্ভব নিশ্চিত করা যাবে। আপনার এলাকার কিছু সংখ্যক গর্ভবতী মায়েদেরকে এই গবেষনায় অংশ গ্রহণের জন্য অনুরোধ করা হচ্ছে। আমরা অনুরোধ করছি যে যখন আপনার সন্তান প্রসব হবে তখন আমাদের একজন মহিলা স্বাস্থ্যকর্মী সেখানে থাকবেন। এর ফলে আমরা জানতে পারবো স্থানীয় ধাত্রীগণ কিভাবে প্রসব করাচ্ছেন এবং প্রসবের পর মা ও নবজাত শিশুর কিভাবে তারা পরিচর্য্যা করেন।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন?	হ্যাঁ	না

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*(Information sheet to obtain **verbal consent** from participants in the **baseline household survey**)*

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গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিন্স্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। সন্তান প্রসব এবং নবজাতকের স্বাস্থ্য সম্পর্কে আপনাদের ধারনা, আপনারা কি ধরনের অসুবিধার সম্মুখীন হন ও কি ধরনের সেবা গ্রহণ করে থাকেন সেটা জানাই এই গবেষনার উদ্দেশ্য। এর উপর ভিত্তি করেই আমরা নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা পরিকল্পনা করব যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথা সম্ভব নিশ্চিত করা যাবে। আপনার এলাকার সকল মায়েদেরকে এই গবেষনায় অংশ গ্রহনের জন্য অনুরোধ করা হচ্ছে। আপনি যদি এই গবেষনায় অংশগ্রহণে সম্মত হন তবে একজন মাঠকর্মী আপনার বাড়ী এক-দুই বার জাবেন এবং আপনার পরিবার সম্পর্কে, আপনি/আপনারা কিভাবে সন্তান প্রসবের যত্ন নেন এবং জন্মের পর কিভাবে শিশুর দেখাশোনা করেন সে বিষয়ে জিজ্ঞাসা করবেন। এ সকল প্রশ্নের উত্তর দিতে প্রায় ৩০ মিনিটের মতো সময় লাগবে।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন?	হ্যাঁ	না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **consent** from participants in the **home-based care** model area)*

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গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। এলাকার মা, ধাত্রী এবং স্বাস্থ্যকর্মীদের নিরাপদ প্রসব সেবা, নবজাতকের সেবা ও নবজাতকদের মারাত্মক অসুস্থতার চিকিৎসা প্রদানের উপর প্রশিক্ষণ দেয়ার মাধ্যমে জীবনের প্রথম মাসে মৃত্যু কমানোই এই গবেষণার উদ্দেশ্য। আগামী এক বছরে সন্তান প্রসবের সম্ভাবনা আছে এমন সকল মাকেই আমরা গবেষনায় অংশগ্রহণের অনুরোধ জানাচ্ছি। আপনি এই গবেষণায় অংশগ্রহণে সম্মত হলে একজন মাঠকর্মী আপনার শিশুর জন্মের পূর্বে আপনার সাথে বাড়িতে গিয়ে দেখা করবেন এবং আপনি ও আপনার পরিবার কিভাবে সন্তান প্রসবের যত্ন নেন এবং জন্মের পর কিভাবে শিশুর দেখাশোনা করেন সে বিষয়ে জিজ্ঞাসা করবেন। এরপর আমাদের একজন কর্মী প্রতি তিনমাস পর পর আরও ১৫ মাস আপনার সাথে দেখা করবেন এবং জন্ম, মৃত্যু, গর্ভাবস্থা বিষয়ে তথ্য সংগ্রহ করবেন। যদি গবেষণায় অংশগ্রহণরত কোন শিশুর মৃত্যু ঘটে, তবে আমাদের মাঠকর্মী আপনার সাথে দেখা করবেন এবং শিশুর মৃত্যুর কারণ বের করার জন্য বিভিন্ন প্রশ্ন করবেন। আমরা জানি যে এ ব্যাপারে প্রশ্ন করলে আপনার মানসিক অসুবিধা হতে পরে। আপনার ইচ্ছা না হলে আপনি এ সকল প্রশ্নের উত্তর নাও দিতে পারেন অথবা মাঠকর্মীকে আরেক দিন আসার জন্য বলতে পারেন। এ সকল প্রশ্নের উত্তর দিতে প্রতিবার আপনার প্রায় ২০ মিনিটের মতো সময় লাগবে।

যিনি আপনার সন্তান প্রসব করাবেন তাকে সাহায্য করার জন্য আমরা একজন প্রশিক্ষণপ্রাপ্ত স্বাস্থ্যকর্মীকে আপনার বাড়িতে পাঠাবো। তিনি কিছুদিন পর পরই আপনার বাড়িতে যাবেন আপনার শিশু সুস্থ্য আছে কি না দেখার জন্য। যদি আপনার শিশুর কোন মারাত্মক রোগের সংকমণ ঘটে, তবে স্বাস্থ্যকর্মী আপনাকে নিকটবর্তী থানা স্বাস্থ্যকেন্দ্রে যাওয়ার জন্য পরামর্শ দেবেন। যদি কোন কারণে আপনার পক্ষে থানা স্বাস্থ্য কেন্দ্র কিংবা অন্য কোন হাসপাতালে যাওয়া সম্ভবপর না হয়, তবে আপনি যদি সম্মত থাকেন তাহলে স্বাস্থ্যকর্মী বাড়ীতেই আপনার শিশুর চিকিৎসা করবেন এবং অ্যান্টিবায়োটিক ইন্‌জেকশন দেবেন। কখনও কখনও ইন্‌জেকশনের জায়গায় ব্যথা হতে পারে বা ঘা হতে পারে। এ সকল অসুবিধার ঝুঁকি কমানোর জন্য স্বাস্থ্যকর্মী সকল সম্ভাব্য সতর্কতামূলক ব্যবস্থা নেবেন। এছাড়া, আপনার শিশুর নাকের ভেতর কি কি জীবানু আছে তা পরীক্ষা করে দেখার জন্য স্বাস্থ্যকর্মী হয়ত তার এক মাস বয়সে তার নাকের ভেতর থেকে তুলা লাগানো একটি কাঠি দিয়ে "সোয়াব" সংগ্রহ করবেন। গবেষণার এই অংশের জন্য আপনার শিশুকে বাছাই করা হতেও পারে বা নাও হতে পারে। যদি আপনার শিশুকে গবেষণার এই অংশের জন্য বাছাই করা হয় অথবা বাড়ীতেই তাকে অ্যান্টিবায়োটিক ইনজেকশন দেয়ার প্রয়োজন পরে তা হলে আমরা তা করার আগে আপনার লিখিত সম্মতি নিয়ে নেব।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। এই গবেষণা কর্মকান্ডে অংশগ্রহণের কারণে আপনার যে সকল চিকিৎসা সেবার প্রয়োজন হবে তার পুরোটাই আপনাকে বিনামূল্যে প্রদান করা হবে। চিকিৎসা সেবা ছাড়া আর কোন ভর্তুকি আপনি পাবেন না। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। যে কোন শারীরিক সমস্যা বা উদ্বেগের জন্য আপনি যত শীঘ্র সম্ভব উক্ত চিকিৎসকের সাথে সাক্ষাত করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। আপনার এই গবেষণায় অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন?	হ্যাঁ	না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **consent** from participants in the **community clinic care** model area)*
ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। এলাকার মা, ধাত্রী এবং স্বাস্থ্যকর্মীদের নিরাপদ প্রসব সেবা, নবজাতকের সেবা ও নবজাতকদের মারাত্মক অসুস্থতার চিকিৎসা প্রদানের উপর প্রশিক্ষণ দেয়ার মাধ্যমে জীবনের প্রথম মাসে মৃত্যু কমানোই এই গবেষণার উদ্দেশ্য। আগামী এক বছরে সন্তান প্রসবের সম্ভাবনা আছে এমন সকল মাকেই আমরা গবেষনায় অংশগ্রহণের অনুরোধ জানাচ্ছি। আপনি এই গবেষণায় অংশগ্রহণে সম্মত হলে একজন মাঠকর্মী আপনার শিশুর জন্মের পূর্বে আপনার সাথে বাড়িতে দেখা করবেন এবং আপনি ও আপনার পরিবার কিভাবে সন্তান প্রসবের যত্ন নেন এবং জন্মের পর কিভাবে শিশুর দেখাশোনা করেন সে বিষয়ে জিজ্ঞাসা করবেন। এরপর আমাদের একজন কর্মী প্রতি তিনমাস পর পর আরও ১৫ মাস আপনার সাথে দেখা করবেন এবং জন্ম, মৃত্যু, গর্ভাবস্থা বিষয়ে তথ্য সংগ্রহ করবেন। যদি গবেষণায় অংশগ্রহণরত কোন শিশুর মৃত্যু ঘটে, তবে আমাদের মাঠকর্মী আপনার সাথে দেখা করবেন এবং শিশুর মৃত্যুর কারণ বের করার জন্য বিভিন্ন প্রশ্ন করবেন। আমরা জানি যে এ ব্যাপারে প্রশ্ন করলে আপনার মানসিক অসুবিধা হতে পরে। আপনার ইচ্ছা না হলে আপনি এ সকল প্রশ্নের উত্তর নাও দিতে পারেন অথবা মাঠকর্মীকে আরেক দিন আসার জন্য বলতে পারেন। এ সকল প্রশ্নের উত্তর দিতে প্রতিবার আপনার প্রায় ২০ মিনিটের মতো সময় লাগবে।

প্রসব সেবা, নবজাতকের সেবা ও নবজাতকের রোগের উপযুক্ত ব্যবস্থা গ্রহণে প্রশিক্ষনপ্রাপ্ত একজন স্থানীয় স্বাস্থ্যকর্মী আপনার এলাকার কমিউনিটি ক্লিনিকে উপস্থিত থাকবেন। আমরা আশা করব যে গর্ভকালীন সময়ে এবং নবজাতকের সেবা গ্রহণের জন্য আপনি কমিউনিটি ক্লিনিকে যাবেন। আমরা আরও আশা করছি যে আপনার শিশু যদি অসুস্থ্য হয়ে পড়ে, তখন তাকে দেখানোর জন্য আপনি কমিউনিটি ক্লিনিকে স্বাস্থ্যকর্মীর কাছে যাবেন। যদি আপনার শিশুর কোন মারাত্নক রোগের সংক্রমণ ঘটে, তবে স্বাস্থ্যকর্মী আপনাকে নিকটবর্তী থানা স্বাস্থ্যকেন্দ্রে যাওয়ার জন্য পরামর্শ দেবেন। যদি কোন কারণে আপনার পক্ষে থানা স্বাস্থ্য কেন্দ্র কিংবা অন্য কোন হাসপাতালে যাওয়া সম্ভবপর না হয়, তবে আপনি যদি সম্মত থাকেন তাহলে স্বাস্থ্যকর্মী অ্যান্টিবায়োটিক ইনজেকশন প্রদানের মাধ্যমে কমিউনিটি ক্লিনিকেই আপনার শিশুর চিকিৎসা করবেন। কখনও কখনও ইন্‌জেকশনের জায়গায় ব্যথা হতে পারে বা ঘা হতে পারে। এ সকল অসুবিধার ঝুঁকি কমানোর জন্য স্বাস্থ্যকর্মী সকল সম্ভাব্য সতর্কতামূলক ব্যবস্থা নেবেন। এছাড়া, আপনার শিশুর নাকের ভেতর কি কি জীবানু আছে তা পরীক্ষা করে দেখার জন্য স্বাস্থ্যকর্মী হয়ত তার এক মাস বয়সে তার নাকের ভেতর থেকে তুলা লাগানো একটি কাঠি দিয়ে "সোয়াব" সংগ্রহ করবেন। গবেষণার এই অংশের জন্য আপনার শিশুকে বাছাই করা হতেও পারে বা নাও হতে পারে। যদি আপনার শিশুকে গবেষণার এই অংশের জন্য বাছাই করা হয় অথবা কমিউনিটি ক্লিনিকেই তাকে অ্যান্টিবায়োটিক ইনজেকশন দেয়ার প্রয়োজন পরে তা হলে আমরা তা করার আগে আপনার লিখিত সম্মতি নিয়ে নেব।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। এই গবেষণা কর্মকান্ডে অংশগ্রহণের কারণে আপনার যে সকল চিকিৎসা সেবার প্রয়োজন হবে তার পুরোটাই আপনাকে বিনামূল্যে প্রদান করা হবে। চিকিৎসা সেবা ছাড়া আর কোন ভর্তূকি আপনি পাবেন না। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। যে কোন শারীরিক সমস্যা বা উদ্বেগের জন্য আপনি যত শীঘ্র সম্ভব উক্ত চিকিৎসকের সাথে সাক্ষাত করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। আপনার এই গবেষণায় অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে? হ্যাঁ না

আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন? হ্যাঁ না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **consent** from participants in the **comparison area**)*

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গবেষণা প্রকল্পের বিবরণ ঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। এই গবেষণার উদ্দেশ্য হলো নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা উদ্ভাবন করা যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথা সম্ভব নিশ্চিত করা যাবে। আগামী এক বছরে সন্তান প্রসবের সম্ভাবনা আছে এমন সকল মাকেই আমরা গবেষনায় অংশগ্রহণের অনুরোধ জানাচ্ছি। আপনি এই গবেষণায় অংশগ্রহণে সম্মত হলে একজন মাঠকর্মী আপনার শিশুর জন্মের পূর্বে আপনার সাথে বাড়িতে দেখা করবেন এবং আপনি ও আপনার পরিবার কিভাবে সন্তান প্রসবের যত্ন নেন এবং জন্মের পর কিভাবে শিশুর দেখাশোনা করেন সে বিষয়ে জিজ্ঞাসা করবেন। এরপর আমাদের একজন কর্মী প্রতি তিনমাস পর পর আরও ১৫ মাস আপনার সাথে দেখা করবেন এবং জন্ম, মৃত্যু, গর্ভাবস্থা বিষয়ে তথ্য সংগ্রহ করবেন। যদি গবেষণায় অংশগ্রহণরত কোন শিশুর মৃত্যু ঘটে, তবে আমাদের মাঠকর্মী আপনার সাথে দেখা করবেন এবং শিশুর মৃত্যুর কারণ বের করার জন্য বিভিন্ন প্রশ্ন করবেন। আমরা জানি যে এ ব্যাপারে প্রশ্ন করলে আপনার মানসিক অসুবিধা হতে পরে। আপনার ইচ্ছা না হলে আপনি এ সকল প্রশ্নের উত্তর নাও দিতে পারেন অথবা মাঠকর্মীকে আরেক দিন আসার জন্য বলতে পারেন। এ সকল প্রশ্নের উত্তর দিতে প্রতিবার আপনার প্রায় ২০ মিনিটের মতো সময় লাগবে। এছাড়া, আপনার শিশুর নাকের ভেতর কি কি জীবানু আছে তা পরীক্ষা করে দেখার জন্য স্বাস্থ্যকর্মী হয়ত তার এক মাস বয়সে তার নাকের ভেতর থেকে তুলা লাগানো একটি কাঠি দিয়ে "সোয়াব" সংগ্রহ করবেন। গবেষণার এই অংশের জন্য আপনার শিশুকে বাছাই করা হতেও পারে বা নাও হতে পারে। যদি আপনার শিশুকে গবেষণার এই অংশের জন্য বাছাই করা হয় তা হলে আমরা তা করার আগে আপনার লিখিত সম্মতি নিয়ে নেব।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। আপনার এই গবেষণায় অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে? হ্যাঁ না

আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন? হ্যাঁ না

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Form to obtain **written consent** from participants **to treat babies with serious infection at home or community clinic with injectable antibiotics**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আপনি জানেন যে আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। আপনি আরও জানেন যে এলাকার মা, ধাত্রী এবং স্বাস্থ্যকর্মীদের নিরাপদ প্রসব সেবা, নবজাতকের সেবা ও নবজাতকদের মারাত্মক অসুস্থতার চিকিৎসা প্রদানের উপর প্রশিক্ষণ দেয়ার মাধ্যমে জীবনের প্রথম মাসে মৃত্যু কমানোই এই গবেষণার উদ্দেশ্য। আপনি ও আপনার নবজাত শিশু এই গবেষণায় অংশগ্রহণ করছেন।

আমাদের মতে আপনার শিশুর মারাত্নক রোগের সংকমণ হয়েছে, তাকে এখনই নিকটবর্তী থানা স্বাস্থ্যকেন্দ্রে নিয়ে যাওয়ার জন্য পরামর্শ দিচ্ছি। তবে আমরা বুঝতে পারছি যে আপনি স্বাস্থ্য কেন্দ্র কিংবা অন্য কোন হাসপাতালে যেতে পারছেন না অথবা যেতে চাইছেন না। আপনি যদি সম্মত থাকেন তাহলে আমরা বাড়ীতেই/ কমিউনিটি ক্লিনিকেই অ্যান্টিবায়োটিক ইন্জেকশন দিয়ে আপনার শিশুর চিকিৎসা করতে পারবো। কখনও কখনও ইন্জেকশনের জায়গায় ব্যথা হতে পারে বা ঘা হতে পারে। এ সকল অসুবিধার ঝুঁকি কমানোর জন্য আমরা সকল সম্ভাব্য সতর্কতামূলক ব্যবস্থা নেব।

বাড়ীতেই/কমিউনিটি ক্লিনিকেই আপনার শিশুর চিকিৎসা করার জন্য আপনার সম্মতি সম্পূর্ণ স্বেচ্ছামূলক। থানা স্বাস্থ্যকেন্দ্রে যাওয়ার সিদ্ধান্ত নিলে আমরা সব সময়ই আপনাকে সেখানেই যেতে বলব। এই গবেষণা কর্মকান্ডে অংশগ্রহণের কারণে আপনার যে সকল চিকিৎসা সেবার প্রয়োজন হবে তার পুরোটাই আপনাকে বিনামূল্যে প্রদান করা হবে। তবে চিকিৎসা সেবা ছাড়া আর কোন ভর্তূকি আপনি পাবেন না।

বাড়ীতেই/কমিউনিটি ক্লিনিকেই আপনার শিশুর চিকিৎসা করার জন্য আপনি সম্মত হলে এই ফর্মে সাক্ষর দিন। আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। যে কোন শারীরিক সমস্যা বা উদ্বেগের জন্য আপনি যত শীঘ্র সম্ভব উক্ত চিকিৎসকের সাথে সাক্ষাত করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। আপনার এই গবেষণায় অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে? হ্যাঁ না

বাড়ীতেই/কমিউনিটি ক্লিনিকেই আপনার শিশুর চিকিৎসা করার জন্য আপনি কি সম্মত? হ্যাঁ না

আপনি এ সকল ব্যবস্থাদিতে সম্মত হলে নিচে আপনার নাম সাক্ষর করুন

Signature of Parent or Guardian

Witness to Consent Procedures*

Signature of Investigator

Date

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION

Void One Year From Above Date
CHR #._____

**Optional, unless subject is illiterate, or unable to sign*

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Form to obtain **written consent** from participants **for collection of nasal swab**)*
ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আপনি জানেন যে আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। আপনি আরও জানেন যে এলাকার মা, ধাত্রী এবং স্বাস্থ্যকর্মীদের নিরাপদ প্রসব সেবা, নবজাতকের সেবা ও নবজাতকদের মারাত্মক অসুস্থতার চিকিৎসা প্রদানের উপর প্রশিক্ষণ দেয়ার মাধ্যমে জীবনের প্রথম মাসে মৃত্যু কমানোই এই গবেষণার উদ্দেশ্য। আপনি ও আপনার নবজাত শিশু বর্তমানে এই গবেষণায় অংশগ্রহণ করছেন।

আপনি যখন প্রথম এই গবেষণায় অংশগ্রহণ শুরু করেন তখন আমরা বলেছিলাম যে আপনার শিশুর নাকের ভেতর কি কি জীবানু আছে তা পরীক্ষা করে দেখার জন্য আমরা হয়ত তার এক মাস বয়সে তার নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করব। নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনার শিশুকে বাছাই করা হয়েছে এবং এই "সোয়াব" সংগ্রহ করার জন্য আপনার সম্মতি চাচ্ছি। আপনি সম্মতি দিলে আজ একজন স্বাস্থ্যকর্মী আপনার শিশুর নাকের ভেতর থেকে তুলা লাগানো একটি কাঠি দিয়ে "সোয়াব" সংগ্রহ করবে। এই পদ্ধতিতে কোন ঝুকি নেই তবে শিশুর একটু অস্বস্তি লাগতে পারে।

আপনার শিশুর নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনার সম্মতি সম্পূর্ণ স্বেচ্ছামূলক। আপনার শিশুর নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনি সম্মত হলে এই ফর্মে সাক্ষর দিন। আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। যে কোন শারীরিক সমস্যা বা উদ্বেগের জন্য আপনি যত শীঘ্র সম্ভব উক্ত চিকিৎসকের সাথে সাক্ষাত করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। আপনার এই গবেষণায় অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে?	হ্যাঁ	না
আপনার শিশুর নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনি কি সম্মত?	হ্যাঁ	না

আপনি এ সকল ব্যবস্থাদিতে সম্মত হলে নিচে আপনার নাম সাক্ষর করুন

Signature of Parent or Guardian

Witness to Consent Procedures*
Signature of Investigator
Date

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION

Void One Year From Above Date
CHR #._____

**Optional, unless subject is illiterate, or unable to sign*

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR,B: Centre for Health and Population Research

Title of Research Project: Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh

*(Information sheet to obtain **verbal consent** from participants in the **worker skill evaluation**)*

ICDDR,B # 2000-037 *CHR#: H.22.00.12.06.B*

গবেষণা প্রকল্পের বিবরণঃ

আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। এই গবেষণা কাজে আপনার অংশগ্রহণের জন্য আপনার অনুমতি চাইছি। সন্তান প্রসব এবং নবজাতকের স্বাস্থ্য সম্পর্কে আপনাদের ধারনা, আপনারা কি ধরনের অসুবিধার সম্মুখীন হন ও কি ধরনের সেবা গ্রহণ করে থাকেন সেটা জানাই এই গবেষনার উদ্দেশ্য। এর উপর ভিত্তি করেই আমরা নিরাপদ প্রসব ও নবজাতকের সেবার এমন ব্যবস্থা পরিকল্পনা করব যা স্থানীয় ধাত্রী এবং স্বাস্থ্যকর্মীদের পক্ষে দেয়া সম্ভব এবং যার ফলে নিরাপদ প্রসব এবং অসুস্থ নবজাতকদের সুচিকিৎসা যথা সম্ভব নিশ্চিত করা যাবে। এই গবেষনার অংশ হিসাবে আমাদেরকে নবজাত শিশুদের পরীক্ষা ও অসুস্থ নবজাতকদের চিকিৎসার উপর অনেক ট্রেনিং দেয়া হয়েছে। আপনার এলাকার সকল মায়েদেরকে এই গবেষনায় অংশ গ্রহনের জন্য অনুরোধ করা হচ্ছে। আপনি যদি অংশগ্রহণে সম্মত হন তবে আজ আমি আপনার নবজাত শিশুকে একটু পরীক্ষা করে ও আপনাকে কিছু প্রশ্ন করে আপনার শিশুর স্বাস্থ্যের অবস্থা নির্ধারণ করতে পারব। এর জন্য প্রায় ১৫ মিনিটের মতো সময় লাগবে। কয়েক ঘন্টার মধ্যে একজন ডাক্তার এসে আপনার শিশুকে আবার পরীক্ষা করবেন এবং দেখবেন শিশুটি কেমন আছে এবং যদি অসুস্থ হয় তাহলে তার চিকিৎসার ব্যবস্থা করবেন।

এই গবেষণা প্রকল্পে আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। যে কোন সময় এই গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার আপনার আছে। আপনি যদি এই গবেষণায় অংশ নিতে না চান, অথবা গবেষণা থেকে নিজেকে প্রত্যাহার করেন, তবুও আপনি "সীমান্তিক" স্বাস্থ্য কেন্দ্র এবং থানা স্বাস্থ্য কেন্দ্র থেকে আগের মতই স্বাস্থ্য সেবা পেয়ে যাবেন। কিছু কিছু প্রশ্ন আপনার কাছে স্পর্শকাতর মনে হতে পারে। আপনি যদি চান তাহলে সে সকল প্রশ্নের উত্তর নাও দিতে পারেন।

আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আজকে আপনার সম্মতির মাধ্যমে আপনি আপনার কাগজ-পত্র এভাবে দেখার ও প্রকাশের অনুমতি দিচ্ছেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

আপনার কি কোন প্রশ্ন আছে? হ্যাঁ না

আপনি কি এই গবেষণা-কাজে অংশগ্রহণ করতে রাজি আছেন? হ্যাঁ না

International Centre for Diarrhoeal Disease Research, Bangladesh
CENTRE FOR HEALTH AND POPULATION RESEARCH
Mail : ICDDR, B, GPO Box 128, Dhaka-1000, Bangladesh
Phone : 880-2-8811751-60, Telex : 642486 ICDD BJ
Fax : 880-2-8823116, 8812530, 8811568, 8826050, 9885657, 8811686, 8812529
Cable : Cholera Dhaka

Memorandum

13 August 2002

To : Dr. Shams El-Arifeen
Public Health Sciences Division

From: David A Sack, MD
Chairman, Research Review Committee (RRC)

Sub : **Proposal for an addendum to protocol # 2000-037**

The Research Review Committee in its meeting held on 8th August 2002 approved an addendum proposal to your protocol # 2000-037 entitled "Community-based interventions to reduce neonatal mortality in Bangladesh". Please submit a modified version of the protocol incorporating the addendum, for record of the RRC Secretariat.

Thank you.

Copy: Associate Director
Public Health Sciences Division

REVISED VERSION: Bangla

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR, B: Centre for Health and Population Research

Title of Research Project: **Addendum to "Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh" (ERC# *2000-037*)**
Principal Investigator: **Dr. Shams El Arifeen**

*(Information sheet to obtain **written consent** from participants **for collection of nasal swabs**)*
Consent form
ICDDR, B # *CHR#:*

গবেষণা প্রকল্পের বিবরণঃ

আপনি জানেন যে আমরা আপনাদের স্থানীয় একটি এন,জি,ও - 'সীমান্তিক' - থেকে এসেছি। আমরা ছোট শিশুদের স্বাস্থ্য সম্পর্কে একটি গবেষণা কাজ করছি। এ ব্যাপারে আমরা যুক্তরাষ্ট্রের জনস্ হপকিনস্ ইউনিভার্সিটি, বাংলাদেশ সরকারের স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রনালয় এবং আই,সি,ডি,ডি,আর,বি-র সাথে এক সংগে কাজ করছি। আপনি আরও জানেন যে এলাকার মা, ধাত্রী এবং স্বাস্থ্যকর্মীদের নিরাপদ প্রসব সেবা, নবজাতকের সেবা ও নবজাতকদের মারাত্মক অসুস্থতার চিকিৎসা প্রদানের উপর প্রশিক্ষণ দেয়ার মাধ্যমে জীবনের প্রথম মাসে মৃত্যু কমানোই এই গবেষণার উদ্দেশ্য। আপনি ও আপনার নবজাত শিশু বর্তমানে এই গবেষণায় অংশগ্রহণ করছেন।

আপনি যখন প্রথম এই গবেষণায় অংশগ্রহণ শুরু করেন তখন আমরা বলেছিলাম যে আপনার শিশুর নাকের ভেতর কি কি জীবানু আছে তা পরীক্ষা করে দেখার জন্য আমরা হয়ত তার এক মাস বয়সে তার নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করব। নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনার শিশুকে বাছাই করা হয়েছে এবং এই "সোয়াব" সংগ্রহ করার জন্য আপনার সম্মতি চাচ্ছি। আপনি সম্মতি দিলে আজ একজন স্বাস্থ্যকর্মী আপনার শিশুর নাকের ভেতর থেকে তুলা লাগানো একটি কাঠি দিয়ে "সোয়াব" সংগ্রহ করবে। এই পদ্ধতিতে কোন ঝুকি নেই তবে শিশুর একটু অস্বস্তি লাগতে পারে।

আপনার শিশুর নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনার সম্মতি সম্পূর্ণ স্বেচ্ছামূলক। আপনার শিশুর নাকের ভেতর থেকে "সোয়াব" সংগ্রহ করার জন্য আপনি সম্মত হলে এই ফর্মে সাক্ষর/আঙ্গুলের ছাপ দিন। আপনার পরিচয় গোপন রাখা হবে। গবেষণার নথিপত্র এবং ফর্মসমূহ তিন বছরের জন্য আই সি ডি ডি আর,বি ঢাকা অফিসে তালাবদ্ধ অবস্থায় রাখা হবে। শুধুমাত্র গবেষনায় কর্মরত লোকজনই এ সকল কাগজ পত্র দেখতে পারবেন। তাছাড়া, যে সকল সংস্থা এই গবেষণায় অর্থ সাহায্য দিচ্ছেন তাদের সদস্যরাও প্রয়োজনে এসব ফর্মসমূহ দেখার অনুমতি পাবেন। আপনি এই পত্রে স্বাক্ষর করার মাধ্যমে ফর্ম সমূহ দেখার এবং তথ্য সমূহ জানার অনুমতি দিলেন।

আমরা আপনারা যে ধরণের চিকিৎসা নেন বা ঔষধ খান/ব্যবহার করেন সে সম্পর্কেও কিছু প্রশ্ন করব। সে সব প্রশ্নের মধ্যে রয়েছে ঔষধের পরিমাণ, কেন ব্যবহার করেন, কোথা থেকে ঔষধ আনেন অথবা নবজাতকের বেলায় তা ব্যবহার করেন কিনা ইত্যাদি। এতে ১৫ মিনিটের বেশী সময় লাগবে না।

এই গবেষনায় অংশগ্রহনের ক্ষেত্রে কোন ঝুঁকি নেই তবে "সোয়াব" নেয়ার সময় সামান্য অস্বস্তি লাগতে পারে। কিন্তু যে তথ্য সংগ্রহ করা হবে তা আপনার এবং আপনার এলাকার মঙ্গল বয়ে আনবে। কারণ, এর মাধ্যমে আমরা আপনার এলাকার জন্য সবচেয়ে মানানসই/প্রযোজ্য ঔষধ নির্ধারণ করতে পারবো।

আপনার প্রশ্ন ও জিজ্ঞাসার উত্তর দেয়ার জন্য জকিগঞ্জ, সিলেটে অবস্থিত "সীমান্তিক" হেড অফিসে একজন চিকিৎসক অবস্থান করবেন। যে কোন শারীরিক সমস্যা বা উদ্বেগের জন্য আপনি যত শীঘ্র সম্ভব উক্ত চিকিৎসকের সাথে সাক্ষাত করবেন। পরবর্তীতে কোন বিষয় যদি আপনি বুঝতে না পারেন তবে এই চিকিৎসক বা নিচে উল্লেখিত ইনভেস্টিগেটরকে আপনি সে বিষয়ে প্রশ্ন করতে পারেন। এই গবেষণায় আপনার অংশগ্রহণ করার সময়ে যে কোন নতুন তথ্য ইনভেস্টিগেটর আপনাকে জানাবেন।

আপনার যদি মনে হয় যে আপনার সাথে অন্যায় করা হয়েছে অথবা এই গবেষণায় অংশগ্রহণের কারণে আপনি কোনভাবে ক্ষতিগ্রস্থ হয়েছেন, কিংবা আপনার যদি এই গবেষণার বিষয়ে কোন প্রশ্ন থেকে থাকে - তবে আপনি এই গবেষণার একজন ইনভেস্টিগেটর ডাঃ সামস্ এল আরেফিনের সাথে আই,সি,ডি,ডি,আর,বি, ঢাকা, বাংলাদেশ-এ ০২-৮৮১ ০১১৫ নম্বরে টেলিফোনে আলাপ করতে পারেন অথবা অফিস অফ রিসার্চ এন্ড এথিকস্ রিভিউ কমিটিস অফ আই,সি,ডি,ডি,আর,বি-তে ০২-৮৮১ ০১১৭ নম্বরে যোগাযোগ করতে পারেন।

উপরে উল্লেখিত পদ্ধতি আমাকে সম্পুর্ণভাবে বুঝিয়ে বলা হয়েছে।

অংশগ্রহনে সম্মত হলে নিচে স্বাক্ষর দিন বা আঙ্গুলের ছাপ দিন।

পিতা-মাতা/অভিভাবকের স্বাক্ষর/আঙ্গুলের ছাপ

কমিটির বা আই,আর,বি-র প্রত্যায়ন সীল ছাড়া এটি অকার্যকর

সাক্ষীর স্বাক্ষর *

গবেষকের স্বাক্ষর

তারিখ

উপরের তারিখের ১ বৎসরের জন্য এটি প্রযোজ্য।

CHR #._____

* *সম্মতিদানকারী অশিক্ষিত/স্বাক্ষরদানে অপারগ হলে*

REVISED VERSION

The Johns Hopkins University School of Hygiene and Public Health: Committee on Human Research
ICDDR, B: Centre for Health and Population Research

Title of Research Project: **Addendum to "Community-Based Interventions to Reduce Neonatal Mortality in Bangladesh" (ERC# *2000-037*)**
Principal Investigator: **Dr. Shams El Arifeen**

*(Information sheet to obtain **written consent** from participants **for collection of nasal swabs**)*
Consent form
ICDDR, B # *CHR#:*

Explanation of Research Project:

As you know, we are from a local non-government organization (NGO) known as Shimantik. We are doing a study on the health of young infants. We are working with Johns Hopkins University, USA, the Ministry of Health and Family Welfare of the Government of Bangladesh and ICDDR, B. You also know that the purpose of the study is to train mothers, birth attendants, and community-based health workers in the provision of improved delivery care, newborn care, and management of serious neonatal bacterial infections to reduce deaths in the first month of life. You and your newborn are currently participating in this study.

During initial enrollment we mentioned that your baby may be selected for collection of a nasal swab to examine the presence of bacteria when the baby is one month old. We are now requesting your permission to collect the swabs from the baby, from you or the primary care-giver, and from the baby's closest sibling. If you provide permission, a health worker will collect a swab from the baby's nose, your (or primary care-giver's) nose, and the nose of the baby's closest sibling. There is no risk in this procedure other than a slight tickle in your nose and the noses of the people we are collecting samples from.

Your permission to collect the swab is completely voluntary. If you provide permission to collect the swab from your child, please sign this form or give a thumb impression. Your identity will remain confidential. The study records/forms will be stored for three years in ICDDR,B head office in Dhaka under lock and key. Only, project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms. By signing this form, you agree to such inspection and disclosure.

We would also like to ask you a few questions about the treatments and medicines you or your family take, how many you take, why you use them, where you get them from and if you use them for new babies. This will take no more than 15 minutes.

Only project staff will have access to these forms. In addition, staff members from organizations funding this study may also review the forms.

There are no risks involved in this study except a little discomfort in taking nasal swabs. This information will be helpful to you and your community because it will allow us to determine what the most appropriate medicines to use in your community are.

There will be a study doctor available to answer your questions and concerns at the Shimantik head office at Zakiganj, Sylhet, Bangladesh. You should report any medical problems or concerns you may have as soon as possible to this doctor. You may ask this doctor or the investigator listed below any questions you may have in the future if you do not understand something that is being done. The investigators will share with you any new findings that may develop while you are participating in this study.

If you want to talk to anyone about this research because you think you have not been treated fairly or think you have been hurt by joining the study, or you have any other questions about the study, you may call Dr. Shams El Arifeen, ICDDR, B, Dhaka, Bangladesh at 2-8810115 who is the local Principal Investigator of this project or call the Office of Research and Ethics Review Committees of ICDDR, B at 2-8810117.

If you would like to participate please sign your name or provide a thumb impression below.

The above procedures have been fully explained to me as I give consent voluntarily.

Signature/left thumb impression of Parent or Guardian

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION

Witness to Consent Procedures*

Signature of Investigator

Date

Void One Year From Above Date
CHR #._____

**Optional, unless subject is illiterate, or unable to sign*