Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial

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Summary

Background Neonatal mortality accounts for a high proportion of deaths in children under the age of 5 years in Bangladesh. Therefore the project for advancing the health of newborns and mothers (Projahnmo) implemented a community-based intervention package through government and non-government organisation infrastructures to reduce neonatal mortality.

Methods In Sylhet district, 24 clusters (with a population of about 20 000 each) were randomly assigned in equal numbers to one of two intervention arms or to the comparison arm. Because of the study design, masking was not feasible. All married women of reproductive age (15–49 years) were eligible to participate. In the home-care arm, female community health workers (one per 4000 population) identified pregnant women, made two antenatal home visits to promote birth and newborn-care preparedness, made postnatal home visits to assess newborns on the first, third, and seventh days of birth, and referred or treated sick neonates. In the community-care arm, birth and newborn-care preparedness and careseeking from qualified providers were promoted solely through group sessions held by female and male community mobilisers. The primary outcome was reduction in neonatal mortality. Analysis was by intention to treat. The study is registered with ClinicalTrials.gov, number 00198705.

Findings The number of clusters per arm was eight. The number of participants was 36059, 40159, and 37598 in the home-care, community-care, and comparison arms, respectively, with 14 769, 16 325, and 15 350 livebirths, respectively. In the last 6 months of the 30-month intervention, neonatal mortality rates were 29·2 per 1000, 45·2 per 1000, and 43·5 per 1000 in the home-care, community-care, and comparison arms, respectively. Neonatal mortality was reduced in the home-care arm by 34% (adjusted relative risk 0·66; 95% CI 0·47–0·93) during the last 6 months versus that in the comparison arm. No mortality reduction was noted in the community-care arm (0·95; 0·69–1·31).

Interpretation A home-care strategy to promote an integrated package of preventive and curative newborn care is effective in reducing neonatal mortality in communities with a weak health system, low health-care use, and high neonatal mortality.

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Introduction

Although many developing countries have had reductions in both postneonatal and 1–4-year-old child mortalities, neonatal mortality has remained constant, with an estimated 4 million deaths per year worldwide.[1–3] In Bangladesh, neonatal mortality accounts for 63% of deaths in infants and 45% in children aged less than 5 years.[4]

Although reductions in neonatal or perinatal mortality were noted in community-based effectiveness trials of maternal and neonatal care packages,[5–7] few large-scale community-based studies have tested strategies to deliver neonatal interventions with the existing health infrastructures and neonatal mortality as an outcome.[2,8,9] The best method for delivery of neonatal intervention packages at population scale in low-resource settings remains to be identified.[8,9]

Health services in Bangladesh are provided by the government's Ministry of Health and Family Welfare, non-government organisations, and private providers. In the government sector, two community-based workers—a family welfare assistant and a health assistant—together serve a population of 6000–7000. First-level outpatient clinics—eg, Union Health and Family Welfare Centre—serve a population of about 20 000. Sub-district hospitals with both inpatient and outpatient facilities serve a population of about 200 000. For study-area residents, the closest emergency obstetric-care facility is outside the study area at the Medical College Hospital in Sylhet city (figure 1).

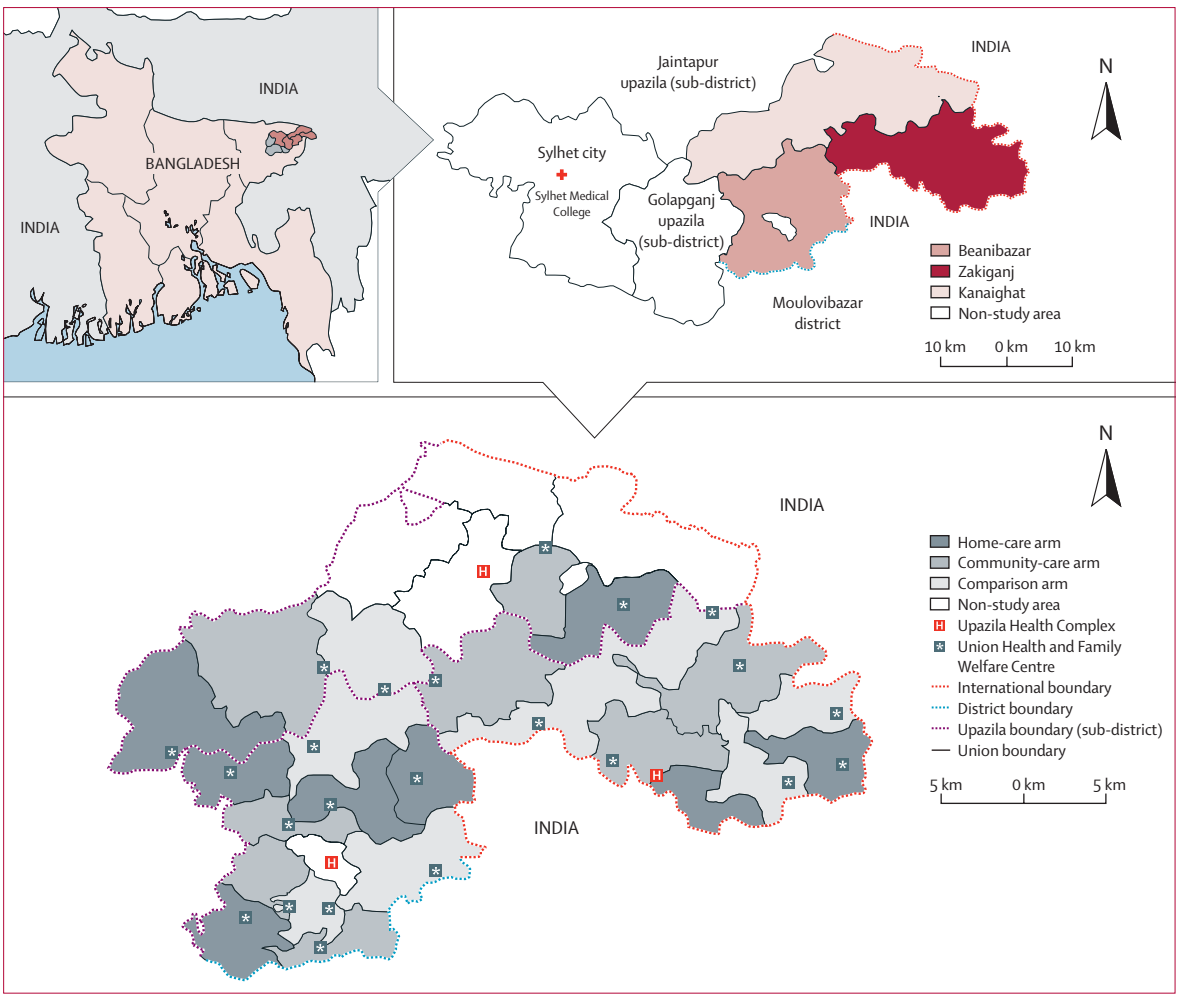

Figure 1: **Map of Projahnmo study area in Sylhet, Bangladesh**

We developed two service-delivery strategies—a home-care model and a community-care model—to promote neonatal health in rural Bangladesh. We postulated that both intervention strategies would result in a 40% reduction in the neonatal mortality rate versus that in the comparison arm. We report here the effect of the intervention on key health-care behaviours and neonatal mortality.

Methods

Study design and participants

The project for advancing the health of newborns and mothers (Projahnmo, which means generation in Bangla) did the study in three rural sub-districts (upazilas; Beanibazar, Zakiganj, and Kanaighat) of Sylhet district (figure 1), which has the highest neonatal mortality rate among Bangladesh's six divisions.[4] This area was selected because it has poor access to health care, about 15 000 livebirths per year, and the presence of non-government organisations with the ability to scale-up the intervention.

Projahnmo developed an intervention package to promote birth and newborn-care preparedness, including pregnancy care, birth planning, essential newborn care, and awareness of when to seek emergency care for maternal and newborn illnesses. The intervention package and the two service-delivery strategies were designed on the basis of focused ethnographic and epidemiological investigations of the study population and recommendations from national and international experts.

24 clusters (unions)—the smallest local government entities in Bangladesh, each with a first-level facility—with an average population of about 20 000 each were randomly assigned to one of two intervention arms—ie, home-care or community-care—or to the comparison arm with computer-generated pseudo-random number sequence without stratification or matching (figure 2). The computer-generated randomisation was implemented by a study investigator who had no role in the implementation of the study. The nature of the intervention meant masking was unachievable. In

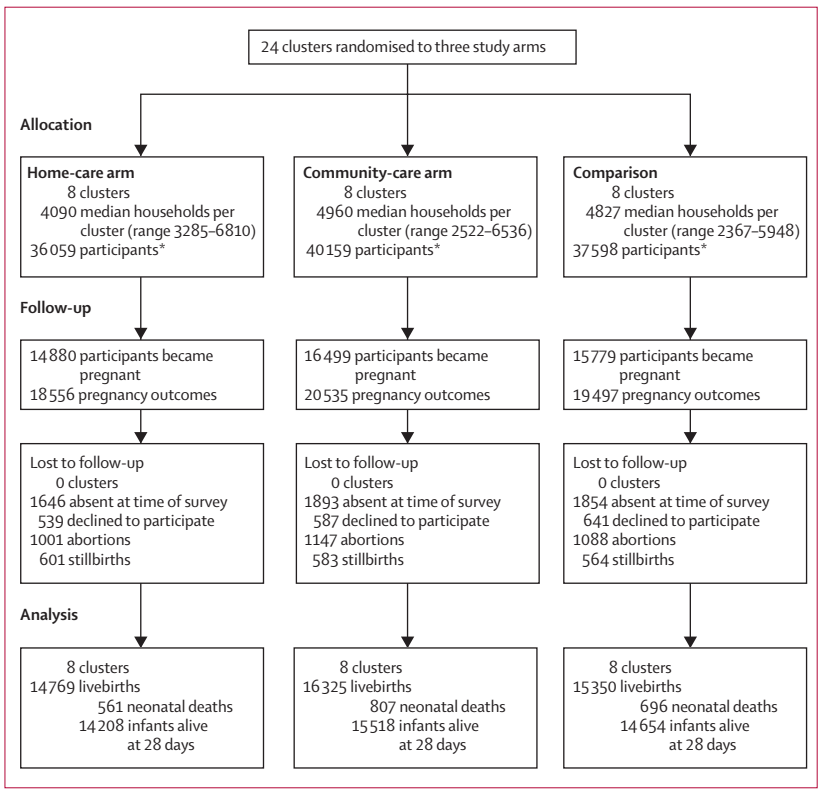

Figure 2: **Trial profile**
*Women of reproductive age (15–49 years).

early 2003, a team of data collectors, supervisors, and researchers who had no role in the implementation of the intervention mapped and listed households to enumerate ever-married women of reproductive age (15–49 years old), and did baseline household surveys to establish coverage of maternal and newborn-care knowledge and practices, and neonatal mortality, with a recall period of 1 year. The list of ever-married women of reproductive age was continuously updated. All married women of reproductive age during the intervention were eligible to participate.

This study received ethical approval from the Johns Hopkins Bloomberg School of Public Health committee on human research and the ethical review committee of the International Centre for Diarrhoeal Disease Research, Bangladesh. Verbal informed consent was obtained from all participants. In the formative research phase, we engaged in consensus-building activities with local communities to gain support for the project.

In the home-care study arm, a non-government organisation partner Shimantik recruited one female community health worker for every four villages (with about 4000 people). The community health workers received 6 weeks of hands-on supervised training in a tertiary-care hospital and in households. The training included skills development for behaviour-change communication, provision of essential newborn care, clinical assessment of neonates, and management of sick neonates with an algorithm adapted from the integrated management of childhood illness.

The community health workers identified pregnancies through routine surveillance during visits to each household once every 2 months; promoted birth and newborn-care preparedness through two scheduled antenatal and three early postnatal home visits; and provided iron and folic acid supplements during birth and newborn-care preparedness visits (table 1). They became aware of births through a community-based notification system, assessed all liveborn neonates, and classified illnesses in the sick neonates into three categories—very severe disease, possible very severe disease with more than one sign, or possible very severe disease with one sign (figure 3). When community health workers diagnosed very severe disease or possible very severe disease with more than one sign, they referred neonates to sub-district hospitals after giving doses of injectable procaine benzylpenicillin (procaine penicillin) and gentamicin. If families were unable to go to a health facility but consented to home treatment, the community health workers continued treatment with procaine penicillin and gentamicin once a day for a total of 10 days.[10] Neonates with possible very severe disease with one sign were not given antibiotics by the community health workers and were referred to sub-district hospitals. When the family was not able to go to the hospital, community health workers made a follow-up visit within the next 24 h to monitor the infant for signs of illness and reinforce referral.

In both intervention arms, male and female community mobilisers were recruited to hold group meetings for the dissemination of birth and newborn-care preparedness messages. In the community-care arm, each female community mobiliser was responsible for a population of 18000, which was divided so that each geographical area of about 225 people was visited once every 4 months; the male community mobilisers visited each area every 10 months. In the home-care arm, fewer female community mobilisers were recruited and each female mobiliser took 8 months to visit her entire catchment area. Additionally, in the community-care arm, female volunteers called community resource people were recruited in each village to identify pregnant women, encourage them to attend community meetings held by the community mobilisers, receive routine antenatal care, and seek care for signs of serious illness in mothers or newborns. Usually these community resource women were already traditional birth attendants in their own communities.

Families in the comparison arm received the usual health services provided by the government, non-government organisations, and private providers. Refresher training sessions for management of maternal and newborn complications were provided for government health workers in all three study arms. Projahnmo staff ensured adequate supplies of

	Home care	Community care	Comparison
Community mobilisation and behaviour-change communication to promote birth and newborn-care preparedness			
Community meetings with pregnant women and female family members	Yes	Yes	n/a
Meetings with husbands/heads of household in mosques and markets	Yes	Yes	n/a
Advocacy meetings with local leaders	Yes	Yes	n/a
Orientation for traditional birth attendants (2 days) on cleanliness during delivery, maternal danger signs, and newborn care	Yes	Yes	n/a
Recruitment of volunteer community resource people to improve attendance at community meetings, and care seeking for maternal and neonatal complications	n/a	Yes	n/a
Household behaviour-change communication, demonstrations, and newborn care			
Twice a month community surveillance to identify pregnant women by community health workers	Yes	n/a	n/a
Two antenatal home visits at 12–16 weeks and 32–34 weeks to promote birth and newborn-care preparedness	Yes	n/a	n/a
Postnatal home visits on days 1, 3, and 7 to reinforce birth and newborn-care preparedness, and provide counselling for breastfeeding difficulties	Yes	n/a	n/a
Algorithm-based routine household screening of newborns on days 1, 3, and 7; referral of sick newborns to government health facilities; and treatment in the home with injectable antibiotics if referral failed. Continued monitoring and advice on home care if illness is not severe	Yes	n/a	n/a
Government health system strengthening, including refresher training for facility-level health providers in treatment of neonatal infections and supply of antibiotics for treatment of neonatal infections at facilities	Yes	Yes	Yes

n/a=not applicable.

Table 1: **Service-delivery strategies by study arm**

antibiotics for treatment of newborn infections at government sub-district hospitals, which served residents in all three study arms. For tetanus-toxoid vaccination in all study arms and for provision of iron and folic acid supplements in the community-care and comparison arms, we relied on existing government mechanisms.

Implementation of the home-care and community-care interventions began in July, 2003. In March, 2004, January, 2005, and September, 2005, interim sample household surveys—hereafter referred to as adequacy surveys—were done to measure intervention inputs, coverage, and changes in key newborn-care practices in all three study arms; the sample included women who had a birth in the 7–8 months before the surveys. An endline survey was done in early 2006 to assess coverage, knowledge, care practices, and neonatal mortality. Women who had a pregnancy outcome during 2003–05 were identified and asked to complete the same surveys that were used at baseline (figure 2).

Primary outcome was changes in the rate of neonatal mortality—defined as the death of a liveborn child within 28 days of life—in the intervention and comparison arms during baseline and endline surveys. A stillbirth was defined as delivery of a dead fetus with a gestational age of 28 weeks or more on the basis of the last menstrual period; and abortion was defined as the loss of a fetus of gestational age less than 28 weeks. The recall period was 3 years for neonatal mortality, which included 6 months of preintervention (January to June, 2003) and 30 months of intervention (July, 2003, to December, 2005). Since the recall period for mortality during the endline survey was 3 years, we were able to calculate neonatal mortality rate by study arm for each 6 months and 12 months beginning January, 2003.

The secondary outcomes were improvements—measured as the difference between baseline and endline—in the intervention and comparison arms in antenatal visits from trained providers, use of iron and folic-acid supplements, use of clean cord-cutting instruments, delays in the newborn's first bath, initiation of breastfeeding within 1 h of birth, and tetanus-toxoid immunisation coverage. The recall period for knowledge, practices, and coverage of the intervention was 1 year (2005).

In addition to independent household surveys, community health workers in the home-care arm maintained routine monitoring and assessment records of pregnancies, births, antenatal and postnatal visits, compliance with maternal and newborn-care practices, birth outcomes, signs of infections, classification, and management of illnesses in neonates.

Women were thought to have had an antenatal check-up from a trained provider if they reported seeing a qualified doctor, nurse, family-welfare visitor, or medical assistant, or if their visit took place at a government or non-government organisation health facility, or at a private clinic or hospital. The umbilical cord was thought to have been cut with a clean instrument if the blade from a clean delivery kit was used or the instrument was boiled before use.

Community health workers' visit records from 2004–05 were used to calculate the number of neonates diagnosed with very severe disease or possible very severe disease, and whether the families complied with referral, accepted home treatment from the community health workers, or sought other care or no care.

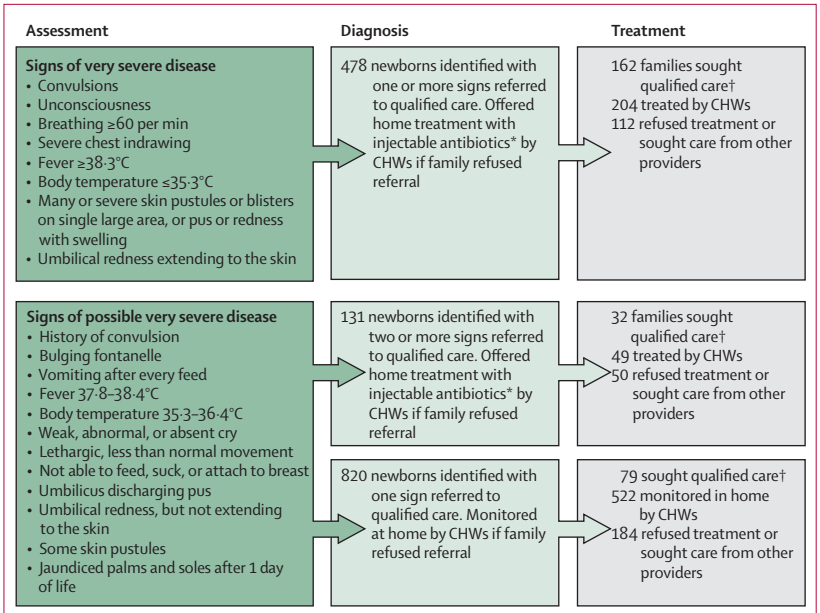

Figure 3: **Algorithm used by community health workers (CHWs) in the home-care arm, number of neonates diagnosed with very severe disease or possibly very severe disease, and treatment patterns in 2004–05**
*Treatment regimen included a total of 10 days of gentamicin and procaine penicillin. Dose of gentamicin was adjusted based on neonate's weight–ie, 10 mg every other day if less than 2·0 kg, 10 mg per day if 2·0–2·5 kg, and 13·5 mg per day if more than 2·5 kg. Dose of penicillin was 80 000 units if less than 2·0 kg, or 160 000 units if equal to or greater than 2·0 kg. †Included treatment at government sub-district hospital or by qualified doctors in private practice.

	Home care	Community care	Comparison
Maternal and newborn characteristics			
Mother's age (years)	27·7 (5·5; 15·0–49·0)	27·9 (6·4; 15·0–49·0)	27·8 (6·2; 15·0–49·0)
Mother's schooling (years)	3·0 (3·2; 0–14·0)	2·8 (3·5; 0–16·0)	3·0 (3·5; 0–14·0)
Child's birth order	3·7 (2·3; 0–16·0)	3·7 (2·5; 0–13·0)	3·7 (2·5; 0–13·0)
Child's sex (male)	51%	51%	50%
Household wealth quintile (distribution)			
First	18%	22%	23%
Second	21%	20%	20%
Third	21%	20%	20%
Fourth	20%	19%	20%
Fifth	20%	19%	17%
Total number of livebirths	2846	2657	2638

Data are mean (SD; range), unless otherwise indicated. Percentages based on cluster averages.

Table 2: **Selected baseline characteristics of women who gave birth during the year (2002) by study arm**

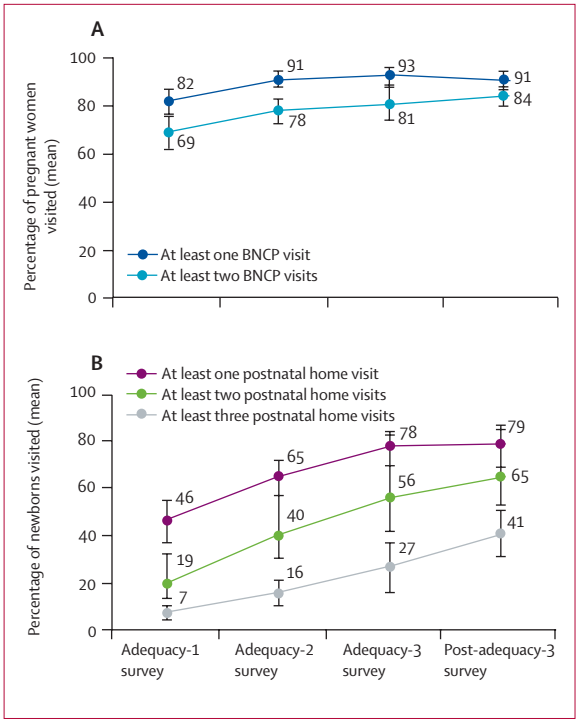

Figure 4: **Antenatal birth and newborn-care preparedness visits (A) and postnatal home visits (B) by community health workers in the home-care arm**
Percentages based on cluster averages. Error bars represent 95% CI. BNCP=birth and newborn-care preparedness.

Statistical analysis

For the baseline survey, sample size was calculated to provide estimates of neonatal mortality for each study arm with or without 10% precision. On the basis of the Bangladesh demographic and health survey's (during 1999–2000) estimated neonatal mortality rate of 81·7 deaths per 1000 livebirths in Sylhet division,[4] we established the sample size requirement per study arm to be 2828 mothers who had a birth in the preceding year. For the adequacy surveys, intervention coverage and practice indicators were measured with give or take 10% precision for each cluster. On the basis of a conservative assumption that the prevalence of each indicator was 50%, a sample of 100 women who gave birth in the preceding 6–8 months was selected per cluster. The baseline survey estimated that the neonatal mortality rate in the study area was about 48 per 1000 livebirths. We attributed the difference in the demographic health survey's estimate of neonatal mortality rate and our estimate largely to the different recall periods—ie, 10 years and 1 year, respectively. The revised sample size was estimated with the binomial method with correction for design effect.[11] Additionally, simulation modelling for power estimation[12] based on the recorded neonatal mortality rates in the baseline survey suggested that the eight clusters per randomised arm had a minimum power of 80% to detect a 20% difference in neonatal mortality rate between the study arms with an unpaired *t* test. For both baseline and endline surveys, a sub-sample of 312 mothers per cluster with a recall period of less than 12 months were interviewed to estimate levels of knowledge, maternal and newborn-care practices, and coverage of intervention components.

Study supervisors and investigators reviewed data forms for accuracy, consistency, and completeness. Data collectors made additional field visits to clarify inconsistencies or obtain missing information as needed. Data were entered in databases with custom-designed

data-entry programs with the necessary range and consistency checks, and were periodically checked by review of frequency distributions and cross-tabulations. Data were analysed with Stata (version 9.0).

We calculated means and proportions of the background characteristics and compared them with *t* tests or χ^2 tests as appropriate to assess the differences between the three study arms at baseline. At baseline and endline, a wealth index score was constructed for each household with the principal component analysis of household durable goods and household circumstances (eg, materials used to construct wall, roof, and floor of houses).[13] Households were ranked according to the total wealth score and then divided into wealth quintiles.

Analysis was by intention to treat at the cluster level. Programme coverage was calculated on the basis of adequacy surveys and data from the endline survey from births that occurred during August to December, 2005 (referred to as post-adequacy 3). Pregnancy and newborn-care practices were measured from baseline and endline household surveys. For pregnancy-care indicators, the denominator was the total number of births; for newborn-care indicators, the denominator was the total number of livebirths that occurred at home.

We used a *t* test to compare differences in neonatal mortality rate between intervention and comparison clusters.[14,15] We estimated the adjusted relative risk (RR) of neonatal mortality for each intervention arm relative to the comparison arm and constructed 95% CIs for RR with Taylor series approximated variance[16] and log-transformed RR, controlling for mother's age and years in education, sex and birth order of the index child, and wealth index.

The study is registered with ClinicalTrials.gov, number 00198705.

Role of the funding source

The study sponsors had no role in the study design, data collection, analysis, interpretation, or dissemination, or in the decision to submit this paper for publication. The corresponding author had full access to all the data in the study and had the final responsibility for the decision to submit for publication.

Results

Mother's age and education, birth order, child's sex, and household wealth were similar at baseline across study arms for a sample of all women who had a livebirth during 2002 (table 2). Figure 2 shows the trial profile. Among the 24 clusters, the endline survey identified 47 158 women with 58 588 pregnancies, 7160 (15%) of whom declined to participate or were absent during data collection. Survey participants reported a total of 46 444 livebirths, of which 44 380 survived the neonatal period. The proportion of women in the home-care arm who received at least one or two antenatal birth and newborn-care preparedness home visits in the first 8 months (before the first adequacy survey in March, 2004) increased by post-adequacy 3 (months 27–30 of intervention; figure 4). About half of neonates born in the first 8 months of the trial received at least one postnatal visit from the community health workers; this proportion increased by about 30% by post-adequacy 3. Attendance by pregnant women in at least one community mobilisation meeting ranged from 19% to 38% in the home-care arm and from 6% to 36% in the community-care arm; about 2% of pregnant women in the comparison arm reported attending community mobilisation meetings (percentages based on cluster averages; data not shown).

	Home care			Community care			Comparison	
	Baseline	Endline	p value*	Baseline	Endline	p value*	Baseline	Endline
Pregnant women								
At least one antenatal check up from a trained provider†	48%	72%	0·0045	50%	62%	0·1248	46%	49%
Iron and folate supplements	43%	84%	<0·0001	45%	45%	<0·0001	40%	25%
At least two tetanus-toxoid immunisations	40%	39%	0·1595	41%	39%	0·1940	41%	35%
Total number of livebirths at home	1589	1449		1779	1368		1791	1426
Newborn-care practices								
Clean cord-cutting instrument used‡	46%	95%	<0·0001	49%	76%	<0·0001	46%	61%
First bath delayed until at least the third day	4%	78%	<0·0001	3%	48%	0·0088	2%	25%
Breastfeeding initiated within 1 h	45%	81%	<0·0001	47%	71%	0·0158	49%	57%
Total number of births	1764	1760		1965	1661		1970	1689

Percentages based on cluster averages. *Calculated with *t* test (intervention arm vs comparison arm at endline). †Includes MBBS-qualified doctor, nurse, or family-welfare visitor, or check-ups were done at a family-welfare centre, government sub-district hospital, or other clinic or hospital. ‡Blade from a clean delivery kit or other instrument that was boiled before use.

Table 3: **Changes in pregnancy and newborn-care practices and use of health care by study arm at baseline (2002) and endline (2005)**

Improvements—measured as the difference between baseline and endline—were recorded in the home-care arm versus the comparison arm in antenatal visits from trained providers, use of iron and folic-acid supplements, use of clean cord-cutting instruments, delays in the newborn's first bath, and initiation of breastfeeding within 1 h of birth; however, tetanus-toxoid immunisation coverage showed no improvement (table 3). In the community-care arm, improvements in antenatal check-ups and newborn-care practices were less striking than in the home-care arm, and no changes in iron and folic-acid supplementation or tetanus-toxoid immunisation coverage were noted (table 3).

In the home-care arm during 2004–05, 194 (32%) of 609 neonates with very severe disease or possible very severe disease with more than one sign were successfully referred and 253 (42%) were treated at home by community-health workers (figure 3).

Among all livebirths, neonatal mortality in the home-care arm was 34% lower during the last 6 months and 30% lower during the last year of the intervention than in the comparison arm (table 4). A pronounced reduction in neonatal mortality was noted for singleton births, 46% in the last 6 months, and 37% in the last year. No neonatal mortality reduction was noted in the community-care arm (table 4).

Discussion

The home-care strategy reduced neonatal mortality by more than a third in the last 6 months of the 30-month trial and improved key maternal and newborn-care practices. Community health workers successfully referred about a third of neonatal infection cases and treated more than a third of cases with injectable antibiotics in the homes (figure 3). Improvements in care practices, but no mortality reduction, were noted in the community-care arm.

Each community health worker was responsible for a population of about 4000, which was similar to the primary health-care worker to population ratio in the Bangladesh government health system, thus facilitating sustainability and scalability of the home-care service delivery approach.

Since the intervention involved behaviour change, a trial in which individuals were randomly assigned was not feasible; therefore, clusters were randomly assigned to the interventions; we accounted for this design with appropriate statistical methods. A potential limitation was that we relied on retrospective recall for information about changes in maternal and newborn-care practices and neonatal mortality. We used standardised data collection methods, and any potential recall lapses were expected to be similar across the study arms.

	Home care					Community care					Comparison	
	Livebirths	NMR	Relative risk (home *vs* comparison)			Livebirths	NMR	Relative risk (community *vs* comparison)			Livebirths	NMR
			Crude	Adjusted* (95% CI)	p value			Crude	Adjusted* (95% CI)	p value		
All livebirths												
2002 (baseline)	2846	46·9	0·98	1·03 (0·69–1·53)	0·917	2657	46·7	0·97	1·01 (0·69–1·48)	0·893	2638	48·0
2003	5139	44·8	0·95	0·94 (0·74–1·19)	0·683	5739	51·1	1·08	0·98 (0·78–1·23)	0·555	5498	47·4
January to June	2561	48·6	0·99	0·98 (0·65–1·49)	0·987	2871	51·0	1·04	0·97 (0·74–1·28)	0·737	2765	48·9
July to December	2578	41·3	0·84	0·89 (0·65–1·23)	0·440	2868	50·7	1·13	1·00 (0·74–1·36)	0·446	2733	45·8
2004	4651	32·8	0·75	0·79 (0·54–1·16)	0·152	5283	45·5	1·05	1·09 (0·86–1·38)	0·674	4895	43·4
January to June	2313	31·9	0·78	0·76 (0·38–1·52)	0·262	2526	44·4	1·08	1·07 (0·78–1·48)	0·560	2369	40·9
July to December	2338	33·8	0·73	0·81 (0·58–1·14)	0·148	2757	46·8	1·02	1·10 (0·79–1·53)	0·895	2526	45·7
2005	4979	31·2	0·72	0·70 (0·56–0·87)	0·023	5303	43·5	1·01	0·91 (0·71–1·18)	0·935	4957	43·1
January to June	2167	33·8	0·80	0·74 (0·48–1·15)	0·228	2294	40·6	0·96	0·84 (0·59–1·20)	0·794	2085	41·9
July to December	2812	29·2	0·67	0·66 (0·47–0·93)	0·011	3009	45·2	1·03	0·95 (0·69–1·31)	0·857	2872	43·5
Singleton livebirths												
2002 (baseline)	2787	39·1	0·98	1·03 (0·72–1·49)	0·912	2596	38·7	0·97	1·00 (0·71–1·42)	0·869	2545	40·0
2003	5008	39·8	0·97	0·99 (0·74–1·32)	0·818	5584	42·7	1·04	0·96 (0·78–1·23)	0·796	5353	41·2
January to June	2506	41·9	0·95	0·97 (0·66–1·43)	0·837	2796	41·7	0·94	0·88 (0·55–1·40)	0·726	2704	44·3
July to December	2502	37·8	1·00	1·02 (0·72–1·44)	0·993	2788	43·2	1·17	1·05 (0·77–1·44)	0·390	2649	37·9
2004	4537	30·2	0·77	0·79 (0·56–1·12)	0·172	5141	40·2	1·03	1·05 (0·86–1·28)	0·807	4790	39·2
January to June	2263	29·2	0·81	0·81 (0·41–1·60)	0·387	2478	41·2	1·15	1·16 (0·85–1·59)	0·335	2307	35·8
July to December	2274	31·5	0·73	0·78 (0·57–1·08)	0·152	2676	39·5	0·94	0·96 (0·71–1·30)	0·706	2483	42·2
2005	4829	25·6	0·67	0·63 (0·50–0·79)	0·010	5171	34·3	0·90	0·82 (0·62–1·08)	0·429	4865	38·1
January to June	2109	29·8	0·81	0·74 (0·42–1·33)	0·325	2250	31·8	0·87	0·78 (0·51–1·19)	0·414	2049	36·1
July to December	2720	22·3	0·56	0·54 (0·39–0·75)	0·003	2921	36·0	0·91	0·84 (0·57–1·25)	0·560	2816	39·7

*For mother's age, mother's years in education, household wealth, child's sex, and birth order. Intercluster correlation=0·012. p values calculated with cluster-level *t* test (intervention arm *vs* comparison arm).

Table 4: **Neonatal mortality rates (NMR) for home-care, community-care, and comparison arms by year and every 6 months**

The findings that home visits by community health workers can improve neonatal health are consistent with those of other studies. The authors of three reviews[17–19] concluded that community health workers can improve health-service use and health outcomes in children aged less than 5 years. Bang and colleagues[5,20] reported a 62% reduction in neonatal mortality in Gadchiroli, India, following 3 years of a community-based neonatal intervention implemented through village health workers. The Gadchiroli study had a four-fold higher health-worker density than our study, and the health workers made eight to 12 postnatal visits, and achieved high coverage of neonatal resuscitation at birth. Our community health workers used an integrated management of childhood illness algorithm, which was adapted from the Bangladesh version, to guide the recognition and management of neonatal disease. The algorithm differed from that used by Bang and colleagues[21] but was similar to the new WHO integrated management of childhood illness algorithm[22] for young infants less than 2 months of age. Jokhio and colleagues[7] reported a 29% reduction in neonatal mortality through improvement of traditional birth attendants' clean delivery practices and linkages with government-health facilities. Other neonatal intervention studies have also reported positive findings after recruitment of community health workers to promote neonatal health, but not all studies have examined neonatal mortality as an outcome or measured reductions in neonatal mortality rate.[23,24]

The reduction in neonatal mortality in the home-care arm in our study was less than the postulated 40%. Community health workers attended less than 5% of all births because of their high workload, travel distances, and difficulties in receiving timely notification of deliveries (data not shown). Efforts were made to improve the quality of services and availability of essential medications for treatment of neonatal infections at government hospitals, a potential benefit for all three study arms. Analysis of behavioural data suggested that some contamination occurred, leading to improved newborn-care practices in the comparison area. For example, the practice of delaying the newborn's first bath received initial community resistance and was subsequently promoted through discussions at mosques that drew residents from all three study arms, leading to the adoption of this behaviour in some households in the comparison area. The possibility of contamination is plausible for other practices as well because the study clusters were geographically contiguous areas, with some degree of movement and communication among clusters. These factors might explain, in part, the less than expected mortality effect.

In the community-care arm, group meetings raised awareness of birth and newborn-care preparedness, and increased community capacity for behaviour change, including routine antenatal care and maternal and newborn curative care. The reduction in iron and folate supplementation and tetanus-toxoid immunisation in the comparison arm, and no improvements in these indicators in the community-care arm, was presumably related to irregular supply by the government-health system. Improvement in appropriate careseeking is recognised as a necessity for child survival, but few programmes have tested strategies to improve careseeking.[25] The Mother and Infant Research Activities (MIRA) group in Nepal noted a 30% reduction in neonatal mortality through a community action-cycle approach.[6] MIRA community mobilisers were responsible for a smaller population (about 7000) than the 18 000 assigned to each Projahnmo community mobiliser. Other differences between the MIRA project and the Projahnmo community-care strategy included the approach to community mobilisation, organisation of the health system, and population characteristics. Implementation of the community-care strategy for an increased period might be needed to achieve an improved coverage and to have an effect. An intensive implementation might be needed for areas with high poverty, poor availability and access to health services, and a general resistance in taking newborns and postpartum mothers outside of the home for treatment.[26–28]

Assessment of the home-care intervention included a cost-effectiveness analysis, which will be reported in detail separately. The cost per neonatal death averted for the home-care arm was US$2995, including health-systems strengthening costs. This estimate includes the intervention costs for 2005 and is thus inclusive of one-time start-up activities for the duration of the project and the implementation costs incurred during that period. This estimate is less than the cost-effectiveness threshold of $14 872 per death averted, derived from a gross national income-based approach used by the commission for macroeconomics, showing that the intervention is highly cost effective.[29] These findings compare favourably with those of the MIRA study—ie, $5801 per neonatal death averted ($6912, including health systems strengthening).[30] Although contextual differences exist between the study sites in Bangladesh and Nepal, our findings in Bangladesh are particularly promising because of the intensity of programme activities, including home treatment of neonates for infection.

Neonatal health programmes should be integrated with other child survival and maternal health programmes. Our findings suggest that existing government and non-government organisation infrastructures could achieve substantial reductions in neonatal mortality if programmes were implemented in a manner that would yield high coverage of antenatal and postpartum home visits to promote preventive and curative care. Availability of referral services and a strong supervisory system were crucial to this intervention and would be a necessary feature of scaling up the intervention. These findings should encourage government and non-government

organisation programmes to develop home-based neonatal-care strategies in settings in which the health system is weak, careseeking is low, and the burden of neonatal mortality is high. Such efforts to scale up the home-care service-delivery strategy for essential newborn care are underway in Bangladesh.

Contributors

AHB, SEA, GLD, IM, PJW, MS, and REB participated in the investigation. AHB, SEA, GLD, SMR, RS, SKS, US, PJW, MS, and REB participated in the design of the study. AHB, SEA, GLD, HRS, IM, SMR, RS, SKS, PJW, MS, and REB participated in the implementation of the study. AHB, SEA, GLD, HRS, and IM participated in data collection. AHB, SEA, GLD, SA, EKW, and IM participated in data analysis. AHB, SEA, GLD, EKW, HRS, IM, SMR, PJW, MS, and REB participated in writing the report. AL participated in the economic evaluation, design and implementation, data collection and analysis, wrote the report section about the economic assessment. All authors have seen and approved the final version of the report.

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Conflict of interest statement

US was the programme manager for the saving newborn lives initiative in Bangladesh by Save the Children (US). The other authors declare that they have no conflict of interest.

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