

RESEARCH

Effect of timing of first postnatal care home visit on neonatal mortality in Bangladesh: a observational cohort study

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ABSTRACT

Objective To assess the effect of the timing of first postnatal home visit by community health workers on neonatal mortality.

Design Analysis of prospectively collected data using time varying discrete hazard models to estimate hazard ratios for neonatal mortality according to day of first postnatal home visit.

Data source Data from a community based trial of neonatal care interventions conducted in Bangladesh during 2004-5.

Main outcome measure Neonatal mortality.

Results 9211 live births were included. Among infants who survived the first day of life, neonatal mortality was 67% lower in those who received a visit on day one than in those who received no visit (adjusted hazard ratio 0.33, 95% confidence interval 0.23 to 0.46; P<0.001). For those infants who survived the first two days of life, receiving the first visit on the second day was associated with a 64% lower neonatal mortality than in those who did not receive a visit (adjusted hazard ratio 0.36, 0.23 to 0.55; P<0.001). First visits on any day after the second day of life were not associated with reduced mortality.

Conclusions In developing countries, especially where home delivery with unskilled attendants is common, postnatal home visits within the first two days of life by trained community health workers can significantly reduce neonatal mortality.

INTRODUCTION

High neonatal mortality is one of the main obstacles to attaining millennium development goal four, which calls for a two thirds reduction in mortality among children under five years of age by 2015. Globally, nearly four million neonates die each year, accounting for almost 40% of deaths in children under five. ¹² Interventions with proven efficacy have been identified, and packages of these interventions show promise for reducing neonatal mortality worldwide. ³⁴ Timely delivery of these interventions at high coverage,

however, is a challenge in settings with weak health systems and low health care usage.

Home visits by trained community health workers to promote preventive care and to provide curative newborn care has been shown to be efficacious at reducing perinatal and neonatal mortality.³⁻¹⁰ According to our data, approximately 30% of neonatal deaths occur on the first day of life and 70% occur within seven days of life (unpublished data). In addition, many feeding problems and treatable infections present at around day three.¹¹⁻¹³ No published studies have examined the effect of the timing of postnatal home visits on neonatal mortality, however, although it is an important question to consider when designing health programmes.

The Project for Advancing the Health of Newborns and Mothers (Projahnmo; a Bangla word that means "generation") tested two strategies—community care and home care—for delivery of a package of community based maternal and neonatal care interventions in rural northeast Bangladesh. If in the home care arm, community health workers made scheduled antenatal and postnatal home visits to deliver the interventions. In our study, we examined the effect of the timing of the first postnatal home visit on neonatal mortality.

METHODS

Data source

Projahnmo was implemented in Sylhet district, Bangladesh, which had skilled birth attendance coverage of approximately 10%, poor health care access, and neonatal mortality of about 48 per 1000 live births. ¹⁵ The study design, including description of the intervention package and delivery strategies, has been presented in detail elsewhere. ¹⁴ Briefly, 24 administrative units, each with a population of about 20 000 and served by a primary care centre, were randomised to home care, community care, or the comparison arm (standard care from governmental and non-governmental organisations). The intervention was rolled out over six months and implemented for 24 months between January 2004 and December 2005.

In the home care arm, one female community health worker was recruited for every 4000 population. Community health workers (hereafter referred to as "health workers") conducted pregnancy surveillance every two months throughout the intervention period to identify pregnant women in their catchment area. An estimated delivery date (and, subsequently, gestational age) was calculated on the basis of reported date of last menstrual period. Health workers were expected to visit all pregnant women twice before birth (at 12-16 weeks and 30-34 weeks of gestation) and all newborns on the first, third, and seventh days of life. During antenatal visits, health workers counselled families on use of preventive care such as routine antenatal check ups at health clinics; birth preparation, including planning for a clean and safe delivery; newborn care such as early and exclusive breastfeeding and hypothermia prevention; umbilical cord care; and recognition of maternal and newborn danger signs and timely care seeking. During postnatal visits, the health workers reinforced the essential newborn care messages, provided support to mothers to establish successful breastfeeding, assessed newborns using an algorithm adapted from the World Heath Organization's Integrated Management of Childhood Illness guidelines, referred newborns who showed signs of serious illness according to the WHO strategy, and delivered gentamicin and procaine penicillin injections to newborns if referral failed but parents consented to antibiotic treatment for suspected serious neonatal infections at home.16 The content of postnatal visits was the same, regardless of timing or number of visits.

The health workers received six weeks of training that included skills for communicating behaviour change, providing essential newborn care, and assessing and managing sick neonates, as well as hands-on clinical training in a tertiary level hospital. Three day refresher training was conducted midway through implementation. One field services supervisor provided ongoing training and support to six to eight health workers. The supervisors spent two days a month accompanying each health worker, evaluated their performance by using a structured checklist, and provided immediate feedback. Health workers also attended meetings every two weeks to review their job responsibilities and receive feedback.

Health workers in the home care arm maintained records of antenatal and postnatal visits and made a final visit to all households between day 29 and day 35 to ascertain final survival status of live born infants. Information was collected on socio-demographic factors, pregnancy history, use of antenatal care, birth preparedness, delivery care, newborn care practices, danger signs in mothers and newborns, referrals, and management of maternal and newborn complications. Field services supervisors routinely checked health workers' records before they were entered into a database. In addition, independent home visits were made by supervisors to all homes with a reported neonatal death and to a random sample of households with a surviving neonate. Problems with data quality were

addressed at the time of identification and during routine twice monthly group meetings with health workers.

Statistical methods

This analysis used data from the health workers' records. In the home care arm, 97% of women received at least one antenatal home visit (data not shown); thus, the effect of antenatal visits was not evaluated. Given that the outcome of interest was neonatal mortality, only live births were included in this analysis. We calculated the proportion of newborns who received no postnatal visit and the proportion who received their first postnatal visit on the day of birth or on the second, third, fourth, fifth, sixth, seventh, or later day of life.

Neonatal mortality was calculated as the number of deaths in the first 28 days of life per 1000 live births. Neonatal mortality and 95% confidence intervals were calculated separately for newborns who received their first postnatal visit on: 1) the day of birth; 2) the second day; 3) the third, fourth, fifth, or sixth day; and 4) the seventh day or a later day of life. Infants who received their first visit during a specified time frame were compared with those who never received a visit. The data from infants visited on days three to six were combined because of the low number of visits on these days; data for days seven and later were combined for the same reason. Survival bias is a concern in studies that examine the effect of time to treatment initiation.¹⁷ In our study, a newborn must have survived up to and including the day of the visit to be included in the analysis. For example, among the 2838 newborns visited on the first day of life, 65 newborns died, but seven died on the day of the visit and were therefore excluded from the analysis. Survival bias would likely be introduced if deaths that had occurred before the visit in question were included in the analysis, resulting in an overestimation of the effect of visits.

To examine for possible confounding factors between those infants who received a postnatal visit and those who did not, the socio-demographic characteristics of women who received at least one postnatal visit versus those who never received a postnatal visit were compared and chi square analysis used to test for differences in the distribution of variables between the two groups. Housing materials used for the roof, floor, and wall were used as a proxy for economic status. Points were assigned for each type of housing material as follows: one point for mud, bamboo, straw, or stick; two points for tin or wood; and three points for cement. The points for roof, floor, and wall were then added and categories were made with approximately one third of the population in each group. The poorest group had less than 4 points, the middle group had four to seven points, and the least poor group had more than seven points. Categories for mother's education and father's education were made on the basis of the reported number of years in education. Other characteristics included in the analysis were first birth (primigravid), preterm birth (<37 weeks gestation), and multiple birth. Missing data were as follows: 791

values for maternal education (7.47%), 621 for paternal education (5.87%), two for gestational age (<1%), 66 for roofing material (<1%), 67 for wall materials (<1%), 71 for flooring materials (<1%), and 31 for primigravid status (<1%). We accounted for the missing values using the hot deck method, in which values are generated from other observations in the sample that have similar characteristics. 18

Unadjusted and adjusted hazard ratios and 95% confidence intervals for neonatal mortality were calculated using a hazard model. To further minimise the risk of survival bias, we fitted a time varying discrete hazards model in which subjects were entered conditionally in the analysis according to risk status for the specified visit, as suggested by Zhou et al.17 Newborns who received their first visit on the day of birth, those who received their first visit on the second day of life, those who received their first visit on the third to sixth day of life, and those who received their first visit on the seventh or later day of life were examined in separate models using infants who never received a postnatal visit as the reference category but including only those newborns who survived up to and including the day of the visit or the first day of an interval being evaluated. The adjusted models included variables known to be associated with neonatal mortality: household economic status, mother's education level, primigravid status, preterm birth, and multiple gestations. The variances estimated by the model were adjusted for clustering at community level using the Taylor linearisation method. Statistical analysis was conducted using the Stata Version 8.2 software (StataCorp; College Station, TX, USA).

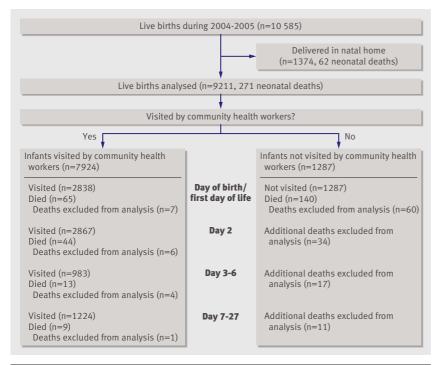


Fig 1 | Design of the study, including distribution of day of first postnatal home visit (January 2004 to December 2005)

RESULTS

The prospective data showed 10 585 live births, 562 stillbirths, and 159 spontaneous or induced abortions between January 2004 and December 2005.

The first postnatal home visit was delayed for many neonates. Some newborns never received a postnatal visit, either because the mother moved outside the intervention area for childbirth—usually to her natal home—or the health worker received delayed notification of the birth. The 1374 women who delivered in their natal home were excluded because they were not eligible for visits by health workers; therefore, 9211 live births that occurred at home or at a facility were included in this analysis.

A total of 2838 (31%) newborns received their first postnatal visit on the first day of life and 2867 (31%) received their first visit on the second day of life, whereas 983 (11%) newborns received their first visit on the third to sixth day of life, 1224 (13%) newborns received their first visit after the first week of life and 1287 (14%) newborns never received a postnatal visit (fig 1). Compared with mothers who had at least one postnatal visit, mothers of neonates who received no postnatal visit had spent longer in education, were more often from wealthier households, were more likely to be primigravid, and more often had preterm deliveries (table 1).

Receiving the first postnatal visit on the day of birth was associated with considerably lower neonatal mortality (20.5, 95% CI 15.6 to 26.4) than receiving no visit (65.2, 52.0 to 80.5; table 2). For those infants who survived the second day, having the first visit on that day was also associated with appreciably lower neonatal mortality (13.3, 9.4 to 18.2) than never having a visit (38.6, 28.4 to 51.1). For visits after the second day of life, the confidence intervals for mortality among those infants who were visited overlapped with those who were not visited; thus, there was no evidence for an effect of timing of first postnatal visit after the second day. When the analysis was restricted to home births only, a visit on the first day was associated with a hazard ratio for neonatal mortality of 0.30 (0.21 to 0.44) and a visit on the second day was associated with a hazard ratio of 0.35 (0.22 to 0.56).

After adjusting for economic status, mother's education, primigravid status, preterm birth, and multiple birth, neonatal mortality was 67% lower in infants who received their first postnatal visit on the day of birth than in those who did not receive a visit (hazard ratio 0.33, 0.23 to 0.46; P<0.001; table 3). Infants who had their first postnatal visit on the second day of life had 64% lower mortality than those who received no visit (hazard ratio 0.36, 0.23 to 0.55; P<0.001). Receiving the first postnatal visit between the third and sixth days or on or after the seventh day of life was associated with non-significantly lower neonatal mortality (hazard ratio 0.60, 0.31 to 1.16 and hazard ratio 0.88, 0.38 to 2.02, respectively). Preterm birth was associated with significantly higher neonatal mortality in all models, and having twins or other multiple births

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Table 1|Distribution of selected maternal, newborn, and household characteristics by postnatal home visit status (2004-5)

| Characteristic | No postnatal visit | At least one postnatal visit | Chi square | P value |
|----------------------------|--------------------|------------------------------|------------|---------|
| Mother's education level | no postnatat visit | postnatat visit | (0.001 | 1 value |
| No education | 46.0 | 49.4 | 10.001 | |
| 1-5 years | 26.9 | 29.5 | | |
| 6 or more years | 27.1 | 21.1 | | |
| Mean number of years ± SD | 3.5±3.7 | 3.0±3.4 | | <0.001 |
| Father's education level | | | <0.011 | |
| No education | 46.6 | 48.6 | | |
| 1-5 years | 29.5 | 31.1 | | |
| 6 or more years | 23.9 | 20.3 | | |
| Mean number of years ± SD | 3.6±4.1 | 3.3±3.8 | | <0.014 |
| Economic status | | | <0.011 | |
| Poorest | 52.7 | 56.6 | | |
| Middle | 30.8 | 29.5 | | |
| Least poor | 16.5 | 13.9 | | |
| Household size | | | <0.019 | |
| 0-4 people | 27.1 | 23.5 | | |
| 5-7 people | 38.4 | 39.9 | | |
| ≥8 people | 34.5 | 36.6 | | |
| Mean number of people ± SD | 7.1±4.1 | 7.3±3.9 | | <0.102 |
| First pregnancy | | | <0.001 | |
| No | 71.3 | 81.6 | | |
| Yes | 28.7 | 18.4 | | |
| Gestational age | | | <0.001 | |
| <37 weeks | 25.5 | 18.8 | | |
| ≥37 weeks | 74.5 | 81.2 | | |
| Multiple births | | | <0.517 | |
| Single | 97.4 | 97.7 | | |
| Twins or triplets | 2.6 | 2.3 | | |
| Total number of newborns | 1287 | 7924 | | |

Numbers in table are percentages unless otherwise stated.

was associated with significantly higher mortality before the seventh day of life.

A quarter (25%) of the neonatal deaths occurred on the first day of life, and these deaths were excluded to avoid survival bias. If it is assumed that the postnatal visits had no effect on deaths that occurred on the first day of life, a postnatal visit on the day of birth would be associated with approximately 50% lower overall neonatal mortality and a day two visit would be associated with 38% lower neonatal mortality.

DISCUSSION

Globally, a third to a half of neonatal deaths occur in the first 24 hours of life, and three quarters occur during the first week.² This analysis has demonstrated that a home visit by a trained community health worker in the first two days of an infant's life can significantly reduce neonatal mortality. Among those infants who survived the day of birth, receiving a visit on that day reduced the risk of neonatal mortality by two thirds compared with those who never received a postnatal visit. Furthermore, receiving a visit on the second day of life reduced the risk by more than half among infants who survived the first two days. Receiving a first home visit more than two

days after birth was not associated with a reduction in neonatal mortality, although this result might reflect the relatively small number of deaths that occurred after two days. We included in the analysis births that occurred either at home or at facilities because we wanted to estimate the population level effect of the programme; however, limiting the analysis to only home births did not change the findings.

Comparison with other studies

The primary causes of neonatal mortality in developing countries are infections, birth asphyxia, and complications of preterm birth.^{2 15} The health workers in this study were trained in communication of behaviour change, provision of essential newborn care, and clinical assessment and management of sick neonates. In a separate analysis, we have shown that newborns treated by health workers have treatment outcomes comparable to those treated by qualified medical providers.¹⁹

Other programmes have been successful at using community based health workers with limited training to identify preterm or low birth weight infants, ¹⁰²⁰ to manage birth asphyxia, ¹⁰²¹ and to recognise and treat sepsis and pneumonia. ⁹²²⁻²⁴ Bang et al implemented in rural India a package of home based interventions for neonates that included recognition and management of newborn illnesses by "village health workers." Health workers were present at 84% of births and made scheduled postnatal visits on days one, two, three, five, seven, 14, 21, and 28. This strategy resulted in a 62% reduction in neonatal mortality over 10 years relative to the control area. ^{521 25} Jokhio et al reported a 30% reduction in neonatal mortality as a result of training traditional birth attendants in maternal and neonatal

Table 2 | Neonatal mortality per 1000 live births by day of first postnatal visit (2004-5)

| | Live births | Deaths | Unadjusted neonatal mortality (95% CI) |
|------------------------------|-------------|--------|-------------------------------------------|
| Day of birth | | | |
| No visit | 1227 | 80 | 65.2 (52.0 to 80.5) |
| Visit | 2831 | 58 | 20.5 (15.6 to 26.4) |
| 2nd day of life | | | |
| No visit | 1193 | 46 | 38.6 (28.4 to 51.1) |
| Visit | 2861 | 38 | 13.3 (9.4 to 18.2) |
| 3rd-6th day of life | | | |
| No visit | 1172 | 29 | 24.7 (16.6 to 35.2) |
| Visit | 979 | 9 | 9.2 (4.2 to 17.4) |
| ≥7 th day of life | | | |
| No visit | 1165 | 18 | 15.5 (9.2 to 24.3) |
| Visit | 1223 | 8 | 6.5 (2.8 to 12.8) |
| Any postnatal visit* | | | |
| No visit | 1287 | 140 | 108.9 (92.2 to 127.1) |
| Visit | 7924 | 131 | 16.5 (13.8 to 19.6) |
| Overall* | 9211 | 271 | 29.4 (26.1 to 33.1) |

A newborn must have survived up to and including the day of the visit to be included in the analysis. Deaths before or on the day of the visit were excluded from each analysis.

*Includes all live births.

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Table 3 | Hazard ratios for neonatal mortality by day of first postnatal home visit (2004-5)

| | Day of birth (hazard ratio (95% CI)) | 2nd day of life (hazard ratio (95% CI)) | 3rd-6th day of life (hazard ratio (95% CI)) | ≥7th day of life (hazard ratio (95% CI)) | | | |
|----------------------------------|--------------------------------------|-----------------------------------------------|---------------------------------------------------|------------------------------------------------|--|--|--|
| Unadjusted analysis | | | | | | | |
| Day of first postnatal visit† | 0.31*** (0.22 to 0.43) | 0.34*** (0.22 to 0.52) | 0.39 (0.14 to 1.13) | 0.87 (0.38 to 1.99) | | | |
| Adjusted analysis | | | | | | | |
| Day of first postnatal visit† | 0.33*** (0.23 to 0.46) | 0.36*** (0.23 to 0.55) | 0.60 (0.31 to 1.16) | 0.88 (0.38 to 2.02) | | | |
| Economic status | | | | | | | |
| Poorest | 1.00 (-) | 1.00 (-) | 1.00 (-) | 1.00 () | | | |
| Middle | 0.60* (0.39 to 0.92) | 0.70 (0.41 to 1.19) | 0.76 (0.37 to 1.55) | 0.62 (0.22 to 1.71) | | | |
| Least poor | 0.57 (0.31 to 1.06) | 0.49 (0.20 to 1.16) | 0.53 (0.15 to 1.81) | 1.01 (0.32 to 3.15) | | | |
| Mother's education | ı | | | | | | |
| No education | 1.00 (-) | 1.00 (-) | 1.00 (-) | 1.00 () | | | |
| 1-5 years | 0.76 (0.50 to 1.16) | 0.90 (0.55 to 1.48) | 0.91 (0.46 to 1.80) | 0.70 (0.28 to 1.75) | | | |
| 6 or more years | 0.80 (0.49 to 1.31) | 0.46* (0.22 to 0.95) | 0.26* (0.07 to 0.88) | 0.40 (0.11 to 1.50) | | | |
| First pregnancy | | | | | | | |
| No | 1.00 (-) | 1.00 (-) | 1.00 (-) | 1.00 () | | | |
| Yes | 1.57* (1.05 to 2.34) | 1.93** (1.19 to 3.14) | 1.58 (0.77 to 3.24) | 1.35 (0.52 to 3.50) | | | |
| Gestational age | | | | | | | |
| <37 wks | 1.00 (-) | 1.00 (-) | 1.00 (-) | 1.00 () | | | |
| ≥37 wks | 0.34*** (0.24 to 0.48) | 0.34*** (0.22 to 0.52) | 0.20*** (0.11 to 0.37) | 0.15*** (0.07 to 0.34) | | | |
| Multiple births | | | | | | | |
| Single | 1.00 (-) | 1.00 (-) | 1.00 (-) | 1.00 (-) | | | |
| Twins or triplets | 3.64*** (1.95 to 6.81) | 6.67*** (3.32 to 13.4) | 6.24*** (2.40 to 16.2) | 3.23 (0.75 to 13.9) | | | |
| | | | | | | | |

A newborn must have survived up to and including the day of the visit to be included in the analysis. Deaths before or on the day of the visit were excluded from each analysis. *P<0.05; **P<0.01; ***P<0.001.

care, including sepsis prevention and referral but not management.26 The study reported 74% coverage of births with trained traditional birth attendants but no additional postnatal visits. In an evaluation of a large scale programme of community based maternal and newborn interventions in rural India, Baqui et al measured no overall reduction in neonatal mortality in the intervention arm relative to the comparison arm. ²⁷ In

WHAT IS ALREADY KNOWN ON THIS TOPIC

The burden of neonatal mortality is high in most developing countries

Studies suggest that postnatal home visit by trained community health workers can reduce mortality, particularly in settings where health systems are weak, but no previous studies have assessed the effect by timing of visit

WHAT THIS STUDY ADDS

Receiving a visit on the day of birth reduced the risk of neonatal mortality by two thirds among neonates who survived the first day of life

Among infants who survived the first two days of life, receiving a visit on the second day reduced the risk of neonatal mortality by 64%

No significant reduction in neonatal mortality was measured among neonates receiving the first home visit after day two of life

Home visit and assessment of neonates by a trained health worker within two days of birth should be made a priority in settings where health systems are weak and coverage of skilled birth attendance is low

a secondary analysis, however, mortality was 34% lower in newborns who received a home visit by a government community based health worker during the neonatal period than in those who received no visit, with three quarters of the reduction among those visited during the first three days of life.

Strengths and limitations

One advantage of this study is that the data on the timing of visits and neonatal mortality were collected prospectively. This analysis also has several limitations. Some women did not receive the intended postnatal visit and were compared with women who did, but this assignment was not random. Randomisation of neonates to postnatal home visit or no visit would not be ethical. Durable household assets and housing materials have been shown to be a reasonable proxy for estimating wealth status, ²⁸⁻³⁰ but our data were limited to housing materials. Selectivity and survival bias were concerns in this analysis; we attempted to account for these by adjusting for differences in background characteristics and by excluding deaths that occurred up to the day of visit. Another potential limitation is that the workers who delivered the intervention also collected data on outcomes. Data quality was maintained through at least two days of field supervision per month for each health worker, by independent home visits by supervisors to all homes with a reported neonatal death and to a random sample of households with a surviving neonate to confirm the survival status of neonates, and by ongoing training, including fortnightly meetings with senior supervisors.¹⁹

An important operational issue is determining the optimal number of postnatal visits. In this study, all newborns were scheduled to receive three postnatal visits, but sick newborns whose parents refused referral received more visits for treatment and follow-up. We are unable, therefore, to examine the effect of the number of visits on neonatal mortality.

Conclusions and policy implications

Early postnatal home visit is one strategy for providing critical interventions to improve newborn survival. Given the compelling data in this study, we recommend that in developing countries, especially those where home delivery with unskilled attendants is the norm, all newborns should receive a home visit and undergo assessment by a trained worker as soon as possible, preferably on the day of birth but no later than 48 hours after birth. The impact of this approach is likely to be dependent on the content, quality, and coverage of the technical interventions included. Reaching neonates within first day or first two days of life is a challenge. Given that the community health workers in this study were not skilled birth attendants and attended only about 5% of deliveries, a complementary strategy will be to ensure skilled attendance at delivery that is linked to essential obstetric care.3132 Further operational research will be needed to develop context specific strategies to reach all newborns as soon as possible after birth.

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[†]The hazard ratio reference category for all "Day of first postnatal visit" is "No postnatal visit".

The Projahnmo 1 Study Group comprised the International Centre for Diarrhoeal Disease Research, Bangladesh; the Bangladesh government's Ministry of Health and Family Welfare; Bangladeshi nongovernmental organisations, including Shimantik, Save the Children, Dhaka Shishu Hospital, and the Institute of Child and Mother Health; and the Johns Hopkins Bloomberg School of Public Health. We thank the many individuals in Sylhet district who gave their time generously, and the field and data management staff of Projahnmo. We thank the members of the Projahnmo Technical Review Committee; the Bangladesh Ministry of Health and Family Welfare colleagues at the sub-district, district, and central levels; and the members of the Shimantik executive committee, for their valuable help and advice. The critical innovative inputs of Projahnmo study group members are acknowledged. The Projahnmo Study Group includes (in alphabetical order): Jahiruddin Ahmed, Saifuddin Ahmed, Ashraful Alam, Ahmed Al-Kabir, Arif Billah Al-Mahmud, Ahmed Al-Sabir, Tariq Anwar, Nabeel Ashraf Ali, Abdullah H Baqui, Nazma Begum, Robert E Black, Atique Iqbal Chowdhury, Mohiuddin Chowdhury, Sameena Chowdhury, Gary L Darmstadt, Milan Krishna Das, Shams El-Arifeen, Zafar Ahmad Hakim, A K M Fazlul Haque, Quamrul Hasan, Daniel Hossain, Shahla Khatun, Paul Law, Amnesty LeFevre, Ishtiag Mannan, Syed Moshfigur Rahman, Qazi Sadequr Rahman, Samir K Saha, Mathuram Santosham, Habibur Rahman Seraji, Rasheduzzaman Shah, Ashrafuddin Siddik, Uzma Syed, Hugh Waters, Emma K Williams, Peter J Winch, and K Zaman. The study is registered as an International Standard Randomised Control Trial, number NCT00198705.

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