Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India

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Summary

Background Neonatal care is not available to most neonates in developing countries because hospitals are inaccessible and costly. We developed a package of home-based neonatal care, including management of sepsis (septicaemia, meningitis, pneumonia), and tested it in the field, with the hypothesis that it would reduce the neonatal mortality rate by at least 25% in 3 years.

Methods We chose 39 intervention and 47 control villages in the Gadchiroli district in India, collected baseline data for 2 years (1993–95), and then introduced neonatal care in the intervention villages (1995–98). Village health workers trained in neonatal care made home visits and managed birth asphyxia, premature birth or low birthweight, hypothermia, and breast-feeding problems. They diagnosed and treated neonatal sepsis. Assistance by trained traditional birth attendants, health education, and fortnightly supervisory visits were also provided. Other workers recorded all births and deaths in the intervention and the control area (1993–98) to estimate mortality rates.

Findings Population characteristics in the intervention and control areas, and the baseline mortality rates (1993–95) were similar. Baseline (1993–95) neonatal mortality rate in the intervention and the control areas was 62 and 58 per 1000 live births, respectively. In the third year of intervention 93% of neonates received home-based care. Neonatal, infant, and perinatal mortality rates in the intervention area (net percentage reduction) compared with the control area, were 25·5 (62·2%), 38·8 (45·7%), and 47·8 (71·0%), respectively ($p<0·001$). Case fatality in neonatal sepsis declined from 16·6% (163 cases) before treatment, to 2·8% (71 cases) after treatment by village health workers ($p<0·01$). Home-based neonatal care cost US$5.3 per neonate, and in 1997–98 such care averted one death (fetal or neonatal) per 18 neonates cared for.

Interpretation Home-based neonatal care, including management of sepsis, is acceptable, feasible, and reduced neonatal and infant mortality by nearly 50% among our malnourished, illiterate, rural study population. Our approach could reduce neonatal mortality substantially in developing countries.

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Introduction

Nearly 5 millon neonates worldwide die each year, 96% of them in developing countries. Neonatal mortality rate per 1000 live births varies from 5 in developed countries to 53 in the least developed countries.[1,2] Immunisation, oral rehydration, and control of acute respiratory infections have reduced the post-neonatal component of the infant mortality rate. Hence, neonatal mortality now constitutes 61% of infant mortality and nearly half of child mortality in developing countries.[1] For further substantial reduction in infant mortality, neonatal mortality in developing countries must be lowered.

63% of neonates in developing countries, and 83% in rural India, are born at home.[2,3] Standard advice is to admit every ill neonate to hospital,[2,4] but hospitals with facilities for neonatal care are inaccessible for rural populations. Parents may be unwilling to move ill neonates from home because of traditional beliefs and practical difficulties.[5–7] Hence, most neonatal deaths occur at home. Because of serious difficulties in transporting sick neonates to hospitals, those who arrive are generally seriously ill. The estimated cost of hospital-based neonatal care in India is very high.[8,9] Hence, to reduce neonatal mortality, ways to provide neonatal care at home must be developed.

The main causes of neonatal death are prematurity, birth asphyxia or injury, and infections.[2,10,11] Efforts to reduce neonatal mortality by management of birth asphyxia,[12] pre-term births, and low birthweight[13,14] have had varied success, but pneumonia, septicaemia, and meningitis (collectively, sepsis) have not been addressed.

Management of children with pneumonia, diarrhoea, or malaria by health workers is the main strategy of several child-survival programmes and of the Integrated Management of Childhood Illnesses programme.[15] This strategy, however, has not been used for management of sepsis in neonates. Our earlier work in management of pneumonia in neonates with oral co-trimoxazole given by village health workers resulted in 20% reduction in neonatal mortality,[5] and led us to believe that management of neonatal sepsis at home may be possible. We developed a package of home-based neonatal care, including the management of sepsis, and tested it in the field trial, with the hypothesis that the intervention will reduce the neonatal mortality rate by at least 25% in 3 years compared with the control area.

Methods

Study area

Our study was done in the Gadchiroli district of India (Maharashtra state), about 1000 km from the state capital, Mumbai (Bombay, figure 1). This is an extremely underdeveloped district, in which rice cultivation and forestry are the main sources of income. Roads, communications, education, and health services are poor. Government health services in the area comprise a male and a female paramedic worker for every 3000 people, and a primary health centre with

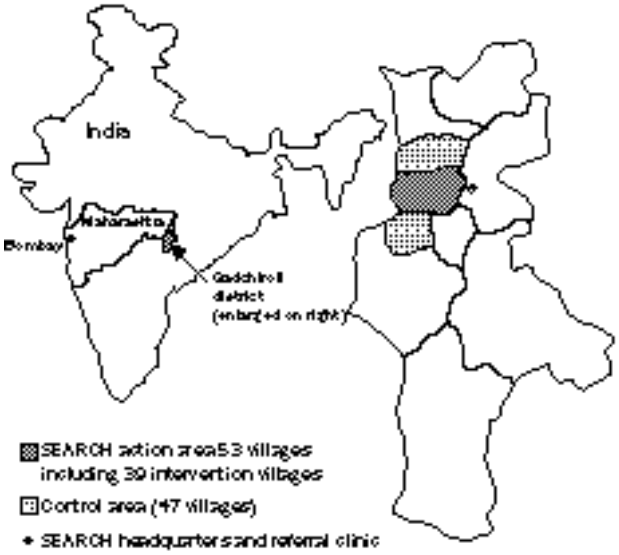

Figure 1: **Gadchiroli district and the research area**

two physicians for every 20 000 people. These services provide prenatal care, immunisation, family planning, control of communicable diseases, and curative medical care. Secondary-care hospitals are located within 30 km of the remotest village in each area, but specialised neonatal care is not available in any of them. Private rural medical practitioners, herbalists, and magic healers form the main sources of curative care. The Integrated Child Development Service (ICDS), run by the government in each village in the district, provides supplementary feeding to pregnant and lactating women, and to children, and management of diarrhoea and acute respiratory infections in children.

SEARCH (Society for Education, Action, and Research in Community Health) is a non-government organisation for community health care and research, established in 1986. Our field trial was done in the field research area (100 villages) of SEARCH, comprising an action area of 53 villages, and an adjacent control area of 47 villages. SEARCH has recorded 98% of all births and child deaths in the field research area.[16]

Since 1988, SEARCH has trained and supported male village health workers and traditional birth attendants in the action area to give case management of pneumonia in children.[16] Traditional birth attendants distribute iron and calcium tablets to pregnant women, treat common reproductive-tract infections in women, and undertake hygienic delivery.[17] SEARCH runs other health programmes in both areas, such as reproductive health education for adolescents, management by village health workers of minor health problems such as malaria, scabies, diarrhoea, or wounds, and consultation and prenatal care at the referral clinic outside the field research area. Training of traditional birth attendants and management of pneumonia in children was not given by SEARCH in the control area, where these tasks were done by the government health services and the ICDS workers. Owing to successful maternal immunisation against tetanus, neonatal tetanus was rare in the intervention of the control area.

Study design

The baseline phase of the study was from April, 1993, to March, 1995. The intervention phase was April, 1995, to March 1998. Male village health workers did census and baseline survey in the field research area (100 villages) in 1993, and collected baseline data from April, 1993 to March, 1995. Live births, neonatal deaths, and infant deaths were defined according to the International Classification of Diseases.[18] Still birth was defined as birth of a dead foetus with a gestation period of 28 weeks or more.

Traditional neonatal care was studied by a female social worker via unstructured interviews and actual observation of neonatal care at home. We subsequently used this information to plan the contents of health education.

We obtained community consent in each of the 53 villages in the action area of SEARCH for our study. Village women with 5–10 years of school education who were willing to work were chosen as village health workers in 39 of the 53 villages. We excluded the remaining 14 villages because the population was less than 300 or because a suitable woman could not be found there. These 39 villages constituted the intervention area, and all 47 villages in the control area of SEARCH constituted the control area for this trial. Female village health workers were not chosen in the control area.

From October, 1994, to March, 1995, we trained the female village health workers to take histories of pregnant women, observe the process of labour, examine neonates, and record findings. Workers were given colour photographs of various neonatal signs for visual reference. The female workers were also trained in case management of pneumonia in children, including neonates, in the same way as the male village health workers had been trained.[15,16]

Neonatal care was introduced in 39 intervention villages in a stepwise manner from April, 1995, to March, 1998. In the first year of the intervention, female village health workers listed pregnant women in the village, collected data by home visits in the third trimester, observed labour and neonates at birth, visited the home on days 1, 2, 3, 5, 7, 14, 21, 28, and on any other day if the family called, to take history and examine mother and child, weighed the child each week, and managed minor illnesses and pneumonia in the neonates. They followed-up the neonates for 28 days after birth, until the mother left the village, or until the neonate died, whichever was earlier. Data from the first year were used to estimate the natural incidence of neonatal morbidities and the need for care (to be published separately), and to plan further interventions.

In the second year of the study, after a survey of 280 parents ("Will you choose to seek care from trained female village health workers if your neonate is sick?"), the female workers were

Contents of neonatal care kit given to village health workers

Flip chart for health education	Soap
Brush for cleaning nails and hands	Cotton
Torch	Spirit
Wristwatch	Sodium hypochlorite solution
Mucus sucker	Gentian violet 1%
Tube and mask for resuscitation	Tetracycline eye ointment
Spring balance for weighing	Disposable insulin syringes and needles
Thermometer	Gentamicin vials (40 mg/mL)
Photo album with reference pictures	Co-trimoxazole syrup
Baby clothes and head cover	Paracetamol (acetaminophen) tablets
Blanket	Vitamin K (1 mg ampoules)
Sleeping bag	
Breast pump for inverted nipples	
Spoon	
Records and file	

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 (1993–95)	25·4*	26·6*
Mortality rates (1993–95)		
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 centres	4	3
Health sub-centres	16	22
Auxiliary nurse-midwives	16	22
Socioeconomic (%)		
Main occupation		
Agriculture labourer	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 & 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.

Table 1: **Baseline characteristics (1993–95) in Gadchiroli**

trained in home-based management of neonatal illnesses. They gave such care from April, 1996; and managed neonatal sepsis from September, 1996, in addition to the earlier tasks.

In the third year, health education of mothers and grandmothers about care of pregnant women and of neonates was added to the programme.

Case management

We decided on simplified diagnostic criteria for various neonatal disorders by use of the recommendations of the National Neonatology Forum of India[19] and the advisory group. The village health workers were issued with a care kit (panel) and trained to diagnose and manage as follows:

Birth asphyxia was diagnosed at 1 min after birth, and managed by clearing mucus with an oral mucus sucker with mucus trap (Romsons, India), tactile stimulation, and, if necessary, giving artificial respiration by mouth to mask or by tube and mask (Phoenix Medical Systems, Chennai, India).

Birthweight was assessed within 6 h of birth by hand-held spring weighing-balance (Salter, UK) with a range of 0–5 kg and discriminating power of 25 g. Neonates with gestation of less than 37 completed weeks (calculated from the last date of menstruation), or those with birthweight below 2000 g were judged high-risk babies to be managed by warmth, frequent breast feeding, and 12 home visits.

Temperature maintenance was ensured by keeping the room warm in winter, by drying the baby immediately after birth and covering in multilayered cloth, by use of head cover and baby clothes, and by wrapping the baby in a blanket in winter. The village health workers measured neonates' skin temperature in axilla by digital thermometer (Sakura, Japan) with a temperature range from 89°F–105°F (31·7°C–40·6°C). High-risk babies or those who became hypothermic (<95°F or 35°C) were kept in sleeping bags after initial warming with heated cloth. Fever (>99°F or 37·2°C) was treated with oral paracetamol (acetaminophen).

Health workers and birth attendants encouraged mothers to start breast feeding in the first h after birth and continue exclusive breastfeeding on demand. If the baby did not suck, expressed breastmilk was fed by spoon. Inverted nipples or painful breasts were managed by health workers. Breast milk, if inadequate, was supplemented by cow's milk fed by spoon.

For prevention of superficial infections, we advised hand washing, cord cutting with a clean blade, and tying with clean

Intervention	1995–96 (%)	1996–97 (%)	1997–98 (%)
Home visits and observation	763/1016 (75·1)	685/804 (85·2)	913/979 (93·3)
Home-based management of neonates	· ·	685/804 (85·2)	913/979 (93·3)
Health education			
In meetings of pregnant women	· ·	· ·	725/1089† (66·6)
During home visits	· ·	· ·	744/977† (76·2)

*Proportion of neonates covered by the particular intervention out of total live births in the intervention area. †Number of pregnant women educated out of total number of pregnant women in the villages at that time—some were educated more than once.

Table 2: **Stepwise introduction of interventions and coverage***

thread (by traditional birth attendants), and applying gentian violet to the umbilical stump. Mothers were encouraged to put breast milk in the eyes of babies (a local practice). Traditional birth attendants and village health workers put tetracycline ointment in the eyes of all babies, encouraged skin hygiene, and applied 1% gentian violet for pyoderma or intertrigo. Village health workers gave an injection of vitamin K 1 mg to each baby.

We used the term neonatal sepsis[20] collectively for septicaemia, meningitis, or severe pneumonia,[21] diagnosed clinically. Sepsis was the most common cause of death in the first year of study; so early detection and treatment of sepsis became the mainstay of home-based neonatal care. Simultaneous presence of any two of the following criteria denoted sepsis: baby's cry became weak or abnormal or stopped; baby stopped sucking or mother felt that sucking definitely became weak or reduced; baby became drowsy or unconscious; skin temperature more than 99°F (37·2°C) or less than 95°F (35·0°C); pus in skin or umbilicus; diarrhoea or persistent vomiting or distension of abdomen; grunting or severe chest indrawing; respiratory rate 60 or more per min in a quiet baby even after two counts.

Sepsis was managed by female village health workers in the following way. Parents were advised to agree to hospital admission for their child. If unwilling, treatment was offered at home after written consent was obtained. Gentamicin (5 mg twice daily for 10 days for preterm babies with birthweight <2500 g; 7·5 mg twice daily for 7 days for full-term babies or those with birthweight >2500 g) was given by intramuscular injection with disposable insulin syringes (40 units/mL). Since the strength of gentamicin was 40 mg/mL, 1 unit in the insulin syringe was equal to 1 mg gentamicin). Syrup co-trimoxazole (sulphamethaxozole 200 mg, trimethoprim 40 mg/5 mL) 1·25 mL was also given twice a day for 7 days.[21] The health workers supported temperature maintenance and breast feeding, treated superficial infections, and undertook follow-up for 7–10 days twice a day. After training, the village health workers were assessed, and on reaching a satisfactory competence they started treating sepsis at home from September, 1996.

The trial did not provide for any referral care to neonates apart from that already available at government hospitals. The family was free to seek care from other sources as well. The rate of hospital admission was recorded.

Health education of pregnant women and grandmothers was actively introduced in the third year of intervention. The

Management	Cases	Deaths	Case fatality (%)
Before training in sepsis management*	163	27	16·6
After training†			
Treated by VHW	71	2	2·8
Not treated (missed by VHW)	19	5	26·3
Parents refused treatment	14	2	14·3
Hospital treatment	7	1	14·3

VHW=village health worker. *April, 1995, to August, 1996, no sepsis management. However, many neonates received co-trimoxazole for pneumonia. †September, 1996, to March, 1998. p<0·001 for comparison of row 1 *vs* row 2, and of row 2 *vs* rows 3 and 4.

Table 3: **Home-based case management of suspected neonatal sepsis and outcome (1995–98)**

	Intervention area				Control area			
	Baseline (1993–95)	Intervention period			Baseline (1993–95)	Intervention period		
		Year 1 (1995–96)	Year 2 (1996–97)	Year 3 (1997–98)		Year 1 (1995–96)	Year 2 (1996–97)	Year 3 (1997–98)
Number of villages	39	39	39	39	47	47	47	47
Total population	39 312	40 110	40 520	41 353	42 617	43 803	44 498	45 383
Live births	1999	1016	804	979	2271	1074	940	1108
Crude birth rate*	25·4	25·3	19·8	23·7	26·6	24·5	21·1	24·4
Still births	66	34	29	26	55	46	36	51
Stil-birth rate†	32·0	32·4	34·8	25·9	23·6	41·1	36·9	44·0
Neonatal deaths								
0–6 days+7–27 days	75+49	33+19	25+4	22+3	96+35	55+15	31+16	55+11
Early neonatal mortality rate‡	37·5	32·5	31·1	22·5	42·3	51·2	33·0	49·6
Late neonatal mortality rate‡	24·5	18·7	5·0	3·1	15·4	14·0	17·0	9·9
Neonatal mortality rate‡	62·0	51·2	36·1	25·5	57·7	65·2	50·0	59·6
Infant deaths (0–11 months)	151	74	38	38	175	96	64	83
Infant mortality rate‡	75·5	72·8	47·3	38·8	77·1	89·4	68·1	74·9
Perinatal mortality rate†	68·3	63·8	64·8	47·8	64·9	90·2	68·7	91·5

Data are number except *per 1000 population, †per 1000 births, ‡per 1000 live births.

Table 4: **Effect of interventions on mortality rates**

education addressed care and nutrition during pregnancy, initiating early and exclusive breast feeding, prevention of infection, temperature maintenance, importance of weight gain, recognising danger signs or symptoms in neonates, and seeking immediate help from a health worker.

A physician visited each village once every 2 weeks. He verified the data recorded by the village health workers, corrected and educated them, and independently recorded parallel observations on a sample of 119 consecutive neonates. No treatment was provided by the physician. If he found a neonate seriously ill, he advised hospital admission, but the final decision was left to the family.

Records of the neonates in the intervention area who were attended by the female village health-workers but who died, were reviewed by an independent neonatologist, who assigned cause of death by use of criteria similar to those used by the expert group of the National Neonatology Forum of India.[11] The primary cause of death[18] included prematurity, birth asphyxia, sepsis, other (eg, malformations, hypothermia, tetanus), and cause not known.

Recording of births and child deaths was done during 1993–98 by an independent set of workers in the intervention and the control areas. Besides prospective reporting, they undertook a house to house survey in both areas, once every 6 months, to detect any missed events. Births and neonatal deaths were counted in the village where they actually occurred. If a hospital-born neonate was brought to a village, it was included. Similarly, if an ill neonate from the area was admitted to hospital and died there, the death was included.

Costs (training, equipments, wages and incentives, medicines and supplies, records, supervision and transport) were recorded. The costs were separated into service costs and research costs.

Statistical analysis

The primary outcome measure was the neonatal mortality rate. The secondary outcome measures were the infant mortality rate and the perinatal mortality rate. The trial compared the changes in the outcome measures in two areas from their respective baselines. To detect a difference of 25% in the neonatal mortality rate, the required sample size was 3000 live births in 3 years in each of the intervention area and the control area (baseline p=0·07). With a local birthrate of 25 in 1000, about 40 000 population was needed in each area.

We analysed the data with SPSS (version 3.1) and FOXPRO (version 2·0) packages, and calculated significance via χ^2 and Z test. For calculation of mortality rates, all births and deaths that occurred in the area were included irrespective of whether or not they received treatment.

Ethical aspects of the trial and the quality were monitored by an external group of neonatologists and paediatricians, which met once a year at the SEARCH headquarters.

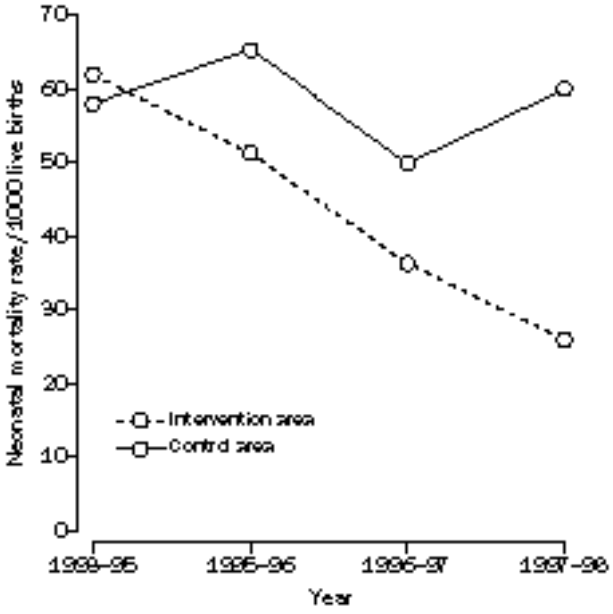

Figure 2: **Neonatal mortality in intervention and control areas 1993–98**

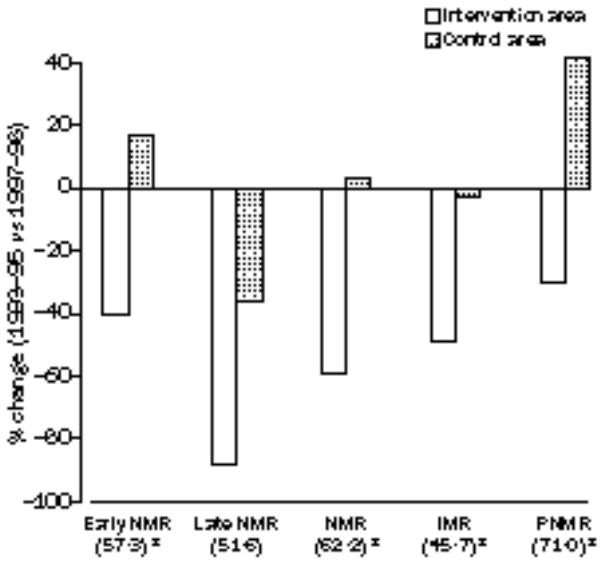

Figure 3: **Effect of interventions on mortality rates**

NMR=neonatal mortality rate. IMR=infant mortality rate. PNMR=perinatal mortality rate. Numbers in brackets are % net change in intervention and control areas. *p<0·001.

	1995–96			1996–97			1997–98			% change in CF (1995–96 to 1997–98)	p
	Deaths	Neonates	CF (%)	Deaths	Neonates	CF (%)	Deaths	Neonates	CF (%)		
Birthweight (g)											
<1500 g	9	13	69·2	6	13	46·2	4	16	25·0	−63·9	0·045
1500–1999	18	61	29·5	4	47	8·5	5	47	10·6	−64·1	0·033
2000–2499	9	246	3·7	4	243	1·6	4	258	1·6	−56·8	0·230
⩾2500	1	417	0·2	2	365	0·5	5	574	0·9	+350·0	0·395
Unknown	3	26	11·5	0	17	—	4	18	22·2	—	
Gestation period (weeks)											
⩽34	15	29	51·7	3	24	12·5	7	21	33·3	−35·6	0·315
35–37	10	46	21·7	3	53	5·7	2	72	2·8	−87·1	0·003
>37	14	673	2·1	10	597	1·7	11	801	1·4	−33·3	0·398
Unknown	1	15	6·7	0	11	—	2	19	10·5	—	
Total	40	763	5·2	16	685	2·3	22	913	2·4	−53·8	0·003

CF=case fatality.

Table 5: **Change in case fatality by birthweight and maturity**

Results

Population characteristics at baseline in the intervention and the control area were similar (table 1).

Of the 763 neonates visited by the village health workers, 722 (94·6%) in the intervention area were home deliveries. Of 737 neonates weighed on the first day, 320 (43%) neonates had low birthweight (<2500 g) in the first year (1995–96). The mean agreement between the data recorded by village health workers and the physician on 47 variables was 92·3% (SD 7·4).

Of the 280 parents interviewed, 273 (97·5%) preferred care for ill neonates from the female village health workers, because of availability within the village, good training, and because the care was free of cost.

Data from mothers and neonates covered by the various interventions over 3 years are shown in table 2. The number of cases of neonatal sepsis and the outcome of treatment are presented in table 3.

The proportion of neonates in the intervention area who were admitted to hospital in different years was: three of 763 (0·4%) in 1995–96; four of 685 (0·6%) in 1996–97, and five of 913 (0·5%) in 1997–98.

The effect of the interventions on mortality rates is shown in table 4. The neonatal mortality rate in the different years of the study is shown in figure 2. The percentage changes in mortality rates in the intervention and the control areas from their baseline values and the net difference are shown in figure 3.

The number of deaths averted by the interventions in 1997–98 (expected number of deaths in the intervention area if the rates were similar to the control area, minus actual deaths in the intervention area) were estimated as 32 neonatal plus 19 fetal deaths—a total of 51 deaths. 913 neonates received care from village health workers. Thus one death was averted among every 18 neonates cared for.

Cause of death*	1995–96 (n=763)		1997–98 (n=913)		Absolute change in rate	Change (%)
	Deaths (n=40)	Mortality rate†	Deaths (n=22)	Mortality rate†		
Prematurity	6	7·9	6	6·6	−1·3	−16·5
Birth asphyxia	8	10·5	5	5·5	−5·0	−47·6
Neonatal sepsis	21	27·5	6	6·6	−20·9	−76·0‡
Other	1	1·3	1	1·1	−0·2	−15·4
Not known	4	5·2	4	4·4	−0·8	−15·4

n=number of neonates attended by village health workers in the intervention area and deaths among them. *Cause of death assigned by neonatologist was available only from 1995–96 to 1997–98, and not for the baseline period. †Per 1000 live births. ‡p<0·005.

Table 6: **Change in cause-specific neonatal mortality rates in the intervention area from 1995–96 to 1997–98**

The change in mortality rates in neonates by their maturity and birthweight is shown in table 5. The change in cause-specific mortality rates (primary causes) in the intervention area in 1997–98 is shown in table 6. Causes of death were not assigned by the neonatologist to the deaths during the baseline period or in the control area, so we compared the first year (1995–96) and the third year (1997–98) of intervention.

The total population of the 14 villages excluded from the intervention area was 4054 in 1993. The baseline mortality rates per 1000 births (neonatal 42·0, infant 54·6, perinatal 45·5) were not significantly different from the baseline rates in the 39 intervention villages. In 1997–98, the rates in the 14 villages were 39·6, 49·5, and 70·2, respectively, and were not significantly different from their baseline rates.

The cost of home-based neonatal care per neonate in 1997–98 was US$1·5 (non-recurring cost) and $3·8 (recurring cost), to give a total of $5·3.

Discussion

In our study, the intervention and the control villages were not randomly selected for reasons of feasibility. Did this introduce a selection bias? Sociodemographic characteristics of the populations in the two areas were similar, and baseline mortality rates were not significantly different (table 1). The study design took account of the marginal baseline differences, because the effect of intervention was estimated by the changes in mortality rates in each area from their baseline.

The sample size was planned to detect 25% difference in neonatal mortality in 3 years. However, since there was no prior experience the interventions were introduced stepwise; the complete package became operative only in the third year of the study, and the effect of intervention increased progressively to peak in that year (table 4). The effect was far greater than the hypothesised 25% reduction in neonatal mortality rate, and the decline in mortality was significant even independently in the third year.

Annual fluctuations in the birth rate, still-birth, and the neonatal mortality rate observed in the control area were probably due to year-to-year variation in crop yield and food supply, and in the number of new marriages related to cultural or economic factors. Similar fluctuations were observed in the birth rate in the intervention area but not in the mortality rates, which showed progressive decline. We cannot explain the degree of increase in still-birth rate in the control area in 1995–96 and 1997–98.

The study area was an underdeveloped agrarian rural

area with baseline neonatal and infant mortality rates similar to those of rural India (52 per 1000 births and 80 per 1000 births, respectively, in 1994[22]). Low female literacy (37·9%) and high proportion of low birthweight (43%) among the study population made reduction of neonatal mortality difficult. Successful reduction of neonatal mortality in such a population shows that our approach is robust.

We used simplified clinical criteria to diagnose sepsis. The criteria were presumptive and may have detected many false-positive cases. Because of lack of laboratory facilities in the villages and the need for immediate treatment, we treated all neonates who met our criteria. We treated 6·5% of the neonates born between September, 1996, and March, 1998, with antibiotics. This was similar to recommended practice in the USA of starting antibiotics on minimum suspicion of sepsis. Remington and Klein[23] showed that between 4·4% and 10·5% of neonates in Boston are given antibiotics, although bacterial cultures are positive in only 4–7% of those who receive antibiotics on suspicion of sepsis. A database from 16 centres in India showed that 9·5% of neonates in hospitals received antibiotics.[11]

Parenteral aminoglycosides, such as gentamicin, and ampicillin are the standard first-line treatment for suspected neonatal sepsis.[23,24] We substituted injection ampicillin with oral co-trimoxazole for three reasons. It reduced the required number of injections; village health workers were already using co-trimoxazole for treating pneumonia in neonates and children, and our sepsis case definition included severe pneumonia; and in the absence of community-based information about the bacteria causing neonatal sepsis, we used the information from an earlier study in the same area[25] in which vaginal swabs taken from rural women were cultured. Of the 280 positive cultures, 93% were sensitive to co-trimoxazole, 95% to gentamicin, and 100% to at least one of the two.[5] Assuming that many of the bacteria that cause neonatal sepsis were of maternal origin, we decided to use co-trimoxazole plus gentamicin for neonatal sepsis. The results (table 3) seem to justify our choice. We did not experience aggravation of jaundice with the use of co-trimoxazole in neonates in this trial or in the earlier study on pneumonia.[5,16] WHO now recommends co-trimoxazole for pneumonia in neonates when hospital admission is not possible.[21]

Reasons for the high acceptance of home-based care were: the huge unmet need of neonatal care in villages, involvement of traditional birth attendants, health education, good quality of care, availability of care at home by a village health worker resident in the village, successful management of sepsis, the faith of rural people in injections, and good motivation, training, supervision and performance-linked remuneration for the village health workers.

The impressive effects of intervention can be attributed to high baseline neonatal mortality, high proportion of neonates covered by home-based care, and successful management of sepsis. From the first to the third year of the study, neonatal mortality due to sepsis was reduced by 20·9 points, accounting for 74% of the total reduction in neonatal mortality (table 6). However, the intervention package substantially reduced mortality in low birthweight and preterm babies (table 5), partly because of successful management of sepsis in such neonates, so it is broadly effective.

Very few studies of home-based neonatal care are available to compare with our results. Two preliminary reports, one from rural Guatemala[26] and another from the slums of New Delhi[7] have reported use of injectable antibiotics to treat suspected neonatal sepsis at home, with a resultant case fatality of none in three cases and three in 90 cases, respectively. We have previously reported 15% case fatality when neonatal pneumonia in rural Gadchiroli was managed at home with oral co-trimoxazole alone.[5] Use of injection gentamicin plus co-trimoxazole to manage sepsis in this study reduced the case fatality to 2·8%.

In an uncontrolled field study near Pune, India,[27] village health workers were trained to detect high-risk neonates and in home-based management of preterm or low birthweight babies, but not in management of sepsis. Reduction in neonatal mortality from baseline in that study was 25·1%, compared with 59% in our study. The difference between the two studies was probably the contribution of sepsis management.

The interventions used in our study are replicable in other rural areas. The simplified plan of diagnosis and management of sepsis that we have developed and tested makes replication feasible. Training a village health worker in injection of gentamicin was similar to training a literate patient with diabetes to inject insulin.

The female village health worker was the key to deliver the planned intervention. Our previous workers—illiterate traditional birth attendants and male village health workers—were unsuitable for the job. However, if other female workers, such as the ICDS workers in India, are already working, they can be trained in home-based neonatal care. The necessary attributes are literacy, village residency, willingness to visit the home at the time of labour and in the neonatal period, and acceptance by the community.

In our study, a physician was entrusted with field supervision to ensure a good quality of research data. While incorporating home-based neonatal care in primary health-care elsewhere, a medical assistant or a nurse can provide field supervision. Good supervision is vital in this approach.

Our physician did not treat sick neonates at home because in the first year (1995–96) we did not have the information necessary to plan simplified diagnostic criteria, nor did we have ethical clearance for home-based management. Hence, except for minor treatments, hopsital admission was advised for all ill neonates (though patients generally did not comply). Subsequently, when home-based management was agreed to by the advisory group, village health workers managed those neonates according to the standing orders. The physician was usually not present in the village when the treatment began. During his fortnightly visits, he corrected any errors in the treatment given by village health workers or advised hospital admission.

At the end of the trial, residual neonatal mortality in 1997–98 occurred mainly in neonates with birthweight of less than 2000 g (nine of 22 deaths) or prematurity (nine of 22 deaths, table 5), in cases of sepsis (six of 22 deaths: either missed by village health workers or treatment was refused by parents), or in cases of birth asphyxia (five of 22, table 6). Future research should address these and other issues, such as improving diagnostic criteria for sepsis, once daily administration of gentamicin,[28] and

identifying neonates at very high risk and admitting them to hospital.

We did not observe any complications in use of injection vitamin K or gentamicin by village health workers. However, to further simplify the parenteral administration of gentamicin, the use of disposable syringes pre-filled with gentamicin, or a single-use simple Uniject device (PATH, Seattle, CA, USA) should be tested.

The cost of neonatal care per neonate (US$5.3) was much lower than the reported cost of hospital-based neonatal care in urban India, which was $17.3–$44.2 per day in Chennai[8] with a mean hospital stay of 8·8 days; and $17 per neonate in Vellore in 1992[9] for ill and "under observation" neonates similar to the neonates in our study.

Neonatal care for most neonates in developing countries, where 96% of the global burden of neonatal deaths occurs, is practically non-existent. These neonates are a vulnerable group and efforts to reduce mortality in such groups will be highly rewarding. Even in populations with poor economic and nutritional status, and low female literacy, the infant mortality rate can be reduced by nearly half through health education and home-based neonatal care. This model can be replicated in other developing countries, in which it should become part of primary health-care and part of the Integrated Management of Sick Children approach proposed by WHO.

Contributors

Abhay Bang designed the study, trained the health workers, monitored the progress of the trial and wrote the first draft of the paper. Rani Bang trained the health workers and traditional birth attendants. Sanjay Baitule supervised the health workers in the field and provided health education. Mahesh Deshmukh monitored the data collection, and M Hanimi Reddy did statistical analysis.

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