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Original Article

Neonatal and Infant Mortality in the Ten Years (1993 to 2003) of the Gadchiroli Field Trial: Effect of Home-Based Neonatal Care

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OBJECTIVES:

1. To evaluate the effect on neonatal and infant mortality during 10 years (1993 to 2003) in the field trial of home-based neonatal care (HBNC) in Gadchiroli.
2. To estimate the contribution of the individual components in the intervention package on the observed effect.

STUDY DESIGN:

The field trial of HBNC in Gadchiroli, India, has completed the baseline phase (1993 to 1995), observational phase (1995 to 1996) and the 7 years of intervention (1996 to 2003). We measured the stillbirth rate (SBR), neonatal mortality rate (NMR), perinatal mortality rate (PMR), postneonatal mortality rate (PNMR) and the infant mortality rate (IMR) in the intervention area and the control area. The effect of HBNC on all these rates was estimated by comparing the change from baseline (1993 to 1995) to the last 2 years of intervention (2001 to 2003) in the intervention area vs in the control area. For other estimates, we made a before–after comparison of the rates in the intervention arm in the observation year (1995 to 1996) vs intervention years (1996 to 2003). We evaluated the effect on the cause-specific NMRs. By using the changes in the incidence and case fatality (CF) of the four main morbidities, we estimated the contribution of primary prevention and of the management of sick neonates. The proportion of deaths averted by different components of HBNC was estimated.

RESULTS:

The baseline population in 39 intervention villages was 39,312 and in 47 control villages it was 42,617, and the population characteristics and vital rates were similar. The total number of live births in 10 years (1993 to 2003) were 8811 and 9990, respectively. The NMR in the control area showed an increase from 58 in 1993 to 1995 to 64 in 2001 to 2003. The NMR in the intervention area declined from 62 to 25; the reduction in comparison to the control area was by 44 points (70%, 95% CI 59 to 81%). Early NMR decreased by 24 points (64%) and late NMR by 20 points (80%). The SBR decreased by 16 points (49%) and the PMR by 38 points (56%). The PNMR did not change, and the IMR decreased by 43 points (57%, 95% CI 46 to 68%). All reductions were highly significant ($p<0.001$) except for SBR it was <0.05. The cause-specific NMR (1995 to 1996 vs 2001 to 2003) for sepsis decreased by 90%, for asphyxia by 53% and for prematurity by 38%. The total reduction in neonatal mortality during intervention (1996 to 2003) was ascribed to sepsis management, 36%; supportive care of low birth weight (LBW) neonates, 34%; asphyxia management, 19%; primary prevention, 7% and management of other illnesses or unexplained, 4%.

CONCLUSIONS:

The HBNC package in the Gadchiroli field trial reduced the neonatal and perinatal mortality by large margins, and the gains were sustained at the end of the 7 years of intervention and were carried forward as improved survival through the first year of life. Most of the reduction in mortality was ascribed to sickness management, that is, management of sepsis, supportive care of LBW neonates and management of asphyxia, in that order, and a small portion to primary prevention.

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INTRODUCTION

The current global estimates put the number of neonatal deaths each year at four million and of stillbirths (beyond 22 weeks' gestation) at another four million.[1,2] Neonatal mortality contributes nearly two-thirds of the infant mortality rate in countries like India, where each year an estimated 1.1 million neonates die.[1] Neonatal mortality and stillbirths pose a global problem of enormous proportion.

We conducted a field trial of home-based neonatal care (HBNC) in rural Gadchiroli, India. The trial had two main outcome measures — the neonatal mortality rate (NMR) and the sepsis-specific neonatal mortality rate. We completed the 5-year trial (1993 to 1998) in 1998 and published the initial

SEARCH (Society for Education, Action and Research in Community Health), Gadchiroli, India.

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results.[3] Some unanswered questions at the time of the first report were:

- Will the observed reduction in neonatal mortality be sustained beyond the duration of research trial?
- Will the reduced neonatal mortality result in survival of biologically frail neonates who would succumb to other infections during the post-neonatal period (1 to 11 months of age) resulting in only a postponement of death without any net gain in child survival? Such phenomenon was earlier described in Africa.[4]
- What proportion of the observed reduction in neonatal mortality was attributable to the individual components in the intervention package of home-based neonatal care?

We continued the interventions and the measurements and, in 2003, the trial completed its 10th year. The **objectives** of this article are:

1. To evaluate the effect on mortality during 10 years (1993 to 2003) in the field trial of HBNC in Gadchiroli.
2. To estimate the contribution of the individual components in the intervention package on the observed effects.

To achieve these objectives, we seek answers to the following **research questions**:

(1) Has the NMR in the control area changed over the 10-year period, 1993 to 2003?
(2) At the end of the 10 years of trial and 7 years of intervention (1996 to 2003), what was the effect of HBNC interventions on the NMR, early as well as on the late NMR?
(3) What was the effect of HBNC on the stillbirth rate (SBR) and the perinatal mortality rate (PMR)?
(4) Did the postneonatal mortality rate (PNMR) in the intervention area increase?
(5) Was the reduction in the NMR in the intervention area reflected in the IMR?
(6) What was the effect on various cause-specific neonatal mortality rates?
(7) What proportion of the reduction in neonatal mortality can be attributed to various components of HBNC, namely, (i) primary prevention of morbidities, (ii) management of sepsis, (iii) supportive care of LBW neonates and (iv) asphyxia management?

MATERIALS AND METHODS

Study Design

The field trial of HBNC in Gadchiroli, India, was conducted by SEARCH (Society for Education, Action and Research in Community Health) from 1993 to 1998.[3,5] SEARCH was working in the area from 1986 and had established a vital statistics surveillance system in the rural field research area, which included an intervention area and a control area. Community-based interventions such as training of traditional birth attendants (TBAs), treatment of pneumonia in children and of minor illnesses, and health education were in operation in the intervention area since 1988. The field trial of HBNC was started in this area in 1993. The intervention and control area were adjacent blocks of villages similar in socio-economic characteristics, availability of health services and baseline vital rates[3,5,6] (Table 1). The design of the field trial, the nested activities, and the subsequent continuation are presented in Figure 1. We continued the vital statistics collection in 47 control villages for 10 years (1993 to 2003). The phases in the 39 intervention villages during these 10 years included baseline vital statistics collection (1993 to 1995), observation of neonates without new interventions (1995 to 1996), introduction of the HBNC interventions (1996 to 1998) and the continuation of interventions (1998 to 2003). For ethical and practical reasons observation of neonates, estimation of the

Table 1 Baseline Characteristics (1993–1994) in the Intervention and the Control Area in Gadchiroli

Characteristics	Intervention area	Control area
Demographic		
Villages (*n*)	39	47
Population (*n*)	38,998	42,149
Sex ratio (F/1000 M)	987	983
Birth rate/1000 population (1993–1995)	25.4*	26.6*
Mortality rates (1993–1995)		
Neonatal/1000 live births	62.0*	57.7*
Infant/1000 live births	75.5*	77.1*
Perinatal/1000 births	68.3*	64.9*
Government health services (n)		
Nearby hospitals	1	2
Primary health centers	4	3
Health subcenters	16	22
Auxiliary nurse-midwives	16	22
Socioeconomic (%)		
Occupation		
Agriculture laborer	24.4	24.8
Farmers (<5 acres)	54.5	55.3
Farmers (≥5 acres)	11.5	13.9
Business/salaried	9.1	5.9
Other	0.4	0.1
Caste		
Scheduled (lowest) castes and tribes	35.6	41.2
Middle castes	63.0	56.6
Others	1.3	2.2
Electricity at home	28.8	28.9
Literacy (M/F)	69.4/37.9	63.2/33.0

*Difference not significant.

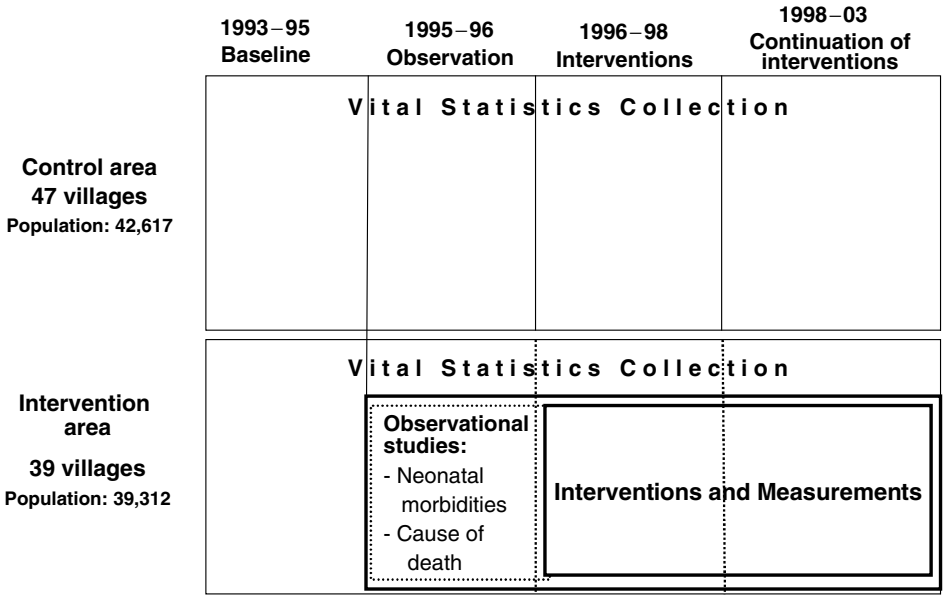

Figure 1. Study design.

incidence of morbidities and assigning cause of death were done only in the intervention area from 1995 to 2003. The HBNC interventions were provided in the intervention area for a total of 7 years (1996 to 2003).

To assess the effect on NMR, SBR and IMR, we compared the change in the vital rates in the baseline 2 years with the last 2 years of intervention between the intervention and control area. To assess the effect on the cause-specific NMRs, and to assess the contribution of various components of intervention, we made comparisons within the intervention arm, between the year of observation (1995 to 1996) when there were few interventions, and the intervention years, either the last 2 years (2001 to 2003) or all 7 years. The reason for selecting the last 2 years instead of the last 1 year was to avoid the undue influence of random annual fluctuations. The 7 years of intervention were used to increase the sample size for estimating the effect on the events whose annual numbers were relatively small.

Sources of Data

(i) Vital statistics were collected in both areas by an independent system of vital statistics surveillance in which male village health workers (VHWs) and their supervisors recorded vital events prospectively, supplemented by 6-monthly house-to-house surveys. An evaluation concluded that this system recorded vital events with 98% completeness.[3,6]

(ii) The newborns were observed in intervention villages by trained female VHWs who made from 8 to 14 visits during the neonatal period and recorded data on a printed mother–newborn form. A visiting physician checked these data for correctness. A validity study found 92% matching in the data recorded by the VHWs with that by the physician.[7,8] Various morbidities were diagnosed from these data by a computer program using clinical definitions; the incidence of various neonatal morbidities was estimated from these diagnoses.[7,8]

(iii) Cause of death was assigned by an independent neonatologist (Vinod Paul, Professor of Pediatrics, All India Institute of Medical Sciences, New Delhi) by going through the neonatal records of those neonates who died in the intervention area during 1995 to 2003. The neonatologist assigned a single ''primary cause'' to each neonatal death. We have published the results of the causes of death in the year 1995 to 1996.[9] We considered that this method, using the recorded prospective observations in the neonatal records and the judgment of a senior neonatologist, was likely to assign cause of death more correctly than the verbal autopsy method, which has not been validated for neonatal deaths.

(iv) The data on sickness management and case fatalities in sick neonates came from the records maintained by the VHWs and the field supervisors[10–12] in the intervention area. The data in the intervention arm on the incidence of morbidities, case fatality, case management and cause of death were (except for the vital statistics) recorded only on the neonates observed by the VHWs during home visits. As earlier reported, during the intervention years they covered 93% of all live births in the area reported by the vital statistics surveillance system.[11] These newborn records were submitted to the statistics division of SEARCH within 15 days of the end of the newborn period, checked for completeness and internal consistency and the data were computer entered within 2 months. These were analyzed every month until 1998, and then once every 3 months.

ANALYSIS

The annual NMR, SBR, PMR, PNMR, and IMR were estimated from vital statistics. We have earlier described our methods.[6] The

NMR, PNMR and the IMR were expressed per 1000 live births, the SBR was the number of births of a dead fetus >28 weeks of gestation per 1000 births and the PMR was the sum of stillbirths and early neonatal deaths per 1000 births. The effect of the HBNC on these rates was assessed by calculating the net difference, that is, the change in the intervention area from the baseline (1993 to 1995) to the last two years of intervention (2001 to 2003) minus the change in the control area in these two time periods. The difference was estimated as the absolute change in the rate, and also as the percent change.

To understand how the HBNC affected mortality, we estimated three effects:

(i) the change in the cause-specific NMRs; 1995 to 1996 vs 2001 to 2003.

(ii) The contribution of primary prevention (reduction in the incidence of neonatal morbidities) vs secondary prevention (reduction in CF in sick neonates as a result of sickness management) in reducing neonatal mortality (Figure 2). For this, we selected the four main morbidities that explained most of the deaths in our neonates, namely, prematurity, intrauterine growth restriction (IUGR), sepsis, and asphyxia.[13]

We estimated the averted number of neonatal deaths attributable to primary prevention (reduced incidence of morbidities from 1995 to 1996 to 2001 to 2003) in this trial by estimating the number of neonatal deaths expected if the incidence of these four morbidities had remained in 2001 to 2003 the same as in 1995 to 1996, but if management of sick neonates had been available — in other words, applying the case fatality as it existed in 2001 to 2003. The difference between the expected number of deaths and actual number of deaths was the estimated number of deaths averted by preventing neonatal morbidities. This estimated number of averted deaths was then converted into neonatal deaths averted/1000 live births.

We estimated the contribution of secondary prevention (management of sick neonates) in this trial by estimating the expected number of deaths in 2001 to 2003 if the incidence of morbidities in 2001 to 2003 was associated with CF at the same level as it was before the interventions, that is, in 1995 to 1996. The difference between the expected number of deaths and actual deaths associated with the main four morbidities produced the estimated number of neonatal deaths averted by the case management of sick neonates. This, too, was converted into deaths averted/1000 live births.

If a neonate had multiple morbidities, which was often the case,[13] it was counted with each morbidity, that is, more than once. Hence, the *estimated* total number of neonatal deaths prevented by managing different morbidities is more than the *actual* deaths prevented. This is an accepted occurrence in a causal analysis that takes multiple causes into consideration.[14]

(iii) The individual contribution of the three kinds of sickness management:

(a) *Sepsis management:* to estimate the number of deaths prevented by sepsis management, we used the data on neonates with sepsis during 1995 to 2003.[10] The difference in the case fatality between those who received treatment vs those who were untreated was used to estimate the total number of deaths prevented by the management of sepsis in those who received treatment during 1996 to 2003.

(b) *Management of birth asphyxia:* the number of deaths prevented by the management of birth asphyxia was estimated similarly from the reduced CF in severe birth asphyxia in 1996 to 2003 compared with the preintervention year (1995 to 1996).

(c) *Management of LBW neonates:* to estimate the contribution of supportive care (i.e., health education, repeated home visiting, breastfeeding, thermal care) vs treatment with antibiotics in the management of LBW neonates we made use of the data on the treated and untreated LBW neonates in the field trial. LBW neonates (<2500 g) were divided into preterm LBW (<37 weeks) and IUGR LBW (>37 weeks). For each category, we had the CF before HBNC (in 1995 to 1996), and then with HBNC (1996 to 2003), in both, those who received only supportive care, and those who received supportive care plus treatment with antibiotics. By comparing the CF in each category who received care with the neonates in the similar LBW category who did not receive that component of care, we estimated the reduction in CF and

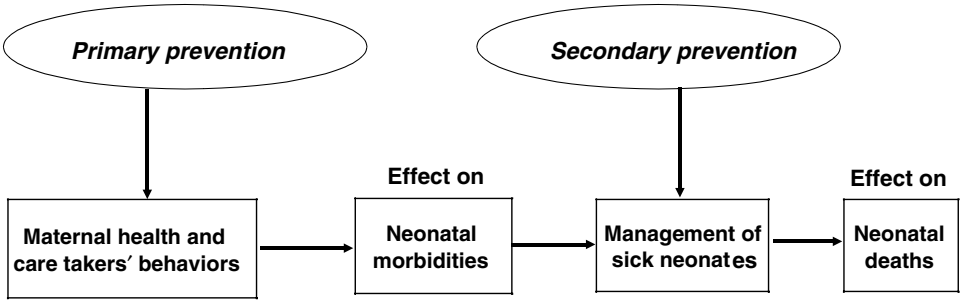

Figure 2. Neonatal health and the interventions.

number of deaths averted by supportive measures and by the treatment with antibiotics. The neonates in the groups compared had similar mean period of gestation. We could not adjust for the small differences in birth weight or period of gestation because too few neonates were available in each category to perform standardization, and there is no other large database on CF in a cohort of rural neonates to be used as the standard population.

The total number of deaths prevented in the intervention years (1996 to 2003) was estimated by subtracting the actual deaths that occurred in 1996 to 2003 from the expected number of deaths (if the %CF of the preintervention year 1995 to 1996 had continued in 1996 to 2003). We then computed the deaths prevented by different components in HBNC as proportions of total prevented deaths in 1996 to 2003.

The data were analyzed by SPSS PC + , Version 3, and Epi info, Version 5. We used the Breslow–Day test of homogeneity for estimating the significance of the difference in change in the control and intervention area in various mortality rates.[15] We used χ^2-test with Yates correction for testing the significance of differences in case fatality, and the two sample *t*-test for independent samples for estimating the significance of differences in mean gestational age groups.

ETHICS

This study was based on the analysis of the past data. The original field trial was monitored and ethical clearance given by an external advisory committee.[3,6] Written consent of the communities in the form of signed resolutions was obtained before the trial began. The parents of the neonates treated for sepsis gave written consent before treatment.[10]

RESULTS

The baseline population characteristics, vital rates and availability of health services in the intervention and the control area are presented in Table 1. For relatively robust rates, the two baseline years (1993 to 1995) have been combined. The two areas, including the vital rates in them, were similar at baseline, though the control area had a few more sources of health care. The rates in the prebaseline years (1991 to 1993) in the intervention area (and the control area in parenthesis) were following: birth rate, 25.9 (25.6); SBR, 29.9 (28.7); NMR, 58.6 (61.9); PMR, 63.3 (67.4). None of the rates in the prebaseline or baseline period in two areas were significantly different.

Total live births during 1993 to 2003 were 8811 in the intervention area and 9990 in the control area. The vital events and various mortality rates in the intervention and the control areas during 1993 to 2003 are presented in Table 2. The initial 3

Table 2 Effect of Home-Based Neonatal Care on Neonatal Mortality and Still Births in Gadchiroli (1993–2003)

	Intervention area						Control area					
	Baseline (1993–1995)	Intervention period					Baseline (1993–1995)	Intervention period				
		1995–1996	1996–1997	1997–1998	1998–2001	2001–2003		1995–1996	1996–1997	1997–1998	1998–2001	2001–2003
Number of villages	39	39	39	39	39	39	47	47	47	47	47	47
Total population	39,312	—	—	—	—	—	42,617	—	—	—	—	—
Live births	1999	1016	804	979	2503	1510	2271	1074	940	1108	2921	1676
Still births	66	34	29	26	84	53	55	46	36	51	145	72
Still birth rate*	32.0	32.4	34.8	25.9	32.5	33.9	23.6	41.1	36.9	44.0	47.3	41.2
Neonatal deaths (0–28 days)	124	52	29	25	77	38	131	70	47	66	195	108
Neonatal mortality rate†	62.0	51.2	36.1	25.5	30.8	25.2	57.7	65.2	50.0	59.6	66.8	64.4
Neonatal deaths (1–7 days)	75	33	25	22	58	33	96	55	31	55	143	85
Early neonatal mortality rate†	37.5	32.5	31.1	22.5	23.2	21.9	42.3	51.2	33.0	49.6	49.0	50.7
Neonatal deaths (8–28 days)	49	19	4	3	19	5	35	15	16	11	52	23
Late neonatal mortality rate†	24.5	18.7	5.0	3.1	7.6	3.3	15.3	14.0	17.0	9.9	17.8	13.7

*Rate per 1000 births.
†Rate per 1000 live births.

years of intervention, 1995 to 1998, are presented individually because the number of interventions was different in each year. During 1995 to 1996, home visiting consisted only of observations on neonatal morbidity and causes of death and treatment of neonatal pneumonia. In 1996 to 1997 interventions were introduced, including the management of sick neonates. In 1997 to 1998, the sickness management matured and health education was added. From then on, the intervention package changed little, and hence the years 1998 to 2001 have been presented together. For a robust comparison with the baseline years, the last 2 years of interventions (2001 to 2003) have been combined.

The outcome indicator, the NMR, at the baseline was almost identical in the two areas, albeit a little higher in the intervention area. The subsequent changes in the NMR are shown in Figure 3. Except for a dip in the year 1996 to 1997, probably a random annual fluctuation, the NMR in the control area remained almost stationary over 10 years, at around 60. The NMR in the intervention area, with the introduction of interventions in 1995 to 1996, showed a progressive decrease until the full package of interventions was operational in 1997 to 1998. Thereafter, it remained at almost the same lower level during the continuation of interventions through 2003.

The effect of HBNC on the NMR is the difference in the changes in the control area (baseline minus last 2 years of intervention) and the intervention area (baseline minus last 2 years of intervention). The experimental design and the changes in the NMR in the intervention and control areas are presented in Figure 4. The numbers have been rounded off to the nearest complete digit.

The total effect on various mortality rates, that is, change in the intervention area minus change in the control area from their respective baselines appears in Figure 5. It is presented for each rate as the absolute change, and also as the percent change in each rate from the baseline rate in the intervention area. All numbers have been rounded off to the nearest complete digit.

The salient observations in Figures 4 and 5 are as follows. The NMR showed a total difference of 44 points, which was equal to a 70% reduction. The reduction in the NMR was contributed by the reduction in the early NMR (ENMR) by 24 points and in the late NMR (LNMR) by 20 points. However, in percentage, the LNMR declined much more, by 80%, reaching a very low level of three in the last years of intervention (Table 2). ENMR, though

Effect on the neonatal mortality rate (NMR)

	Control area	Intervention area
Baseline (1993-95)	58	62
Intervention (2001-03)	64	25
Change	+7	-37

Total difference in NMR (37 + 7) = 44

Figure 4. Effect of home-based care on neonatal mortality rate: 1993–1995 to 2001–2003.

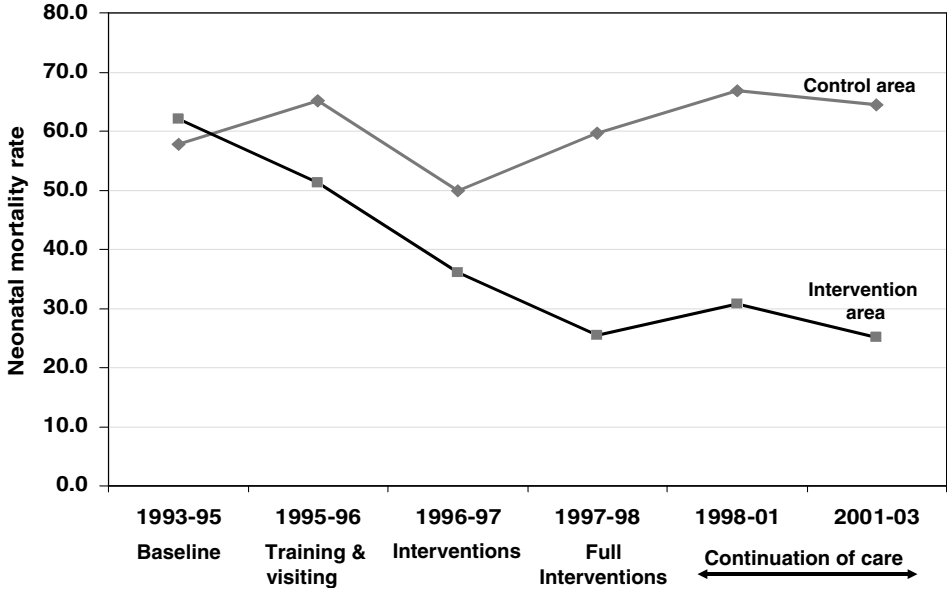

Figure 3. Neonatal mortality rate in intervention and control areas: 1993–1995 to 2001–2003.

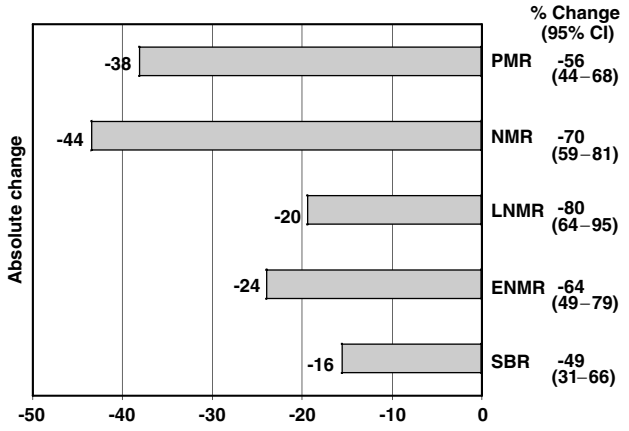

Figure 5. Effect of home-based neonatal care: absolute difference between the intervention and control area and percent change in different mortality rates.

substantially reduced by 64%, contributed most of the residual NMR (22 out of 25) in the year 2001 to 2003 (Table 2).

The SBR showed a small increase (+2) in the intervention area but, notwithstanding the annual fluctuations (which were insignificant), the SBR increased by 18 points in the control area (Table 2), and hence the net effect was a reduction in the intervention area by 16 points or 49%. The PMR similarly increased in the control area by 25, and decreased in the intervention area by 13, resulting in a total reduction of 38 points (56%). All reductions were highly significant ($p<0.001$, for the SBR it was <0.05).

The effect of HBNC on the postneonatal mortality rate and the IMR are presented in Table 3, and further in Figures 6 and 7. Table 3 and Figure 6 show that, notwithstanding the fluctuations, the IMR in the control area has remained mostly in the 70s, and it was virtually identical at the baseline (77) and at the end of intervention (76). In contrast, the IMR in the intervention area progressively declined to 31 in 2001 to 2003. The absolute reduction in the IMR (Figure 7) was by 43 points, almost identical to the total reduction in the NMR, by 44 points (Figure 5).

The postneonatal mortality rate (in the second month and in months 1–11) showed an almost identical reduction in the control and the intervention areas (Table 3), and hence HBNC had no effect on postneonatal mortality. It is noteworthy that, in the last 5 years (1998 to 2003), the mortality rate in the second month of infancy in the intervention area was down to the levels of 4.0 and 2.0, similar to the late NMR of 3.0.

The cause-specific neonatal mortality rates (CSNMRs) based on the primary cause of death are presented in Table 4. The absolute and the percent changes in the CSNMRs from the first year of observation (1995 to 1996) to the year 2001 to 2003 are presented here. The effect on the CSNMRs is also presented as the proportion of the total reduction in the NMR. The reduction in the CSNMR

Table 3 Effect of Home-Based Neonatal Care on Postneonatal and Infant Mortality Rates in Gadchiroli (1993–2003)

	Intervention area						Control area					
	Baseline (1993–1995)	Intervention period					Baseline (1993–1995)	Intervention period				
		1995–1996	1996–1997	1997–1998	1998–2001	2001–2003		1995–1996	1996–1997	1997–1998	1998–2001	2001–2003
Live births	1999	1016	804	979	2503	1510	2271	1074	940	1108	2921	1676
Deaths in 29–59 days	8	10	4	9	10	3	18	7	8	10	19	8
2nd month mortality rate*	4.0	9.8	5.0	9.2	4.0	2.0	7.9	6.5	8.5	9.0	6.5	4.8
Deaths in 1–11 motnhs	27	22	9	13	31	9	44	26	17	17	48	19
Postneonatal mortality rate*	13.5	21.7	11.2	13.3	12.4	6.0	19.4	24.2	18.1	15.3	16.4	11.3
Infant deaths	151	74	38	38	108	47	175	96	64	83	243	127
Infant mortality rate*	75.5	72.8	47.3	38.8	43.1	31.1	77.1	89.4	68.1	74.9	83.2	75.8

*Rate/1000 live births.

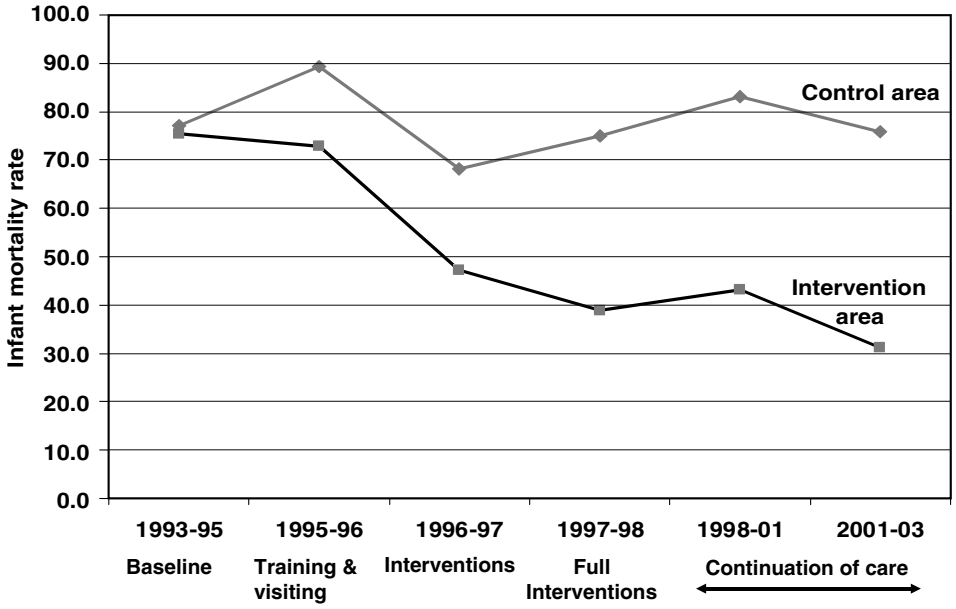

Figure 6. Infant mortality rate in intervention and control areas in Gadchiroli: 1993–1995 to 2001–2003.

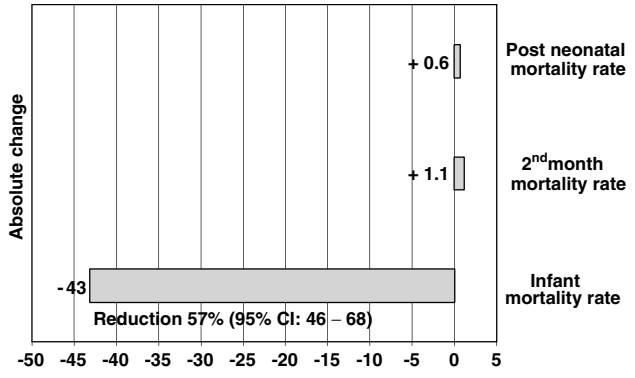

Figure 7. Effect of home-based neonatal care: absolute difference between the intervention and control area and percent change in different mortality rates.

due to sepsis was a very striking 24.7 points or 90%, explaining 67% of the total reduction in the NMR. Decreases, although smaller in absolute terms, occurred in the CSNMR due to asphyxia, prematurity and hypothermia. Only one primary cause was assigned to each death; LBW was not considered a primary cause of death. Hence the reduction in the associated or indirect causes of death is not reflected in the CSNMR estimates. The primary cause of death was assigned only in the neonates observed by the VHWs. Hence, the NMRs in Table 4, to some extent, differ from those based on the vital statistics (Tables 2 and 3).

The contribution of primary vs secondary prevention to the reduction in the NMR in the intervention area from 1995–1996 to 2001–2003 is presented in Tables 5–7. Table 5 presents the estimated number of neonatal deaths prevented by the primary prevention measures. It is estimated separately for the four main morbidities. When the results are converted into averted deaths/1000 live births, we see that prevention of IUGR and sepsis averted 1.1 and 3 deaths respectively, per 1000 live births. Prematurity and asphyxia deaths were not affected by primary prevention; their incidence did not change.

Table 6 shows the estimated number of deaths prevented by secondary prevention (management of sick neonates). If a neonate had more than one morbidity, it was counted in each morbidity; therefore, the total deaths prevented by management of all four morbidities is more than the actual number of deaths prevented. The last column presents the number of neonatal deaths prevented per 1000 live births. The management of sick neonates prevented 25 deaths/1000 live births in preterm neonates, 15 in sepsis, 12.5 in asphyxia and 7.2 in IUGR.

Table 7 compares the effect of primary vs secondary prevention. Primary prevention contributed 6.5% while secondary prevention contributed 93.6% to the reduction of an estimated 64 neonatal deaths. For prematurity and asphyxia, 100% of the reduction was due to secondary prevention, while for IUGR it was 86.6% and for sepsis, 83%.

Management of the LBW neonates included supportive care and, in those with suspected sepsis, treatment with antibiotics. The contribution of these two measures to the observed reduction in deaths in LBW neonates is presented in Table 8. To achieve a sufficient number of cases for analysis, the entire intervention period of 7 years is included. The effect of care in preterm LBW and

Table 4 Changes in the Cause-Specific Neonatal Mortality Rates 1995–1996 to 2001–2003

Cause	Cause-specific neonatal mortality rate (CSNMR)/1000 live births*					Total reduction in CSNMR (1995–1996 vs 2001–2003)		
	1995–1996 ($n=763$)	1996–1997 ($n=685$)	1997–1998 ($n=913$)	1998–2001 ($n=2351$)	2001–2003 ($n=1415$)			
	Deaths = 40	Deaths = 16	Deaths = 22	Deaths = 63	Deaths = 22	Absolute reduction	% (95% CI)	% of total reduction in NMR (95% CI)
Sepsis	27.5	8.8	6.6	7.2	2.8	24.7	89.8 (78.6–101.0)	66.8 (51.6–82.0)
Asphyxia	10.5	4.4	5.5	2.1	4.9	5.6	53.3 (23.8–82.8)	15.1 (3.6–26.6)
Prematurity[†]	7.9	8.8	6.6	10.2	4.9	3.0	38.0 (4.3–71.6)	8.1 (−0.7–16.9)
Hypothermia[‡]	1.3	0.0	0.0	1.7	0.0	1.3	100.0 —	3.5 (−2.4–9.4)
Other[§]	0.0	0.0	1.1	0.9	1.4	−1.4	−100.0 —	−3.8 —
Not known	5.2	1.5	4.4	4.7	1.4	3.8	73.1 (34.2–111.9)	10.3 (0.5–20.1)
Total (NMR[¶])*	52.4	23.5	24.2	26.8	15.4	37.0	70.6[‖] (58.2–83.0)	100.0 —

*In the neonates observed by village health workers.
[†]Prematurity was considered a probable cuase of death only in neonates with <32 weeks of gestation.
[‡]Hypothermia was considered as a probable cause of death, in the absence of any other explanation for hypothermia, such as prematurity or sepsis.
[§]Other causes include: tetanuas (1), aspiration (1), and malformation (2).
[¶]Neonatal mortality rate/1000 live births.
[‖]Percent reduction in NMR.

Table 5 Contribution of Prevention of Neonatal Morbidities in Preventing Neonatal Deaths in the Intervntion Area in Gadchiroli (1995–1996 vs 2001–2003)

Morbidity	1995–1996, neonates = 763, deaths = 40				2001–2003, neonates = 1415, deaths = 22				During 2001–2003			
	Neonates	% Incidence	Actual deaths*	% Case fatality	Neonates	% Incidence	Actual deaths*	% Case fatality	Expected[†] deaths*	Actual deaths*	Prevented deaths (No.)*	Deaths prevented/1000 live births (95% CI)
IUGR[‡]	253	33.2	11	4.4	349	24.7	5	1.4	6.60	5	1.60	1.1 (0.6–1.6)
Preterm (<37 weeks)	75	9.8	25	33.3	142	10.0	12	8.5	11.75	12	−0.25	0.0 (−1.9 to 1.6)
Sepsis (clinical)	130	17.0	24	18.5	163	11.5	9	5.5	13.31	9	4.31	3.0 (1.6–4.5)
Asphyxia[§]	26	4.6	10	38.5	54	4.9	7	13.0	6.49	7	−0.51	0.0 (−2.1 to 1.4)

*A neonate having more than one morbidity is counted in each morbidity. Hence, the sum may be more than the total neonatal deaths, or deaths prevented.
[†]If 1995–1996 incidence of morbidities held true in 2001–2003.
[‡]Intrauterine growth restriction (full-term, with birth weight <2500 g).
[§]The denominators for estimating the incidence in 1995–1996 was 570 and in 2001–2003 was 1098 neonates.

Table 6 Contribution of the Management of Sick Neonates in Preventing Neonatal Deaths in the Intervention Area in Gadchiroli (1995–1996 vs 2001–2003)

Morbidity	1995–1996, neonates = 763, deaths = 40				2001–2003, neonates = 1415, deaths = 22				During 2001–2003			
	Neonates	% Incidence	Actual deaths*	% Case fatality	Neonates	% Incidence	Actual deaths*	% Case fatality	Expected† deaths*	Actual deaths*	Prevented deaths (No.)*	Deaths prevented/1000 live births (95% CI)
IUGR‡	253	33.2	11	4.4	349	24.7	5	1.4	15.17	5	10.01	7.2 (1.2–13.5)
Preterm (<37 weeks)	75	9.8	25	33.3	142	10.0	12	8.5	47.33	12	35.33	25.0 (14.3–35.7)
Sepsis (clinical)	130	17.0	24	18.5	163	11.5	9	5.5	30.09	9	21.09	14.9 (7.2–22.5)
Asphyxia§	26	4.6	10	38.5	54	4.9	7	13.0	20.77	7	13.77	12.5 (3.4–21.8)

*A neonate having more than one morbidity is counted in each morbidity. Hence, the sum may be more than the total neonatal deaths or deaths prevented.
†If 1995–1996 case fatality held true in 2001–2003.
‡Intrauterine growth restriction (full-term, with birth weight <2500 g).
§The denominators for estimating the incidence in 1995–1996 was 570 and in 2001–2003 was 1098 neonates.

in IUGR-LBW neonates is presented separately. The CF when no care was available (1995 to 1996) is compared with the CF during the 7 years of intervention with only supportive care, and with antibiotics + supportive care. The period of gestation of the groups of neonates compared was almost identical. The difference in the case fatality gives the estimated effect of the supportive measures and of the treatment with antibiotics. Estimates of the number of deaths prevented by each component of management are shown in the last column. At the bottom of each half of the table, the estimated number of deaths averted by each intervention is presented. In the preterm LBW neonates, supportive care (to all preterm LBW neonates) contributed 75% of the prevented deaths vs 25% contributed by the treatment with antibiotics (in a selected few neonates). On the other hand, in the IUGR-LBW neonates, supportive care did not contribute to preventing deaths, and 100% of the prevented deaths were attributed to the treatment with antibiotics. Since these estimates are for the 7 years of intervention, the actual numbers do not match with the deaths prevented per 1000 live births in 2001 to 2003, presented earlier in Tables 6 and 7.

The number of deaths prevented by different components in HBNC during 1996 to 2003 is presented in Table 9. The total neonatal deaths prevented are estimated to be 161. Based on the difference in CF in 1995 to 1996 (without sickness management) and in the intervention years (1996 to 2003), it is estimated that the number of deaths actually prevented in seven intervention years by the management of sepsis was 58 and by the management of asphyxia was 31. The number of deaths prevented by supportive care in LBW neonates was 55 and 10 deaths were prevented by primary prevention.

The proportion of deaths averted by different components of HBNC, as estimated above, is presented in Figure 8. It is seen that sepsis management averted 36% of the deaths, asphyxia management, 19%; supportive care (breast feeding, and thermal management) in LBW neonates, 34% and primary prevention, 7%. The remaining 4% were due to management of other illnesses or were unexplained.

DISCUSSION

This analysis, covering a period of 10 years including the 7 years of interventions, in the field trial of home-based neonatal care in Gadchiroli, India, revealed that the total effect on the neonatal mortality rate was a reduction by 44 points or by 70% (95% CI, 59 to 81). It was contributed more or less equally by reductions in early and late neonatal mortality. The SBR and the PMR also declined by nearly 50%. The mortality reductions were sustained up through 2003. Moreover, the postneonatal mortality rate did not increase, as may occur due to increased deaths by other causes, and the IMR decreased by 43 points (57%, 95% CI, 46 to 68), reaching the level of 31. The reduction in the NMR was mostly

Table 7 Contribution of Primary Prevention vs Management of Sick Neonates in Reducing Neonatal Deaths in Gadchiroli (Proportion of Deaths Prevented in 2001–2003 Per 1000 Live Births)

	Prevented deaths per 1000 live births				
		By primary prevention		By case management	
	Total*	No.	%	No.	%
IUGR	8.2	1.1	13.4	7.2	86.6
Preterm (<37 weeks)	25.0	0.0	0.0	25.0	100.0
Sepsis (clinical)	17.9	3.0	16.8	14.9	83.2
Asphyxia	12.5	0.0	0.0	12.5	100.0
Total (95% CI)	63.7	4.1	6.5 (0.4–12.4)	59.6	93.6 (87.5–99.6)

*A neonate having more than one morbidity is counted in each morbidity. Hence, the sum may be more than the total neonatal deaths, or the deaths prevented.

Table 8 Case Fatality in Low Birth Weight (LBW) Neonates: Effect of Supportive Care and Treatment with Antibiotics

Group	Year	Intervention	Neonates	Mean gestation (days)	*p*	Deaths	%CF*	*p*	Absolute reduction in %CF†	Deaths prevented in 1996–2003‡
1. Preterm, LBW										
Without sepsis	1995–1996	No care	39	244	NS	11	28.2	<0.01	—	—
Without sepsis	1996–2003	Only supportive care	270	243		31	11.5		16.7	45
With sepsis	1995–1996	No care	23	245	NS	14	60.9	NS	—	—
With sepsis	1996–2003	Only supportive care	25	240		12	48.0		12.9	3
With sepsis	1996–2003	Antibiotics+supportive care	53	244	NS	7	13.2	<0.005¶	47.7	25
Total	—	—	—			—	—	—	—	73
Net effect of treatment with antibiotics-viz: reduction in CF = 47.7–12.9 = 34.8 percentage points Deaths prevented by treatment with antibiotics = 53 × 34.8% = 18 Deaths prevented by supportive care in preterm-LBW neonates with sepsis = (25–18) = 7 Deaths prevented by only supportive care = 45+3+7 = 55 Percent contribution of supportive care to total number of prevented deaths (55/73) = 75% (95% CI = 65–85%) Percent contribution of antibiotics to total number of prevented deaths (18/73) = 25% (95% CI = 15–35%)										
2. Fullterm, LBW (IUGR)										
Without sepsis	1995–1996	No care	204	278	NS	2	1.0	NS	—	—
Without sepsis	1996–2003	Only supportive care	1409	278		21	1.5		−0.5	0‖
With sepsis	1995–1996	No care	49	275	NS	9	18.4	NS	—	—
With sepsis	1996–2003	Only supportive care	45	277		9	20.0		−1.6	0‖
With sepsis	1996–2003	Antibiotic+supportive care	181	275	NS	16	8.8	<0.05¶	9.6	17
Total	—	—	—			—	—	—	—	17
Deaths prevented by treatment with antibiotics = 17 Deaths prevented by supportive care = 0 Percent contribution of antibiotics to total number of prevented deaths = 17/17 = 100%.										

*Case fatality.
†Compared to no care.
‡Number of neonates in 1996–2003 × absolute reduction in %CF.
¶Difference in case fatality: with antibiotics vs without antibiotics.
‖Assuming that supportive care cannot increase deaths.

Table 9 Deaths Prevented by Different Components of Home-Based Neonatal Care (HBNC) in Gadchiroli: 1996–2003

Components of HBNC	No management (1995–1996)		With management (1996–2003)		Deaths prevented during 1996–2003		
	Deaths/Cases	%CF	Deaths/Cases	%CF	Expected deaths*	Actual deaths	Deaths prevented (95% CI)
	1	2	3	4	5	6	7
Neonatal mortality in neonates†	40/763	5.2	128/5510	2.3	289	128	161 (76–247)
Sepsis management	44/221‡	19.9	31/448	6.9	89	31	58 (35–82)
Asphyxia management	10/26	38.5	34/168	20.2	65	34	31 (1–62)
Primary prevention§	—	—	—	—	—	—	10 —
Supportive care in LBW¶ neonates‖	—	—	—	—	—	—	55 —
Management of other sicknesses/unexplained**	—	—	—	—	—	—	7 —

CF, case fatality.
*If the case fatality in cases without management holds true in managed cases (column 2 × number of cases in 3).
†Neonates visited by village health workers.
‡Total neonates with sepsis during 1995 to 2003, who did not receive sepsis management.
§Table 7, primary prevention reduced 6.5% of the total prevented deaths = 161 × 6.5% = 10.
¶Low birth weight.
‖Table 8.
**Total prevented deaths, 161−(58+31+10+55) = 7.

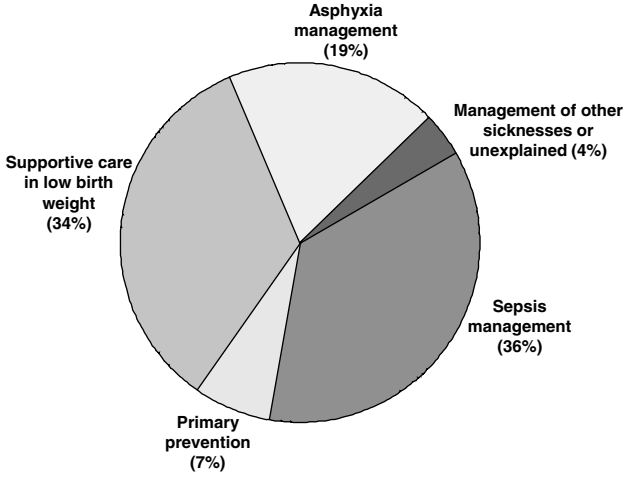

Figure 8. Proportion of neonatal deaths prevented by different components of home-based newborn care: 1996 to 2003 (total deaths prevented = 161).

explained as an effect of the management of sick neonates (93%) and only a small fraction (7%) by the primary prevention of neonatal morbidities. The reduction in neonatal mortality was contributed by different components of HBNC in the following proportions — sepsis management 36%, supportive care of LBW neonates 34%, asphyxia management 19%, primary prevention 7%, other/unexplained 4%.

Are the Estimated Effects Valid?

The estimated reductions in the mortality rates are based on a controlled trial and are very robust. The intervention and control villages were not assigned randomly and were selected *enbloc*. Hence, we compared the effect of HBNC on two populations and not on two random samples. Their baseline population characteristics and vital rates were similar (Table 1). Moreover, the estimated effect is the net difference in the before–after change in each area, which should take care of any minor baseline differences in two areas (Figure 4).

The estimated numbers of deaths prevented by different components of HBNC are based on a nested before–after comparison in the intervention arm. It should be noted that they are based on a period of 7 years of intervention and a large number of neonates. However, the validity of these estimates is limited by the lack of a control group and by a possibility that the treated and the untreated groups may not be similar on risk factors. Because untreated sick neonates as a randomly assigned control group is ethically impossible, we have identified, within the intervention arm, untreated neonates as the comparison group. The main risk factor, period of gestation, was almost identical in the groups compared (Table 8). The best method to assess the effect of various components of HBNC will be to conduct a series of controlled trials. But since field trials take many years for completion and are difficult and costly, we have used available information from the only trial of this approach conducted so far.

Estimation involves many assumptions, and the estimates would vary if the assumptions were different. The estimated effect on the cause specific NMRs and the estimated number of prevented deaths are based on a comparison of the intervention years with the mortality in the observation year (1995 to 1996). But as Table 2

and Figure 3 reveal, the NMR in the intervention area had decreased in the year 1995 to 1996, from the baseline 62 to 51, that is, nearly 25% of the total reduction of 44 points. Hence, a comparison of the intervention years with the year 1995 to 1996 may have underestimated some of the effect by almost 25%.

Effect on the NMR

The effect of the HBNC on the NMR, a reduction of 44 points, is very encouraging and is very relevant to areas with high NMR. The NMR in the control area did not decrease in the 10 years of observation. This speaks very loudly for a need for immediate interventions in such areas. Figure 3 reveals that almost all reduction in the NMR in intervention area occurred during 1995 to 1998. The reduction started when the HBNC was introduced in 1995 to 1996, beginning with the home visiting by VHWs for observing the neonates. This reduction is explained by one or more of the following: (i) annual random fluctuation; (ii) effect of the treatment with co-trimoxazole of 55 neonates with pneumonia by the VHWs, and (iii) *Hawthorne effect* — due to repeated home visiting by VHWs. The reduction continued in 1996 to 1998 when management of sick neonates and health education were introduced. After that, no further decline occurred. However, the fact that the NMR did not increase after 1998 when the interventions entered the continuation phase suggests that HBNC can be a stable approach to health care in community.

Effect on Perinatal Mortality

Table 2 and Figure 5 reveal that, out of the 44-point reduction in the NMR, 24 points were contributed by the reduction in the early NMR. It is generally believed that the ENMR, SBR, and PMR mostly depend upon obstetrical care. However, in this trial no new obstetrical interventions were introduced during 1995 to 2003. These results show that it is possible to reduce both the ENMR and the PMR by home-based interventions addressing mother and newborn.

The SBR in the control area was similar to one in the intervention area in the pre-baseline period (29 vs 30). It shows random annual fluctuations (none of which are significant) during 1993 to 2003, probably because of the relatively small study population and annual variations in the rainfall, crop yield and number of new marriages. It rose to 41 in 2001 to 2003. This may be a random variation or may be a true increase. If later, it would mean that the HBNC interventions (such as antenatal health education, presence of VHW during home delivery and resuscitation of asphyxiated neonates) prevented similar parallel increase in the intervention area. The higher SBR in the control area during intervention phase is not likely to be due to a bias or improved recording in the control area because: (i) these were recorded in both the areas by an independent vital statistics surveillance system; (ii) the recording started long before the trial began in 1993, and (iii) the recorded rates in two areas were similar before or during the baseline. Hence, the increase in the SBR in control area appears to be a true increase.

The late NMR during 2001 to 2003 reached a very low level of 3.3, almost equaling the mortality rate of 2.0 observed in the second month of infancy (Table 3). In contrast, the early NMR in 2001 to 2003 was 22 (Table 2), contributing nearly 90% of the remaining neonatal mortality, and representing the challenge to be addressed.

Effect on the IMR

The phenomenon of so-called ''replacement mortality'' has been earlier reported from other areas.[4,16] It was suspected that the reduction in mortality in an age group, achieved by a child survival intervention such as immunization, was partly neutralized by an increase in mortality in the subsequent age group, because biologically weaker children survived and reached a later age group to die of other causes. These 7 years of data show that the PNMR in the intervention area did not increase in comparison to the control area and, hence, the entire gain of the reduction in the NMR was reflected in the reduced IMR.

We should point out that various child survival interventions were already operational in the intervention area before the trial began. The management of pneumonia with antibiotics and oral rehydration therapy for diarrhoeal diseases were provided by the male VHWs and the TBAs of SEARCH since 1988,[5,17] and by the government nurses, multipurpose health workers and the integrated child development service (ICDS) workers in both the areas. Immunization and nutrition supplementation were provided by the national programs. If these had not been protecting the 1-month to 5-year-old children, increased deaths in the postneonatal age group might have occurred.

In comparison to the control area, the IMR in the intervention area changed by −43, reaching as low as 31 in the years 2001 to 2003 (Table 3). To reduce the current high level of the IMR in India from nearly 70 to a low level of 30 is the goal of the National Population Policy of India.[18] This evidence shows that the HBNC promises to achieve that low level of the IMR.

Effect on Cause-Specific Mortality

Table 4 showed that the maximum reduction, by 25 points, occurred in the cause-specific NMR due to sepsis, explaining 67% of the total reduction in the NMR between 1995–1996 and 2001–2003, followed by asphyxia and, to a lesser degree, by prematurity and hypothermia. The pronounced reduction in the sepsis-specific mortality rate is primarily due to the intervention of sepsis management. But it is also partly due to assigning a single primary cause to each death, in which the contribution of associated and indirect causes is not recognized.[19,20] In assigning the primary cause of death by a neonatologist, LBW was not considered a primary cause of death and prematurity was considered the probable cause only in neonates <32 weeks of gestation.[9] These

can underestimate the reduction in the deaths due to prematurity and IUGR, and cause relatively more representation of sepsis as the primary cause of death. Yet, it is noteworthy that during 2001 to 2003, the sepsis-specific mortality rate was only 2.8 (Table 4). The CSNMR due to asphyxia also showed a significant reduction, corroborating the reduction in the SBR.

Effect of Primary Prevention

We estimated the total number of deaths prevented in the intervention years (1996 to 2003) by estimating the expected number of deaths (if the CF of the observation year 1995 to 1996 had continued in 1996 to 2003) minus actual deaths that occurred in 1996 to 2003. The deaths prevented by different components in HBNC as proportions of total prevented deaths in 1996 to 2003 were computed. The disaggregating of HBNC into primary prevention and secondary prevention (Tables 5–7) showed that 93% of the reduction in mortality was explained by the reduction in CF as a result of sickness management and only 7% by the primary prevention of neonatal morbidities.

We have earlier reported that overall, the incidence of 17 neonatal morbidities declined by 50%.[21] However, many of these morbidities were not life-threatening; hence, a reduction in their incidence improved the proportion of morbidity-free neonates but did not translate in the same proportions into reduced number of deaths. The deaths prevented because of the prevention of morbidities was 13% in IUGR (Table 7) the incidence of which declined from 33 to 25% (Table 5), 17% in sepsis (Table 7), the incidence of which declined from 17 to 11.5% (Table 5) (part of the apparent reduction in the incidence of sepsis was probably due to a lower number of false positive cases) and zero for asphyxia and preterm birth, whose incidence did not decline. Our method of estimating the effect of primary vs secondary prevention estimates the actual contribution of these two components to the observed reduction in the Gadchiroli trial. This does not represent the theoretical potential of averting deaths by primary prevention. For estimating that, one would multiply the observed reduction in the incidence of a morbidity by the %CF in the observational year (1995 to 1996) without intervention.

Effect of Sickness Management

The vast majority (93.6%) of the deaths prevented were explained by the reduction in %CF due to sickness management (Table 7). Within that, the management of preterm neonates produced the largest decrease in deaths (25), followed by sepsis management (15), asphyxia management (13) and management of IUGR neonates (7). This was consistent with our hypothesis that although preterm and IUGR births cannot currently be prevented, prevention and management of comorbidities will reduce neonatal mortality.[13]

The management of LBW neonates (preterm and IUGR) included supportive measures as well as, when necessary, treatment with antibiotics. The data allowed us to estimate the contribution of these two components (Table 8). While supportive measures (breastfeeding, thermal care, home-visiting) played the major role (75%) in preventing deaths in preterm LBW neonates, it played no role in preventing deaths in IUGR neonates, in whom treatment with antibiotics was entirely responsible for the prevented deaths.

Contribution of Different Components of HBNC

By integrating various estimates, we have estimated the proportion of total neonatal deaths prevented by different components of HBNC (Table 9 and Figure 8). These are not based on multiple overlapping management, but are estimated effects of the exclusive intervention components. Although these tentative estimates involve many assumptions, and are not based on a controlled trial, they can be useful for program managers in selecting interventions.

Comparison with Other Studies

Reduction in neonatal case fatality has been earlier reported for individual interventions such as breastfeeding,[22] hypothermia management,[23] resuscitation of asphyxiated neonates[24] or management of neonatal infections.[25–27] In each of these studies, the CF was reported to have decreased. A WHO supported study in Pune, India, used identification of high-risk neonates in rural community by home visiting by a VHW, providing supportive care at home and referral to the health center.[28] The study did not have a control group. It reported a 25% decrease in the NMR in 2 years, as compared to a 70% reduction in Gadchiroli.

The explanation of the higher results in Gadchiroli: The reduction of higher degree in the Gadchiroli trial may be explained by:

(i) a more comprehensive package — health education, frequent (8 to 14) home visits, and management of high-risk or sick neonates;
(ii) diagnosis and management of suspected sepsis using two antibiotics;
(iii) well-developed management algorithms for breast-feeding problems, hypothermia, preterm or <2000 g neonates, and birth asphyxia including equipping the VHWs with bag and mask for resuscitation;
(iv) a curative role for the VHW including the use of vitamin K injections in every neonate and gentamicin in the neonates with clinical sepsis;
(v) a well-developed training method and continued education;
(vi) close supervision and monitoring of quality as well as coverage of care;
(vii) remuneration to VHWs linked to the actual work done and its quality, and, finally,
(viii) cooperation of the community, with $>90\%$ neonates receiving HBNC.

Recently, Manandhar and colleagues have reported an exciting approach of mobilization and health education of rural women for better practices and care seeking. This cluster randomized controlled trial in Makwanpur, Nepal reported 30% reduction in the NMR, no reduction in SBR, and 78% reduction in the maternal mortality ratio.[29] This shows the potential of educating rural women and of demand generation. The approach in the Gadchiroli trial included health education of pregnant women — individually and in groups — to change health behaviors as well as to increase care seeking. Additionally, it also supplied home-based neonatal care. This comprehensive nature of the package may explain the greater reduction in the NMR in Gadchiroli (by 70%) than in Makwanpur (by 30%).

We had earlier reported the results of the HBNC trial up to 1998.[3] In the subsequent years, the reductions in the NMR and the IMR have been sustained. The NMR or the IMR in the intervention area remained almost stationary during 1998 to 2003. This suggests that some newer interventions that we tried (kangaroo mother care or referral to hospital) did not cause any further reduction, primarily because these were not accepted by the community.[11]

Although, for the purpose of analysis, the effects of various interventions in the HBNC are artificially disaggregated, it must be remembered that these interventions are heavily interdependent. Thus, the effect of health education or the acceptance of HBNC and care seeking by parents is highly dependent on the effective curative role of the VHW, especially the management of asphyxia or sepsis which, in turn, depend on supportive care, that is, breast feeding and thermal care for the survival of the treated neonates. The total effect is that of an integrated package, and delivery of only one component without the others may be difficult and much less fruitful. For example, without monitoring by frequent home visiting, detection of early sepsis may not occur. Without regular administration of injectable vitamin K to each neonate, the VHW may not be able to administer gentamicin injections when needed.

Need for Further Research

Further research is necessary to understand the effect of HBNC on the NMR in different geographic areas and at the different levels of NMR. Also needed are controlled trials of the individual intervention components.

SIGNIFICANCE

1. These findings on the reduction in the NMR and IMR will be of interest to program managers and policy makers facing the challenge of reducing the IMR and NMR from their current high levels in developing countries.[1] The Millennium Development Goals[30] and country-specific goals such as India's goal of reducing the IMR from the current level of 72 to 30 by the year 2010[18] can be possibly addressed with the HBNC approach, which successfully reduced the IMR from 76 in 1993 to 1995 to a low level of 31 in 2001 to 2003.
2. This analysis also shows the importance of the management of sick neonates including the management of neonates with sepsis, LBW, and asphyxia. These components are currently missing in most child survival programs, including the Integrated Management of Childhood Illness (IMCI).[31] These need to be incorporated.
3. The absence of increased post-neonatal mortality should reassure policy makers and donors that the gains of reducing the NMR continue in the form of improved survival.

Although the Gadchiroli trial demonstrated the feasibility and efficacy of HBNC in a small area, the methods of scaling need to be developed and effectiveness tested in larger operational programs.

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