Community-Based Intervention to Reduce Neonatal Mortality in Bangladesh

Projahnmo - I
Project for Advancing the Health of Newborns and Mothers

Sylhet District, Bangladesh

Final Report

January 17, 2007

Principal Investigators:
Abdullah Baqui and Shams El-Arifeen
## Table of Contents

I. **INTRODUCTION** ................................................................................................................................................4
   I. BACKGROUND ...............................................................................................................................................4
   II. PROJAHMO-I OVERVIEW ............................................................................................................................6
   III. SPECIFIC AIMS ............................................................................................................................................6
   IV. STUDY SITE ................................................................................................................................................7

II. **METHODS AND DESIGN OF INTERVENTION** ..........................................................................................7
   I. INTERVENTION DESIGN .................................................................................................................................8

III. **MONITORING AND EVALUATION** .............................................................................................................12
   I. OBJECTIVES OF ADEQUACY ASSESSMENT ...............................................................................................13
   II. ESTIMATION OF THE SAMPLE SIZE ............................................................................................................13

IV. **DATA ANALYSIS** .......................................................................................................................................13

V. **DETERMINATION OF COSTS AND COST-EFFECTIVENESS** .................................................................14

VI. **TIMEFRAME** ............................................................................................................................................16

VII. **RESULTS** ..................................................................................................................................................16
   I. COVERAGE ..................................................................................................................................................16
   II. PRACTICES .................................................................................................................................................17
   III. COMMUNITY-BASED MANAGEMENT OF NEWBORN INFECTION .............................................................17
   IV. NEONATAL MORTALITY ...............................................................................................................................18

VIII. **INTERPRETATION OF RESULTS** ...........................................................................................................18

IX. **CONCLUSIONS AND RECOMMENDATIONS** .........................................................................................19

X. **REFERENCES** ..........................................................................................................................................21

XI. **APPENDIX** ...........................................................................................................................................22
# List of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC</td>
<td>Antenatal Care</td>
</tr>
<tr>
<td>BNCP</td>
<td>Birth and newborn care preparedness</td>
</tr>
<tr>
<td>CC</td>
<td>Community Care</td>
</tr>
<tr>
<td>CHW</td>
<td>Community Health Worker</td>
</tr>
<tr>
<td>CM</td>
<td>Community Mobilizer</td>
</tr>
<tr>
<td>FWC</td>
<td>Family Welfare Clinic</td>
</tr>
<tr>
<td>GoB</td>
<td>Government of Bangladesh</td>
</tr>
<tr>
<td>HC</td>
<td>Home Care</td>
</tr>
<tr>
<td>ICMH</td>
<td>Institute of Child and Mother Health</td>
</tr>
<tr>
<td>JHU</td>
<td>Johns Hopkins University</td>
</tr>
<tr>
<td>MOHFW</td>
<td>Ministry of Health and Family Welfare</td>
</tr>
<tr>
<td>Projahnmo</td>
<td>Project for Advancing the Health of Newborns and Mothers</td>
</tr>
<tr>
<td>SNL</td>
<td>Saving Newborn Lives Initiative</td>
</tr>
<tr>
<td>TRC</td>
<td>Technical Review Committee</td>
</tr>
<tr>
<td>TBA</td>
<td>Traditional Birth Attendant</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>UHC</td>
<td>Upazilla Health Complex</td>
</tr>
</tbody>
</table>
I. Introduction

In the context of high neonatal morbidity and mortality in Bangladesh, the Project for Advancing the Health of Newborns and Mothers (Projahnmo) was conceived to test the effectiveness of two different service delivery models of a community based maternal and newborn care interventions package. Established in 2002, Projahnmo is a broad-based partnership of Johns Hopkins Bloomberg School of Public Health (JHSPH), Johns Hopkins University (JHU), USA with a number of Bangladeshi institutions including the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), Shimantik, Dhaka Shishu (Children’s) Hospital, the Institute of Child and Mother Health (ICMH), and the Ministry of Health and Family Welfare (MOHFW) of the Government of Bangladesh (GoB). Projahnmo is funded by the United States Agency for International Development (USAID) and the Saving Newborn Lives (SNL) Initiative of the Save the Children – USA. Additional support is provided by the GoB in terms of provision of staff time, supplies, and facilities. GoB also provides support and guidance to the project through a national level Technical Review Committee (TRC).

i. Background

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 for cultural reasons as well as limitations in routine monitoring and information systems [1]. 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 [2].

Figure 1. Timing of newborn deaths [3]

![Figure 1. Timing of newborn deaths](image)
The Lancet neonatal series, published in 2005, highlighted the need to improve delivery and postnatal care [3-6]. In an effort to address this need, 16 interventions with proven efficacy or effectiveness were identified and packaged into three service delivery modes: Family and Community, Outreach, and Facility-based care [6]. Facility-based interventions were identified as being the most cost-effective, achieving estimated reductions in neonatal mortality by 23% to 50%. Family and Community-based interventions were similarly estimated to correspond to reductions in neonatal mortality ranging from 15% to 32%. Overall, the compilation of packages of interventions when delivered at a 90% coverage rate, are estimated to save up to two-thirds of all newborn deaths.

Despite the promise of the interventions highlighted within the Lancet neonatal series, demonstrated effectiveness data are available for only three of the 16 interventions identified. Further, only limited large scale implementation of the interventions has occurred and consequently, coverage rates remain persistently low. In addition, differentials in coverage rates across socio-economic status are evident, with coverage being lowest among the poorest (Figure 2).

The persistent weak state of health systems, coupled with the slow progression of efforts to improve coverage rates of skilled providers, has highlighted the need to develop interim, simpler approaches at the Family-community level for reducing neonatal mortality. In an effort to address this need, Projahnmo was established as a project which could be implemented through the infrastructures of a non-government organization partner and the MOHFW. In contrast to interventions in other settings, which have sought to improve a singular facet of services and/or are limited in their ability to focus on the continuum of maternal and newborn care services, Projahnmo aims to bridge the gap between community and formal sector health services and effectively ensure access to high quality maternal and newborn care. Accordingly, barriers, which impede access to (e.g. financial, cultural, geographic, etc.) and the provision of care (e.g. drug/supplies, capacity, supervision, etc.) are addressed through the major components of the Projahnmo intervention. The following
section provides an overview of the Projahnmo, highlighting these and other features of the project.

ii. Projahnmo-I Overview

Projahnmo was a cluster randomized community-based program, which aimed to evaluate the impact of an obstetric and neonatal care package of services in the reduction of neonatal mortality in three sub-districts of Sylhet district of Bangladesh. Sub-districts were divided into 24 clusters (unions), each comprised of an estimated 20,000 people. These clusters were randomly allocated to one of the three study arms:

- Home care (HC)
- Community care (CC) and
- Comparison

The study outcomes were maternal and newborn care knowledge and practices, cost and cost-effectiveness, equity, and neonatal mortality.

iii. Specific Aims

Primary Aims

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 management of neonatal infections by first-line health workers, either in the home or at community clinics, on neonatal mortality rates.

Secondary Aims

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

3. To evaluate the relative cost-effectiveness of the intervention models to provide enhanced obstetric and neonatal care at the community level by skilled health workers, including home or community clinic-based management of serious neonatal bacterial infections.
iv. **Study Site**

The study was conducted in three rural sub-districts of Sylhet district of Bangladesh, Beanibazar, Zakigang and Kanaighat. Sylhet district is considered low-performing in terms of its health and family planning program performances compared with other regions in the country. The estimated total population of the study area is about 480,000.

![Figure 3: Study Arms by Upazilla](image)

Site selection was based on high rates of neonatal and infant mortality and home delivery; poor access to health care; and a minimum of 12,500 live births per year. Additional consideration was the presence of NGO partners with the ability to scale-up the intervention if the intervention proves to be effective.

**II. Methods and design of intervention**

Efforts to address the high neonatal mortality rates focused first on the development of a feasible, effective, and culturally appropriate package of community-based interventions. The processes for defining the contents of a package of interventions and delivery strategies included the following activities:
• **Formative research** including qualitative studies, surveys, and review of existing knowledge, experiences and institutional capacities;

• **Design of key messages and strategies** based on expert inputs in a participatory design workshop participated by program managers, policymakers and researchers;

• **Field testing** of the intervention including behavioral trials and negotiation for alternative care practices.

Figure 4 depicts the major milestones associated with the intervention. Service delivery strategies, while initially defined based on formative research experiences, were allowed to evolve based on field observations and analysis of data collected through management information system, process documentation, and periodic sample household surveys known as “adequacy” surveys.

### Figure 4: Milestones in Project Development

<table>
<thead>
<tr>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>--Approvals</td>
<td>--Training Materials Design</td>
<td>Period of Adequate Implementation</td>
<td>--Endline Survey</td>
<td>--Data analysis</td>
<td>--Dissemination</td>
</tr>
<tr>
<td>--Formative Research</td>
<td>--Training</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--Baseline Survey</td>
<td>--Randomization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--Inventory of Services</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**i. Intervention Design**

Based on formative research and other processes listed above, the project developed a package of maternal and newborn care interventions and evaluated the impact of this package when implemented through two different community-based delivery strategies, namely Home Care (HC) and Community Care (CC) models.

As individual-level allocation of these interventions was not feasible, clusters were the units of randomization. Clusters consist of a group of geographically associated villages known as unions, which are the lowest administrative units in Bangladesh. Twenty-four selected unions of three *upazilas* (sub-district) of Sylhet district were randomly assigned to one of the two intervention arms, or to the comparison arm.

In both the CC and HC arms, services were delivered through community-based workers recruited through the NGO partner, Shimantik and the Government of Bangladesh and NGO facilities. In both intervention arms, Community Mobilizers (CMs) were hired by the NGO-partner of the project to conduct community mobilization activities to disseminate project messages and encourage women and families to seek antenatal, delivery and
postpartum care for the mother and the newborn. Additionally, CMs identified community change agents in CC arm. In the CC area, female CMs were responsible for covering about 18,000 populations, divided into 40 units and 80 sub-units, covering one sub-unit per day. In the HC area, each female CM was responsible for 42,000 populations, divided into 40 units of 1,050 populations each, and four sub-units per unit, with approximately 263 people each. The CMs covered one sub-unit every day. Each male CM in both the CC and HC areas was responsible for 80,000 populations. The working area was divided into 40 units, and each of the units is further divided into five sub-units with a population of approximately 2,000 and the male CM covered one sub-unit everyday.

All CMs were responsible for promoting community engagement in newborn health care and building a sense of ownership on the issue of newborn care and BNCP. Thus, they organized community meetings with both male and female members of the households and community. At the household level, CMs focused on female members such as pregnant women, senior female family members, and other married women of reproductive age. Male mobilizers focused on husbands of both pregnant women and non-pregnant women of reproductive age and household heads. The usual channel of communication was community meetings.

In the HC model, education, counseling, and selected services were provided at the home level by project-supported Community Health Workers (CHWs) recruited through the NGO - Shimantik. The CHWs reinforced project messages and encouraged the family to seek antenatal care and to receive delivery, postpartum, and newborn care. She provided intensive counseling and education on birth and newborn care preparedness. The project comparison area continued to receive current services as provided by the Ministry of Health and NGOs.

**Interventions Components of Projahnmo**

Projahnmo interventions included contact and care to improve pregnancy care, delivery care, postpartum care, and essential and sick newborn care. In both the HC and CC arms, interventions included:

- Health education and counseling to improve maternal and newborn health;
- Provision of essential maternal and newborn care; and
- Strengthening of existing government health facilities and capacity building.

**Health education and counseling:**

Birth and newborn care preparedness (BNCP) was the main strategy for health education and counseling in both the HC and CC arms. Information on the importance of use of antenatal care, including tetanus toxoid immunizations; the importance of taking iron/folate during pregnancy to prevent or treat anemia; selection of a skilled birth attendant; obtaining a clean birth kit; early recognition of and care-seeking for pregnancy and obstetric danger signs; use emergency obstetric care preparedness, including, identification of health facility, means of transport and saving money for emergencies; and essential newborn care, including thermal care, clean cord care, and exclusive breastfeeding and recognition and management of birth asphyxia, prematurity/ very LBW, and sepsis were key elements of BNCP. In the HC model, counseling was conducted at home with pregnant women and their families by CHWs. In the CC arm, women received these messages through community meetings by CMs and during ANC visits by governmental primary health workers and paramedics.

CMs, and CHWs were trained in essential newborn care, cleanliness during delivery, and recognition of maternal and newborn danger signs. Traditional birth attendants (TBAs)
were given orientation on clean delivery, maternal danger signs and on newborn care. In both arms, community-based meetings were conducted by CMs to provide information and to build awareness about the importance of proper antenatal care, delivery care, postpartum care, and newborn care and to promote involvement of the mothers and other family members (e.g., husbands, mother-in-laws) in the decision-making process for appropriate and timely care-seeking and making them aware of how and from where care can be obtained. In CC arms, CMs identified a cadre of community volunteers known as community change agents who reinforced the messages regarding preventive care and danger signs and thereby creating awareness and promoting behavior change.

Service provision:

The project emphasized referral for antenatal care including tetanus toxoid immunization, delivery care, and for maternal and newborn complications. In the HC arm, CHWs issued specific referral slips if any maternal complication or a sick newborn was identified during home visits, and encouraged families to seek care.

The project emphasized clean and safe delivery through training of birth attendants on clean delivery care practices through the provision of a clean birth kit and through promotion of danger sign recognition. These kits contained soap, a clean plastic sheet, a new blade, thread and a piece of gauze. Distribution of iron/folate was another key service provided in this project. In the HC arm, CHWs distributed both clean birth kits and iron/folate to pregnant women, while in the CC arm, the clean birth kits and iron/folate were distributed during antenatal care at health facilities.

During BNCP counseling, pregnant women and their families were encouraged to identify and utilize a skilled or trained birth attendant during delivery. Since facility-based delivery is uncommon, if facility-based delivery is not feasible and accepted and if the family/pregnant women were not able or willing to avail a skilled attendance, the family was counseled to have a trained TBA to attend the delivery, and to promptly seek care at a properly equipped health facility if complications arose. In the HC arm, CHWs were encouraged to attend the delivery to ensure that the TBA/birth attendant used clean delivery practices, recognized danger signs of the mother and the newborn and refers if necessary, and facilitated immediate newborn care, including resuscitation of the asphyxiated babies.

In the HC model, CHWs provided the interventions to pregnant women and their families in their homes. CHWs were from the communities themselves, and they served as the liaison between family members and the formal health system. Each CHW was responsible for about 4,000 populations. CHWs visited each woman twice during pregnancy; once between 12-16 weeks and once between 32-34 weeks of gestation. Attendance at deliveries by CHWs was stressed, although this was proven difficult to implement. The CHWs visited the mother and newborn three times during the postpartum period: at delivery (or within the first 24 hours if attendance at delivery is not possible) and on the 3rd and 7th days post partum. During these visits the CHWs assessed the newborns using a IMCI-type algorithm (Please see annex -1). If newborns with “severe disease” were identified, CHWs referred them to sub-district hospitals. CHWs were trained to treat newborns with injectable penicillin and gentamicin if referral failed.
### Table 1: Key Intervention Activities

<table>
<thead>
<tr>
<th>Health Facility Level</th>
<th>HC ARM</th>
<th>CC ARM</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upazilla Health Complex</strong></td>
<td>Training of key staff in maternal and newborn health</td>
<td>Training of key staff in maternal and newborn health</td>
<td>Usual care provided by MOHFW and NGOs</td>
</tr>
<tr>
<td></td>
<td>Provision of key ENC drugs and supplies</td>
<td>Provision of key ENC drugs and supplies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creation of tracking system for neonatal utilization</td>
<td>Creation of tracking system for neonatal care utilization</td>
<td></td>
</tr>
<tr>
<td><strong>Family Welfare Clinic</strong></td>
<td>Training of key staff in maternal and newborn health</td>
<td>Training of key staff in maternal and newborn health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provision of key ENC drugs and supplies</td>
<td>Provision of key ENC drugs and supplies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creation of tracking system for neonatal care utilization</td>
<td>Creation of tracking system for neonatal care utilization</td>
<td></td>
</tr>
<tr>
<td><strong>Community Health Workers</strong></td>
<td>Training in ENC and Safe Motherhood</td>
<td>Training in ENC and Safe Motherhood</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Capacity to treat neonatal sepsis in the event of non-adherence to referral</td>
<td>Capacity to treat neonatal sepsis in the event of non-adherence to referral</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Antenatal Care</strong></td>
<td><strong>Antenatal Care</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BNCP1 visit at 12-16 weeks of pregnancy</td>
<td>BNCP1 visit at 12-16 weeks of pregnancy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BNCP2 visit at 32-34 weeks of pregnancy</td>
<td>BNCP2 visit at 32-34 weeks of pregnancy</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Intrapartum Care</strong></td>
<td><strong>Intrapartum Care</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NC-1: At the time of delivery (Day 0), or within 24 hours if not possible to attend delivery</td>
<td>NC-1: At the time of delivery (Day 0), or within 24 hours if not possible to attend delivery</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Postnatal Visits</strong></td>
<td><strong>Postnatal Visits</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NC-2: 1st visit – on the 3rd day after delivery</td>
<td>NC-2: 1st visit – on the 3rd day after delivery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NC-3: 2nd visit – on the 7th day after delivery</td>
<td>NC-3: 2nd visit – on the 7th day after delivery</td>
<td></td>
</tr>
<tr>
<td><strong>Community Mobilizers (male and female)</strong></td>
<td>Female mobilizers responsible for 42,000 population and male mobilizers for 80,000 population</td>
<td>Female mobilizers responsible for 18,000 population and male mobilizers for 80,000 population</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Training in ENC and Safe Motherhood</td>
<td>Training in ENC and Safe Motherhood</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Work to inform CHWs in the event of a delivery, identify maternal and newborn illnesses, and promote referral</td>
<td>Work to inform CHWs in the event of a delivery, identify maternal and newborn illnesses, and promote referral</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Community meetings and advocacy</td>
<td>Community meetings and advocacy</td>
<td></td>
</tr>
<tr>
<td><strong>Traditional Birth Attendants</strong></td>
<td>Training in ENC and Safe Motherhood</td>
<td>Training in ENC and Safe Motherhood</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Work with CMs to inform CHWs in the event of a delivery, identify maternal and newborn illnesses, and promote referral</td>
<td>Work with CMs to inform CHWs in the event of a delivery, identify maternal and newborn illnesses, and promote referral</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Health systems strengthening:

Health care facilities, the Union Health and Family Welfare Centers (H&FWCs) and Upazilla Health Complexes (UHC) were strengthened for maternal and newborn care in both the HC and CC arms. Providers were trained in obstetric and postpartum care and essential and sick newborn care (ENC). In addition, essential equipment, supplies and drugs were provided by the project. A supervision system was in place which was conducted jointly by Government Officials and Projahmo project managers. Table 2 presents the intervention delivery strategies in the home care and community care models.
Table 2: Intervention delivery strategies in the two intervention arms of the study

<table>
<thead>
<tr>
<th>Intervention strategy</th>
<th>Home care</th>
<th>Community care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married women of reproductive age (MWRA) registration and pregnancy surveillance</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Birth and neonatal care preparedness (BNCP) (*visits 3rd, 8th mo)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Community mobilization</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Targeted advocacy meetings</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Clean delivery and identification and referral of emergency obstetric cases</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Newborn care visits, identification and referral of sick newborns and mothers (days 1, 3, 7)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Improved routine maternal and neonatal health care at health facilities</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Management of maternal and newborn complications at health facilities</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Home management of newborn infections at home if referral fails</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Intervention adjustments:

The intervention package was not static but dynamic. Adjustments were made in response to findings from the routine monitoring and periodic review (particularly the mid-term review in 2004 sponsored by SNL). A formal mid-term review was conducted in mid-2004 by a team of experts. This was near the mid-point of the intervention phase and included the examination of key process and output indicators, as well as information on implementation progress, problems encountered, critical concerns and potential solutions. The full review report is available.

Examples of some of the changes in the interventions include the addition of the process of identifying a cadre of community volunteers to assist the community mobilizers, increasing the density of community mobilizers in the CC arm and changing the process of orienting TBAs from formal class-room sessions to on-the-job orientation during pregnancy counseling sessions.

III. Monitoring and Evaluation

Projahnmo-I had an ongoing supportive supervision, monitoring, and evaluation system in place. A baseline survey was conducted in January-May 2003 and an end line survey was completed during January-June 2006. In order to measure the adequacy of the implementation of the interventions, three interim sample household surveys were conducted in March 2004, January 2005 and September 2005. In addition, a detailed record keeping system including information on assessment and management of newborns was maintained in the HC and qualitative process documentation was conducted to investigate the factors that facilitated or impeded the implementation of selected components of the intervention package and strategies.
i. **Objectives of adequacy assessment**

The purpose of adequacy and monitoring studies was to assess how well the project was implementing the intervention. The adequacy indicators were analyzed from two different perspectives.

(i) The first was to provide feedback to the intervention team about the level of implementation of the interventions. This feedback was used by the team to make necessary adjustments in the implementation process as necessary.

(ii) The second purpose was to document the implementation processes and relate processes with inputs and confounding factors to identify factors that facilitated or impeded the changes.

ii. **Estimation of the sample size**

Sample sizes for outcome measurements 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 46 per 1,000, an individually randomized study having 1,750 newborns in each group would be sufficient to detect a reduction of 40% in the intervention arm. Since we randomized communities, rather than individuals, we tripled the sample size (actual design effect based on baseline data was 3.1) to account for between-community variability. Therefore, we needed 5,250 newborns in each study arm or a total of 15,750 newborns in the study. An 18 months effective implementation of the intervention package would allow us to assemble this numbers of newborns.

Since the intervention involved behavior change and strengthening government health system, we had to allow adequate time for the maturation of the intervention to reach adequate levels (in fact we had to allow 12 months to mature the intervention in the HC area and 18 months in the CC area). Although most of the components of the intervention began in both the intervention arms in July 2003, we were able to ensure implementation of the full package in the HC by December 2003. The interventions stabilized in the HC area by June 2004. The CC model required further adjustments, thus a modified and strengthened intervention strategy was implemented beginning July 2004. The CC model stabilized by December 2004. To ensure 18 months effective implementation, we continued the intervention until June 2006.

The survey included all mothers who had a pregnancy outcome in the three years preceding the end-line survey because inclusion of all mothers would provide important programmatic information including time needed to fully implement interventions within the health system, including behavior change communication and strengthening the government health system. This information would be critical to our partners including ministry of health and non-governmental organization during scaling up of the intervention.

IV. **Data Analysis**

The main outcome of the study was the change in NMR in the intervention area relative to the comparison area from baseline to the end of the project, as determined through
cross-sectional surveys. Baseline characteristics of the intervention and control groups were documented and any significant baseline differences were controlled for during data analysis. To account for the clustered nature of the data, appropriate statistical methods were employed. Effectiveness evaluation was done by comparing the primary outcome measure (neonatal mortality) in the intervention area and the comparison area after controlling for the baseline differences. The baseline rates were calculated using the baseline survey data. For calculation of mortality rates, all births and deaths that occurred in the study area were included irrespective of whether or not they received the treatment (i.e. intent-to-treat). To detect statistical differences in neonatal mortality changes in the study arms, a t-test was performed using cluster level neonatal mortality rates.

V. Determination of Costs and Cost-Effectiveness

Effectiveness trial activities were supplemented by an economic evaluation component whose primary objective was to determine the cost-effectiveness of home-care and clinic-care arm activities as compared to existing practice. Economic evaluation activities were initiated in late 2005 and data retrospectively amassed for the 2002-2005 period from the societal perspective, including program costs, users’ costs, and provider costs. Program costs included all costs incurred during project period by the implementing agencies: ICDDR,B and Shimantik. Users’ costs included: (1) out-of-pocket expenditures for routine and emergency maternal and newborn care; and (2) productivity losses stemming from the illness of either the mother or newborn. Users’ cost data were collected via an independent household survey administered to recently delivered women and key household decision-makers. Provider costs included all capital and recurrent costs associated with the provision of maternal and newborn care services in 16 primary and three secondary level facilities in Sylhet.

Data collection efforts were completed in late 2006 and included (1) financial data collection; (2) time-allocation interviews with providers; and (3) extraction of utilization data (including individual patient drug and supply consumption) from the inpatient, outpatient and Emergency Departments for the year 2005. Efforts to analyze cost effectiveness data, while underway, have followed standardized WHO-CHOICE methodology, emphasizing: (1) the generation of incremental cost-effectiveness ratios (ICERs) for major outcome measures (e.g. cost per neonatal death averted) by study arm; (2) the generation of a Cost Effectiveness Plane (CEP); and (3) conduct of sensitivity analyses.

Preliminary findings have revealed that the average annualized total program cost is $144,327.13 for the HC arm and $48,483.22 for the CC arm. These average annualized program cost estimates fall below data for the year 2005, which reflects a time-period during which project maturation had occurred. Estimates for this year suggest that annualized program costs for the HC arm are $204,719.31 and $63,923.98 for the CC arm. In both study arms, the distribution of costs are consistent in that personnel costs comprise the bulk of expenditures, followed by travel and training costs. Figure 5. depicts annualized total program costs for 2005 by study arm.
Efforts to evaluate the costs of specific components of the Projahnmo project were informed by emerging estimates of staff time allocation. Time allocation data collection focused on the conduct of in-depth interviews and focus groups with all cadres of project personnel, including CHWs and CMs. Findings from CHWs interviews and focus groups suggested that on average, CHWs spend the bulk of their time on administrative activities (40%), followed by community-based activities such as BNCP visits (17%), newborn care visits (16%), Other neonatal home visits (15%), and MWRA registration (4%). The remaining 8% of CHW activities are spent on supervisory activities and monthly review meetings. The estimates of time allocation were used in conjunction with emerging estimates from ALL project personnel to determine the total cost of the CHW program. Preliminary findings suggest that for 2005, the annualized CHW program cost was $157,885.68 or roughly 77% of HC arm costs. The BNCP component of CHW program costs is estimated to be $26,835.47 or 17%.

Collectively, these preliminary estimates suggest that HC area costs constitute 76% of total project costs for 2005. While these findings reflect but one component of a vast economic evaluation – the analyses of which are nearing finalization— they nevertheless suggest that intervention costs are not insurmountable and largely associated with the provision of community-based maternal and newborn care services. Efforts to link program, users’ and provider data with mortality data are currently underway and anticipated to result in the generation of ICERs and CEPs in early February. Ultimately, findings from this study...
are anticipated to contribute to the paucity of data on the costs of community-based neonatal interventions in low resource settings. The results are anticipated to be instrumental in informing planning and policy making with regard the development of effective strategies for improving maternal and newborn health nationally, regionally, and globally.

VI. Timeframe

As alluded to in an earlier section, most of the components of the intervention began in both the intervention arms in July 2003. We were able to ensure implementation of the full package in the HC by December 2003. The intervention in the HC area stabilized by June 2004. The CC model required further adjustments, thus a modified and strengthened intervention strategy was implemented in July 2004. To ensure 18 months effective implementation, intervention of the study was continued until June 2006, however, the end-line survey started in January 2006.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formative research</td>
<td>December 2001– July 2002</td>
</tr>
<tr>
<td>Intervention Design Workshop</td>
<td>July 2002</td>
</tr>
<tr>
<td>Baseline Survey</td>
<td>January 2003</td>
</tr>
<tr>
<td>Adequacy survey 1</td>
<td>April 2004</td>
</tr>
<tr>
<td>Adequacy survey 2</td>
<td>January 2005</td>
</tr>
<tr>
<td>Adequacy survey 3</td>
<td>September 2005</td>
</tr>
<tr>
<td>End-line survey</td>
<td>January – June 2006</td>
</tr>
<tr>
<td>Data analysis and write-up</td>
<td>June – December 2006</td>
</tr>
</tbody>
</table>

VII. Results

i. Coverage

Overall, coverage of BNCP visits was high in the home-care arm, but attendance at delivery remained low. In the home-care study arm, coverage of BNCP visits was high at both BNCP-1 and BNCP-2 visits. The BNCP-1 coverage remained high (96%-99%) during the entire project period, and the BNCP-2 visit coverage ranged from 74% to 85%, depending on the season. Neonatal care coverage was initially low but increased over time. Assessment within 24 hours increased from 42% to 81%, assessment within 5 days increased from 61% to 88%, and assessment within 7 days increased from 71% to 90%.
ii. Practices

Findings from household surveys indicate that ANC use increased by 30% in Home Care, 17% in Community Care, and 20% in Comparison area. Bathing of the newborn was delayed for 3 days in 49% of home care babies and 34% of community care babies. A small increase was also seen in comparison arm. Use of ‘trained’ TBAs increased by 35% in Home Care, 24% in Community Care, and 7% in Comparison area. The use of clean cord cutting instruments increased in all arms, but more so in the intervention areas (from 46% to 97%) followed by in CC area from 49% to 77%, compared with 46% to 66% in comparison areas.

Results from the MIS and adequacy data indicate that a cadre of Community-based Health Workers can gain high acceptance in the community with the information they provide, reach families and achieve changes in practices. However, attendance at delivery by CHWs was not always possible, and increasing post-natal visits was much more challenging than antenatal visits. Overall, practices improved in all arms but were more pronounced in HC arm. Improvements in comparison area suggest diffusion of messages.

iii. Community-based Management of Newborn Infection

A clinical algorithm (see Appendix-1) was used by CHWs to assess all newborns for perinatal asphyxia and infections, primarily classified in to very severe disease (VSD) and possible very severe disease (PVSD). VSD (5.6%) and PVSD (11.2%) were the two most common causes of neonatal morbidity in the Sylhet home care area between January 2004 and December 2005. The case fatality rate for reported birth asphyxia was 16.2%, and for very severe disease was 13.4%. These two conditions were associated with the highest case fatality rates in neonates. The highest number of very severe disease cases occurred immediately
following birth and declined thereafter, whereas the number of newborns with onset for possible very severe disease spiked at 4, 7 and 9 days following birth. These peaks coincided with CHW visits and thereby suggested timing of identification of VSD and PVSD and not necessarily timing of onset of these conditions.

Out of the 478 sick neonates identified with VSD during the project period, 34% were referred successfully, 43% were treated by CHWs due to unsuccessful referral, 5% received care from another sources and 18% did not receive any outside care. The case-fatality rate for those successfully referred was 14.2%, for CHW treatment in the home was 4.4%, and about ~30% for whom referral was unsuccessful and for those who refused treatment by CHW indicating a high success rate for those neonates treated at home by CHWs, for who referral was not successful.

iv. Neonatal mortality

In terms of our main outcome of interest, neonatal mortality rate, a 33% reduction in NMR was shown in the last 6 months of intervention implementation in the home care arm, and no reduction was seen in the community-care arm for all live births. For singletons, there was a 43% reduction in mortality for home-care and a 9% non-significant reduction for community-care.

Figure 8.

VIII. Interpretation of Results

In the home-care arm, the postnatal visit rate increased over time but this was not universal. Despite education on danger sign to mothers and families, recognition of VSD and
PVSD largely remained dependent on CHW visits. Additional care of LBW and pre-term babies was difficult to implement. There was also a high attrition of workers at the beginning of the intervention. Reaching households, particularly during monsoon, proved to be challenging.

The lack of impact in the community-care arm is difficult to interpret and requires further exploration. The community-care model may also be effective but perhaps it takes a longer period of implementation before any impact is observed. Alternatively, the inputs in the CC might have been inadequate for an under-served population such as Sylhet to achieve a mortality impact.

The Projahnmo-1 study was designed as an effectiveness trial. The population-worker ratio (1/4000) in the HC arm was similar to MOH, the workers were recruited through a NGO partner, and the project relied on existing MOH and NGO facilities for referral care. We rolled out the intervention in an estimated 320,000 population (HC and CC combined) over a six months period and implemented the intervention for 24 months. This time schedule was very tight; we might have seen a larger impact if we could allow more time for maturation of the intervention, particularly for the CC arm. The diffusion of information and consequent 10% reduction of NMR in comparison area reduced our ability to demonstrate a larger impact.

IX. Conclusions and Recommendations

The implementation of activities undertaken as part of this study have facilitated in the development of an effective model to reach neonates in the home soon after delivery. Partnerships and strengthening relationships between community-based traditional birth attendants, CMs and CHWs have resulted in increased care-seeking behaviors by pregnant women, increased knowledge and uptake of appropriate newborn care practices, and improved recognition and treatment of sick infants in the community. These activities suggest a potential model for integrated community-based care of newborns in rural Bangladesh.

Results of this study indicate that under both the HC and CC models there have been significant improvement in a number of outcome and impact indicators, including coverage of essential services and important behavioral changes. However, the most significant improvements, particularly in the main outcome measure of interest, neonatal mortality, were seen only in the HC arm.

Given these findings, the following are recommendations for programmatic efforts:

- **Scaling-up of essential newborn care package:** Successful components from both the HC and CC models should be integrated and scaled-up in rural communities in order to improve neonatal health services where facility-based interventions may not be feasible. The HC model, using trained CHWs, proved to be acceptable by families, cost-effective, and successful at reducing neonatal mortality rates.

- **Possible home treatment for infection using antibiotics:** Given the successful treatment rate in the home for newborns identified by CHWs as having VSD and PVSD, and for whom facility referral was unsuccessful, home treatment with CHWs administering antibiotics seemed to be an important component for home-care delivery strategies.
Increased support for CHWs: Given that recognition of VSD and PVSD largely remained dependent on CHW visits, and attendance at delivery remained low, support for CHWs in conducting postnatal visits and implementation of a successful communication system for families to notify CHWs of deliveries are essential to any home-based model for neonatal care.

Further investigation on community-care service delivery strategies: Given the time constraints for implementation of two models in this study, it is important to continue to investigate the potential effectiveness of a community-care model since it could take a longer period of implementation before any impact may be observed. Since CHW attendance at delivery remained low, our intervention package was limited in its ability to prevent deaths from birth asphyxia. Effective strategies against asphyxia deaths need to be linked to attendance at delivery, particularly by skilled attendants.
X. References

XI. Appendix

Clinical Algorithm for assessing perinatal asphyxia and very severe disease

<table>
<thead>
<tr>
<th><strong>ASSESS the baby</strong></th>
<th><strong>SIGNS</strong></th>
<th><strong>CLASSIFY AS</strong></th>
<th><strong>TREATMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CHECK immediately during delivery: Look for crying and breathing</td>
<td>At 1 min, No cry and no breathing or Gasping or Slow breathing (&lt;30/min)</td>
<td>Perinatal asphyxia</td>
<td>Resuscitation: Dry &amp; wrap, position, stimulate, Mouth to mouth breathing Continue resuscitation until breathing is normal but not for more than 20 min if breathing normal (within 20 min) after resuscitation observe for another 1 hour, apply algorithm for serious disease if breathing not normal after 20 min resuscitation, refer urgently to the hospital If NO breathing after 20 min resuscitation, stop, baby is dead</td>
</tr>
</tbody>
</table>

**ASK:**
- Has the baby had convulsion?
- Does the baby vomit everything?

LOOK, LISTEN, FEEL: (Note: Newborn baby must be calm to assess breathing)
- Look for jaundice
- Look for umbilical infection
- Look for skin infection
- Measure body temperature

**SIGNS**
- Observed Convulsions
- Unconscious
- Fast breathing (60 per minute or more)
- Severe chest in-drawing
- Fever (101°F or above)
- Low body temperature (less than 95.5°F)
- Many or severe skin pustules or blisters or single large area of pus or redness with swelling
- Unbilical redness extending to the skin

**CLASSIFY AS**
- **VERY SEVERE DISEASE**
  - If there is one or more sign give first dose of intramuscular antibiotics and refer urgently.
  - Ensure proper feeding to prevent low blood sugar
  - Advise mother how to keep the baby warm on the way to the hospital.
  - If referral fails continue treatment at home.

**POSSIBLE VERY SEVERE DISEASE**
- If there are at least two signs
  - Give first dose of intramuscular antibiotics and refer urgently
  - If referral fails continue treatment at home.
  - If referral fails and there is only one sign, see the baby again later in the day and reassess.
  - But if referred fails and there is only one of the following sign: Teach mother to treat at home (half-strength gentian violet 0.5%) & go for follow up in 2 days
    - Umbilicus discharging pus
    - Umbilical redness, but not extending to the skin
    - Jaundiced palms & soles after 1 day
  - If referral fails continue treatment at home.

Ensure proper feeding to prevent low blood sugar
Advise mother how to keep the baby warm on the way to the hospital.
If referral fails and there is only one sign, see the baby again later in the day and reassess