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Neonates in Gadchiroli:

Field trial of home-based neonatal care in rural India (1993-2003)

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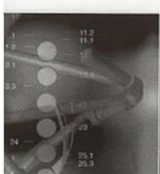

Neonates in Gadchiroli:

Field Trial of Home-Based Neonatal Care in Rural India (1993–2003)

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Editorial

Original Articles

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Editorial

Guest Editorial for Journal of Perinatology Supplement on the Gadchiroli Field Trial

Robert L. Parker, MD, MPH

Journal of Perinatology (2005) **25,** S1–S2. doi:10.1038/sj.jp.7211279

Neonatal health in developing countries has only recently emerged as a public health priority. In the 1980s and 1990s, the ''Child Survival Revolution'' focused on interventions that showed the greatest potential to reduce mortality and morbidity among children under 5 years of age. The implementation of several child survival programs — including childhood immunizations, antibiotics to treat pneumonia, oral rehydration fluids to control diarrheal disease,and nutrition monitoring and intervention — led to steady decreases in child mortality in many countries. Since parallel improvements in neonatal survival were small, many in the public health community then believed that neonatal interventions could only be effective in countries with better and easily accessible health care facilities. Thus, as under-five mortality decreased overall, neonatal deaths made up an increasing share of under-five mortality.

It wasn't until after the year 2000 that the potential for significantly reducing neonatal mortality in resource-poor areas of the world through the use of simple approaches for recognizing, preventing, and treating neonatal problems at the community level became increasingly apparent. This was due in large part to the publication of a study in 1999 by Dr. Abhay Bang and colleagues in Gadchiroli, India at SEARCH (the Society for Education, Action, and Research in Community Health), which demonstrated a 62% decline in neonatal mortality rate in rural communities using a ''home-based neonatal care'' approach.[1] In 2001, another publication based on the same study described the burden of morbidity among neonates in this rural setting and estimated their unmet need for health care in the preintervention period.[2] The interventions that worked so well in these remote villages with limited access to formal health care included training local women as village health workers to provide antenatal education visits, to assist traditional midwives at delivery by assuming care of the newborn, and to follow-up the mother and newborn with visits during the neonatal period. The village health workers were also trained in how to manage birth asphyxia and low birth weight neonates at home, and how to recognize and treat neonatal sepsis. Along with these low-cost technical interventions, the approach succeeded because of the less tangible but equally important long-term relationship of the study team with the communities in solving their health-care problems.

Since the publication of the original study, SEARCH continues to implement and monitor neonatal interventions in the study site. The study team has worked in 39 intervention villages and 47 control villages for more than a decade, effectively turning the community into a neonatology ''laboratory,'' and providing a longer horizon to judge the effectiveness of the home-based neonatal care approach. The project also provides population-based information not previously available on neonates born in homes and critical insights into why the interventions work. Finally, they provide useful guidance to investigators, program managers and policy makers in how to implement essential newborn care at the community level.

Long-term community-based studies provide a rare opportunity to study the health of populations and to develop new health care interventions. Dr. Bang and his colleagues had the foresight to establish such a community-based study site, making the findings reported on in this supplement possible.

The studies in the following pages cover an intriguing range of issues. The authors provide a detailed background of the study setting, including the methods of data collection, the home-based interventions introduced, and the baseline situation to introduce readers unfamiliar with the originally published papers. They then present new analyses and data available from the study site since 1999, including important information on the cause of death among neonates in the study site and their relationship to underlying morbidities; how various combinations of morbidity affect the risk of death as a guide to intervention strategies; new details on the effectiveness of home-based treatment of neonatal sepsis and other neonatal problems; comparisons of different approaches to neonatal resuscitation in home deliveries; management of low birth weight and preterm neonates in the home; and the long-term impact of the interventions in the study site. A summary provides a quick overview of the supplement, conclusions drawn from the findings, and implications for providing care of the newborn in other resource-poor settings.

Senior Research Advisor, SNL, Save the Children, USA; and Adjunct Associate Professor, International Health; The Johns Hopkins University Bloomberg School of Public Health, USA.

Journal of Perinatology 2005; 25:S1–S2

The hope of significantly reducing neonatal deaths in developing countries has spurred new research efforts, advocacy and development of new health programs that integrate neonatal interventions into existing maternal and child health care programs — both in homes and within health care systems. It is hoped that the studies published in this supplement will help accelerate more effective newborn care throughout the developing world.

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Original Article

Background of the Field Trial of Home-Based Neonatal Care in Gadchiroli, India

Abhay T. Bang, MD, MPH
Rani A. Bang, MD, MPH

The field trial of home-based neonatal care was conducted in Gadchiroli, India during 1993 to 1998. Owing to its new approach and the success in reducing newborn mortality in a rural area, it has attracted considerable attention. In this article, we describe the background of the trial — the situation in 1990, why the problems of neonatal mortality and neonatal infection were selected for research, the area — Gadchiroli district — where the study was conducted, and the background work and philosophy of the organization, SEARCH, which conducted the study. This history and background will help readers understand the origins and the context of the field trial and the subsequent research papers in this supplement. We also hope that sharing this will be of use to other researchers and program managers working with communities in developing countries.
Journal of Perinatology (2005) **25,** S3–S10. doi:10.1038/sj.jp.7211267

INTRODUCTION

Today, in 2004, we know that nearly four million neonatal deaths and an equal number of stillbirths occur each year around the world. Of these neonatal deaths, 98% occur in developing countries; most of these infants die at home without receiving medical care.[1] The world is awakening to the needs of the newborn.

Nearly 40% of childhood deaths occur in neonates. Yet this period of highest risk in life receives little attention from health services in developing countries. Most child survival interventions, such as control of diarrheal diseases or acute respiratory infections in children or the Integrated Management of Childhood Illnesses, practically exclude the neonatal period. Hospital-based neonatal care is not available or is very costly. To compound the problem, parents are generally not willing to take sick neonates to the hospital. How can neonatal care be provided in developing countries to reduce neonatal mortality? This is a huge challenge for health policy makers.

By addressing these questions, the Gadchiroli field trial of home-based neonatal care has generated considerable interest.[2–5] The purpose of this article is to describe the historical background of the field trial, the study hypothesis, and the objectives, and to acquaint the readers with the study area and background work that was carried out before the trial.

HISTORICAL BACKGROUND OF THE FIELD TRIAL IN GADCHIROLI

Emergence of the Problem of Neonatal Mortality

Our team faced the emerging problem of neonatal mortality and lack of effective neonatal health care in 1990 while working in the Gadchiroli district in India. In this rural area with high child mortality, we had just completed a field trial (1988 to 1990) of the management of pneumonia in children. We had trained village health workers (VHWs), traditional birth attendants (TBAs) and paramedics in 58 villages in the management of childhood pneumonia, resulting, by the end of the first year of interventions, in a reduction in the infant mortality rate (IMR) from 121 to 89 per 1000 live births.[6] Out of the resultant IMR of 89, the neonatal mortality rate (NMR) of 68 constituted 76%. Pneumonia deaths in neonates accounted for 62% of the pneumonia-specific mortality in children under 5.[6] Thus, we identified neonatal mortality and neonatal pneumonia as the next major challenges.

A review of the literature at that time revealed a situation that remains similar today. Neonatal mortality accounted for 60 to 65% of infant deaths in many developing countries, including India.[7,8] The most important causes of neonatal deaths were: (i) preterm births or low birth weight, (ii) birth injury and asphyxia and (iii) bacterial infections of neonates. What was the possible solution? Interventions to improve birth weight were generally not successful because many of the determinants were beyond the scope of the health-care system.[9,10] Prevention of birth injuries required good prenatal screening and either institutional deliveries of the high-risk pregnancies or availability of emergency referral and obstetric care. The situation in this regard was dismal.[11] Bacterial infections offered greater possibilities for responding to health interventions. Deaths due to neonatal tetanus had shown a documented decline.[8] But deaths due to neonatal sepsis posed a major challenge.

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

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Neonatal Sepsis

Pneumonia, septicemia and meningitis in the neonatal period are described together as neonatal sepsis (defined as a syndrome characterized by symptomatic, systemic illness and bacteremia) because their causative organisms, clinical presentation and treatment are similar.[12] In 1989, the Acute Respiratory Infections Control Programme of the World Health Organization recognized it as the problem of highest priority.[13] Intervention trials in many countries had successfully reduced pneumonia-specific mortality in children under 5 by using the case management approach, but neonatal pneumonia remained the most resistant problem.[6,13] A prospective study in rural Guatemala had reported that, among infants dying between the second and 28th day after birth, symptoms suggestive of neonatal sepsis were present in two-thirds of the cases.[14]

The diagnostic criteria and treatment recommended for childhood pneumonia were often not applicable or effective in the neonatal period. The WHO Technical Advisory Group on ARI recommended immediate research focusing on clinical characterization, pathogenic organisms and case management of neonatal pneumonia and sepsis.[13] Since meningitis and septicemia resemble neonatal pneumonia and were major causes of deaths, it was necessary to develop an intervention against all of them together.[15] As it is not possible to perform blood cultures on newborns in rural areas, the ARI Control Programme of WHO suggested using simple signs or symptoms for diagnosing serious infection in neonates.[16]

Given the poor prognosis for neonatal sepsis or pneumonia, the WHO programme suggested that these children be referred to hospital, "but if referral is not possible, treat the child with antibiotics and follow closely." Yet hospitals were generally far away, neonatal care in hospitals was costly, and parents were unwilling to move sick neonates out of the home.[17] *Hence, the referral guidelines only offered an apparent ethical consolation. In reality, these neonates died at home. Could they be managed at home?*

Earlier Studies

Little had been published on the management of neonates or neonatal infections in home settings. In a field study in Haryana, oral penicillin was used to treat pneumonia in low birth weight infants with a successful, although not statistically significant, reduction in mortality.[18] A study in a rural area near Pune, India, using a risk approach, identified low birth weight or preterm babies, babies with asphyxia, feeding problems or illness as the babies at risk.[19] The intervention involved home visiting to provide education about neonatal care and feeding. This resulted in about a 25% reduction in neonatal mortality — 50% in the late neonatal period and 10% in the early neonatal period. The maximum case fatality was in preterm newborns (35%), or in newborns with infection (44%) and with feeding problems (47%). Small sample sizes in both studies resulted in inability to show statistically significant results. Moreover, both the studies were without a control group.

The study in rural Guatemala had reported identifying and referring high-risk neonates. When referral was not possible, neonates with suspected sepsis were treated by TBAs with injections of ampicillin and gentamicin twice a day for 10 days. Of the 13 cases so treated, all but one survived.[14] The sample size of the study was small, but the experience pointed at the feasibility of such an approach.

The experience of ARI control in seven studies in different countries showed that case management of childhood pneumonia in villages was possible.[13] Our experience in the ARI field trial in Gadchiroli — to reduce the mortality due to childhood pneumonia — clearly showed that TBAs and VHWs could be trained to recognize childhood pneumonia and successfully treat it with oral cotrimoxazole.[6]

In 1990, we analyzed the data on case management of pneumonia in neonates in the ARI in Gadchiroli. The case fatality in neonates treated for pneumonia was 15% when trained workers used oral cotrimoxazole for treatment. This intervention had reduced the pneumonia-specific mortality in neonates by 40% and the NMR by 24% as compared to the control area in the two and half years from 1988 to 1990.[17] These results were encouraging but not satisfactory, because the sensitivity of diagnostic criteria, the coverage and the efficacy of treatment in neonatal period were poor. But it was clear that a special approach was warranted.

Situation in Developed Countries

The philosophy of managing suspected neonatal sepsis in developed countries was stated as follows in 1990: "Since neonatal sepsis often progresses rapidly and has a very high mortality, early presumptive therapy must be instituted when this diagnosis is suspected. Many infants are treated for minimal indications and only a few will prove to have sepsis."[20] "In one report, 6.5% of 1551 infants in two nurseries in Boston were treated with antibiotics for presumed sepsis, but only 6% of those treated had positive blood cultures. Rapid early treatment is essential even though it is recognized that many patients may be treated unnecessarily".[21]

Thus, satisfactory clinical criteria for diagnosing neonatal sepsis were not available, even in developed countries. Some suggested composite criteria or scales had failed to provide good sensitivity and specificity.[22] Hence, even with the best diagnostic facilities, the initiation of antimicrobial treatment in neonatal infection was most often based on clinical suspicion and presumptive diagnosis. In developing countries, where bacterial infections were more common, early presumptive therapy made even more sense.

STATEMENT OF THE PROBLEM AND THE POSSIBLE SOLUTION

We summarized the situation in the new research proposal written in 1990 as follows:

> High neonatal mortality in developing countries is a major obstacle in achieving the global goal of IMR less than 60 by the year 2000. Neonatal deaths due to sepsis contribute about one-third of these deaths, and this problem has prominently emerged after the successful reduction of neonatal tetanus and childhood pneumonia. Effective antimicrobial agents are available to control the infection by the organisms commonly responsible for neonatal sepsis. Since most of these neonates never reach referral care, it is necessary that a simplified approach be developed to recognize and treat the cases of neonatal sepsis in villages.
>
> Our earlier experience of pneumonia case management suggests that such an approach might be feasible. At the same time, efforts must be made to improve the hygiene and practices associated with home delivery and neonatal care. High-risk newborns should receive special attention. Such a comprehensive approach may be able to effectively reduce total neonatal mortality''.[23]

AREA

The Maharashtra state occupies the western part of India, with a population of nearly 79 million in 1991 and nearly 100 million in 2003. The state sprawls from the west coast, where the state capital Mumbai (Bombay) is located, nearly 1000 km to the east, reaching to the center of India at the city of Nagpur (Figure 1a). Gadchiroli district is situated at the eastern end of the Maharashtra and 175 km south of Nagpur. The Wainganga river runs along the western border of the district from the north to south. A 25-km wide zone along the river is primarily an agricultural, rural area, with a mainly Hindu population of various castes. This rural area in Gadchiroli is economically and educationally less developed and is representative of rural India. The district

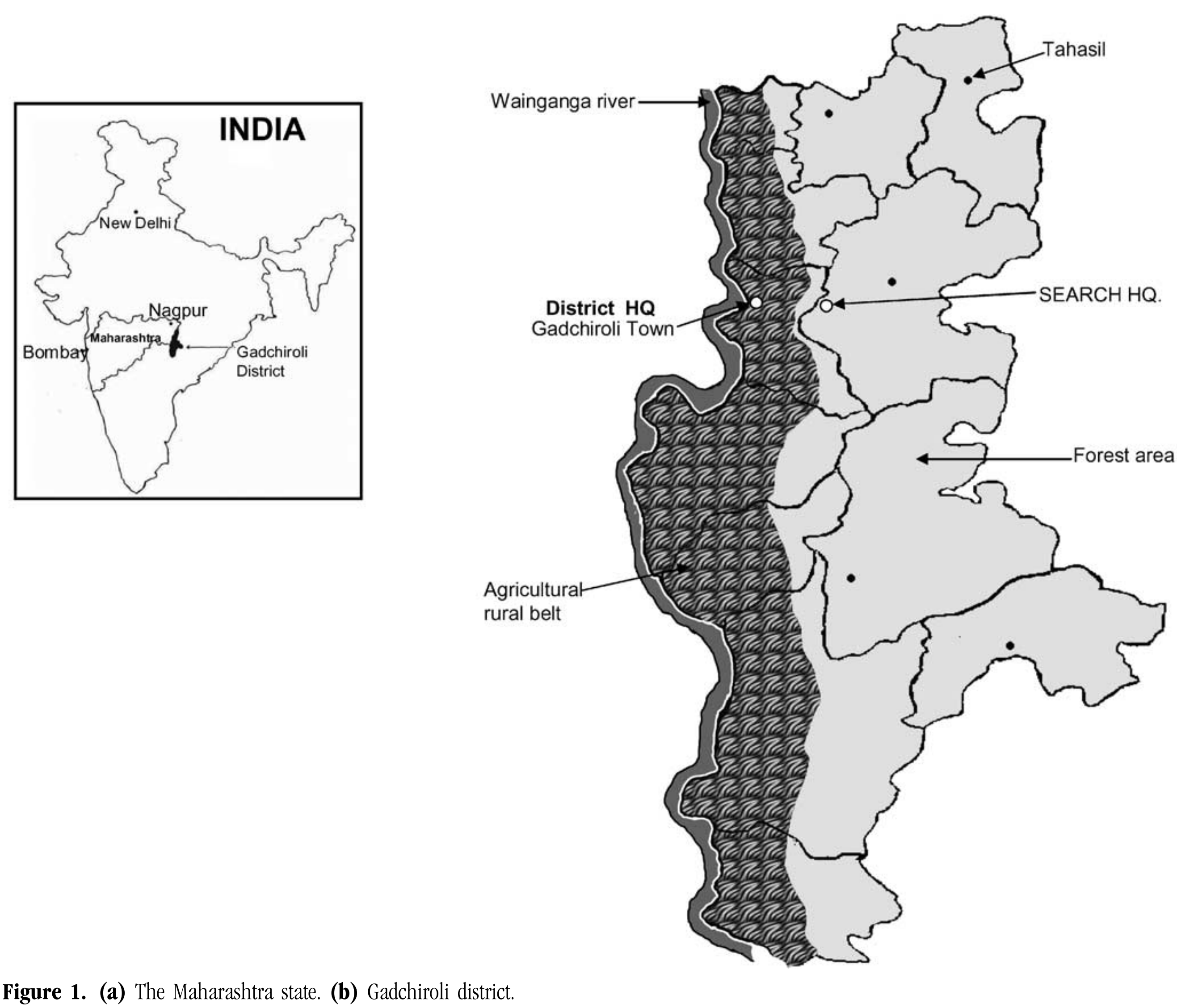

Figure 1. (a) The Maharashtra state. **(b)** Gadchiroli district.

headquarters town, Gadchiroli, with a population of about 25,000, is situated in this rural belt, about 10 km from Wainganga (Figure 1b).

The major portion of the land in the district — mainly the central and the eastern part — is covered by a thick forest. This is the forest, mentioned as *Dandakaranya* in the ancient epics in India, inhabited almost exclusively by tribes, mostly the *Gond* tribe. The tribal culture, economy, social life, and environment are quite different from that of the agricultural area.

Thus, the district has three distinct types of populations: a small proportion (8.7%) of urban population living in the district town and

Table 1 Gadchiroli District Profile: 1991

Characteristic	Gadchiroli		Maharashtra
	Number	%	
Population	787,010	—	
Males	398,364	50.6	
Females	388,646	49.4	
Decadal population growth rate	—	23.5	
Population density per square km	55	—	257
Sex ratio of population	975.6	—	
Rural–urban distribution			
Rural	718,445	91.3	61.3%
Urban	68,565	8.7	38.7%
Proportion of 0 to 6 population — total	—	18.0	
Males	—	18.0	
Females	—	18.0	
Sex ratio of 0 to 6 population	980	—	946
Number of villages	1679*	—	
Number of villages with pucca (all weather) road	795*	—	
Number of villages with telephone	123*	—	
Families with electricity	—	31.0	69.4%
Families with safe drinking water facility	—	38.7	68.5%
Families with septic latrine	—	7.1	
Literacy — in population aged 7 and above: total	—	42.9	64.9%
Males	—	56.6	76.6%
Females	—	28.9	52.3%
Scheduled caste (lower castes) population	95,996	12.2	11.1%
Scheduled tribe (tribal) population	304,535	38.7	9.3%
Per capita domestic product Rs. per annum: 1993–1994	11,784† ($ 261.86)	—	
Percent population below poverty line in 1997–1998	—	55.2	34.6%
Under 2 years child malnutrition (weight, −2 SD)	—	50.8‡	40.6%‡
Under 2 years child malnutrition (weight, −3 SD)	—	21.9‡	15.9%‡
Hospitals	8	—	
Primary health centers (PHC)	42	—	
Subcenters (SC)	349	—	
Hospital beds	310	—	
Integrated community development scheme (ICDS) centers	1274*	—	
Percent couples using family planning methods	—	71.3*	
Infant mortality rate (IMR) per 1000 live births	106	—	74
Under 5 mortality per 1000 live births	144	—	91
Percent fully immunized children	—	85.7*	

Source: The Human Development Report, Government of Maharashtra, 2002, Mumbai, quoting the statistics from: (i) The Census, Government of India (1991); (ii) The Census, Government of India (2001); (iii) Surveys by the Registrar General of India.
*Year 2000–2001.
†US$ 1 = Rs. 45.
‡Year 1997.

a few tahasil (a block of nearly 100 villages) towns; a larger proportion, nearly 50%, of agricultural, rural, Hindu population living in the western part of the district; and nearly 40% of the tribal population spread sparsely in the large forests in the central and the eastern part. For this study, we are mainly concerned with the agricultural, rural, Hindu area because our study area is located there.

Table 1 presents the government statistics on various characteristics of the total population in Gadchiroli district, and, for a comparison on a few characteristics, some data on Maharashtra state[24] (Table 1). Gadchiroli is the state's least developed district, with no industry, no railway network, and poorly developed communication, education and health-care services. The main sources of income are agriculture, mostly paddy cultivation during June to October (Figure 2), and collection of forest produce.

Government Health Services (Figure 3) in the district follow the national pattern, although with slightly different population norms, as applicable to the tribal areas. Thus, there is a 100-bed district hospital in the district town, a 30-bed rural hospital in tahasil towns and one primary health center (PHC) staffed by two doctors and four nurses for every 20,000 rural population. Each PHC has six satellite subcenters (SCs), one per 3000 population. These are staffed by (i) one female multipurpose health worker (MPW), often called auxiliary nurse midwife (ANM), who has had 18 months of training in health work after 12 years of schooling, and (ii) in many places, a male MPW as well. The MPWs are supposed to provide primary health care and implement various national health programs. In reality, the work of the PHCs and SCs is often plagued by staff absenteeism, poor motivation and poor supervision. The main focus of the work is determined not by community needs, but by national and state priorities determined by policymakers. For the last 15 years, these have been mainly family planning and immunization and, to a much lesser degree, maternal and child health, control of communicable diseases such as malaria, tuberculosis and epidemics, and treatment of minor illnesses.

In addition, an Integrated Child Development Scheme (ICDS) has a center in most villages, where supplementary feeding is provided to children and to pregnant and lactating women. The ICDS worker is also trained to give nutrition education to mothers and to treat minor illnesses.

Figure 2. Agricultural life in rural Gadchiroli.

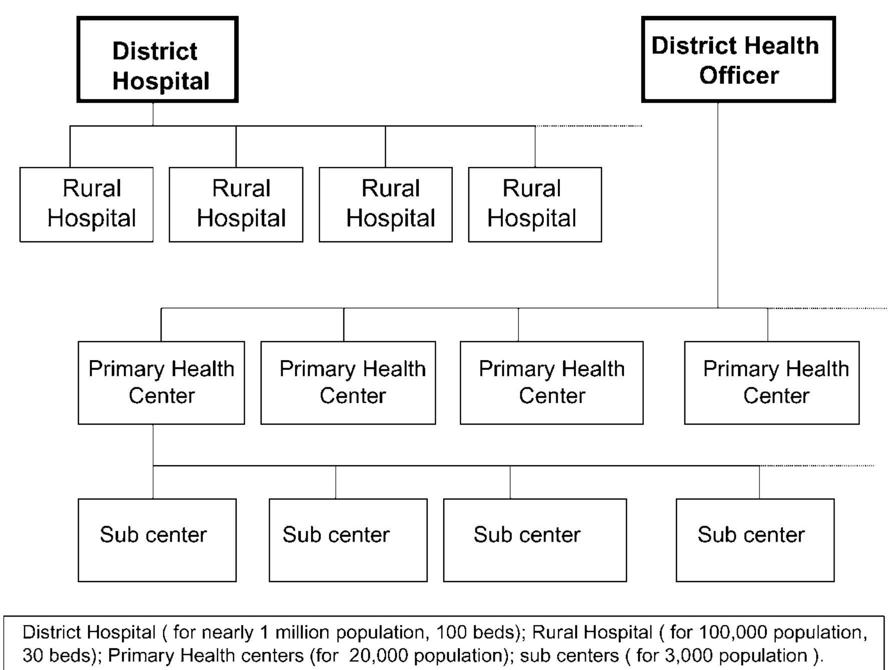

Figure 3. Government health services.

Box 1 The Community Health Action and Research Approach of SEARCH

Live close to communities
↓
Listen to their health problems
↓
Provide appropriate health care for the immediate needs
↓
Conduct quality anthropologic and epidemiologic studies on the health problems with the involvement of local people
↓
Dialogue with communities and inform them about the evidence
↓
Based on the evidence and the dialogue, select a priority problem for solving.
↓
Develop a low-cost solution, appropriate to the rural setting and which empowers local people in solving their health problem
↓
Design and conduct field trials with scientific rigour
↓
The local community benefits from interventions, resulting in improved health
↓
Publish to inform the scientific community
↓
Demonstrate the model and the evidence to policy makers
↓
Influence health policy — nationally and internationally
↓
Go back to communities for a dialogue on the next problem

Figure 4. Shodhgram.

SEARCH AND ITS APPROACH

A nongovernmental organization, SEARCH (Society for Education, Action and Research in Community Health), was founded in Gadchiroli in 1986 and has been working there ever since.[25,26] The founders have a background based on the social philosophy of Mahatma Gandhi, and they have medical training in India and training in public health at the Johns Hopkins University.

The organization has chosen three missions:

- providing health care to local populations;
- training and education in health;
- research to shape health policies.

As a principle, the research should take place with the participation of local people — "Research, not *on* people, but *with* people." SEARCH has carved out an approach to community health work that can be depicted by the sequence shown in Box 1. Various studies or interventions by SEARCH in Gadchiroli district are summarized in Box 2.

SEARCH activities were independent of the government health services described above, except for the referral of emergencies to the district hospital. In general, SEARCH tried to avoid duplicating the services provided well by the government, such as the immunization.

SEARCH Headquarters Village

A new campus village named *Shodhgram* (which in Indian languages literally means "village for searching") was established in the tribal area in 1993, outside the intervention and the control areas. This harbors a 20-bed, tribal-friendly hospital, a reproductive health clinic for women, a deaddiction center, and a training

Box 2 The Background Work of SEARCH

A. Studies and Interventions on Women's Reproductive Health	***Findings/Contents***
1. A community-based study of the prevalence of gynecological morbidities and reproductive tract infections	1. As many as 92% of rural women had one or more gynecological morbidities, nearly half of them infections, but only 8% received medical care for them[27]
2. Trained the traditional birth attendants (TBAs)	2. TBAs were trained in relaying reproductive health messages and managing common gynecological problems, in carrying out safe home delivery and in making appropriate referrals. They received on-going training and supplies from SEARCH[28]
3. A reproductive health clinic	3. Services in clinic included antenatal examination, treatment of gynecological infections, abortion and family planning services, and management of infertility
4. A comprehensive model of women's reproductive health care was proposed[28,29]	
5. Qualitative studies in women's reproductive health culture[30–32]	
B. Studies and interventions on Child Mortality	
6. A vital statistics surveillance system was developed in an area of 102 villages in the agricultural western part of the district	6. The vital rates were first estimated in 1988. The infant mortality rate was 121 per 1000 live births
7. The verbal autopsy method was further developed[33]	7. Specific criteria for determining cause of death in children were developed. Pneumonia was one of the causes in nearly 40% of child deaths
8. A field trial of case management of childhood pneumonia in an intervention area with 58 villages and a control area with 44 villages	8. (i) Study of local beliefs and practices (ii) Incidence of acute respiratory infections was estimated in 700 randomly selected children in 43 villages (iii) Male village health workers (male VHWs), TBAs and the government health workers (MPWs) in the 58 intervention villages were trained to diagnose pneumonia in children and treat it with oral co-trimoxazole (iv) Parents were provided health education on seeking care for pneumonia (v) The coverage of the pneumonia treatment was 76% in the first year (1988 to 1989) and 106% in the second year (vi) The observed case fatality in treated cases was 0.8% as compared to the indirectly estimated 13.5% in the control area (vii) The pneumonia-specific mortality rate in the intervention area was 54% lower, and the infant mortality rate (IMR) 27% lower, than in the control area[6,17,34]
9. A simple device, named "breath counter," was developed	9. To assist TBAs in making a correct diagnosis of pneumonia[35]
10. Treatment of neonatal pneumonia with cotrimoxazole by these workers	10. Both the cause-specific mortality rate for neonatal pneumonia and the neonatal mortality rate decreased[17]
C. Alcohol and Social Policy	
11. In response to the strong need expressed by women, participatory research work was started in 1988, which culminated in a districtwide social campaign against alcohol	11. A total of 600 villages, 350 local groups and thousands of women participated, resulting in 1993 in the introduction of prohibition of sale and consumption of alcoholic beverages in the entire district, and introduction of some measures for the social control on the alcohol trade in the entire state in 1994, by the government of Maharashtra
12. A deaddiction therapy center and a village-based deaddiction and preventive education approach were started (1994)	

center to train the TBAs, village health workers, SEARCH staff and persons from other nongovernmental organizations. Administrative support and research monitoring are also provided from here. Nearly 30 full-time staff members, including the directors of SEARCH, live here. This helps in building the spirit of a community working for a mission. Shodhgram has gradually become well known in Maharashtra and is looked at as a model of community-based service and research (Figure 4).

To summarize, before the home-based neonatal care trial began, SEARCH had developed a modest but effective human infrastructure in Gadchiroli, with a community health care program, a social mobilization action against alcohol and a field research area in 102 villages, and had carried out a series of research studies on women's reproductive health and on child survival.

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Original Article

Methods and the Baseline Situation in the Field Trial of Home-Based Neonatal Care in Gadchiroli, India

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In this paper, we describe the planning of the field trial and the methods used for collecting baseline health and ethnographic data in a rural field study site. We describe the study hypotheses, specific objectives, study design, sample size estimates, selection of study area, community consent, the organization of study teams, review mechanism, financial support and baseline data collection. Baseline population characteristics and vital statistics are presented. The qualitative information on traditional beliefs and practices prevalent in the study area revealed that parents felt powerless about newborn health and sickness. There was an enormous unmet need to reach the home-delivered neonates and their care-givers with the correct knowledge and health-care practices.
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BACKGROUND

High neonatal mortality was the main component of a high infant mortality rate (IMR), and neonatal infections were a major cause of neonatal mortality in India. As majority of the neonates in rural India were born and cared at home, a nongovernment organization, SEARCH (Society for Education, Action and Research in Community Health), decided to develop a new approach of home-based neonatal care. SEARCH worked in a less developed rural district, Gadchiroli, in the Maharashtra state in India. It had already established an action — research field base in rural Gadchiroli during 1986 to 1993, when the decision to conduct the field trial on neonatal health was made.[1]

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

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AIM OF THE STUDY

The aim of this study was to develop a home-based neonatal care package that provides low-cost, primary neonatal care to neonates using the human potential available in villages and thereby to reduce neonatal mortality and improve neonatal health.

HYPOTHESES

Hypothesis 1. It is possible to develop and implement home-based neonatal care interventions consisting of:

(i) Health education of mothers, families, traditional birth attendants (TBAs) in the better care of mothers and neonates.
(ii) Surveillance to identify those neonates at high risk of death.
(iii) Training a cadre of female village health workers (VHWs) in the care of normal, high-risk and sick neonates at home.
(iv) Recognition and treatment of sepsis by trained VHWs.

Hypothesis 2. Such home-based neonatal care will be able to cover at least 75% of the neonates in the community and 60% of the neonates with sepsis.

Hypothesis 3. Such an intervention package will reduce the neonatal mortality rate (NMR) in intervention villages by at least 25%, and the mortality due to sepsis by 40% in three years.

SPECIFIC OBJECTIVES

These included the following:

(1) To understand the local beliefs and practices related to neonatal health, sickness and care.
(2) To develop a surveillance system to identify and register pregnancies by the 5th month of gestation.
(3) To study the natural history of neonates in rural areas by observing the pregnancies, home deliveries and neonatal period (0 to 28 days) in order to estimate the incidence of maternal morbidities, neonatal morbidities, care received, natural outcome (survival or death) and the causes of neonatal deaths.
(4) To develop simple clinical criteria to identify neonates at high risk of death and neonates with sepsis.
(5) To develop a surveillance system to identify the high-risk neonates early.

(6) To educate mothers, grandmothers, families and TBAs in better care of neonates so that they can recognize danger signs, including those of sepsis, and seek early care.
(7) To train VHWs as the providers of neonatal care, including:
   (i) To provide health education to mothers and families.
   (ii) To identify high-risk and sick neonates early and provide care at home or make referrals.
   (iii) To recognize neonatal sepsis and manage it either by referral or treatment.
(8) To provide home-based neonatal care for at least 75% of the neonates and 60% of the neonates with sepsis in the intervention villages.
(9) To evaluate the interventions by monitoring:
   (i) *The primary outcome indicators*: (a) the NMR and (b) the sepsis-specific NMR in the intervention and the control areas.
   (ii) *Secondary indicators (coverage indicators)*: proportion of neonates covered by home-based neonatal care, and proportion of neonates with sepsis who are treated.
(10) To identify problems and issues for further research.

STUDY DESIGN

For evaluating the effect on the primary outcomes (the NMR and the sepsis-specific NMR), we chose the study design of controlled field trial having an intervention and control area. The rest of the studies (ethnographic study, the study of natural history of neonates, developing high-risk criteria and the criteria to diagnose sepsis, feasibility of health education, training and management of the high-risk or septic neonates, the study of coverage) were nested in the intervention arm of the field trial (Figure 1).

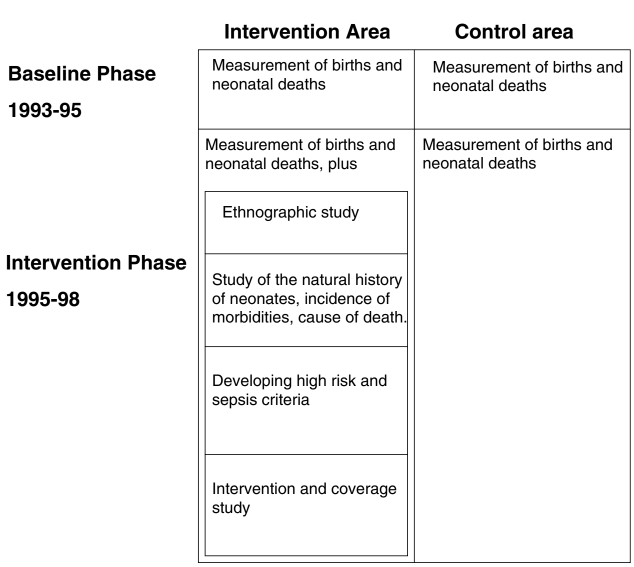

Figure 1. The study design of the field trial of home-based neonatal care in Gadchiroli.

SAMPLE SIZE[2]

(1) To reduce the NMR by 25% in 3 years,

$$\alpha = 0.05,\ \text{two} - \text{tailed},\ \beta = 0.2$$

$$P_0 = \text{baseline proportion of live births resulting in neonatal deaths} = 70/1000 \geq 0.07$$

$$d = \text{expected reduction} = 25\% \text{ of } 0.07 = 0.0175$$

$$P_1 = \text{probability of death after interventions that is, } 0.07 - 0.0175 = 0.0525$$

$$P = \frac{P_1 + P_0}{2} = \frac{0.525 + 0.07}{2} = 0.0612$$

$$q = 1 - P = 0.939$$

$$n = \frac{2 \times (Z_\alpha + Z_\beta)^2 \times pq}{(d)^2} = \frac{2 \times (1.96 + 0.84)^2 \times 0.0612 \times 0.939}{(0.0175)^2}$$

$$= 2942, \text{ or, approximately, } 3000 \text{ live births (in 3 years) in each area.}$$

(2) To reduce the mortality due to neonatal sepsis by 40% in three years,

$$p = \text{mortality due to neonatal sepsis expressed as proportion of neonatal mortality} = 0.33$$

$$\text{Expected reduction } 40\% = 0.13$$

$$n = \frac{2 \times (1.96 + 0.84)^2 \times 0.33 \times 0.67}{(0.13)^2}$$

$$= 209 \text{ neonatal deaths (in 3 years) in each area.}$$

With the then-prevailing NMR of about 70/1000 live births,[1] about 3000 live births were required in the control area for studying the required 209 neonatal deaths. After a 25% reduction, with the NMR of 53/1000 live births in the intervention area, 4000 live births were required in the intervention area in 3 years. At the then-prevailing crude birth rate of nearly 30 per 1000 population, we estimated the required study population to be 33,000 (33,300 × birth rate 30 × 3 years = 3000 births) in the control area and 45,000 (45,000 × 30 × 3 = 4000 births) in the intervention area.

SELECTION OF STUDY AREA FOR THE FIELD TRIAL

For this field trial, the agricultural area in Gadchiroli district (Maharashtra state), generally representative of the less developed rural areas in India, was selected.[1] For operational feasibility, the trial was conducted in the field area of SEARCH that, in 1993, consisted of an intervention area of 53 villages (from the 58 intervention villages in the earlier pneumonia management trial[3]) and a control area of 47 villages (32 from the previous pneumonia management trial, and 15 newly selected in 1991). The intervention area was a contiguous block, while the control area was in two blocks, one on either side of the intervention area, separated from it by intervening buffer zones of 5 to 10 km to avoid any so-called ‘‘contamination effect’’ of the availability of interventions in the control area. The SEARCH headquarters was situated outside both the areas (Figure 2).

Random allocation of villages to intervention and control groups was considered not possible. It would be difficult not to provide care in one village when the adjacent one received care. Communities would demand care or the individuals would go to the intervention villages and seek care. Hence, the intervention and control areas in the SEARCH field area were selected *en bloc* as the potential intervention and control areas for the new field trial of neonatal care. The intervention and control blocks of villages were, by our information and judgment, very similar — geographically, economically, socially, by the availability of health services and on the vital indices for the period 1991 to 1993. (This was subsequently evaluated by the census and the baseline comparison of the two areas.) All 47 villages in the then-control area of SEARCH were included because these contained the population required to provide nearly 1000 births per year.

In all, 14 villages in the intervention area had to be excluded for three reasons. Some villages had a population less than 300, too small to sustain a newborn care worker. In some villages, we did not find a suitable woman to work as the VHW to provide the home-based neonatal care. Some villages were too close to the town and, hence, were rapidly changing to a periurban character. Thus, 39 villages were finally selected as the intervention villages, providing a population of nearly 40,000.

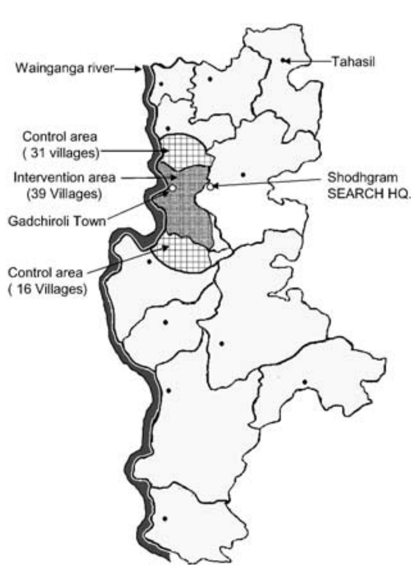

Figure 2. The field trial area in Gadchiroli.

COMMUNITY CONSENT

Since neonates were to be studied and subsequently cared for in the intervention area, we obtained consent from the intervention villages. By meeting the individual village leaders and holding group meetings, we explained to the villagers the problem of neonatal mortality and the prevailing situation about beliefs, practices and the availability of health care to neonates. The elected village council (*gram panchayat*) and the women's groups (*mahila mandals*) in each village were requested to pass a signed resolution as the expression of their desire to participate in the study. Probably due to the earlier good experience of the pneumonia management trial,[3] and the training of TBAs by SEARCH,[1] all villages gave their written consent.

TIME LINE OF THE STUDY

Time line of the study is presented in Figure 3.

ORGANIZATION OF THE STUDY

The study had two teams — intervention and data monitoring:

1. The intervention team did selection of female VHWs, training, field supervision and supported the intervention in villages. This team also supervised the data collection on mother and newborn health and the quality of the interventions.
2. The data monitoring team monitored and analyzed:
   - The census.
   - Vital statistics in the intervention and control area, collected by the vital statistic surveillance system consisting of male VHWs and their field supervisors.
   - Mother and newborn health data in the intervention area, collected by the female VHWs and supervised by the intervention team.
   - Data on the coverage and quality of interventions.

In addition, administrative support and referral support were given by the headquarters. The study director, Abhay Bang, MD, MPH, directed the entire study.

FINANCIAL SUPPORT

The John D. and Catherine T. MacArthur Foundation, Chicago, and the Ford Foundation, New Delhi, supported the study.

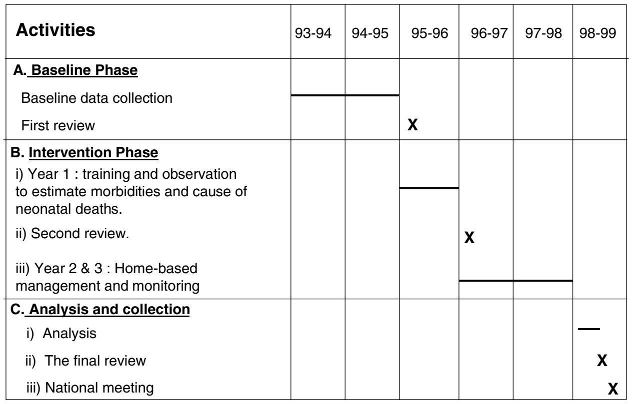

Figure 3. Time line of the study.

ETHICAL REVIEW

An external group of pediatricians, neonatologists and public health management experts of national standing advised and reviewed the study at three points in time and gave ethical clearance. The group consisted of Drs. Meharban Singh, Vinod Paul, and Ashok Deorari (All India Institute of Medical Sciences, New Delhi), Ramesh Potdar (Mumbai), M.R. Lokeshwar (L.T. Medical College, Mumbai), Shashi Vani (B.J. Medical College, Ahmedabad), Shanti Gosh (New Delhi), Sanjeev Kumar (UNICEF, New Delhi), Dileep Mavalankar (Indian Institute of Management, Ahmedabad), Uday Bodhankar (Nagpur), and M.S. Rawat and Sushama Dani (Government Medical College, Nagpur).

BASELINE DATA COLLECTION

The *census* and the *baseline survey* of the population characteristics in the intervention and the control area were carried out in 1993. Trained male village workers with 7–12 years of school education, resident of the village, who had been collecting vital statistics since 1988, collected the data by house-to-house survey. Their data collection was supervised by male field supervisors (one per 20 villages) who checked the records and also verified the correctness of data by visiting a randomly selected 5% of families. The data were entered and analyzed using SPSS PC and Epi Info software.

The *vital statistics surveillance* system was in operation in both areas since 1988,[3] except in the newly selected 15 villages in the control area in which it was started in 1991. Since most of the births and child deaths occurred at home, most often without any medical care or medical certificate, registration of births and deaths did not occur. In our vital statistics surveillance system, the trained male VHWs prepared a list of pregnant women in a village in a 6-monthly house-to-house survey. They followed up pregnant women and prospectively recorded all births — live or still — and child deaths. TBAs, who conducted most of the deliveries and also witnessed most of the still births and neonatal deaths, were visited once a month by the field supervisor and asked about births and deaths. They were paid a small amount of incentive money for every reported birth and death.

To mop up the missed events, especially because women often moved to a parent's home for delivery, the male VHWs, in the 6-monthly house-to-house survey, inquired about vital events. All births and child deaths reported by the male VHWs or TBAs in prospective reporting or in 6-monthly surveys were verified by the supervisor by visiting the family. Moreover, he gave a printed birth certificate to parents (which they valued as a useful document and hence actively reported births).

Live births, neonatal deaths and infant deaths were defined according to the International Classification of Diseases.[4] Still birth was defined as birth of a dead fetus with completed gestation of 28 weeks or more.

Since medical certificates to assign a cause of death were almost never available, a simpler method, called *verbal autopsy*, had to be used to determine the most probable cause of death (a tool commonly used in field studies in developing countries[5,6]). The field supervisors conducted the cause of death inquiry of every still birth and death of children under 5 years of age by the verbal autopsy method using a questionnaire developed by SEARCH. The cause of death was then assigned by a computer program using criteria for diagnosing causes of death.[7]

The male VHWs were also paid incentive money for every reported birth and child death. We periodically evaluated the completeness of recording of births and child deaths by this system using the Chandrasekaran – Demming method[8] and found the reporting to be 98% complete.[3] Since the study aimed to evaluate the effect of home-based neonatal care on neonatal mortality, we decided to count the births and neonatal deaths in villages where the events actually occurred — the so-called "*de facto* method", and not where the mother originally came from — the "*de jure* method". If a hospital-born neonate was brought to a village and spent a part of its neonatal period there, it was included in that village. Similarly, if an ill neonate from a village was taken to a hospital and died there, the death was included in the village in which the newborn became sick.[9]

BASELINE POPULATION CHARACTERISTICS AND VITAL RATES

The baseline population characteristics as recorded in the census conducted in 1993 and vital rates recorded by the vital statistics surveillance system during 1993 to 1995 are summarized in Table 1.

The table reveals that the two areas were similar on various population characteristics. The control area was divided into two blocks of villages and each block was served by a government hospital. The number of health subcenters (and hence the number of auxiliary nurse midwives) was more by six in the control area. Although the number of government health service units was higher in the control area, since very few neonates were taken to health facilities in either of the areas, that difference may not matter substantially, as is evident in the almost equal mortality rates.

The 2-year baseline birth rate and the neonatal, perinatal and IMRs were also similar in the two areas. Although the NMR and the perinatal mortality rate were a little less in the control area than in the intervention area, the differences were not significant. The NMR contributed nearly 75% of the IMR. The IMR and the NMR were comparable to the national estimates by the Registrar General of India.[10] The birth rate 25 to 26 per 1000 population was less than 30, which we had assumed while calculating the required sample size in 1990.

Other socioeconomic characteristics were consistent with the situation described in the background section.[1] Nearly 90% population was involved in agricultural operations, 35 to 40% population belonged to lower castes and tribes, only one-third of women were literate and 28% houses electrified.

Table 1 Baseline Characteristics (1993) and Vital Rates (1993–95) in the Intervention and the Control Area in Gadchiroli Field Trial

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 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.

TRADITIONAL BELIEFS AND PRACTICES IN NEWBORN CARE IN GADCHIROLI: A CULTURAL BLACK BOX

Most of the babies in the villages in Gadchiroli were born at home. What happened in those home delivery rooms? How were the neonates cared for at home? What did people believe about newborns' diseases and what were the sources of health care? We studied the local culture surrounding the newborn care by developing a list of 35 questions based on the initial discussions with mothers and TBAs, and based on the observations made by a social worker who visited 30 families with a newborn. Using these questions, a local field supervisor held 30 focused group discussions in different villages. The participants, usually 8 to 10, included mothers, grandmothers and men. Focus group discussions were held separately with the 86 TBAs in four groups. The responses were analyzed and tabulated by question. Then, they were grouped under four categories — beliefs and practices before delivery, during delivery, after delivery, and about newborn risks, sickness and care seeking (Figure 4).

Before Delivery

Pregnant women often moved to their parents' home for delivery. To reduce the risk of a difficult delivery, they preferred a small-sized baby. To achieve this goal, pregnant women, either voluntarily or under pressure (usually from the mother-in-law), reduced their food intake during the later half of pregnancy.

Different types of qualities were attributed to food items (''hot, cold, windy, antidotes to the effect of medicines, difficult to digest'', etc.). These traditional beliefs prevented women from eating as many as 49 different food items. These mainly were different kinds of: (a) vegetables; (b) fruits; (c) milk and dairy products; (d) meat, fish and eggs and (e) certain kinds of beans and pulses.

Dietary indiscretions by the mother were considered to be a major reason for any subsequent sickness in the newborn. White vaginal discharge, night blindness, swelling of feet and fever during pregnancy were also believed to be associated with newborn ill health.

Usually a relatively unused room or a portion of the house was selected as the delivery room. Windows, if any, were packed by gunny bags or thick cloth because, the women said, ''wind is harmful''. The floor was cleaned and plastered with cow dung (the usual way of preparing the flooring in rural India).

Figure 4. Home delivery room and newborn care.

Birth preparations did not include provision for seeking emergency medical care.

Delivery

After the onset of strong labor pains, the TBA was usually called. When the baby came out, the TBA received it in her hands and placed it on the floor until the placenta came out. The cord was cut after the placenta was delivered. (In earlier days various sharp objects were used to cut the cord. However, in the past decade, with training, the TBAs have used new, clean blades). Only after that did the baby receive attention.

If the baby did not cry, the TBA cleaned its mouth, held it upside down, stroked the head and back, immersed the baby (except head) in cold water, warmed the placenta on the fire, milked the cord toward the baby or rubbed rice bran on the placenta.

The TBA then cleaned the baby. To remove the vernix, she rubbed wheat or rice flour or rice bran on the skin of the baby. Then, the baby was given a bath, usually with warm water, and partially wrapped in an old, used piece of soft cloth, and kept in a broad, open bamboo basket (*soop*) on a layer of rice or wheat, which served as the bassinette.

The baby remained in the basket until the mother was cleaned and given a bath and was ready to receive the baby.

After her bath, the mother slept on the bed. An old, used leather footwear was kept on the bed. Another pair of footwear was kept outside the door on a stick of a plant called "Tembhurni". Leather footwear is supposed to repel the evil forces. No baby clothes or headwear were used for an initial 7 days.

"There is no true milk in breasts for the first 3 days. The thin liquid *(cheek)* in the breast is harmful to the baby". So it was discarded. The baby was only fed sweetened boiled water. Even if mother had a little milk or her breasts got engorged and painful, the milk was squeezed out and thrown on the coals; it was not fed to the baby.

After Delivery

After 3 days, a small ritual was performed (*til-gul*) and then the mother started breastfeeding. The mother and the baby were kept in strict isolation until the cord fell off, which usually occurred by the 7th day. The mother was not allowed to leave the delivery room until then. A pit was dug in one corner of the delivery room. The placenta and cord were buried in it. These were considered very vulnerable to black magic and hence needed to be carefully buried. The corner with the pit was the "bathroom" in the delivery room.

For the next 7 days, the baby was given a bath in the same bathroom. Mother used the pit for her toilet needs, for defecation and urination. The pads and baby's nappies were washed in the same bathroom. The pit was covered only with sticks. It generated a foul odor in the delivery room. To reduce her toilet needs, mother's intake of water and food was minimized during the first 7 days. She was given little solid food, *ambil* — a local soured starch drink, with sweet tea.

The falling off of the cord was considered very important. Until then, the mother and the baby were considered polluted, not to be touched except by the TBA, grandmother or mother-in-law. To promote the falling off of the cord, linseed oil, powder of the roof tile or turmeric was applied to the cord. When the cord fell off (between the 5th and 9th days), a purifying social – religious ceremony (*baj kadhane*) was performed. The pit in the delivery room was closed. The family gave neighbors a small feast. Hereafter, other persons were allowed to touch and hold the baby. Women in the neighborhood very enthusiastically did that. The TBA was paid 100 to 125 Rs and, sometimes, given a piece of cloth and some rice.

The mother now could go out of the delivery room. Her diet was gradually increased over a period of a few weeks. "If she does any indiscretion or eats more, she may develop pus or her milk will change, causing the baby to develop indigestion, abdominal distention and vomiting".

Since the mother was now going out of the house for her toilet needs in the open (the usual practice), she was likely to catch an evil eye (especially because her breasts were full). Hence, on returning home, she was required to purify herself before breastfeeding her baby. The ritual involved washing feet, hands and breasts, cleaning the room with a broom, then cleaning the breast with the broom, touching the leather footwear to the breast, then spitting on the breasts. Then she breastfed the baby.

New clothes were put on the newborn baby only after *baj kadhane*. Until then, he/she was without clothes, wrapped in an old piece of multi-layered cloth (*bothary*).

For the first 7 to 12 days, the newborn was given a daily bath by the TBA and massaged with an oil. Oil drops were inserted into the nose and ears. If the eyes were sore, drops of the mother's breast milk were put in the eyes. Skin cracking in the neck or groin (intertrigo) was treated with turmeric powder and oil.

The list of foods the mother should not eat in the postpartum or lactating period included 51 food items.

Newborn risks, sicknesses and care seeking

The preterm babies were considered high risk, but a strange belief was that newborns who had completed 8 months of gestation were at a higher risk than those who were born after completing 7 months. The weak babies (preterm or those with wrinkled skin or weak movements) had a higher risk of death, especially during the first 1 to 2 weeks, and up to 5 weeks. However, ''any infant can die''. Newborns were named only after the high-risk period was over, which could be any time between 1 and 6 months.

Danger signs in newborn included: stops breastfeeding, does not open eyes, distension of belly, body becomes cold, unconscious, grunting, chest in-drawing, loose motions, limbs became flaccid and no movements.

The beliefs about why neonates became sick, and the responses of families to newborn sickness are summarized in Box 1.

Box 1 The Powerlessness of Parents about Newborn Health

	Newborn illnesses attributed to		Responses
1.	Mother's indiscretions in eating result in the ill effects transmitted to the baby through milk.	1.	Home remedies were tried (but very few were listed as compared to the long lists for illnesses in children or adults).
2.	Evil eye, evil forces, witchcraft.	2.	Witchcraft or evil eye was dispelled by the magic healer (*mantrik*)
3.	Weakness of the baby.	3.	''Nothing can be done to save the weak newborns''. ''It is futile to run around making efforts''.
4.	God's desire.	4.	''Newborn babies are at God's mercy. They come with their destiny. If they have been sent for a short period, they go back. What can be done to save them?'' ''Nobody understands about newborn sicknesses''.

CONCLUSION

Home delivery and newborn care took place in the strict privacy of the delivery room. These ill-ventilated, ill-lit, unhygienic rooms were visited by a selected few persons. The local culture had very limited knowledge about newborn health but had a large number of beliefs, taboos, rituals and practices. Many of them appeared likely to be of no use or even harmful. Parents felt very powerless about newborn health and sickness. There was an enormous unmet need to reach the home-delivered neonates and their care-givers with the correct knowledge and health-care practices.

The subsequent study of the incidence of neonatal morbidities, care seeking and causes of neonatal deaths will reflect the influence of these practices.

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Original Article

The Incidence of Morbidities in a Cohort of Neonates in Rural Gadchiroli, India: Seasonal and Temporal Variation and a Hypothesis About Prevention

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BACKGROUND:

The incidence of morbidities among home-cared neonates in rural areas has not been studied.

OBJECTIVES:

1. To estimate the incidence of various neonatal morbidities and the associated risk of death in home-cared neonates in rural setting.
2. To estimate the variation in the incidence of neonatal morbidities by season and by day of life.
3. To identify the scope for prevention of morbidities and suggest a hypothesis.

STUDY DESIGN:

A prospective observational study nested in the first year of the field trial in rural Gadchiroli, India. Trained village health workers in 39 villages observed neonates at the time of birth and in subsequent eight home visits up to 28 days. We diagnosed 20 neonatal morbidities by using clinical definitions. The data were analyzed for the incidence, case fatality, and relative risk of death and for the seasonal and day-wise variation in the incidence of morbidities.

RESULTS:

We observed total 763 neonates in 1 year. The incidence of morbidities was a mean of 2.2 morbidities per neonate. The case fatality in 13 morbidities was >10%. Only 2.6% neonates were seen or treated by a physician, and 0.4% were hospitalized. Hypothermia, fever, upper respiratory symptoms, umbilical and skin infections, and conjunctivitis showed statistically significant seasonal variation. Although the morbidities were concentrated in the first week of life, new cases continued to appear throughout the neonatal period. Various morbidities showed different distribution of incidence during 1 to 28 days.

CONCLUSIONS:

A large burden of disease occurs in rural home-cared neonates, and many morbidities are associated with high case fatality. Some morbidities show strong seasonal and day-wise variation in incidence, indicating poor care at home. We hypothesize that changes in practices and better home-based care will prevent the seasonal and temporal increase in morbidities. Some morbidities may not be preventable and will need early detection and treatment. Therefore, frequent home visits by a health worker are necessary to identify sick neonates.
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INTRODUCTION

Very little is known about the natural history of neonates born in rural areas in developing countries because most of them are never seen by a physician. We have earlier reported the findings of the first prospective observational study of home-cared neonates in rural Gadchiroli.[1] We found a 48.2% incidence of high-risk morbidities (those associated with >10% case fatality (CF) in the observed neonatal population) and a 72% incidence of low-risk morbidities (CF<10%).

The occurrence of neonatal morbidities is largely determined by maternal health and the postnatal environment — both of which are influenced by seasons. Previous studies have reported on seasonal variation of birth weight,[2–8] pre-term deliveries[9–11] and hypothermia.[12] The possibility of seasonal variation in the incidence of other neonatal morbidities such as asphyxia, sepsis, breast feeding problems, diarrhea, fever, skin and umbilical infections, and upper respiratory infections has not been evaluated or reported. This occurs because modern life and hospital care shield neonates from the harsh effects of seasons. Standard textbooks of pediatrics or neonatology do not describe the seasonality of neonatal diseases.[13–15] Neonates in communities in developing countries are cared for at home mostly in rural settings and often in inadequately protected environments.[16,17] Study of the effect of seasons on neonatal diseases in developing countries may help in identifying the gaps in home care.

Many morbidities such as preterm birth, low birth weight (LBW), or asphyxia ''occur'' at the time of birth. The remaining morbidities appear at different times during days 1 to 28. Except for neonatal jaundice, tetanus, and early- and late-onset sepsis, we found no description in the literature about how the incidence of different moribidities is distributed during different days and weeks of the neonatal period. Study of that will help in understanding their epidemiology and might throw light on the causative mechanisms.

In addition, such description about the timing of morbidities will facilitate making informed decisions about the needed days of visit to neonates by the care providers.

This article has three objectives:

1. To estimate the incidence of various neonatal morbidities and the associated risk of death in home-cared neonates in rural setting.
2. To estimate the variation in the incidence of neonatal morbidities by season and by day of life.
3. To identify the scope for prevention of morbidities and suggest a hypothesis.

We tried to get answers by analyzing the data collected on the neonates in 39 intervention villages in the first year (1995 to 1996) of the intervention phase of the field trial in Gadchiroli.

METHODS

The area, the study design, and the methods of data collection have already been described.[1,16,17] In the first year of the intervention (April 1995 to March 1996), the main role of the village health worker (VHW) was to observe and record maternal and newborn health with few interventions. The VHW was present at the time of home delivery — usually conducted by traditional birth attendants (TBAs) with the help of relatives. The VHW examined and recorded observations on the day of birth (called the first day) at 1 minute, 5 minutes, and within 6 hours after birth, and on days 2, 3, 5, 7, 15, 21, and 28. She instructed parents to call her immediately if the baby developed any problem on other days. Her data were checked by a physician who visited each village once in 15 days.

The VHW was trained in the first year of the intervention phase to treat minor illnesses in older children and adults, but not in neonates — except pneumonia, which was treated with co-trimoxazole in the intervention villages in all children, including neonates.[18,19] The other treatments that newborns received were tetracycline eye ointment, applied at birth routinely by TBAs, and home remedies. A few neonates were seen by doctors or hospitalized. We have earlier described the traditional beliefs and practices of neonatal care in the study area.[17]

We developed simple clinical definitions of neonatal morbidities, applicable in a field setting, from those recommended by the National Neonatolgy Forum of India.[20,1] These are reproduced in Appendix A1. We estimated the incidence of various morbidities by applying these definitions to the field data. We grouped the morbidities into ''high risk'' and ''low risk'' by arbitrarily using 10% CF as the cutoff.

Based on the local climate, we divided the year into the following seasons: summer (March – June), rainy season (July – October), and winter (November – February). The local temperature reached its maximum in summer, especially mid-April to mid-June, reaching as high as 117°F (47°C) in May, and its minimum in winter, going as low as 41°F (5°C). Average rainfall during the rainy season was usually 150 cm. During summer and rainy season, especially during April – August, collection of forest produce and paddy cultivation were the major activities, involving strenuous work mainly by women. This was also the lean period for food availability. The new crop was usually harvested in November, so food availability was better from November to March. Housing and clothing being poor, people were exposed to both high and low temperatures without much protection. Neonates were not well protected with warm clothes because of poverty and traditional beliefs. They were often not put to breast for 1 to 3 days after birth.[17] The home delivery room was kept warm in winter with the help of a fire and burning cow dung, which emitted a lot of smoke. Most houses had neither toilets nor running tap water. The mother and the newborn were strictly isolated for the first 7 days. Social contact increased after a small ceremony, *baj kadhane*, usually performed on the 7th day.

From the 20 types of morbidities diagnosed and earlier reported,[1] (Tables 1 and 2), we selected 15 for which the number of reported neonates was at least 25 or more, for seasonal analysis. We also analyzed the incidence of these morbidities by day of occurrence, that is, the day it was first recorded by VHWs. Depending on the fixed days of visit by VHWs, the 28-day neonatal period was divided into the following unequal intervals: days 1, 2, 3, 4 to 5, 6 to 7, 8 to 15, 16 to 21, and 22 to 28.

Since asphyxia, preterm birth, LBW, or delay in the initiation of breast feeding occurred only on the day of birth, we excluded them from the day-wise variation.

Although we made effort to study all neonates born in 39 villages, VHWs could not study some neonates because they were unaware of the birth. The independent vital statistics system of the study recorded all births and child deaths in the area.[17] Neonates observed by VHWs and not observed were estimated by comparing with these data.

Consent and ethical clearance have already been described.[1,17]

RESULTS

A total of 1016 neonates were born in 39 villages in year one (1995 to 1996), out of which 763 (75.1%) were studied. A total of 95%

Table 1 Incidence of High-Risk Health Problems, Associated Fatality, and Relative Risk of Death in Home-Cared Neonates ($n = 763$)

High-risk* health problems[†]	Sick neonates (1–28 days) No.	Sick neonates (1–28 days) Incidence (%)	Deaths[‡] No.	Deaths[‡] CF (%)	Relative risk of death
Congenital anomaly	10	1.3	2	20.0	4.0
Multiple pregnancy	22	2.9	8	36.4	8.4
Birth asphyxia					
Severe	26/570[§]	4.6	10	38.5	8.0
Indirect asphyxia	3/193	1.6	2	66.7	13.9
Preterm	75	9.8	25	33.3	15.3
Birth weight <2000 g	74	9.7	27	36.5	19.3
Neonatal sepsis (clinical)	130[¶]	17.0	24	18.5	7.3
Only pneumonia[‖]	8	1.0	0	—	—
Delayed breast feeding	71	9.3	8	11.3	2.4
Problems in breast feeding					
Total	124	16.3	28	22.6	12.0
As part of sepsis	61	8.0	22	36.1	14.1
Independent morbidity	63	8.3	6	9.5	2.0
Meconium aspiration	4	0.5	4	100.0	21.1
Hyaline membrane disease	4	0.5	4	100.0	21.1
Hypothermia (<95°F)					
Total	130	17.0	20	15.4	4.9
As part of sepsis	24	3.1	11	45.8	11.7
Independent morbidity	106	13.9	9	8.5	1.8
Hemorrhage	11	1.4	8	72.7	17.1
Abnormal jaundice	15	2.0	3	20.0	4.0
Neonates with any one of the high-risk health problems (95 % CI)	370	48.5 (45.0 – 52.0)	38	10.3 (7.2 – 13.4)	20.2 (4.9 – 83.1)

*High risk = CF >10%.
[†]For diagnostic criteria, see Appendix A1.
[‡]Most deaths occurred in neonates with multiple problems. Such deaths were included with more than one health problem. Thus, associated % CF shown here does not imply that death was entirely attributable to that problem.
[§]Actual observations at birth were made by VHWs on 570 neonates.
[¶]A total of 54 cases out of 130 were treated with co-trimoxazole, because they fulfilled the criteria of pneumonia as well.
[‖]Respiratory rate ≥60, but no other sign of sepsis present. All the cases received treatment with co-trimoxazole, hence included in high-risk category in spite of no fatality.

were born by home delivery and only 5% in the hospital. As many as 81% of deliveries were conducted by TBAs.

We have earlier reported the incidence of the 20 types of neonatal morbidities and associated case fatalities.[1] These are reproduced here with some minor revision in estimates (Tables 1 and 2). Almost half (48%) of neonates suffered from high-risk morbidities (i.e. those with associated CF >10%) and nearly 72% suffered from low-risk morbidities (CF<10%). Some 42% of neonates were born with LBW, and 9.8% were preterm. The mean number of morbidities per neonate was 2.2. Nearly 18% neonates gained <300 g weight during neonatal period. Only 2.6% of neonates were seen and treated by a doctor, most often private, and 0.4% were hospitalized.

Table 3 presents the incidence by season of 15 morbidities. Hypothermia, unexplained fever, upper respiratory symptoms, skin infection, umbilical infection, and conjunctivitis show a statistically significant variation seasonally, and feeding problems, LBW, and preterm birth show a nonsignificant, but substantial, seasonal variation.

Asphyxia (mild and severe), preterm birth, LBW, or delay in the initiation of breast feeding occur only on the first day of life. The distribution of the incident cases of the remaining nine morbidities during 1 to 28 days of life is presented in Figures 1–3.

While the ‘‘incidence’’ represents the occurrence of new cases, the total number of cases, old and new, at any given point of time is represented by the ‘‘point prevalence’’. Point prevalence of feeding problems on various days is shown in Figure 4a and that of hypothermia in Figure 4b. Their prevalence markedly decreases during 2 to 4 weeks. On the contrary, the prevalence of upper

Table 2 Incidence of Low-Risk Health Problems, Associated Fatality in Home-Cared Neonates ($n=763$)

	Sick neonates (1–28 days)		Deaths[‡]	
Low-risk* health problems[†]	No.	Incidence (%)	No.	CF (%)
Birth weight 2000 – 2499 g	246	32.2	9	3.7
Birth asphyxia — mild[§]	81/570	14.2	3	3.7
Upper respiratory symptoms	153	20.1	1	0.7
Diarrhea	42	5.5	0	0.0
Unexplained fever	87	11.4	2	2.3
Umbilical infection	151	19.8	4	2.6
Bacterial skin infection	88	11.5	2	2.3
Conjunctivitis	94	12.3	1	1.1
Neonates with any one of the low-risk health problems (95% CI)	548	71.8 (68.6–75.0)	19	3.5 (1.9–5.0)

*Low risk = CF <10%.
[†]For diagnostic criteria, see Appendix A1.
[‡]Most deaths occurred in neonates with multiple problems. Such deaths were included with more one health problem. Thus, associated % CF shown here does not imply that death was entirely attributable to that problem.
[§]Actual observations at birth were made by VHWs on 570 neonates.

Table 3 Seasonal Variation in the Incidence of Neonatal Morbidities in Gadchiroli: 1995-96 ($n=763$)

	Percent incidence by season			
Type of morbidity	Rainy ($n=330$)	Winter ($n=274$)	Summer ($n=159$)	p*
Preterm	10.7	10.3	7.9	NS
Birth weight <2000 g	11.7	8.2	9.9	NS
Birth weight 2000 – 2499 g	35.4	34.6	27.0	<0.15
Mild asphyxia	15.2[a]	13.5[b]	13.6[c]	NS
Severe asphyxia	4.6[a]	2.7[b]	8.7[c]	<0.06
Delay in breast feeding	10.6	8.0	8.8	NS
Feeding problems (total)	18.2	12.4	18.9	<0.10
Hypothermia	14.8	21.5	13.8	<0.05
Neonatal sepsis	17.6	17.2	15.7	NS
Upper respiratory symptoms	16.1	29.9	11.3	<0.001
Diarrhea	5.2	5.8	5.7	NS
Unexplained fever	10.3	5.5	23.9	<0.001
Umbilical infection	20.3	26.3	7.5	<0.001
Bacterial skin infection	9.7	17.2	5.7	<0.001
Conjunctivitis	13.9	13.9	6.3	<0.04

*χ^2 test 2×3.
VHW did not attend all deliveries. Hence, asphyxia was observed in total 570 out of 763 neonates: a, 244; b, 223; c, 103. NS: nonsignificant.

respiratory symptoms (Figure 4c) remarkably increases during 2 to 4 weeks. A comparison with the reported incidence of the upper respiratory symptoms (Figure 2a) shows a much higher prevalence than incidence.

The neonatal mortality rate (NMR) in the observed neonates was 40/763 or 52.4/1000, and in the unobserved group it was 12/253 or 47.4/1000 ($P=0.88$). The respective still-birth rates per 1000 births were 24 and 25 ($P=0.55$).

DISCUSSION

We found a high incidence of neonatal morbidities in this cohort of home-cared neonates; many of these morbidities

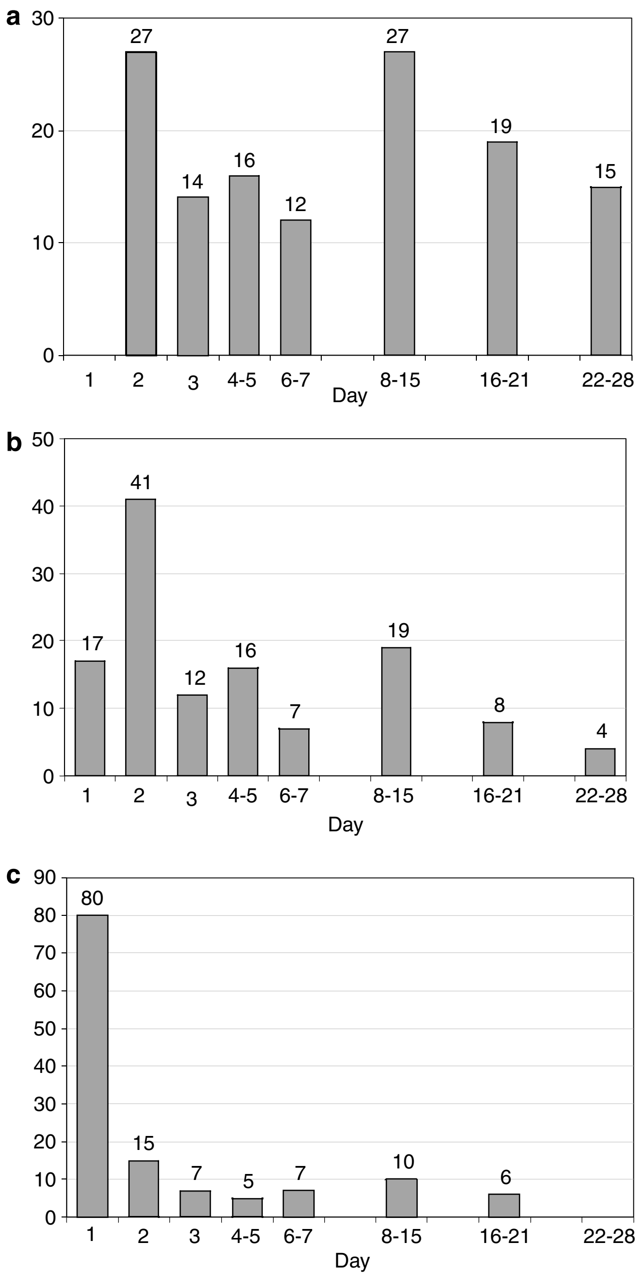

Figure 1. Distribution of incident cases of neonatal morbidities by day and week of life (Gadchiroli, 1995 to 1996) ($n = 763$). (**a**) neonatal sepsis; (**b**) feeding problems; (**c**) hypothermia.

were associated with high CF. The incidence of hypothermia, fever, upper respiratory symptoms, skin and umbilical infections, and conjunctivitis showed a significant seasonal variation. Nonsignificant seasonal variation was also observed in the incidence of preterm birth, LBW, severe asphyxia, and feeding problems. Sepsis and diarrhea did not vary seasonally.

The incidence of most morbidities showed a marked variation by the day of life. Some morbidities were concentrated in the first week of life (hypothermia, feeding problems), while others — most infections — were distributed in different weeks of neonatal life, suggesting an acquired mode of transmission. Nearly 30% cases of neonatal sepsis occurred on days 1 to 3, probably of maternal origin.

To our knowledge, this is the first report of a large cohort of neonates in a community in a developing country setting followed from birth to the 28th day for morbidities by day of life and compared by season. Some of the seasonal variations or the

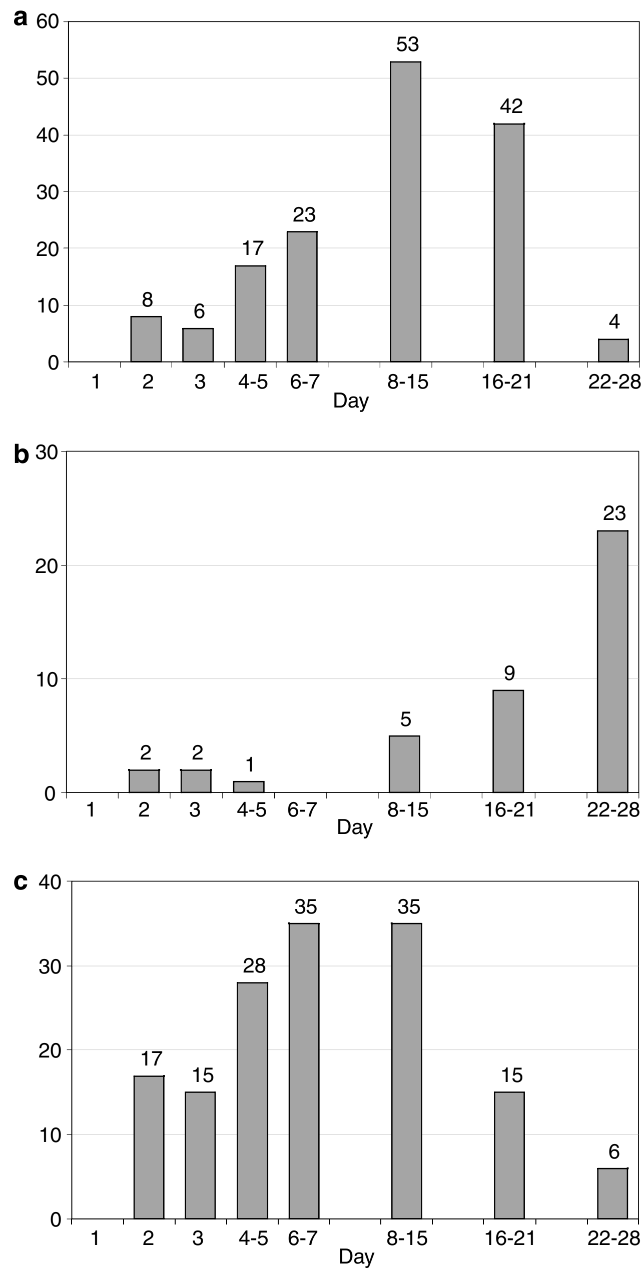

Figure 2. Distribution of incident cases of neonatal morbidities by day and week of life (Gadchiroli, 1995 to 1996) ($n = 763$): (**a**) upper respiratory symptoms; (**b**) diarrhea; (**c**) umbilical infection.

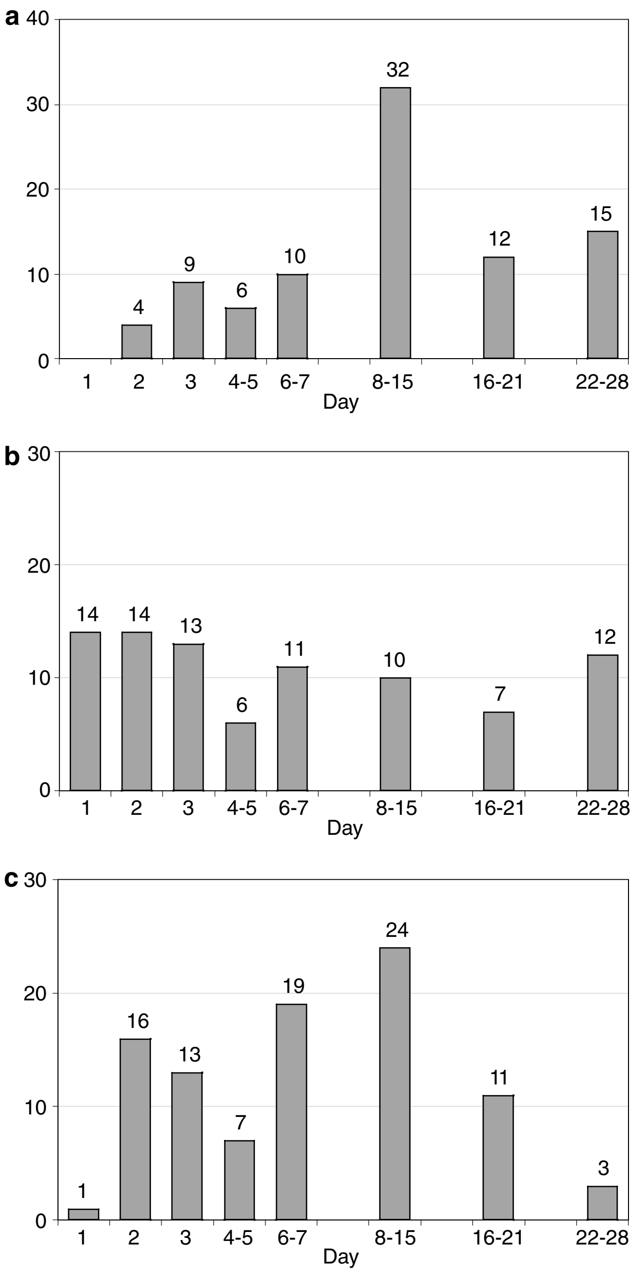

Figure 3. Distribution of incident cases of neonatal morbidities by day and week of life (Gadchiroli, 1995 to 1996) ($n = 763$):
(**a**) bacterial skin infection; (**b**) unexplained fever; (**c**) conjunctivitis.

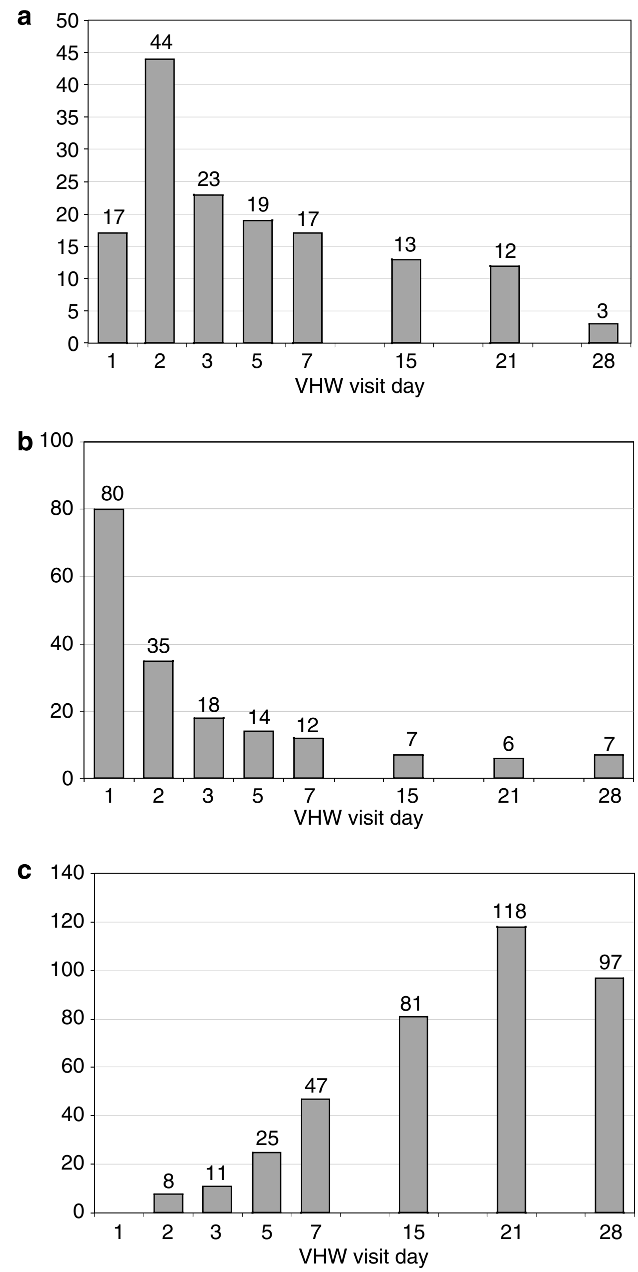

Figure 4. Prevalence of feeding problems, hypothermia and upper respiratory symptoms by day and week of life (Gadchiroli, 1995 to 1996) ($n = 763$):
(**a**) feeding problems; (**b**) hypothermia; (**c**) upper respiratory symptoms.

infections acquired after birth may point to inadequate protection from the influence of environment and infections (Figure 5), and therefore, likely to be amenable to interventions. We hypothesize that a proportion of the morbidities with varying seasonal and temporal incidence can be prevented by better home care and change in practices.

The findings should be interpreted with the understanding of the limitations of the methods. The diagnoses were based on data collected by trained VHWs to which clinical definitions (Appendix A1) were applied by a computer program. No laboratory investigations were possible. Hence, there was scope for imprecision in diagnosis. However, the quality of the data was checked by a physician in the field. The clinical definitions used were developed by an expert group (National Neonatology Forum Nomenclature),[20] and the use of a computer program eliminated subjective judgment.

We studied 75% of all babies born in 39 villages. This may have introduced a selection bias, as an unstudied group is often different from the one studied. However, the close similarity of the NMR (52 vs 47) and SBR (24 vs 25) does not suggest a significant bias.

Figure 5. Poor thermal protection and hygiene in the home care of rural neonates in Gadchiroli (note the house-flies on the neonates).

These limitations are inherent in the subject of study. Home-delivered neonates in rural area are difficult to access and are scattered geographically and temporally, and hence, surveillance is difficult. Taking blood or other specimens from such neonates and conducting laboratory investigations in the field was not possible. Within these circumstantial limitations, our methods were the available practical alternative.

The observed seasonal variations, significant or of borderline significance, have possible explanations (Table 4), which lead to potential interventions.

Severe climatic changes in temperature can be countered by good housing with devices for thermal control. Socio-economic factors determine availability of housing, heating, warm clothes, toilets, and time. Neonates in rural community get inadequate protection due to lack of those facilities. Although immediate changes in housing or socio-economic conditions may not be possible, neonatal care practices offer more opportunities to change and thereby to reduce the incidence of many morbidities.

A closer look at the incidence of morbidities by day of life reveals several interesting features.

Sepsis (Figure 1a): The diagnosis was entirely clinical and presumptive. By our definition, sepsis was usually not diagnosed on

Table 4 Possible explanations of the seasonal variations

Morbidity	Observed variation	Possible factors			
		Climatic	Housing/ delivery room	Socio-economic	Maternal and newborn care beliefs and practices
Hypothermia	↑ in winter	+	+	+	Neglect at birth No early breast feeding Early and exposed bathing No clothing up to 7th day
Fever	↑ in summer	+	+	+	Keeping the delivery room unventilated Restricted fluid intake by mother during first 7 days may result in reduced breast milk and poor hydration of neonates
Upper respiratory symptoms	↑ in winter		+		Crowding and indoor smoke increased in winter
Umbilical infection	↑ in winter and rainy season			+	Reduced hygiene, bathing, and skin care in winter and rainy season due to inadequate hot water or dry clothes
Skin infections	↑ in winter			+	Reduced hygiene, bathing, and skin care in winter
Conjunctivitis	↑ in winter and rainy season		+	+	Reduced cleanliness and increased indoor smoke in winter and rainy season due to lack of running/hot water and the cold climate
LBW	↑ in rainy season			+	Lower maternal food availability and increased hours of work during summer and rainy season
Feeding problems	↓ in winter				Mother spends more time and has more skin contact with baby

the first day. Over half of the sepsis cases (69/130) occurred in the first week of life. Nearly 40 cases (30%) on days 2 and 3 indicate the importance of early onset of sepsis in which the infection is maternal in origin. We have earlier reported a high prevalence of gynecological infections in this rural area.[21] New cases of sepsis continued to occur up to the fourth week, but in decreasing numbers. A total of 89 cases (70%) of late-onset sepsis (4 to 28 days) point toward environmentally acquired infection. Possible factors involved could be poor hygiene in the delivery room and in neonatal care, not feeding colostrum, umbilical or skin infections during the late neonatal period, and high rates of LBW and prematurity — all contribute to an increased risk of sepsis.

Continued occurrence of new cases after the first week (61 cases during days 8 to 28) indicates the need for repeated home visits during the late neonatal period as well. Even if these were babies born by hospital deliveries, the mothers would be usually discharged on the second day. Hence, 103 cases of presumptive sepsis would occur at home, pointing to the need for home-based care even in institutionally delivered neonates.

Feeding problems: Figure 1b reveals the importance of the first week, especially the second day when the largest number of mothers or babies had difficulty with breast feeding. Occurrence of new cases in weeks 2 to 4 was relatively low. Figure 4a shows the point prevalence of breast feeding problems during days 1 to 28. The problem persisted in fewer than 2% of babies as observed by the VHWs on the day of visit during 8–28 days. Most of these problems were resolved by the 28 day. Overall, this points to successful breast feeding in most neonates in a traditional rural area.

However, this is an incomplete picture, based on the difficulty reported by mothers. Weight gain <300 g during the neonatal period was observed in 17.9% of neonates on the 28th day. This points to a much larger prevalence of the problem of inadequate feeding in home-cared neonates. Some of this could also be associated with the occurrence of other morbidities such as infections. As we have reported earlier, postnatal infant mortality was significantly higher in those neonates who gained weight <300 g.[1]

Hypothermia (Figure 1c and 4b): The new cases of hypothermia occurred mainly on the first day. Few new cases occurred subsequently — although some of those diagnosed on the first day persisted on subsequent days, as seen in the point prevalence on subsequent days in Figure 4b. These figures underscore the crucial role of newborn care on the first day and the first week of life and a large scope for improvement in thermal protection. This need is also seen in the increased hypothermia in winter (Table 1). Hypothermia in winter has been reported from other developing countries as well.[12]

Upper Respiratory Symptoms (Figures 2a and 4c): Their incidence increased progressively, with the peak in the second and third weeks. The increased incidence observed in winter (Table 1) and the variation in the incidence by day of life suggest that these symptoms (cough or nasal discharge for >3 days) may be occurring due to two main factors: (1) infection transmitted to newborns through increased human contact after the first week when the isolation period ended (see traditional care);[17] and (2) increased crowding and indoor smoke inhalation from the fire in the delivery room. Not feeding colostrum would further decrease the neonate's immunological protection.

Comparison of the incidence (Figure 2a) with the prevalence (Figure 4c) of upper respiratory symptoms reveals a disturbing feature. Although the incidence seems to have markedly decreased on day 28, this is deceptive. Due to our definition — persistence of these symptoms >3 days — the new symptoms appearing on days 27 and 28 are not included as new cases because they were not observed for the required 3 days before the observation ceased on the 28th day. On the contrary, in spite of the low incidence, prevalence is high in the third and fourth weeks. Prevalence is a product of incidence and duration of illness. Hence, low incidence but high prevalence suggests prolonged duration of upper respiratory symptoms in home-cared neonates.

Diarrhea (Figure 2b): The incidence of diarrhea increased between the second and fourth weeks. It did not show seasonal variation (Table 3), and the total number of cases was small. Incidence of diarrhea did not follow the incidence of breast feeding problems. Breast feeding problems (Figure 1b) showed a decreasing trend from the early to the later part of neonate life, opposite to that of diarrhea. Moreover, there is no practice of giving complementary feeds beyond the first 3 days. Hence, the cases of diarrhea were probably due to poor hygiene, especially related to hand washing and cleanliness of breasts (see traditional care).[17] More persons handling the baby may also be a contributory factor.

Umbilical infection (Figure 2c): A sizable number of babies developed umbilical infection, peaking on the seventh day and into the second week. The maximum number occurred in week 1 (95), followed by week 2 (35), but new infections continued to occur during weeks 3 and 4 as well. The picture suggests a need for improving the traditional method of cord care.

Skin infections (Figure 3a): This included the cases of intertrigo and pyoderma. It showed distributions similar to umbilical infection, with the peak in the second week. The peak in winter (Table 3), when bathing, hand washing, and washing of clothes may diminish due to severe cold, suggests that the skin infections probably were due to lack of hygiene and skin care.

Unexplained fever (Figure 3b): Fever not accompanied by other clinical manifestations such as cough, diarrhea, sepsis, etc., was called unexplained fever. A total of 58 cases occurred in the first week, as compared to 7 to 12 during weeks 2 to 4. This may be explained by the neonate's inability to cope with the environmental temperature in the early neonatal period, and by delayed initiation of breast feeding and mothers restricting their fluid intake in the first week.[17] Both can result in diminished breast feeding, causing dehydration of the baby. Fever showed a higher incidence in summer (Table 3) when the environmental temperature reached high (up to 47°C). Thus, the fever seems to be related to both environmental temperature and breast feeding practices.

Conjunctivitis (Figure 3c): The cases peaked in the first week (56), and then progressively decreased. The presence of only one case on day 1, 19 cases on days 6 to 7, and 24 during days 8 to 15 suggests that these were not cases of gonoccocal ophthalmia neonatrum. We have earlier reported low prevalence of gonococcal infection in women in this area,[21] and tetracycline eye ointment was routinely put in eyes at birth by the TBAs. Hence, probably these were cases of bacterial conjunctivitis acquired postnatally due to poor hygiene or due to indoor smoke.

We did not find significant seasonal variation in the incidence of LBW or preterm birth as others have reported.[2–10] This probably was due to smaller sample size, because seasonal variation in the incidence of these two problems is apparent in Table 3, but it does not reach a significant level. This effect may become significant as data from more years accumulate.

Near-significant seasonal variation in the incidence of asphyxia (Table 3), especially the increase in summer, is a surprising and unexplained finding. It should be evaluated further as data from more years accumulate.

CONCLUSIONS

To summarize, three striking points emerge from the distribution by day of life: (1) the importance of the first week of the neonatal period wherein many of the discussed morbidities were concentrated (and not discussed morbidities such as preterm, LWB, and asphyxia), (2) the problem of infections most probably acquired postnatally from the environment, and (3) the important role of neonatal care practices as an explanation of the seasonal and temporal variation in the incidence of many morbidities.

Based on these findings, we suggest that a large proportion of morbidities such as hypothermia, fever, feeding problems, and various infections, such as of upper respiratory tract, skin, conjunctiva, and to some extent sepsis, can be prevented by (1) repeated visits by the health worker, especially in the first week, and (2) changes in neonatal care practices at home.

To prevent these morbidities, neonatal care at home should include (1) improved cleanliness and hygiene, (2) reduced contact of neonates, especially with infected persons, (3) early and exclusive breast feeding, (4) proper thermal protection, beginning on the first day, (5) cord care and (6) early detection and treatment of infections such as sepsis, skin infections, umbilical infection, and conjunctivitis.

We hypothesize that health education and repeated home visits by a trained health worker will reduce a substantial proportion of these neonatal morbidities by helping to substitute improved neonatal care at home for some traditional beliefs and practices. We shall test this in the intervention phase (see ''The reduced incidence of neonatal morbidities'', J Perinatol 2005;25:S51–S61).

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Appendix A1

Diagnostic Definitions of the Neonatal Health Problems

1. Birth asphyxia
   (i) Mild: At 1 minute after birth, no cry, or the breath was absent or slow, weak or gasping.
   (ii) Severe: At 5 minutes after birth, the breath was absent or slow, weak or gasping.
   (iii) Indirect: In the absence of direct observations by VHWs about newborn's condition at 1 and 5 minutes, presence of the following:
   (a) baby did not cry on its own, so the care provider had to make efforts to make the baby cry; and
   (b) color of the umbilical cord was green or yellow.
2. Preterm: Less than 8 months and 14 days (37 weeks) of gestation counted from the onset of the last menstrual period as per the history given by the mother.
3. LBW: Weight less than 2500 g.
4. Delayed breast feeding: Due to traditional practice, breast feeding not started in first 24 hours after birth, but baby licked/sucked the sweetened water.
5. Problems in breast feeding: Presence of any one of the following:
   (i) Baby did not suck breast for more than continuous 8 hours even when offered.
   (ii)
   - Mother unable to breast feed, or
   - baby fed on extracted breast milk, goat, or cow milk, or by bottle, or on sweetened water beyond 3 days, or
   - inadequate breast milk evidenced by continuous crying of baby and failure to gain weight.
6. Diarrhea: Watery, liquid motions three or more, or >9 motions of normal consistency in 24 hours, or mucus or blood in liquid stool.
7. Neonatal sepsis (septicemia, meningitis, or pneumonia diagnosed clinically): Simultaneous presence of any two of the following six criteria any time during 0 to 28 days:
   (i) Baby which cried well at birth, its cry became weak or abnormal, or stopped crying; or baby who earlier sucked or licked well stopped sucking, or mother feels that sucking became weak or reduced; or baby who was earlier conscious and alert became drowsy or unconscious.
   (ii) Skin temperature >99 or <95°F.
   (iii) Sepsis in skin or umbilicus.
   (iv) Diarrhea or persistent vomiting or distention of abdomen.
   (v) Grunt or sever chest indrawing.
   (vi) Respiratory rate (RR) 60 or more per minute even on counting twice.
8. Hemorrhage: bleeding from mouth, anus, eyes, nose, or in skin or in urine any time or vaginal bleeding after first week.
9. Conjunctivitis: Mother complained of excessive discharge from the eyes of baby, and on examination, eyes were red and with purulent discharge or dried pus.
10. Skin infection:
    (i) Pyoderma: Pus, ulcer, boil, pustule in skin.
    (ii) Intertigo: Excoriation with moist, cracked skin at skin folds.
11. Abnormal jaundice: Skin or eyes yellow on the first day or yellowness persisted at 3 weeks, or when yellowness associated with sepsis.
12. Meconium aspiration: History of difficult delivery or presence of birth asphyxia and respiratory distress (RR 60 or more; or severe indrawing of lower chest) started in first 24 hours after birth.
13. Hyaline membrane disease: Respiratory distress started within 6 hours after birth in preterms baby.
14. Pneumonia: RR 60 or more, persistent even when counted twice (Increased RR when associated with other signs symptoms of sepsis was included in neonatal sepsis).
15. Upper respiratory symptoms: Cough or nasal discharge present for 3 days or more without respiratory distress or increased RR.

16. Hypothermia: Axillary temperature $<95°F$.
17. Umbilical infection: Pus discharge from umbilicus.
18. Tetanus: Baby which earlier sucked well, stopped taking feeds from fourth day or more; and appearance of seizures, spasm and trismus.
19. Convulsive Disorder: Seizures but baby conscious, alert and feeds well between seizures (excludes tetanus, asphyxia, sepsis).
20. Unexplained fever: Axillary temperature $>99°F$ without any attributable cause.
21. Failure to gain weight: Total weight gain during 0 to 28 days <300 g.

Original Article

Why Do Neonates Die in Rural Gadchiroli, India? (Part I): Primary Causes of Death Assigned by Neonatologist Based on Prospectively Observed Records

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OBJECTIVE:

To determine the primary causes of death in home-cared rural neonates by using prospectively kept health records of neonates and a neonatologist's clinical judgment.

STUDY DESIGN:

In the first year (1995 to 1996) of the field trial in Gadchiroli, India, trained village health workers observed neonates in 39 villages by attending home deliveries and making eight home visits during days 0 to 28. The recorded data were validated in the field by a physician. An independent neonatologist assigned the most probable single primary cause of death based on these recorded data.

FINDINGS:

A total of 763 neonates were observed, of whom 40 died (NMR 52.4/1000). The primary causes of death were sepsis/pneumonia 21 (52.5%), asphyxia 8 (20%), prematurity <32 weeks 6 (15%), hypothermia 1 (2.5%), and other/not known 4 (10%). Most of the prematurity or asphyxia deaths occurred during the first 3 days of life. All 21 sepsis/pneumonia deaths occurred during days 4 to 28. A similar picture existed in England before the antibiotic era.

CONCLUSION:

Sepsis/pneumonia is the primary cause in half the deaths in rural neonates cared for at home in Gadchiroli, followed by asphyxia and prematurity. Infections cause a larger proportion of deaths in neonates in the community compared to the reported proportion in hospital-based studies.

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INTRODUCTION

Although the causal analysis can be extended far beyond medical factors, we shall limit this inquiry into "Why do neonates die in rural homes?" only to medical causes of death. The purpose is to estimate the contribution of the main diseases in causing neonatal deaths, and, thereby, to estimate the potential for preventing deaths by preventing or treating these diseases and finally, to select the correct priorities for action. We do this in two parts:

Part I. Primary causes of death, assigned by a neonatologist.

Part II. We find that most often, death results not due to a single morbidity but due to multiple morbidities. Hence, using a multicausal analysis, we estimate the population attributable fractions of six major causes of death, and also identity different combinations of morbidities causing neonatal deaths. We estimate the proportion of deaths that would be prevented by addressing some of the main causes. We finally identify priorities based on this analysis. We also propose a hypothesis on how neonatal mortality can be reduced.

In the absence of access to hospital care, most neonatal births and deaths in rural areas in developing countries occur at home.[1] Hence, for selecting the appropriate interventions to reduce neonatal mortality, it is essential to know the causes of neonatal deaths in rural homes. However, most available studies are hospital based.[2–4] The situation of neonatal health in rural homes cannot be extrapolated from the hospital-based studies because the conditions are radically different. Besides, only selected neonates reach hospitals. Therefore, we need information from population-based studies.

Population-based studies have invariably used retrospective inquiry or "verbal autopsy" to determine the cause of death.[5–7] However, this method has not been validated for neonatal deaths, except for neonatal tetanus.[8] The diagnosis of birth asphyxia as the cause of death, based on history alone, may be invalid, since mothers may not be able to correctly report the condition of the baby at birth. Determining that low birth weight (LBW), sepsis or hypothermia is the cause of death needs ante-mortem clinical observations and measurements, which are not available in verbal autopsy. Thus, the currently available community-based information on causes of neonatal deaths is of questionable validity.

This lack of valid information may affect the choice of interventions. To determine causes of death, the neonates in rural homes need to be prospectively observed, their medical data recorded, and the causes of death determined from such medical record review. Prior to the field trial in Gadchiroli, India,[9,10] such studies have not been conducted because of absence of any observer and of prospectively recorded data on neonates in rural homes.

During the first year of our field trial of Home-based Neonatal Care in rural Gadchiroli, we prospectively observed the neonates in 39 villages.[9–11] This study was conducted to answer the question: ''What are the primary causes of deaths in home-cared neonates in a rural community?''

METHODS

The first year of the intervention (1995 to 1996) in the field trial was devoted primarily to observing neonatal health with few interventions. The present study is an outcome of this observation period. The study design, area, and the methods of data collection have been extensively reported.[9–11] Therefore, their presentation here is brief.

After appropriate training, female village health workers (VHWs), one each in 39 villages, collected data on mothers during pregnancy by making three home visits. Most women in the area delivered at home, attended by traditional birth attendants (TBAs). The VHWs were also present at the home deliveries and made observations, including assessment of neonates at 1 and 5 minutes after birth. Subsequently, they visited mothers and neonates on eight fixed days (1, 2, 3, 5, 7, 15, 21, and 28) during the neonatal period, taking history, examining the baby, and recording the findings. They made additional visits on other days if the baby was sick and they were informed.

The record filled by VHWs included four sections:

(a) information during pregnancy,
(b) information during labor,
(c) first examination of newborn within 6 hours after birth, and
(d) information about mother and newborn, collected during eight or more postnatal home visits.

Altogether, information on 18 maternal and 28 neonatal variables was recorded.

In the first year of intervention, VHWs were not trained in the treatment of sick neonates. The newborns received care from the family and TBA and, if invited by the family, also from a government nurse or private doctor. The VHWs recorded the findings until the baby reached 28 days, or left the village, or died. In case of death, VHWs made efforts to collect information from the family about the circumstances before death, symptoms in the neonate, and the treatment provided. The data collection started on April 1, 1995, and continued for 1 year, until March 31, 1996.

A supervisory physician from the study team (S.B.B.) visited each neonate at home once in 2 weeks, verified the data recorded by the VHW, and noted any other observations. If a newborn was found to be sick, the family was advised to hospitalize the baby; SEARCH offered free ambulance service for transporting the sick baby; but the final decision was left to the family, who most often decided not to go to hospital. The care seeking behavior has been described earlier.[10,11]

Records of the 40 neonates who died during 1 year of the study period were reviewed by a neonatologist (V.K.P.) at the All India Institute of Medical Sciences, New Delhi, who assigned the most probable cause of death. The primary cause of death was defined as ''the disease or injury which initiated the train of morbid events leading directly to death''.[12] Although many conditions/complications contribute to death, in view of the difficulties and uncertainty involved in assigning the cause of death in neonates, we selected a limited number of principal entities as the primary causes of neonatal death: (i) prematurity, (ii) birth asphyxia, (iii) sepsis/pneumonia, (iv) tetanus neonatorum, (v) hypothermia, and (vi) others. LBW per se was not considered as the primary cause of death.

The neonatologist carefully evaluated the information in the case record. The assignment of the primary cause was based on the answer to the following question: ''Which of the six categories of primary causes of death fits best with the clinical course of the baby?'' In spite of the overlapping clinical features of various primary causes, the evolution of the clinical picture and the course of events allowed assigning a primary cause to most of the deaths. Since we were determining the primary cause as against the contributory causes, prematurity was considered only if the period of gestation was less than 32 weeks, and hypothermia (skin temperature $<95^\circ$F) only if it was persistent (recorded more than once) in the absence of any other major cause. Tetanus neonatorum was diagnosed if the baby of an unimmunized mother died at any time from the fourth day onwards because of inability to feed, trismus, and spasms. Sepsis was diagnosed if the baby died with features suggestive of systemic bacterial infections manifesting as septicemia, meningitis, or pneumonia. Birth asphyxia was diagnosed if the baby had failed to establish breathing at birth with subsequent features suggestive of hypoxemic ischemic encephalopathy or hypoxic damage to other organ systems. "Others" included congenital malformations or any other cause, or where a definite cause could not be established.

A vital statistics surveillance system involving male village health workers and supervisors independently recorded births and deaths in the study area. This system was earlier evaluated to be 98% complete.[9,10]

The ethical clearance for the study was granted by an external committee.[9]

RESULTS

The vital statistics surveillance system recorded a total of 1016 live births in the 39 villages during the 1-year of study, and 52 of these babies died during the neonatal period. Out of the total live births, 763 neonates (75.1%) were studied by female VHWs, and 253 were not studied. A total of 40 neonates died from among the 763 studied; and 12 died from among the 253 not studied. The neonatal mortality rate in the two groups was 52.4 and 47.4, respectively ($p > 0.5$). The still birth rate (SBR) in the births observed was 24/1000 births and 25/1000 in the unobserved births ($p > 0.5$). Hereafter, the 763 observed neonates constitute the study population. Socio-demographic characteristics of the population in the 39 villages, the completeness of recording births and deaths, and the lack of selection bias in the neonates included in this study population have been published.[10,11,13]

Nearly 95% of mothers delivered at home and 81% were delivered by TBAs. VHWs were present during labor (74.7%) and within 6 hours of the birth (92.4%). Data on maternal and labor characteristics and the incidence of various neonatal morbidities and the associated case fatality have been published.[10,13] In all, 42% neonates were LBW (<2500 g), 75 (9.8%) were preterm (<37 weeks), 130 (17%) had clinical features suggestive of infection, and 26 (4.6%) had severe asphyxia at birth. Only three (0.4%) neonates were hospitalized for sickness. None of them died.

A total of 40 neonatal deaths occurred in the 763 study neonates, giving the neonatal mortality rate of 52.4 per 1000 live births (95% CI: 36.6 to 68.2). Of this, early NMR (during days 1 to 7) was 30.1 per 1000 live births (23/763), and late NMR (during days 8 to 28) was 22.3 per 1000 live births (17/763).

The primary causes of death are shown in Figure 1. Sepsis 21 deaths (52.5%, 95% CI 37.0 to 69.0), asphyxia 8 deaths (20%, 95% CI 7.6 to 32.4), and prematurity <32 weeks 6 deaths (15%, 95% CI 3.9 to 26.1) were the most common primary causes. The temporal distribution of neonatal deaths by the primary cause is presented in Table 1. Almost all deaths due to asphyxia and prematurity occurred in the first 3 days, while all sepsis deaths occurred after 3 days of life. Out of the 17 deaths in the late neonatal period, 16 occurred due to sepsis. The mean day of death due to sepsis was 12.5.

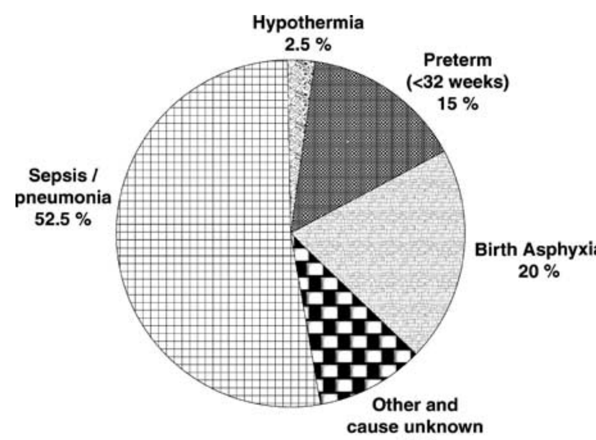

Figure 1. Proportion of neonatal deaths by the primary cause of death.

Table 1 Primary Causes of Neonatal Deaths and the Day of Death ($n = 40$ Deaths)

Primary cause	Day of death					% Deaths (95% CI)	Mean age at death (days)	CSNMR/1000 live births*
	1–3	4–7	8–14	15–28	Total			
Preterm <32 weeks	6	—	—	—	6	15.0 (3.9–26.1)	2.0	7.9
Birth asphyxia	7	1	—	—	8	20.0 (7.6–32.4)	1.8	10.5
Sepsis/pneumonia	—	5	11	5	21	52.5 (37.0–69.0)	12.5	27.5
Tetanus neonatorum	—	—	—	—	—	—	—	—
Hypothermia	—	1	—	—	1	2.5 (−2.3–7.3)	5.0	1.3
Other and cause not known	1	2	—	1	4	10.0 (0.7–19.3)	8.5	5.2
Total	14	9	11	6	40	100.0	7.9	—

*Cause specific neonatal mortality rate/1000 live births.

DISCUSSION

This is the first study in which the neonates in rural homes were prospectively observed, including during home-delivery and at birth, and the causes of death determined from these ante-mortem records. It revealed that sepsis was the primary cause in half of the deaths, with most of the sepsis deaths occurring during 4 to 28 days of life. This picture is quite different from the one gained from hospital-based studies. The primary causes of neonatal deaths reported in the hospital-based National Neonatal Perinatal Database, India (1996)[2] were prematurity (31.0%), birth asphyxia (26.0%), infections (22.0%), and malformations (9.6%). Similarly, the World Health Organization estimates (in 2001) that, globally, the causes of neonatal deaths are: birth asphyxia/injury 29%, complications of prematurity 24%, and infections: (sepsis + pneumonia) 26%, tetanus 7%; congenital malformations 11%. LBW was an important secondary factor in 40 to 80% of neonatal deaths.[1] The proportion of deaths due to sepsis observed in this study was twice these estimates.

Are Our Findings an Artifact?

The study area and the socio-demographic characteristics were similar to most villages in India.[9–11] The NMR of 52.4 in the study population during 1995 to 1996 was virtually identical to the 52.3 reported by the Sample Registration System of the Govt. of India in 1995.[7] The reporting of births and deaths in the study area was 98 to 99% complete.[9] Although not all neonates born in the 39 study villages could be studied, there was no apparent selection bias in the neonates studied and not studied,[10,13] and the quality of data collected was verified in the field by a physician and also validated by parallel observations.

The date of last menstrual period was recorded by VHWs during early pregnancy. Hence, the period of gestation could be estimated based on history. Only deaths in neonates <32 weeks were considered for prematurity as the primary cause of death. Therefore, prematurity as an associated cause of death in neonates >32 weeks is not represented in this analysis. (It is included in the next article, "Why do neonates die in rural homes, part II".)

As the VHWs were present at the time of home deliveries and recorded the cry and breathing at 1 and 5 minutes after birth, this cohort of neonates provides a reliable estimate of the incidence of birth asphyxia in home-delivered neonates. Of the 10 neonatal deaths that occurred in severely asphyxiated neonates, asphyxia was assigned as the primary cause in eight deaths. Thus, the estimated proportion of deaths due to asphyxia (20%) in this cohort seems reliable.

The diagnosis of sepsis in this study was based on data prospectively collected by the VHW as interpreted by a neonatologist. Some degree of inaccuracy is inherent in an approach that is based on clinical findings only and not on laboratory workup including bacterial cultures. Many conditions in neonates may mimic sepsis. We recognize this limitation of the study. However, radiological and bacteriological investigations are unlikely to be available in the near future to the population of interest, that is, home-cared rural neonates. Hence within these limitations, the method adopted in this study appears to be the best available.

In our study, sepsis/pneumonia was not identified as the cause of death for infants who died in the first 3 days of life. It is quite possible we misclassified these early deaths and hence missed some cases of early-onset sepsis. Based on the onset, it is customary to classify neonatal sepsis into early (onset within 3 days) or late (onset after 3 or more days) varieties. Early-onset sepsis may occur as pneumonia presenting as respiratory distress, which may be, quite often, indistinguishable from that due to lung immaturity (hyaline membrane disease), aspiration syndromes, or metabolic disease. Out of 14 deaths on days 1 to 3, 13 were assigned to prematurity and asphyxia (Table 1). Infection may have contributed to death in premature neonates, or may result in failure to establish breathing at birth mimicking asphyxia. Hence, early-onset sepsis may be a cause of death in some of the deaths occurring during 1 to 3 days of life. It is also possible that sepsis may have had an early onset, but it actually killed the infant after 3 days of life, and hence the death was included in the later time period.

How can the Finding of the High Proportion of Neonatal Deaths due to Sepsis be Explained?

A high proportion of LBW (42%) and preterm (10%) babies in the neonates exposed to unhygienic conditions and care, resulting in a large proportion acquiring infections (umbilical infection, skin infection, and clinically suspected sepsis), and lack of access to medical care seem to be the main reasons for such a high proportion of deaths due to infections.[10,11,13]

The study population being community-based may be another explanation for this observed difference. Since hospital-born neonates receive hygienic care and early treatment with antibiotics on the slightest suspicion of infection, the incidence of sepsis as well as deaths due to sepsis are expected to be low in them. Moreover, hospital-delivered neonates are very often discharged within a few days after birth,[14] but almost all sepsis deaths in this study occurred after 3 days of birth. Hence, it is likely that hospital-based information selectively underrepresents sepsis deaths. In a global review, the proportion of neonatal deaths attributed to infections (including tetanus) were reported to be 4 to 56% in hospital-based studies vs 8 to 85% in community-based studies.[15] This supports our contention.

This view is also supported by the causes of neonatal admissions to the peripheral hospitals. Sepsis is the most common indication for neonatal admissions to the district and subdistrict hospitals.[16] In a district hospital in Himachal Pradesh, India, 96% of neonates were admitted with the clinical diagnosis of septicemia or pneumonia.[17] Similarly, 82% neonates admitted to a subdistrict hospital had septicemia, pneumonia, meningitis, or cellulitis as the main diagnosis.[18] Thus, it appears that if the study population is community-based or from peripheral hospitals, infections predominate as the cause of illness or death.

The probable reasons for such a high proportion of deaths due to infections in our study were poor hygiene in rural homes,[11,13] a high proportion of reproductive tract infections in mothers,[19] 42% of neonates being LBW, and the traditional custom of not breast feeding for the first 3 days, thus depriving the baby of colostrum. The observed incidence of umbilical infection was 19.8% and of skin infections was 11.5%. All these factors predispose the neonates to infections and could explain the high (17%) incidence of suspected sepsis in the 763 observed neonates.[11,13]

As many as 54.4% of the observed 763 home-cared neonates in this study had indications for medical attention. However, only 2.6% of neonates were seen by a doctor, most often an unqualified village doctor, and only 0.4% were hospitalized.[13] Parents were either unwilling or unable to hospitalize the sick neonates, and existing primary health care essentially did not provide neonatal care. The lack of medical care certainly contributed to deaths due to infection.

Most community-based studies used retrospective inquiry to determine the causes of death.[5–7] The clinical manifestations of systemic infections, except tetanus, may be subtle, varied, and insidious,[20] and hence missed in the retrospective inquiry. Our study, based on a detailed recording of prospective observations made at home, is more likely to detect infection as the cause of death. However, even a recent community-based study in rural Gambia, using retrospective inquiry, estimated that 57% deaths in neonates were due to infections.[21]

A recent global review of infections in neonates estimated that 30 to 40%, that is, approximately 1.2 to 1.6 million, neonatal deaths occur each year due to infections.[15] Our study supports this, and puts the proportion of deaths due to sepsis at nearly 50%. Yet, our estimate is not unique, and the reported proportion in community-based estimates has ranged from 8% to as high as 85%.[15]

A similar pattern existed in developed countries before the antibiotic era. The Royal College of Obstetricians and Gynaecologists and the British Paediatric Association appointed a Joint Committee to investigate the causes of the high infant mortality rate in England (47/1000 live births) in 1945. It reported on a large series of necropsies on neonates in 1943, which showed that 36.5% of dead neonates had infections, and this proportion was 73.6% in the neonatal deaths occurring during 8 to 28th days of life.[22]

The limitations of this study must be kept in mind. Nearly 25% of births and neonatal deaths in the area were not observed by VHWs and hence not included in the study. Moreover, this is a relatively small size study, in one area. Hence, the estimates have wide confidence intervals. Other prospective observational studies on home-cared neonates need to be conducted in other areas to confirm our findings. The pattern of cause of death seen in this study may vary with the different levels of NMR. The proportion of deaths due to infection may be smaller at the lower levels of NMR. However, the picture reported in this study may be relevant to a large number of developing countries, including the Indian subcontinent, where NMR remains high.

We have already mentioned the limitations of diagnosis based only on history and physical examination, without laboratory investigations. Attributing death to a single primary cause is convenient but arbitrary. In reality, most deaths were associated with multiple, overlapping morbidities and mean number of morbidities per 763 observed neonates was 2.2. Hence, although this analysis provides very useful information it does not provide the complete picture. In a subsequent analysis, we attempt to take into consideration multiple morbidities as the cause of death.

CONCLUSIONS

This prospective observational study of home-cared neonates in a poor, rural community suggests that infections are the most important cause of neonatal deaths. Infections contribute a larger proportion of neonatal deaths at a high level of NMR such as is prevalent in rural India, and in the community-based estimates. No death occurred due to tetanus — probably because 79% of mothers received tetanus toxoid[10] and because TBAs were trained and provided with clean blades and thread. Since all sepsis deaths occurred from day 4 onwards, we see an opportunity for reducing the incidence of acquired infection by providing health education, improving hygiene, and promoting early breast feeding. And finally, those who develop clinical features suggestive of sepsis need early treatment with antibiotics. Since the mean day of death due to sepsis was 12.5, most of these neonates are likely to be at home. If monitored for sepsis, it may be possible to detect and treat them in time.

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Original Article

Why Do Neonates Die in Rural Gadchiroli, India? (Part II): Estimating Population Attributable Risks and Contribution of Multiple Morbidities for Identifying a Strategy to Prevent Deaths

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OBJECTIVES:

The understanding about why neonates die in rural areas in developing countries is limited. In the first year (1995 to 1996) of the field trial of home-based neonatal care in rural Gadchiroli, India, we prospectively observed a cohort of neonates in 39 villages. In Part I of this article, we presented the primary causes of death. The data were further analyzed:

1. To estimate the population attributable risk (PAR) of death for the main causes of neonatal mortality.
2. To evaluate the effect of a multiplicity of morbidities and to identify which morbidity combinations cause neonatal deaths.
3. To develop a hypothesis about how best to reduce neonatal mortality.

STUDY DESIGN:

We analyzed the observational data by logistic regression to estimate the PAR of death for six major morbidities. The effect of the number of morbidities per neonate on case fatality (CF) was estimated. Then we identified the main combinations of morbidities as the component causes leading to death. We estimated the excess deaths attributable to sepsis.

RESULTS:

This cohort included 763 neonates among whom 40 neonatal deaths occurred. Six major morbidities were associated with the following proportion of deaths: preterm, 62.5%; sepsis, 60%; intrauterine growth restriction (IUGR), 27.5%; asphyxia, 25%; hypothermia, 22.5%, and feeding problems, 15%. The estimated PARs were: preterm, 0.74; IUGR, 0.55; sepsis, 0.55; asphyxia, 0.35; hypothermia, 0.08, and feeding problems, 0.04. The CF associated with the number of morbidities per neonate was: with no morbidity, 0.3%; one morbidity, 2.1%; two morbidities, 15.3%; three or more morbidities, 41.4% ($p<0.001$). In all, 82.5% of all deaths occurred in neonates with two or more morbidities. The proportion of total deaths associated with only preterm was 7.5%, and with only IUGR was 2.5%; however, with the main morbidity combinations it was preterm + sepsis, 35%; IUGR + sepsis, 22.5%; preterm + asphyxia, 20%; preterm + hypothermia, 15%; and preterm + feeding problem, 12.5%. The % CF with low birth weight (LBW) <2500 g alone was 5.2% and with infection alone was 1.9%, but with LBW + infection it was 31.9%. The estimated excess deaths caused by sepsis over and above LBW was 44% of the total deaths.

CONCLUSIONS:

Preterm and IUGR are ubiquitous components, but usually not sufficient to cause death. Most deaths occur due to a combination of preterm or IUGR with other comorbidities. If preterm birth or IUGR cannot be prevented, the strategy should be to ensure neonatal survival by addressing comorbidities, that is, infections, asphyxia, hypothermia, and feeding problems in that order of priority. We hypothesize that the prevention and/or management of neonatal infections will reduce neonatal mortality by 40 to 50%.
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INTRODUCTION

The World Health Organization has estimated[1] that the direct causes of neonatal deaths globally are: infections, 32%; asphyxia, 29%; complications of prematurity, 24%; congenital anomalies, 10%, and other, 5%. In the first year of the field trial of home-based neonatal care in rural Gadchiroli, India, the primary cause of death was sepsis/pneumonia, 52.5%, followed by asphyxia, 20%; prematurity, 15%; hypothermia, 2.5%, and other, 10%.[2]

A single primary cause of death makes for convenient analysis and presentation of data. However, it suffers from certain limitations. First, it oversimplifies the complex reality by ignoring the contribution of associated causes. Second, in spite of the guidelines[3] for assigning the primary or underlying cause of death, the selection of one cause from among many does involve a subjective judgment.[4–6] Hence, attributing death to a single cause may be difficult and even misleading. It also shrinks the opportunity for intervention by ignoring the contributory causes.

This was consistent with the current multicausal understanding of the causal mechanism as described by Rothman and Greenland.[7] According to this, the "one cause–one effect" understanding is a simplistic misbelief. In reality, most outcomes — whether disease or death — are caused by a chain or web consisting of many component causes. A combination of multiple causes that results in disease or death is considered a "sufficient cause." Some of its components are "necessary" but insufficient to cause the effect by themselves. When the causal mechanism includes the necessary components and also becomes sufficient, the effect is produced.

Which morbidities or combinations of morbidities constituted the causal web sufficient to cause neonatal deaths? What proportion of neonatal deaths were attributable to each of these component causes? In epidemiology, population attributable risk (PAR), also called attributable fraction, is used for estimating the proportion of disease or death in a population that can be ascribed to a cause or a combination of causes. It is also a useful measure of what proportion of disease or deaths can be prevented if that component cause is removed.[8,9] The purpose of this paper is to identify which morbidity or morbidities can be targeted to reduce neonatal mortality. The prospectively observed data on a cohort of rural neonates in the first year of the Gadchiroli trial offered a unique opportunity because it represented the natural history of rural neonates. We analyzed these data with the following objectives:

1. To estimate the population attributable risk (PAR) of death for the main causes of neonatal mortality.
2. To evaluate the effect of a multiplicity of morbidities and to identify which morbidity combinations cause neonatal deaths.
3. To identify the priority for action and to develop a hypothesis about how best to reduce neonatal mortality.

METHODS

We conducted a field trial of home-based neonatal care in rural Gadchiroli (India), in a block of 39 intervention villages. Agriculture was the main occupation of the population, and deliveries occurred mostly at home, assisted by traditional birth attendants. The selection of the area, characteristics of the study population, the study design, and methods of data collection have been described earlier in detail.[10–12] Trained village health workers (VHWs) collected data on neonates born in 39 villages by making three home visits during pregnancy, attending home delivery, and eight home visits during days 1 to 28 of neonatal life. A supervisory physician who visited each village once in 15 days checked the quality of data. The births and neonatal deaths were recorded by VHWs as well as by an independent vital statistics surveillance system. The quality and the completeness of data was >90%.[12,13]

From the observational data prospectively collected in 39 villages in the first year of the trial (April 1995 to March 1996) on the incidence of various neonatal morbidities and the associated number of deaths in 763 neonates,[10,13] we selected the six morbidities associated with the most deaths. (We use the term "morbidity" to include risk factors such as low birth weight (LBW) or preterm birth as well as diseases.) These were (1) preterm birth (<37 weeks); (2) full term birth with intrauterine growth restriction (IUGR), that is, gestation of 37 weeks or more, but birth weight <2500 g; (3) clinical sepsis (when any two of the following six clinical criteria were simultaneously present in a neonate: (i) previously normal cry became weak/stopped or previously normal baby became drowsy/unconscious or previously normal sucking became weak or stopped, (ii) baby cold to touch or feverish (skin temperature >99°F), (iii) skin infection or umbilical infection, (iv) Vomiting or diarrhea or abdominal distension, (v) respiratory rate ≥ 60 and (vi) grunting or chest indrawing); (4) severe asphyxia (breathing not well established at 5 minutes after birth); (5) feeding problems; and (6) hypothermia (skin temperature <95°F). Birth defects were not a major cause of death in this cohort. The period of gestation was calculated from the date of last menstruation (which was recorded by the VHWs at the time of registering the pregnancy, usually in the 4th or 5th month). The birth weight was recorded in most neonates within 6 hours of birth using a spring balance (Salter, UK). The details of recording the data have been published earlier.[10] We assessed the validity of gestational age by cross-tabulating against the birth weight. In many neonates, feeding problems and hypothermia were not present initially, but appeared on later days as a part of the clinical diagnosis of sepsis. In such neonates, we decided to count these two as manifestations of sepsis and not as independent morbidities. But if these occurred independent of clinical sepsis in the same neonates or in different neonates, they were considered a morbidity per se.

By univariate analysis, we calculated the incidence, case fatality, and relative risk of death associated with each of these six morbidities. This being a multicausal analysis, a neonate was counted in each morbidity from which it suffered. When multiple morbidities occurred in the same neonate, such neonates were counted more than once.

To remove the confounding effect caused by the presence of multiple morbidities in the same neonate and to estimate the odds ratio (OR) of death associated with each morbidity, we performed logistic regression analysis. (An explanation of the statistical method is provided at the end of the Methods section.) From these ORs, we estimated the PAR of neonatal death attributable to each morbidity. The PAR was calculated by the equation:[14]

$$\mathrm{PAR} = \frac{P(\hat{R}R - 1)}{1 + P(\hat{R}R - 1)}$$

To evaluate the effect of the multiplicity of morbidities, neonates were categorized by the number of morbidities they suffered from during the first 28 days. We then analyzed the number of deaths associated with each category, the percent case fatality (% CF), and the distribution of the neonatal deaths in these categories.

To identify how the individual morbidities, alone and in combinations, affected neonatal survival, we tabulated the neonates: those with no morbidity, with a single morbidity, and with various combinations of morbidities, and the associated number of neonatal deaths. We also tabulated the mean birth weight and period of gestation of neonates in each category. From these, we identified five causal combinations that explained most deaths.

We further assessed the effect of the combination of LBW and infection, by analyzing % CF in LBW without sepsis, in sepsis without LBW, and in neonates with LBW + sepsis. We estimated by logistic regression the OR of death for LBW alone, sepsis alone, and for the interaction of these two.

Since the earlier reviews of field trials and programs have found that LBW or preterm birth are usually not preventable at the population level,[15–17] we explored how many deaths could be prevented by addressing the other component cause, namely, infection, even in the presence of LBW (which included most (62/75) preterm and all IUGR neonates). To do this, we estimated the excess number of deaths contributed by clinical sepsis by calculating the number of deaths with sepsis minus the number of deaths without sepsis in different birth weight strata. For example, the excess deaths caused by sepsis in neonates with birth weight 2000 to 2499 g were estimated from the deaths observed in neonates of birth weight 2000 to 2499 g with sepsis, minus deaths expected if sepsis was absent (the percent case fatality in neonates without sepsis $\times$ the number of neonates with sepsis in that birth weight group).

We then summarized in one table the various estimates we had arrived at by different methods and in a hierarchal order of magnitude.

We used SPSS PC + and the Epi-info softwares for data analysis.

[Statistical explanation: Strong correlations between independent variables in a logistic regression model may sometimes cause multicollinearity, which may even result in incorrect conclusions (Kleinbaum DG. Logistic Regression. New York: Springer-Verlag; 1994. p. 168). The independent variables in our models are six neonatal morbidities, and there is a possibility that the presence of one or more of them may be associated with the presence of one or more of the others. We used χ^2 test to assess the associations among the different morbidities. We found statistically significant associations ($p<0.05$) of preterm birth with LBW as well as with birth asphyxia, sepsis, and feeding problems, and of LBW with sepsis. Hence, we further assessed the presence of any multicollinearity among the variables included in the logistic regression model by using a SAS Macro that outputs the condition indices (CI) and variance decomposition proportions (VDP). As is customary, a CI value of 20 or more was taken as an indicator of collinearity and VDP values of 0.5 or higher were used to identify specific variables involved in the collinearity (1. Kleinbaum DG. Epidemiologic Modeling. Course material for the course Epi 740, Rollins School of Public Health, Emory University, Atlanta; 2. David Garson. Quantitative Research in Public Administration. Course material for the course PA 765, North Carolina State University, Raleigh, North Carolina). No collinearity was identified in the model. The highest CI value was 7.34, much less than the cutoff value of 20.]

RESULTS

Out of total 1016 live births in the year 1995 to 1996 in 39 villages, 763 neonates (75%) were studied, among whom 40 deaths occurred during the neonatal period. The number of neonates with different gestational age and their mean birth weight in parentheses was: <32 weeks: 11 (1484 g), 33 to 34 weeks: 15 (1742 g), 35 to 36 weeks: 46 (2188 g), 37 to 38 weeks: 189 (2416 g), 39 to 40 weeks: 302 (2549 g), and >40 weeks: 162 (2613 g). The date of last menstruation of the mother or birth weight of the neonate was not recorded in 38 cases.

The six main morbidities (those associated with most of the deaths), their incidence, associated case fatality, proportion of deaths, and the relative risk of death are presented in Table 1. In this cohort, the incidence of LBW was high, 41.9%. Since the incidence of preterm birth was 9.8%, the majority of the LBW neonates were IUGR. The incidence of sepsis (clinical) and hypothermia was also >10%. In this univariate analysis, most deaths were associated with preterm (62.5%), sepsis (60%), IUGR (27.5%), and asphyxia (25%).

Univariate analysis does not take into consideration the confounding effect caused by the presence of multiple morbidities in a neonate. The logistic regression adjusts for such an effect and provides the estimates of risk, as ORs, associated with individual morbidities. The ORs estimated by logistic regression and the estimated PAR associated with these six morbidities are presented in Table 2. The ORs of preterm birth, sepsis, IUGR, and asphyxia are highly significant, but not for hypothermia and feeding problems.

PAR is highest, 0.74, for preterm, followed by 0.55 for sepsis, 0.55 for IUGR, and 0.35 for asphyxia. PAR for hypothermia and feeding problems is low. Since neonates having multiple morbidities were counted with each morbidity, the sum total of PARs was more than 1. This is an accepted and expected phenomenon with multicausal situations.[8,9]

The effect of a multiplicity of morbidities in a neonate was assessed by estimating the percent case fatality in neonates with different numbers of morbidities. Case fatality steeply and progressively increased with the increase in the number of morbidities per neonate (Figure 1).

To assess the effect of individual morbidities and their combinations, neonates were tabulated according to morbidities, singly and in various combinations. Table 3 shows their incidence,

Table 1 Case Fatality and Relative Risk of Death Associated with Selected Neonatal Morbidities: Univariate Analysis (1995–1996, $n = 763$, neonatal deaths = 40)

Morbidity	Sick neonates		Deaths		RR† of death (95% CI)	Proportion of total deaths (40)*
	N*	% Incidence	N*	% Case fatality		
Preterm (<37 weeks)	75	9.8	25	33.3	15.3 (8.4–27.7)	62.5
Clinical sepsis	130	17.0	24	18.5	7.3 (4.0–13.4)	60.0
Intrauterine growth restriction (IUGR)‡	253	33.2	11	4.3	0.8 (0.4–1.5)	27.5
Severe birth asphyxia	26§	4.6	10	38.5	8.0 (4.4–14.9)	25.0
Hypothermia¶	106	13.9	9	8.5	1.8 (0.9–3.7)	22.5
Feeding problems¶	63	8.3	6	9.5	2.0 (0.9–4.5)	15.0

*A neonate having more than one morbidity is counted in each category. Hence, the sum may be more than the total neonates or deaths in the study population.
†Relative risk.
‡Full term (37 completed weeks or more) with birth weight <2500 g.
§Observed in 570 neonates.
¶Excluding when present in neonates with sepsis.

Table 2 Odds Ratio (OR) and Population Attributable Risk (PAR) of Death for Individual Morbidities ($n = 763$, deaths = 40)

Morbidity	Odds ratio* (95% CI)	Significance	Population attributable risk†
Preterm (<37 weeks)	29.79 (9.4–94.5)	<0.001	0.74
Clinical sepsis	8.17 (3.6–18.6)	<0.001	0.55
Intrauterine growth restriction (IUGR)‡	4.69 (1.4–15.4)	<0.011	0.55
Severe birth asphyxia	12.80 (3.8–43.6)	<0.001	0.35
Hypothermia	1.61 (0.6–4.2)	NS	0.08
Feeding problems	1.47 (0.5–4.7)	NS	0.04

*Adjusted OR determined by logistic regression.
†A neonate having more than one morbidity is counted in each category. Hence, the sum of PARs is more than 1.
‡Full term (37 completed weeks or more) with birth weight <2500 g.
NS = not significant.

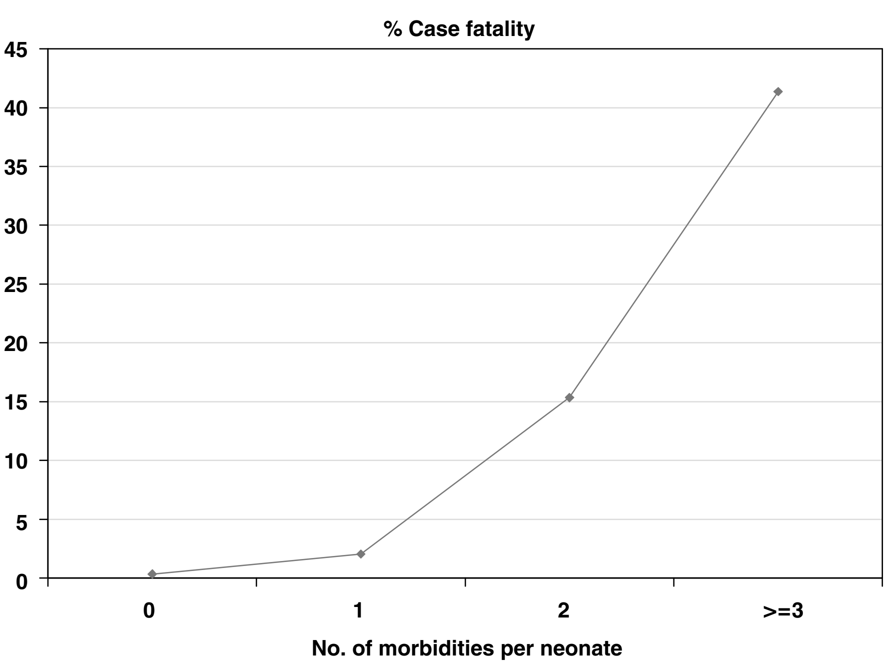

Figure 1. Effect of the number of morbidities per neonate on case fatality.

Table 3 Combinations of Neonatal Morbidities: Incidence, Case Fatality and Presence in Neonatal Deaths (1995–1996, $n = 763$, neonatal deaths = 40)

Morbidity categories*	No.	Mean birth weight (g)	Mean days of gestation	% Incidence	Deaths	% CF	% of deaths (40)
(A) *No morbidity*	308	2741[a]	281[b]	40.4	1	0.3	2.5
(B) *Single morbidity*	289	2388[c]	276[d]	37.9	6	2.1	15.0
Only asphyxia without other morbidity†	8	—	—	1.0	2	25.0	5.0
Only IUGR[1] without other morbidity	155	—	—	20.3	1	0.6	2.5
Only preterm[2] without other morbidity	27	—	—	3.5	3	11.1	7.5
Only sepsis[3] without other morbidity	40	—	—	5.2	0	0.0	0.0
Only hypothermia[4] without other morbidity	40	—	—	5.2	0	0.0	0.0
Only feeding problems without other morbidity	19	—	—	2.5	0	0.0	0.0
(C) *Only two morbidities*	137	2191[e]	268[f]	17.9	21	15.3	52.5
IUGR+sepsis	41	—	—	5.4	7	17.1	17.5
IUGR+feeding problems	16	—	—	2.1	1	6.3	2.5
Preterm+severe asphyxia	6	—	—	0.8	4	66.7	10.0
Preterm+sepsis	15	—	—	2.0	7	46.7	17.5
Preterm+feeding problem	6	—	—	0.8	1	16.7	2.5
Sepsis+hypothermia	8	—	—	1.0	1	12.5	2.5
Other combinations of two morbidities	45	—	—	5.9	0	0.0	0.0
(D) *Three or more morbidities*	29	1911	258	3.8	12	41.4	30.0
Total	763	2472[g]	276[h]	100.0	40	5.2	100.0
(E) *Morbidities in combination with preterm*§							
Only preterm	27	2228	244	3.5	3	11.1	7.5
Preterm+sepsis	27	1899	246	3.5	14	51.9	35.0
Preterm+asphyxia	12	1617	237	1.6	8	66.7	20.0
Preterm+hypothermia	14	1856	251	1.8	6	42.9	15.0
Preterm+feeding problems	14	1815	247	1.8	5	35.7	12.5
(F) *Morbidities in combination with IUGR*§							
Only IUGR	155	2181	278	20.3	1	0.6	2.5
IUGR+sepsis	49	2094	275	6.4	9	18.4	22.5
IUGR+asphyxia	3	2083	278	0.4	0	0.0	0.0
IUGR+hypothermia	38	2193	276	5.0	2	5.3	5.0
IUGR+feeding problems	20	2141	276	2.6	1	5.0	2.5

*A,B,C,D are exclusive categories. Under E and F, neonates from B,C,D are included, the combinations are overlapping, and same neonate may be included in more than one category.

a: 290, b: 296, c: 284, d: 287, e: 134, f: 136, g: 737, h: 748 are the corresponding neonates.

†Severe asphyxia.

1 = intrauterine growth restriction; 2 = <37 weeks, 3 = clinical diagnosis of sepsis, 4 = skin temperature <95°F.

§A neonate may have multiple morbidities simultaneously, and is included in each combination. Hence the total is more than 100%. Similarly, neonates from the earlier categories A, B, C, and D are also included under categories E and F, when appropriate.

the percent case fatality, and the percent of deaths associated with each category. A, B, C, and D, are exclusive categories. The percent case fatality is very low in neonates without morbidity. Among the single morbidities, only asphyxia and preterm have a high CF of 25 and 11%, respectively. The CF increases especially with two or more morbidities in a neonate, and when morbidities occur in combination with preterm or IUGR. Under E and F are presented various morbidities in combination with preterm and IUGR. Percent case fatality was very high in neonates with preterm and any other morbidity. On the other hand, CF in the presence of IUGR was high only in combination with sepsis (18.4%). The maximum number of deaths, 23/40 or 57.5%, were caused when sepsis occurred in the presence of preterm or IUGR.

Also seen in Table 3 is that the mean birth weight and the period of gestation decrease as the number of other morbidities increases. In other words, neonates with lower birth weight or shorter period of gestation suffer from more comorbidities. The higher case fatalities are, thus, a total effect of lower birth weight/gestation and number of comorbidities.

Effect of the interaction between LBW and infection on CF was analyzed. As compared to the zero % CF in neonates without LBW or infection, the % CF was 1.9% in neonates with clinical sepsis without LBW, 5.2% in neonates with LBW without sepsis, and increased to 31.9% when these two occurred together. The interaction showed in logistic regression an OR of 3.8, and was not statistically significant.

The excess deaths contributed by the addition of sepsis are presented in Table 4. The % CF in neonates with and without sepsis is compared in different birth weight strata. The net difference is presented as the absolute difference in % CF. The second-to-last column presents the estimated number of residual deaths expected to occur when sepsis is prevented and, hence, the estimated excess deaths contributed by sepsis are shown in the last column. The total excess deaths caused by sepsis are thus estimated to be 17.58 or 44% of the total deaths in this cohort of neonates. We also note that the PAR for sepsis estimated by this method (0.52) comes very close to the PAR estimated by the logistic regression (0.55).

Table 5 compares the results of four different methods we used to assess the contribution of different morbidities to neonatal deaths in the two papers (including the present one), titled "Why do neonates die in rural homes? Parts I and II". The data on the primary cause of death[2] assigned by neonatologist are based on the same cohort of neonates in Gadchiroli. The remaining three estimates are drawn from different tables in the present paper. Although the absolute values of PARs and the proportion of deaths vary depending on the method used, the rankings show a fairly consistent pattern.

In Table 5, section A, the PARs are presented for individual morbidities. Preterm ranks highest, followed by sepsis and IUGR, having equal ranking, followed by asphyxia, hypothermia, and feeding problems. When morbidity combinations are seen as the cause of death, section B, preterm or IUGR are the ubiquitous components, and their combination with sepsis occupies the first two ranks.

The contribution of sepsis to total deaths is estimated by different methods to be 52.5, 55, 57.5, and 44% (Table 5).

DISCUSSION

Although most neonatal deaths occur in neonates with preterm or IUGR birth, when these morbidities occur alone without other comorbidities, the case fatality is low and these contribute only a small proportion (10%) of deaths. By contrast, most deaths occur when preterm or IUGR is of a more severe degree and is combined with other morbidities: sepsis, asphyxia, hypothermia, or feeding problems, in that order. Hence, LBW (preterm or IUGR) in combination with one of these four morbidities constitutes sufficient cause of death. The most important among these combinations is the combination of LBW and sepsis. The case fatality increases many fold when these two occur together. We estimate that nearly three-fourths of neonatal deaths can be attributed to preterm birth and nearly half to sepsis, and that LBW

Table 4 Case Fatality in Different Birth Weight Groups With and Without Clinical Sepsis, and Estimating the Number of Excess Deaths Caused by Sepsis

	Without sepsis			With sepsis								
Birth weight (g)	Neonates	Deaths	% CF*	Neonates	Deaths	% CF*	Absolute difference in % CF*	p	Relative risk†	PAR‡	Expected deaths in sepsis cases§	Estimated excess deaths¶
≥2500	363	0	0.0	54	1	1.9	1.9	<0.130	—	—	0.00	1.00
2000–2499	201	3	1.5	45	6	13.3	11.8	<0.002	—	—	0.67	5.33
<2000	47	10	21.3	27	17	63.0	41.7	<0.001	—	—	5.74	11.26
Not recorded	22	3	13.6	4	0	0.0	—	—	—	—	—	—
Total	633	16	2.5	130	24	18.5	15.9	<0.001	7.3†	0.52†	6.42	17.58

*Case fatality.
†Of death for sepsis.
‡Population attributable risk for sepsis.
§Expected deaths in sepsis cases if sepsis was prevented, and hence CF in neonates without sepsis would apply.
¶Excess deaths caused by sepsis.

Table 5 Summary of the Proportion of Deaths Attributed to Different Causes by Different Methods of Estimation and Proportion of Deaths Preventable

Cause of death	% of deaths attributed			
	Primary cause (assigned by neonatologist)*	PAR† in multicausal analysis‡	Proportion of all deaths§	Ranking
(A) Individual morbidity				
Preterm	15.0	0.74	—	1
Sepsis	52.5	0.55	—	2
Intrauterine growth restriction	NR	0.55	—	2
Asphyxia	20.0	0.35	—	4
Hypothermia	2.5	0.08	—	5
Feeding problems	NR	0.04	—	6
Not known	10.0	—	—	—
(B) Combinations of morbidities				
Preterm+sepsis	—	—	35.0	1
IUGR+sepsis	—	—	22.5	2
Preterm+asphyxia	—	—	20.0	3
Preterm+hypothermia	—	—	15.0	4
Preterm+feeding problems	—	—	12.5	5
(C) Deaths preventable by preventing/ managing sepsis, even if LBW persisted	Preventable deaths¶ 17.58		Proportion of total deaths(40) preventable 44.0%	

*Bang, Paul and Reddy, Why do neonates die in rural homes? Part I.
†Population attributable risk.
‡Table 2 in the present paper.
§Table 3 in the present paper.
¶Table 4 in the present paper.
NR: not recorded as the primary cause.

(preterm or IUGR) + sepsis combined is responsible for nearly 60% of deaths.

Since the causal web can be interrupted by addressing one of the component causes, sepsis, asphyxia, hypothermia, and feeding problems, in that order, provide opportunity for preventing neonatal deaths, even if LBW or preterm continues at the current level. Of these, sepsis ranks as the highest priority. It is unlikely that, with the current state of knowledge, we will be able to reduce significantly the incidence of preterm or IUGR births in developing countries. Hence, the strategy of choice will be to address infections. We hypothesize that prevention and/or treatment of infections will reduce neonatal mortality by 40 to 50%.

This is an observational study showing associations between selected morbidities and neonatal deaths. It cannot be considered to provide irrefutable evidence of a cause-and-effect relationship. However, of the various causal criteria provided by Hill and further commented on by Rothman,[7] morbidities as a cause of neonatal death meet, in this study, the criteria of temporality, strength of association, and plausibility.

Other limitations of the study are that the observations are only from one site and made only in 1 year. Sample size is relatively small. Although 25% neonates in the area, among whom 12 died, were not studied, as we have earlier published, the studied and unstudied groups had similar neonatal mortality rate.[10–12] As to the quality and completeness of data, and the definitions and validity of diagnoses of morbidities, these have been discussed elsewhere.[10–12] The mean birth weight closely followed the gestational age (Results text) indirectly validating the assessment of gestational age. The diagnosis of sepsis was entirely clinical, without any laboratory backup. Hence there is bound to be substantial imprecision, and false-positive diagnosis. This is reflected in Tables 3 and 4 in which the case fatality of sepsis in some categories is very low. We have estimated the sensitivity, specificity, and positive predictive value of these criteria.[18]

The strength of this analysis is that it is based on prospectively observed, community-based data on neonates in rural homes. In addition, the observations cover all major morbidities in neonates. Hence, these data represent the natural history of neonates in the rural community and allow a comprehensive assessment of the interactions of various morbidities and their contribution to death. To our knowledge, this is the first such comprehensive and quantitative assessment on neonates in a community setting in a developing country.

The proportion of neonatal deaths attributable to different causes, especially to infections, is different in this assessment than the global assessment[1] in which the direct causes of death are infections, 32%; asphyxia, 29%; complications of prematurity, 24%; and congenital anomalies, 10%. Why this difference? The limitations of this study, mentioned earlier, may be responsible for some of this difference. However, the alternative explanations are: (1) The global data are presented in the form of single cause of death. In this analysis, we have included all major causes and, moreover, analyzed deaths by combinations of morbidities. (2) This analysis was performed on a community-based situation in a rural area setting. Many of the global or national estimates[19] use hospital-based data. (3) And, finally, this analysis is based on prospective observations compared to the retrospective inquiries about probable cause of death that are the bases for estimating the causes of death in rural infants in many national estimates.[20,21]

We found in this analysis, presented in Figure 1 and Table 3, that, in rural Gadchiroli, neonatal deaths are caused not by a single morbidity but by a combination of multiple morbidities. Most deaths occurred when LBW (preterm or IUGR) was complicated by sepsis, asphyxia, hypothermia, or a feeding problem. This is consistent with the current causal understanding.

Using the multicausal model, the logistic regression yielded the estimated risks of death (represented by the OR) and PAR for each morbidity (Table 2). Preterm birth emerged at the top, followed by sepsis and IUGR. The sum total of PARs was more than 1. This is inevitable when multiple causes are assigned to each death.[9] However, each PAR represents the proportion of deaths that can be attributed to that cause. Does this imply that we could prevent more than 100% deaths if we prevented all causes — an impossible proposition? It only means that there is more than one way of preventing the same death, and hence, that death is counted in both the categories.

If there is more than one pathway for preventing deaths, then which pathway or morbidity should be selected?

An important insight from this analysis is the quantitative assessment of the contribution of infection to neonatal deaths. The excess neonatal mortality caused by sepsis was estimated to be 17.6/40 or 44% (Tables 4 and 5). There is a remarkable consistency in the results by different methods (Table 5). Preterm births showed the highest PAR. Sepsis ranked second. Sepsis with preterm or IUGR birth formed the causal combinations accounting for a total of 57.5% of deaths.

SIGNIFICANCE

This analysis presents the complex web of causes of deaths in rural neonates more faithfully than do single-cause estimates. In line with current thinking about causality, it looks at neonatal morbidities in combinations and brings out the fact that, among the neonates in rural settings, neonatal deaths occur most often when sepsis, asphyxia, hypothermia, or feeding problems occur in combination with LBW (preterm or IUGR). This is what physicians have always known and, hence, in caring for neonates — whether LBW/preterm or normal — the emphasis has been on ensuring air, warmth, milk, and prevention or treatment of infections.[22,23] If these morbidities are prevented or treated, an LBW or preterm baby has better chances of survival.

This analysis provides evidence leading to a hypothesis that despite continued high rates of preterm or IUGR, a large proportion of these neonates can be saved. It also provides a quantitative estimate that nearly half of the neonatal mortality in rural settings can be reduced by addressing infections. This provides a hypothesis for testing in intervention trials, as well as a strategy for preventing neonatal deaths. The order of priority for efforts to prevent neonatal deaths should be sepsis, asphyxia, hypothermia, and feeding problems. A comprehensive approach addressing all four problems should achieve maximum results.

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Original Article

How to Identify Neonates at Risk of Death in Rural India: Clinical Criteria for the Risk Approach

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OBJECTIVE:

Majority of neonates in developing countries are born at home and most neonatal deaths occur without receiving medical care. This retrospective analysis was undertaken to develop simple clinical criteria for use in rural community to identify neonates at risk of death.

STUDY DESIGN:

By analyzing the observational data on two cohorts of neonates in 39 villages in different years of the Gadchiroli field trial, we selected a minimum set of clinical features. We evaluated this set for its sensitivity, specificity and predictive value to detect eventual neonatal death, the primary study outcome.

RESULTS:

The cohorts included 763 neonates with 40 deaths in 1995 to 1996, a year with minimum interventions, and 1598 neonates with 38 deaths in 1996 to 1998, the years of intensive interventions. On the day of birth, presence of any one of the three: (1) birth weight <2000 g, (2) preterm birth or (3) baby not taking feeds; or, during the rest of neonatal life, mother's report of reduced or stopped sucking by baby, were identified as the predictors of neonatal deaths. The combined set gave a sensitivity of 95%, specificity, 77.3%; predictive value, 18.8%; and the yield, 26.5% in 1995 to 1996 and, respectively, 86.8, 78, 8.8, and 23.5% in 1996 to 1998. The mean lead time gained was 3.4 to 6.6 days.

CONCLUSION:

Presence of any one of the four predictors will identify with high sensitivity and moderate specificity nearly a quarter of the neonates in rural community as high risk, 3.4 to 6.6 days in advance, for intensive attention at home or referral.

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INTRODUCTION

The State of the World's Newborn report acknowledges that 98% of the estimated four million neonatal deaths globally occur in developing countries, most of them at home.[1] In India, nearly two-thirds of babies are born at home,[2] and few are taken for medical care, even if sick.[3–5] Thus, a crucial question in providing care and reducing neonatal mortality is, how can the home-cared neonates at higher risk of death be identified early?

By screening a population to identify those at higher risk of disease or death, one can select a smaller number for intensive attention, early treatment or referral. Screening tests are usually evaluated for their performance against some recognized standard. The measures of performance are *sensitivity* (ability of the test to correctly identify true positive individuals) and *specificity* (ability to correctly identify those who do not have the disease or risk of death, i.e. true negative individuals). The amount of time the diagnosis is early is called the *lead time*.[6]

Higher sensitivity is desirable, especially when the outcome being screened for is death. However, it is specificity that determines the total number of false positives.[6] Even a small loss of specificity can result in a large increase in the total number identified as positives, *the yield*, which includes true positives and false positives. The lower the specificity, the higher the yield (and false positives), making it more difficult and costly to find the true positives and to provide focused attention or care or referral. This attribute, the proportion of the yield that is truly positive is expressed by the *positive predictive value*.

There is a need to develop validated criteria to screen neonates at home and identify those at the risk of death. Integrated Management of Childhood Illnesses (IMCI) program of the WHO and UNICEF suggests a set of clinical danger signs for the referral of sick young infants.[7] But these have never been evaluated in community and validated. Low birth weight (LBW) or its surrogates identify high-risk neonates but may identify too many, nearly one-third, neonates in community in South Asia,[1] or may fail to identify some neonates dying of other causes such as infection or asphyxia.

The objective of this study is to develop simple clinical criteria for use in home-cared neonates for early identification of risk of death.

METHODS

To develop the criteria for identifying neonates at risk of death, we used the data collected in the field trial of home-based neonatal

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care in rural Gadchiroli[5,8,9] on a cohort of 763 neonates in 39 villages for the year April 1995 to March 1996, among whom 40 neonatal deaths occurred. Rothman and Greenland recommend that a screening test developed on one population usually performs less satisfactorily when applied to another. Hence, to assess the performance of a test, it should also be tested on another population besides the one on which it was originally used.[6] Accordingly, the screening criteria developed on this cohort were then further evaluated on the another cohort of neonates in the same 39 villages in the subsequent years April 1996 to March 1998, a period of active interventions in the field trial. We evaluated the criteria against neonatal deaths during days 0 to 28.

In the first year of the field trial, 39 trained female village health workers (VHWs) in 39 villages examined the neonates born in their villages. They did this on the day of birth within 6 hours and, subsequently, by making seven more home visits on days 2, 3, 5, 7, 15, 21, and 28. On the first day, they measured the birth weight using Salter weighing scales. They estimated the period of gestation from the history of the last menstrual period, usually recorded by them during the fourth month of pregnancy. In each home visit, they recorded the data on various maternal and neonatal symptoms and signs and these data were checked by a physician who visited each neonate in the field once in 15 days. A parallel recording of data on neonatal variables in a sample of 119 neonates revealed 92% agreement between the data recorded by the VHWs and the physician.[5,9,10] The neonatal births and deaths were recorded by the VHWs, as well as by an independent vital statistics surveillance system. We have earlier described the methods of clinical data collection, definitions, frequencies and percent fatality in various morbidities, and the surveillance of vital statistics.[5,8,9]

To identify the neonates at risk of death, we first searched for a set of clinical predictors present on the day of birth. Using univariate analysis, we evaluated 25 clinical variables on which data were collected in 1995 to 1996. Those with significant or near-significant association with neonatal death were further analyzed by logistic regression. Although all three birth weight categories showed significant association, we selected only one, <2000 g, for entering in the logistic regression model because it had the highest relative risk, and because other category, <2500 g, would have included a very large proportion (42%) of neonates. In the gestational age categories, <37 weeks was entered, which included other two categories of preterm birth. Thus, total 14 variables were entered in the regression model.

[Strong correlations between independent variables in a logistic regression model may sometimes cause multicollinearity, which may even result in incorrect conclusions (Kleinbaum DG. *Logistic Regression*. New York: Springer-Verlag; 1994). We assessed for the presence of multicollinearity among the selected 14 variables, using SAS Macro. A condition index (CI) of ≥ 20 indicates presence of collinearity in the model, and variance decomposition proportion (VDP) of ≥ 0.5 identifies the specific variables involved in collinearity (1. Kleinbaum DG. *Epidemiologic Modeling. Course Material for the Course Epi 740*. Rollins School of Public Health, Emory University, Atlanta; 2. David Garson. *Quantitative Research in Public Administration. Course Material for the Course PA 765*. North Carolina State University, Raleigh, North Carolina). We found multicollinearity between ''chest indrawing'' and ''grunt'' (highest CI 27.60 and highest VDP 0.97). After removing the chest-indrawing variable from the model, there was no multicollinearity among the remaining 13 variables. (Highest CI 6.5 and VDP as 0.22.)]

By backward elimination from the 13 remaining noncollinear variables in the regression model, we identified a smaller set, in which each clinical variable had a significant association with death. The presence of any one clinical feature in the set was evaluated[6] for its ability to predict neonatal death by estimating sensitivity, specificity, positive predictive value and yield. We then attempted to improve the predictors by eliminating one clinical variable at a time and estimating the resultant performance of the remaining predictors as well as the resultant yield. We selected a set of three clinical variables. We then evaluated this set against the other cohort of neonates from the same 39 villages on which data were collected during the intervention phase (1996 to 1998) of the trial.

To further improve the sensitivity of the criteria present on the day of birth, we explored the danger signs that mothers could identify/report on the remaining days of the neonatal period (days 2 to 28). We evaluated 13 maternally reported symptoms for their ability to identify additional neonatal deaths that the clinical features on the first day had missed. We evaluated the three symptoms that identified maximum additional deaths during the entire neonatal period. The best performing symptom among these was added to the three earlier identified high-risk criteria present on the day of birth. The performance of this combined set of four criteria was evaluated first on the cohort of 1995 to 1996, and then in the intervention years (1996 to 1998). We assessed the lead time, that is, days prior to death that would allow these criteria to identify the neonates as high risk. In those neonatal deaths that were missed (false negative) by this final set of criteria, we also looked into the causes of death[11] and the antemortem clinical features to explore whether we could have identified these deaths by any other clinical predictor.

We used SPSS PC+, version 5 for data analysis. This study is based on the analysis of data collected in another study,[5,8,9] which also reported on the consent and the ethical aspects.

RESULTS

The neonatal cohort in 1995 to 1996 included 763 neonates, of whom 40 died during neonatal period. The frequency of different clinical features present on the day of birth among the neonates who subsequently died and among those who survived; and the association with neonatal death represented by the relative risk are presented in Table 1. The 18 clinical variables showed significant or near-significant association. The nonsignificant variables are listed in the footnote of Table 1.

When the 13 significant clinical variables were put into the logistic regression model and backward elimination applied, five showed significant association. Table 2 shows these five: birth weight <2000 g, preterm birth (<37 weeks completed), skin color pale or yellow, baby not taking feeds and baby's skin temperature <95°F.

Table 3 presents the performance of "presence of any one of this set of five clinical variables" as a screening test, and the effect of eliminating the variable "color of the skin pale or yellow" and "baby's skin temperature <95°F". Removing these two variables caused little loss of sensitivity, but improved specificity, and thereby reduced the yield from 26.5% to 18.5%. Thus, only the remaining three, that is, birth weight <2000 g, preterm birth or baby not taking feeds on the first day, were selected as the clinical predictors of a high-risk neonate. When this set was evaluated on the cohort of 1598 neonates and 38 neonatal deaths during the 1996 to 1998 intervention phase (Table 3), the performance level was less. The resultant sensitivity was 68.4%; specificity, 83.4%; positive predictive value, 9.1% and yield, 17.8%.

Among maternally recognized symptoms, Table 4 shows the performance of the three selected symptoms in neonates during days 1 to 28 that identified the largest number of deaths. The "reduced or stopped sucking" present in 137 neonates of whom 31 died gives the highest sensitivity (77.5%) as well as the longest lead time: 4.9 days. It identifies three deaths missed by the earlier criteria on the day of birth.

Since "not taking feeds" was also one of the three selected clinical criteria on the day of birth, the symptom of reduced/stopped sucking on days 2 to 28, reported by mother, was added to the three criteria on the day of birth. The performance of the combined set is presented in Table 5. The combined set (any one of the three on day of birth or reduced/stopped sucking on days 2 to

Table 1 Association of Selected* Clinical Features Present on the Day of Birth with Eventual Neonatal Death (1995 to 1996, $n = 763$ and Neonatal Deaths = 40)

Clinical features	Present in deaths (40)		Present in survivors (723)		Relative risk	*p*
	No.	%	No.	%		
Weak cry/respiration at 1 minute	16	40.0	100	13.8	3.7	<0.001
Weak cry/respiration at 5 minutes	15	37.5	74	10.2	4.5	<0.001
Birth weight (g)						
<1500	9	22.5	4	0.6	16.8	<0.001
<2000	27	67.5	47	6.5	19.3	<0.001
<2500	36	90.0	284	39.3	12.5	<0.001
Gestation period (weeks)						
<35	15	37.5	9	1.2	18.5	<0.001
<36	19	47.5	32	4.4	12.6	<0.001
<37	25	62.5	50	6.9	15.3	<0.001
Drowsy or unconscious	3	7.5	1	0.1	15.4	<0.001
Cry weak or no cry on 1st day	9	22.5	9	1.2	12.0	<0.001
Breast problems	4	10.0	24	3.3	3.0	<0.08
Baby not taking feeds	9	22.5	30	4.1	5.4	<0.001
Skin color; pale or yellow[a]	8	21.6	6	0.8	14.5	<0.001
Chest indrawing[b]	4	10.8	1	0.1	18.2	<0.001
Grunt[c]	3	8.1	4	0.6	9.4	<0.001
Baby skin temperature <95°F[d]	11	31.4	68	9.9	3.7	<0.001
One limb unable to move[e]	2	5.7	6	0.8	5.7	<0.001
Less tone of limbs	5	12.5	4	0.6	12.0	<0.001

*Other seven signs and symptoms evaluated showed nonsignificant association with death. They are: mother had fever 7 days prior to delivery, prolonged rupture of membrane, prolonged labor, neonatal respiratory rate ≥60, blue color of tongue, stops breathing intermittently, abnormal head size.
Corresponding denominators among dead and survivors respectively; a: 37 and 714, b: 37 and 719, c: 37 and 718, d: 35 and 684, e: 35 and 720.

Table 2 Clinical Features* Present on the Day of Birth, Selected by Logistic Regression for their Significant Association with Neonatal Death

Variable	Beta	Odds ratio	95% CI	*p*
Birth weight <2000 g	2.4151	11.2	4.7–26.6	<0.000
Gestation period <37 weeks	1.9837	7.3	3.1–17.3	<0.000
Color of skin pale or yellow	1.7280	5.6	1.4–22.8	<0.016
Baby not taking feeds	1.5191	4.6	1.5–14.2	<0.009
Baby's skin temperature <95°F	1.2024	3.3	1.2–9.0	<0.019

*The logistic regression model tested included following other variables: weak cry/respiration at 1 minute, weak cry/respiration at 5 minutes, drowsy or unconscious, cry weak or no cry, breast problems, grunt, one limb unable to move, loose strength of limbs. These nine clinical features were rejected after backward elimination.

28) gave, in 1995 to 1996, a sensitivity of 95.0%; specificity, 77.3%; predictive value, 18.8% and yield of 26.5%; in 1996 to 1998 these values were 86.8, 78.0, 8.8 and 23.5%.

The mean lead time gained by different criteria in the preintervention year and the intervention years is presented in Table 6. The mean lead time was 6.6 days in 1995 to 1996 and 3.4 days in 1996 to 1998.

The number of deaths missed by the final set was only two in 1995 to 1996 and five in 1996 to 1998. Review of their antemortem records did not reveal any clinical feature that could have predicted the risk of death. The cause of death assigned by the neonatologist[11] showed that no cause could be assigned in five out of these seven deaths. In the remaining two (both during 1996 to

Table 3 Evaluation of the Sets of Clinical Criteria on the Day of Birth to Predict Neonatal Death

Set of Clinical criteria (presence of any one or more on the day of birth)	True positive	False negative	False positive	True negative	% Sensitivity	% Specificity	% PPV*	% NPV†	% Yield
In 1995 to 1996									
A. Selected by logistic regression: Birth weight <2000 g; Gestation period <37 weeks; Color of skin pale or yellow; Baby not taking feeds; Baby's temperature <95°F	37	3	165	558	92.5	77.2	18.3	99.5	26.5
B. After removing "color of skin" from A	37	3	165	558	92.5	77.2	18.3	99.5	26.5
C. After removing "baby's temperature <95°F" from B	35	5	106	617	87.5	85.3	24.8	99.2	18.5
Performance of the selected set in 1996 to 1998									
Birth weight <2000 g; Gestation period <37 weeks; Baby not taking feeds	26	12	259	1301	68.4	83.4	9.1	99.1	17.8

*Positive predictive value.
†Negative predictive value.

Table 4 Performance of Maternally Reported Symptoms during 1 to 28 Days as Predictors of Neonatal Death

	Neonates	Deaths	Additional deaths*	% Sensitivity	% Specificity	% PPV†	% Yield	Mean day of diagnosis	Mean day of death	Lead time available
In 1995 to 1996 (n = 763, deaths = 40)										
Cry weak/different	90	23	3	57.5	90.7	25.6	11.8	4.1	8.1	4.0
Sucking reduced or stopped	137	31	3	77.5	85.3	22.6	18.0	4.3	9.2	4.9
Drowsy or unconscious	46	23	2	57.5	96.8	50.0	6.0	5.1	9.0	3.9
In 1996 to 1998 (n = 1598, deaths = 38)										
Cry weak/different	150	21	4	55.3	91.7	14.0	9.4	2.8	5.8	3.0
Sucking reduced or stopped	207	31	7	81.6	88.7	15.0	13.0	2.5	4.9	2.4
Drowsy or unconscious	72	16	4	42.1	96.4	22.2	4.5	4.3	6.8	2.5

*Over and above those identified by the three criteria on the day of birth (Table 3).
†Positive predictive value.

Table 5 Final Set of Clinical Criteria to Predict Neonatal Death

Clinical criteria (presence of any one or more)	True positive	False negative	False positive	True negative	% Sensitivity	% Specificity	% PPV*	% NPV†	% Yield
Presence of any one on the day of birth	In the preintervention year (1995 to 1996, $n = 763$, neonatal deaths = 40)								
Birth weight <2000 g	38	2	164	559	95.0	77.3	18.8	99.6	26.5
Gestation period <37 weeks	In the intervention period (1996 to 1998, $n = 1598$, neonatal deaths = 38)								
Baby not taking feeds	33	5	343	1217	86.8	78.0	8.8	99.6	23.5
Or, mother reports that sucking reduced/stopped during 2 to 28 days									

*Positive predictive value.
†Negative predictive value.

Table 6 Lead Time with High-Risk Criteria Selected

Period of observation	No. of deaths identified	Mean day of diagnosis	Mean day of death	Lead time available (days)
1995 to 1996 (n = 763, deaths = 40)				
Any one of the three high-risk criteria on first day	35	1.0	7.9	6.9
Any one of the three high-risk criteria on first day or sucking reduced or stopped 2 to 28 days	38	1.5	8.1	6.6
1996 to 1998 (n = 1598, deaths = 38)				
Any one of the three high-risk criteria on first day	26	1.0	4.6	3.6
Any one of the three high-risk criteria on first day or sucking reduced or stopped 2 to 28 days	33	2.1	5.5	3.4

1998), cause could not be assigned from the data recorded by the VHWs, but sepsis was assigned as the most probable cause, based on the additional information retrospectively collected by the supervisor.

DISCUSSION

This inquiry into clinical predictors that can identify neonates in community at risk of death used prospectively observed data on the cohorts of neonates in 39 villages during 1 year of minimum interventions and 2 years of full interventions. It yields two clinical sets as the possible predictors of high-risk neonates, which can be used in different settings:

(1) Where a visit by health workers to neonates on the day of birth is possible, these three criteria on the first day of life: birth weight <2000 g, preterm birth (<37 weeks) or baby not taking feeds; and mother's report that baby's feeding has decreased or stopped at any time during days 2 to 28 together make a good combination. Presence of any one of these four criteria predicted eventual neonatal death with high sensitivity (87 to 95%) and moderately high specificity (77 to 78%), identifying nearly a quarter of neonates in community as high-risk neonates, 3.4 to 6.6 days ahead of death.

(2) Where a visit or evaluation on the day of birth is not possible, the mother's report about feeding alone on days 1 to 28 can be used as the danger signal. This will give 77% sensitivity and 85% specificity and will identify 18% of neonates as high-risk, an average 4.9 days ahead of death. However, such maternal reports were elicited in this field trial only when a health worker made eight home visits to inquire about symptoms. In the absence of home visits, the frequency of maternal reporting and hence sensitivity may decline steeply.

There are a few limitations of this study. In the first year of observation, 75% of neonates born in the 39 study villages were observed, while 268 neonates and 12 neonatal deaths were not observed.[5] The two groups may not be completely similar. However, the stillbirth and the neonatal mortality rates in the observed and unobserved births were similar. Moreover, in the subsequent years the proportion of neonates not observed decreased. Thus, in 1997 to

1998, only seven percent of neonates were not observed.[8] Since the predictors were evaluated on these data from later years as well, the effect of selection bias in the observed group, if any, is expected to be small.

The quality of data collection was highly satisfactory, showing 92% agreement with the data collected by a physician on a subsample.[5,8,10] The birth and child death recording by the vital statistics surveillance system was high, at 98%.[8]

The decreased sensitivity of the clinical predictors in the intervention years, as compared to the minimum intervention year as seen in Table 3, is probably due to the fact that, during the intervention phase many neonates with clinical features were treated, and deaths averted. Hence, the neonatal mortality rate decreased from 52 in 1995 to 1996 to 25 in 1997 to 1998.[8] This probably resulted in selectively difficult-to-detect high-risk neonates in the cohort in 1996 to 1998. That may also explain why the mean lead time declined from 6.6 to 3.4 days.

LBW (<2500 g) is often used to mark high-risk neonates. It is true that the LBW neonates are at a higher risk of death and between 40 and 80% deaths globally occur in LBW neonates.[1] Used alone, it may identify between 40 and 80% neonates at the risk of death, that is, it has only a moderate sensitivity. Moreover, in South Asia, where nearly a third of the babies are born LBW,[1] it is somewhat less specific. In this cohort, 42% neonates were born LBW,[5,10] hence the yield would be 42%. In comparison, our criteria are more specific, since they identify approximately 25% of the neonates in community as high risk. They are more sensitive as well, giving a sensitivity of 85 to 95%.

Many investigators have evaluated different surrogates to birth weight. But these all were evaluated in neonates in hospitals.[12–14] No other clinical predictors of high risk in neonates have been evaluated on a cohort of neonates in community in developing country setting. Hence it is not possible to compare the performance of our criteria with others.

These criteria were developed in a field trial in rural Gadchiroli. Their generalizability in other areas and other developing countries needs to be tested. Their performance is conditional on using similar field methods. The prerequisites are:

1. Recording last date of menstrual period in pregnant women to assess the period of gestation at birth.
2. Presence of a trained health worker to measure birth weight on the day of birth or within a short time.
3. Repeated home visits to inquire about symptoms (''reduced or stopped taking feeds'') in neonates.

In the absence of a routine evaluation on the day of birth, the mother's history of the baby's ''reduced or stopped taking feeds'' may be used as it shows fairly high sensitivity in this study wherein VHWs made frequent home visits to inquire. Depending only on parents' ability to recognize and voluntarily report this symptom to a source of care may be insufficient, as low care-seeking has been observed for neonatal sicknesses.[4,5] Whether health education can improve the voluntary care seeking to high level is not known. Neonates who are born in hospitals are usually discharged within 24 to 48 hours, and most of them do not receive any postnatal visit.[15] In such situation, only the three high-risk predictors on the first day may be used, albeit with lower sensitivity.

SIGNIFICANCE

These high-risk criteria will identify nearly 25% of neonates in rural homes in India in whom 85 to 95% of neonatal deaths are expected to occur. The performance of these criteria will go a long way toward making the high-risk approach practicable.

Neonates are delicate and vulnerable human beings. They need care and attention. However, if the care and attention can be focused on those at higher risk, the returns in terms of lives saved will be much higher. These criteria allow a trained health worker and mother to identify neonates needing more attention. Such high-risk neonates should receive more visits by health workers and early treatment for any identified sickness. Alternatively, they can be referred to a medical facility where more evaluation and/or management can be provided.

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Original Article

Reduced Incidence of Neonatal Morbidities: Effect of Home-Based Neonatal Care in Rural Gadchiroli, India

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OBJECTIVE:

We found a high burden of morbidities in a cohort of neonates observed in rural Gadchiroli, India. We hypothesised that interventions would reduce the incidence of neonatal morbidities, including the seasonal increase observed in many of them. This article reports the effect of home-based neonatal care on neonatal morbidities in the intervention arm of the field trial by comparing the early vs late periods, and the possible explanation for this effect.

METHODS:

During 3 years (1995 to 1998), trained village-health-workers (VHWs) in 39 villages prospectively collected data by making home visits during pregnancy, home-delivery and during neonatal period. We estimated the incidence and burden of neonatal morbidities over the 3 years from these data. In the first year, the VHWs made home visits only to observe. From the second year, they assisted mothers in neonatal care and managed the sick neonates at home. Health education of mothers and family members, individually and in group, was added in the third year. We measured the coverage of interventions over the 3 years and evaluated maternal knowledge and practices on 21 indicators in the third year. The effect on 17 morbidities was estimated by comparing the incidence in the first year with the third year.

RESULTS:

The VHWs observed 763 neonates in the first year, 685 in the second and 913 in the third year. The change in the percent incidence of morbidities was (i) infections, from 61.6 to 27.5 (−55%; $p<0.001$), (ii) care-related morbidities (asphyxia, hypothermia, feeding problems) from 48.2 to 26.3 (−45%; $p<0.001$); (iii) low birth weight from 41.9 to 35.2 (−16%; $p<0.05$); (iv) preterm birth and congenital anomalies remained unchanged. The mean number of morbidities/100 neonates in the 3 years was 228, 170 and 115 (a reduction of 49.6%; $p<0.001$). These reductions accompanied an increasing percent score of interventions during 3 years: 37.9, 58.4 and 81.3, thus showing a dose−response relationship. In the third year, the proportion of correct maternal knowledge was 78.7% and behaviours was 69.7%. The significant seasonal increase earlier observed in the incidence of five morbidities reduced in the third year.

CONCLUSION:

The home-based care and health education reduced the incidence and burden of neonatal morbidities by nearly half. The effect was broad, but was especially pronounced on infections, care-related morbidities and on the seasonal increase in morbidities.
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INTRODUCTION

Diseases during the perinatal period rank as the third leading cause of the global burden of disease.[1] Four million neonates die each year, 98% of them in developing countries.[2] The global burden of neonatal morbidities has been estimated to be: 4 to 7 million cases of birth asphyxia,[3] 20 million low birth weight (LBW) babies[2] and 30 million bacterial infections.[4] However, the lack of community-based data on neonatal morbidities in developing countries makes such an estimation difficult.

We prospectively observed neonates in 39 villages in Gadchiroli, India, during 1 year (1995 to 1996) in order to estimate the burden of neonatal morbidity. A total of 48.2% neonates had high-risk morbidities, which was nearly 10 times the neonatal mortality rate (NMR) of 52 per 1000, and 72% neonates had low-risk morbidities.[5] These morbidities can cause death or long-term consequences in childhood and adulthood, making huge demands on family and on the health-care system. To compound the problem, most neonates in developing countries are born and cared for at home and cannot be taken for medical care even if sick.[6,7] Hence, providing health care to neonates in rural homes is an enormous challenge in developing countries.

Based on the observed variations in the incidence of neonatal morbidities by season and day of life,[5] and the gaps in the traditional beliefs and practices of neonatal care that we observed in the preintervention period, we hypothesised that improved neonatal care would reduce morbidities that showed significant variation by season and by the day of life.[8]

We have reported earlier a field trial of "Home-based Neonatal Care" (HBNC) in rural Gadchiroli (1993 to 1998), in which the neonatal and perinatal mortality rates declined by 62 and 71%, respectively ($p<0.001$).[9] Although it reduced mortality, did HBNC affect the larger problem of neonatal morbidity? To answer this question, we further analysed the data from the Gadchiroli field trial, with the following objectives:

1. To evaluate the effect of HBNC on (a) the incidence of 17 neonatal morbidities; (b) the burden of morbidity, measured as the mean number of morbidities per 100 neonates; and (c) the proportion of morbidity-free neonates.
2. To assess whether the effect can be explained by (a) the percent coverage of mothers and neonates by different interventions in HBNC, and (b) the resultant maternal knowledge and behaviours.
3. To test whether the seasonal variations in the incidence of neonatal morbidities observed in the first year changed as a result of HBNC.

METHODS

Study Design

It would have been ethically wrong and practically difficult to closely observe the neonates in the control area for morbidities without making interventions. Hence, we observed neonatal morbidities only in the 39 intervention villages, without much intervention in the first year and with increasing interventions in the second and the third years. The effect was estimated by comparing the first year with the third year and noting the trend.

We have earlier reported the study area, subjects, methods of observing, the definitions and the incidence of the 'baseline' morbidities during 1995 to 1996, subsequent interventions, and the effect on the mortality rates.[5,8,9] Here we describe only the relevant background and the additional information.

Gadchiroli is the most underdeveloped and remote district in Maharashtra state. The HBNC field trial area consisted of 39 intervention villages (population 38,998) and 47 control villages (population 42,149). A well-established surveillance system collected vital statistics during 1993 to 1998. At baseline the two types of villages had similar socioeconomic characteristics, birth rates, and neonatal and infant mortality rates.[9] In the intervention villages, traditional birth attendants (TBAs), trained by our organisation (SEARCH), provided basic maternal and childcare from 1988 onwards.[10,11] Antenatal care was provided by government nurses (1:3000 population) and at a women's clinic of SEARCH located outside the field area. Emergency care was available at the government district hospital in the adjacent town.

All neonates who spent the whole or a part of the neonatal period in the intervention villages during 1995 to 1998 were eligible for inclusion in the study. These included neonates (i) home-delivered in intervention villages; (ii) born outside but brought into the intervention villages for home-care during days 1 to 28; or (iii) born in the intervention villages but moved out before day 28.

Data Collection

During the preintervention period (1993 to 1995), we did a qualitative study of the traditional beliefs and practices about pregnancy, delivery and neonatal care. In 1995, 39 female village health workers (VHWs) were selected, trained and introduced into the intervention villages. They interviewed the mothers thrice during pregnancy, attended and observed home deliveries (most often conducted by TBAs), and subsequently made eight home visits to observe the neonates up to the 28th day, with little intervention during the first year (1995 to 1996). We estimated the baseline incidence of neonatal morbidities from these data using simplified clinical criteria.[5,8]

To ensure quality, a physician made home visits once every 2 weeks to all neonates and checked the data. Moreover, on-site training and economic incentives/disincentives were used to ensure the completeness and quality of the observations. To evaluate the quality, the physician independently recorded parallel observations on 119 consecutive neonates.

Interventions

Based on this information, we trained the female VHWs in 1996 to advise, demonstrate and help mothers in neonatal care at home, identify neonatal morbidities such as asphyxia, prematurity, birth weight <2000 g, sepsis, hypothermia, breast feeding problems, conjunctivitis, skin infections, umbilical sepsis, fever and treat these illnesses appropriately[9] (Figure 1). Although VHWs advised hospitalisation for every serious illness, families rarely followed this advice. Hospital care was not a part of our intervention package, but when the baby was hospitalised, it was recorded.

Recording of various observations about mother, delivery and neonates by the VHWs, and the supervision by the physician continued during 1996 to 1998 with the same frequency and methods as during the first year.

Health Education

We introduced intensive health education in the third year (1997 to 1998). The messages were based on the observations made about the traditional beliefs and practices and the barriers to better care experienced during 1996 to 1997. The health education was delivered by three methods.

1. TBAs who were earlier trained by SEARCH continued their advice to mothers.
2. Group meetings of pregnant women and grandmothers were organised every 4 months in each village. The supervisor and

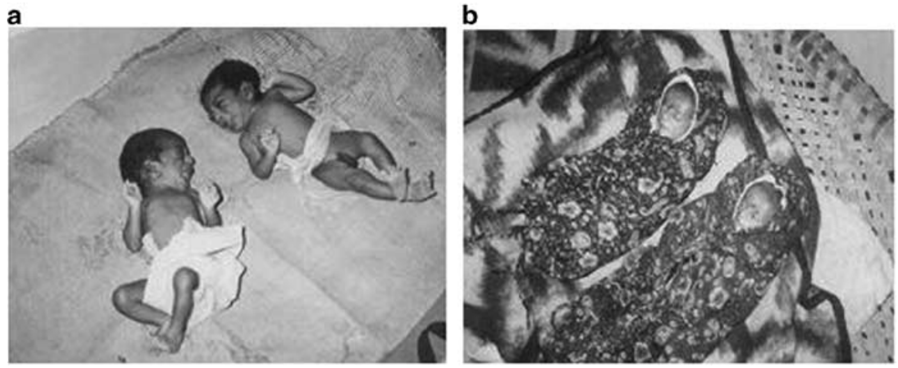


Figure 1. Thermal care in home. (**a**) The traditional practice. (**b**) Keeping the LBW twins warm at home by covering loosely in a warm bag.

the female VHW gave information and demonstrations about nutrition and weight gain during pregnancy, antenatal care, preparation for delivery and the baby, breast feeding, keeping the baby warm, cleanliness, danger signals in the baby and seeking early care from the VHW. Songs, role-plays, games, slide shows, posters, demonstration, case stories and experience sharing were used during these sessions. The retention of information and effect on the beliefs was assessed by way of a questionnaire completed by VHWs by home visits to the mothers 2 weeks after the group meeting.

3. The VHW gave health education to the mother and the family during her home visits using a flip chart. During the eighth and ninth months of pregnancy, she gave 10 messages and a printed pamphlet about mother and baby care. On the first day after delivery she repeated these messages, weighed the baby and demonstrated how to keep the baby clean and warm and how to breastfeed. She also described nine danger signals requiring early care. If, on day 1, the VHW identified the baby as high risk, she gave additional messages and help. During the subsequent home visits, seven by the VHWs and one or two by the supervisory physician, they persuaded the mothers to follow the advice. TBAs, the mainstay of traditional care, also reinforced the messages and practices.

We assessed the interventions on an ongoing basis by the coverage (percent of mothers/neonates covered) and quality. The supervising physician verified this information. The births and child deaths were independently recorded by an ongoing system of SEARCH with the help of the male VHWs and their supervisors. The coverage of the neonates attended by the female VHWs was evaluated against these data. We also assessed the beliefs and behaviours of mothers and the quality of home-based care by introducing an evaluation form in 1997 to 1998, completed by the supervising physician for each baby based on the observations made during home visits. Antenatal care and government health services were not part of the package, so these were not recorded, nor were TBAs interventions measured.

Analysis

For measuring the effect of interventions on the incidence of neonatal morbidities, we compared the incidence in the first vs the third year of interventions. Information about various components in the intervention package and about the effect on behaviour could be analysed for selected indicators in all 3 years. Mothers' knowledge and practices were evaluated only in the third year (1997 to 1998). The data were analysed by SPSS-PC and FOXPRO packages. The significance was tested by the χ^2 test.

Consent, Quality and Ethical Clearance

Written community consent for conducting the study and subsequent interventions was obtained from all intervention villages. An external group of paediatricians and epidemiologists reviewed the technical guidelines, quality of data collection and gave the ethical clearance.[5,8,9]

RESULTS

We have earlier reported the population characteristics and the maternal health indicators in the 39 study villages.[5,9,12] Female literacy was 37.9% and mean maternal height was 149.6 cm. During the baseline years (1993 to 1995), the birth rate was 25.4/1000 population, the NMR was 62.0/1000, the infant mortality rate was 75.5/1000 and the perinatal mortality rate was 68.3/1000 births.

In the first year, out of the total 1016 live births in the study villages, 763 (75.1%) neonates were observed by VHWs and 253 were not observed. The NMRs in the observed neonates (52.4/1000) and in the unobserved neonates (47.5/1000) were similar ($p>0.5$). The proportion of the observed newborns in the subsequent years was 85.2% (685/804) in 1996 to 1997, and 93.3% (913/979) in 1997 to 1998.

The data collected by VHWs and the parallel data collected by physician in 119 neonates showed mean 92.7% agreement (SD 6.7), the range being 70.2 to 100%. The traditional beliefs and practices reported elsewhere[12] are summarised in Panel 1.

Panel 1 Traditional Beliefs and Practices.

(i)	Women underfed themselves during pregnancy to ensure a small baby for easy delivery.
(ii)	The babies were often not breast-fed on the first three days and were given sweetened water.
(iii)	The babies were not covered properly immediately after birth; baby-clothes were not used until a ceremony (*baj kadhane*) performed on the seventh day.
(iv)	Mothers could not leave the delivery room until *baj kadhane*. To minimize the toilet needs during this period, they severely restricted their intake of fluids and food.
(v)	Mothers did not wash hands properly, their clothes and linens were often dirty, and the delivery rooms were poorly ventilated.
(vi)	Newborns were usually not named until they had lived one month because of the uncertainty about their survival.
(vii)	The usual explanations for the sicknesses in neonates were " the evil eye," "witchcraft" or the mother's body humours or indiscretions in eating.
(viii)	Newborn babies, even if sick, were not moved out of the home.
(ix)	Families believed that nurses or doctors could not effectively treat the sick newborn or change the course of the events.
(x)	Neonatal death was stoically accepted.

The incidence of various neonatal morbidities in the 3 years is presented in Table 1. Most infections and the care-related morbidities showed progressive reduction. Except for the LBW, morbidities related to maternal factors did not decline significantly. The proportion of neonates with any morbidity also declined.

The mean birth weight was 2471 g (SD 427) in 1995 to 1996; and 2539 g (SD 420) in 1997 to 1998 ($p<0.001$) with a mean net increase of 68 g.

The effect on the burden of morbidities, estimated as the mean number of morbidities per 100 neonates, is presented at the end of Table 1. In Figure 2a, we present the change in the burden in three categories. Infections declined by 66.6% (from 98.7 morbidities to 33 morbidities per 100 neonates; $p<0.001$), care-related morbidities by 53.6% (from 72.0 to 33.4; $p<0.001$) and maternal-factor-related morbidities by 13% (from 53.1 to 46.2, $p<0.05$).

Figure 2b presents the effect on the incidence of neonatal morbidities categorised into high-risk (case fatality >10%) and the low-risk (case fatality <10%).[5] The main high-risk morbidities were preterm, birthweight <2000 g, sepsis, pneumonia, hypothermia, breast-feeding problems and severe asphyxia. The proportion of morbidity-free neonates increased from 12.8 to 36.3% (+184%, $p<0.001$).

The effect on the primary outcome measure of the HBNC field trial, the NMR, is presented in Figure 2c.

The phased manner of introducing interventions and their coverage during different years is presented in Table 2. The coverage of some pre-existing interventions and of most new interventions progressively increased, with the highest levels reached in 1997 to 1998. The mean percent score of interventions on 12 indicators (Table 2, bottom) rose from 37.9 in year 1, to 58.4 in year 2 and to 81.1 in year 3. ($p<0.001$).

The effect of HBNC on breastfeeding is presented in Figure 3. Significant increase occurred in the proportion of newborns breastfed early and exclusively and in the number of feeds per day.

The mean weight gained during days 0 to 28 increased by only 9 g (not significant), but the proportion of neonates with inadequate weight gain (<300 g) during days 0 to 28 declined from 17.9 to 12.4% ($p<0.05$).

The knowledge and behaviour of mothers, assessed in 1997 to 1998 on 21 indicators (Table 3) shows high levels reached for all but two indicators. We did not measure the baseline levels, except for the qualitative data on the beliefs and behaviours (Panel 1).

The seasonal variation observed in the first vs the third year of interventions is presented in Table 4. It shows that the significant seasonal variation present in 1995 to 1996 in the incidence of many morbidities was no longer significant in 1997 to 1998; however, fever in summer, though at reduced incidence, continued to be significant.

The VHWs missed collecting some information. For example, VHWs were not present at the time of some deliveries though they observed these neonates on subsequent days. To ascertain the selection bias, we compared the stillbirth rate in two groups in the observed neonates in 1995 to 1996. It was 24/1000 (14/584) in the deliveries attended by VHWs, and 25/1000 (5/198) in the unattended deliveries ($p>0.5$).

The proportion of hospital deliveries or hospitalisation of sick neonates in the intervention villages (Table 2) remained practically the same during the period of measurement, as did the NMR in the control area (Figure 2c).

DISCUSSION

In this field trial of HBNC, the incidence of a broad range of neonatal morbidities declined in the intervention villages. The burden of morbidities per 100 neonates declined by 49.6%, from 227.9 to 114.8% ($p<0.001$) and the proportion of morbidity-free neonates increased by 184%, from 12.8 to 36.3% ($p<0.001$). The effect on morbidities shows a dose–response relationship with the multiple interventions in HBNC, their increasing coverage and the resultant high levels of knowledge and correct practices in mothers. Hence the observed reduction in morbidities can be attributed to the interventions. The hypothesis that the incidence of morbidities and the seasonal variation will decrease with HBNC was proved.

Table 1 Incidence of Neonatal Morbidities During Different Years of Intervention Phase in Gadchiroli (1995–1998)

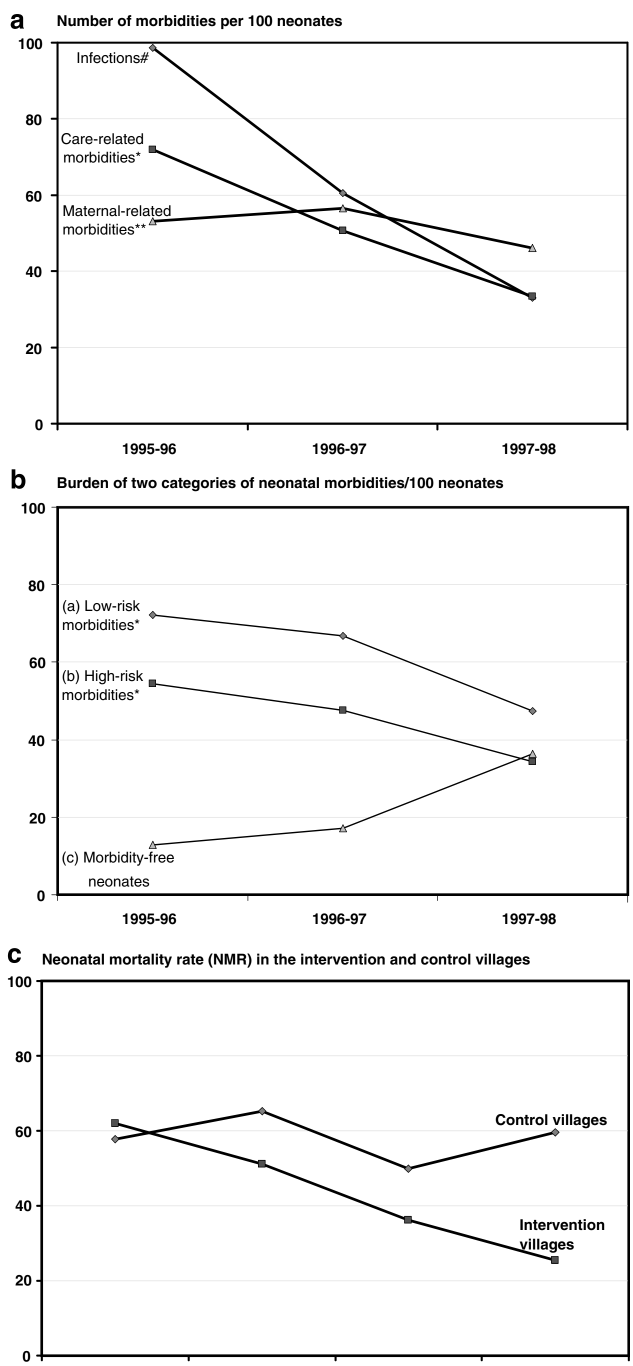
Morbidity*	Incidence (%)				p (for trend)
	1995–1996 ($n=763$)	1996–1997 ($n=685$)	1997–1998 ($n=913$)	% reduction from 1995–1996 to 1997–1998	
(A) *Infections*					
(1) Umbilical sepsis	19.8	6.6	2.0	−89.9	<0.001
(2) Skin infection	11.5	7.0	2.7	−76.5	<0.001
(3) Conjuctivitis	12.3	4.2	1.2	−90.2	<0.001
(4) Neonatal sepsis	17.0	9.6	8.2	−51.8	<0.001
(5) Pneumonia only	1.0	1.0	1.0	0.0	NS
(6) Unexplained fever	11.4	10.8	5.0	−56.1	<0.001
(7) Diarrhoea	5.5	3.5	2.1	−61.8	<0.001
(8) Upper respiratory infection	20.1	18.1	11.2	−44.3	<0.001
Any of the above infections	61.6	46.1	27.5	−55.3	<0.001
(B) *Care-related morbidities*					
(9) Mild asphyxia	14.2[a]	9.1[b]	7.9[c]	−44.4	<0.001
(10) Severe asphyxia	4.6[a]	2.4[b]	2.5[c]	−45.7	NS
(11) Breast feeding problems (Total)	22.8	16.8	10.0	−56.1	<0.001
Delayed breast feeding (cultural)	9.3	1.0	0.0	−100.0	<0.001
Breast feeding problems	16.3	16.4	10.0	−38.7	<0.001
(12) Hypothermia (total)	17.0	8.6	3.6	−75.8	<0.001
Hypothermia ≤92°F	4.2	1.0	0.5	−88.1	<0.001
Hypothermia 92.1–94.9°F	12.8	7.6	3.1	−75.8	<0.001
(13) Weight gain in 0–28 days <300 g	17.9[d]	19.0[e]	12.4[f]	−30.3	<0.05
Any of the care-related morbidities	48.2	38.1	26.3	−45.4	<0.001
(C) *Morbidities due to maternal factors*					
(14) Pre-term	9.8	11.2	10.2	+4.1	NS
(15) Low birth weight (total)	41.9	44.2	35.2	−16.0	<0.05
Weight <2000 g	9.7	8.7	6.9	−28.9	<0.04
Weight 2000–2499 g	32.2	35.5	28.3	−12.1	NS
(16) Congenital anomalies	1.3	1.0	0.9	−30.8	NS
Any morbidity due to maternal factors	44.0	49.8	39.8	−9.5	NS
(D) *Other problems*	3.7	2.3	2.1	−43.2	NS
Total incidence of any of the above 17 morbidities	87.2	82.8	63.7	−26.9	<0.001
Mean number of morbidities per 100 neonates	227.9	170.1	114.8	−49.6	<0.001

*Clinical definitions of morbidities — Bang AT et al., 2005;25:S18–28.[8]
Observations were recorded in neonates: a = 570, b = 508, c = 772, d = 654, e = 573, f = 814.
NS = nonsignificant.

Is the Observed Effect on Morbidities True?

A limitation of the study is the absence of a control group for ethical reasons. Hence, we have compared early vs late intervention years. However, the field trial included monitoring of mortality in a control area, and there, the NMR remained at around 60 during these years except a transient and insignificant reduction in 1996 to 1997 (Figure 2c). Similarly, the IMR and the NMR in India remained practically unchanged during these years.[13] Hence, it can be assumed that the neonatal morbidities in the control area did not change substantially during this period and that, therefore, the observed change in the intervention villages was not due to a background change.

By comparing the first year (1995 to 1996) with the third year (1997 to 1998) of intervention, we may, in fact, have underestimated the effect. The activities of the female VHWs in 1995 to 1996 (Table 2) may have caused a change in the behaviour of mothers and TBAs, and hence in neonatal health. Evidence of this is seen in Figure 2c, wherein the NMR in the intervention villages declined from the baseline (1993 to 1995) level of 62.0, to 51.2 in the first year (1995 to 1996).[9] Hence, by comparing the first and third years, the effect was underestimated.



Was There a Selection Bias?

Some neonates were not observed by VHWs. The comparison of NMR in the neonates observed vs unobserved (52.4 vs 47.5) ($p > 0.5$) or of stillbirth rate in the deliveries attended vs unattended (24 vs 25) do not suggest such selection bias.

Was the Observed Effect Due to Imprecise Measurement?

Diagnoses of neonatal morbidities were based on clear definitions, applied objectively to the data. Validity of the methods has been discussed elsewhere.[5] Since the definitions were entirely clinical, an imprecision in the diagnosis is very likely. However, since these definitions remained uniform during 1995 to 1998, the observed effect cannot be attributed to them. In addition, the quality of data collected by VHWs was validated by the 92% agreement with the parallel data collected by the physician.

Can the Observed Effect be Attributed to the Interventions?

The effect on the incidence of morbidities was broad, occurred on multiple morbidities and increased progressively (Table 1 and Figure 2a). The number of interventions, their coverage and effect show similar features (Tables 2 and 3). Three aspects in particular are relevant: (i) the progressive increase in the elements of interventions as well as their percent coverage, (ii) intensive health education, with good coverage (66 to 76%), (iii) the resultant high scores of correct knowledge and behaviour of mothers (Table 3). These dose–response relationships between the interventions and the reduced morbidities suggest a cause and effect relationship.

Seasonal variation observed in some morbidities disappeared or decreased (Table 4), proving our hypothesis that the seasonal variation was suggestive of lack of adequate protection from the effects of environment, and that the HBNC shall decrease this variation.[8]

However, the magnitude of the effect on morbidities varied. A pronounced reduction occurred in almost all infections (Table 1), suggesting an improved immunity or decreased exposure to

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Figure 2. Effect of HBNC on neonatal morbidities and mortality. (**a**) Burden of three categories of neonatal morbidities/100 neonates. #Eight types of infections (see Table 1) *Includes hypothermia, breast feeding problems and asphyxia. **Includes pre-term, low birth weight, congenital anomalies. (**b**) Incidence of high-risk and low-risk morbidities, and the morbidity free neonates. Bang AT et al., 2005; 25:S18–28.[8] (a) Low-risk morbidities (morbidities with natural case fatality <10%*) (b) High-risk morbidities (morbidities with natural case fatality >10%*) (c) Proportion of morbidity-free neonates. (**c**) Neonatal mortality rate (NMR) in the intervention and the control villages.

Table 2 Elements of Interventions and Percent Coverage of the Target Population (Mothers or Neonates): 1995–1998

	1993–1995 Preintervention	1995–1996 ($n=763$)	1996–1997 ($n=685$)	1997–1998 (n = 913)	p (for trend)
Phased Interventions					
(A) Pre-existing interventions (Home delivery conducted by trained TBA, ANC care)	+	+	+	+	
(B) Home visits by VHW during pregnancy, delivery and neonatal period	–	+	+	+	
(C) Home-based care of neonates assisted by VHWs and sickness management	–	–	+	+	
(D) Intensive health education	–	–	–	+	
Selected indicators of the interventions					
(A) 1. Tetanus toxoid received during pregnancy	NR	79.3	95.8	95.4	<0.001
2. Percent deliveries at home, conducted by trained TBA	NR	81.3	94.2	94.6	<0.001
3. Hospital delivery*	NR	5.4	3.5	4.2	NS
4. Caesarian section delivery*	NR	0.5	0.4	1.1	NS
(B) 5. Home visits and observations by VHW	0.0	75.1	85.2	93.3	<0.001
6. VHW present at the time of delivery	0.0	74.7	69.9	81.5	<0.001
7. Ointment put in eyes	NR	16.8	30.7	41.3	<0.001
8. Cord blood milked before cutting the cord	NR	78.8	95.0	94.4	<0.001
(C) 9. Exclusive breast feeding started within 6 hours	NR	47.5	81.9	89.7	<0.001
10. Preterm or LBW babies received added care at home	0.0	0.0	NR	88.1	–
11. Management of neonatal sepsis out of the incident cases	0.0	0.0	27.3 (18/66)	70.7 (53/75)	<0.004
12. Blanket/warm-bag used to keep the at-risk (preterm/LBW<2000 g/hypothermic) baby warm	NR	1.9 (4/211)	62.7 (94/150)	83.9 (125/149)	<0.001
13. Sick neonate hospitalised*	NR	0.4	0.6	0.5	NS
(D) 14. Health education at home	0.0	0.0	0.0	76.2	–
15. Group health education attended	0.0	0.0	0.0	66.6	–
Mean coverage on the 12 indicators of home-based care (excluding 3, 4 and 13)*	–	37.9	58.4	81.3	<0.001

+, Component operational.
–, Component not operational.
NR, Not recorded; NS, nonsignificant.
*Not a part of the home-based neonatal care.

infections or both. Improved immunity can occur due to increased breastfeeding (Figure 3), especially in the first week when the colostrum is rich in immunoglobulins. A meta-analysis of studies on the protective effect of breastfeeding on infections in children has reported an odds ratio of 5.8 in breastfed infants <2 months of age.[14] In addition, high levels of maternal knowledge and practices about cleanliness and antenatal care seeking for infections (Table 3) can result in reduced exposure of neonates to infections acquired from mother or the environment.

Care-related morbidities of all types declined substantially (Table 1 and Figure 2a). Asphyxia was reduced (by approximately 45%) by the early resuscitation measures of VHWs who were present at birth. Earlier, the TBAs were primarily anxious about the mother and were unable to pay adequate attention to the baby. This experience suggests the need for an additional attendant at the time of birth, besides the TBA.[15]

The incidence of hypothermia showed a more pronounced reduction, 78.8% (Table 1), which can be attributed to the better thermal protection practices, the special care of the preterm/LBW babies (Table 2 and Figure 1) and the early and more frequent breastfeeding (Figure 3). Reduction in hypothermia can contribute to improved neonatal survival and reduced susceptibility to infections.

The incidence of LBW showed a small (16.0%) but significant reduction, especially in birth weight <2000 g. This can contribute to improved survival because the neonatal mortality in 1995 to 1996 was concentrated (27/40 deaths) in the LBW babies of <2000 g.[5,9]

Increased birth weight (by mean 68 g) was an unexpected finding because the HBNC did not include any major intervention to improve birth weight. The traditional practice of restricting food intake during pregnancy (Panel 1) is common in many developing

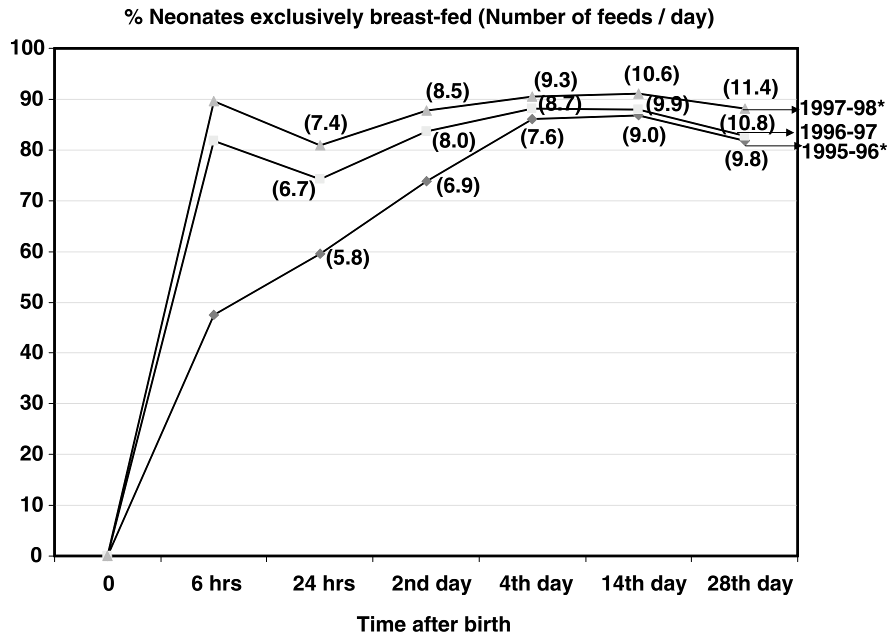

Figure 3. Effect of HBNC on breastfeeding. Proportion of the neonates exclusively breast-fed and (in parantheses) the mean number of feeds/day. *All the differences between 1995 to 1996 and 1997 to 1998 in the proportion exclusively breastfed, $p<0.001$, except on 4th and 14th day $p\leq 0.05$. *All the difference in the number of feeds per day $p<0.001$.

countries.[16] The intensive health education probably changed this practice (Table 3) to some extent and improved birth weight. Since we did not measure dietary intake and there was no control group, the hypothesis cannot be conclusively proved or disproved. However, this finding suggests a modestly effective intervention, cheaper than food supplementation during pregnancy[17] and more relevant in the region of South Asia characterised by cultural restrictions on maternal food intake[16] and a high, 31%, incidence of LBW.[2]

The effect on breastfeeding reveals four striking changes. (i) Early and exclusive breastfeeding increased steeply, with nearly 90% of neonates put to breast within 6 hours of birth in 1997 to 1998 (Figure 3). (ii) The frequency of breastfeeding increased significantly. (iii) The incidence of breast-feeding problems decreased substantially (Table 1). and (iv) The mean weight gain during the neonatal period increased by a small amount (9 g) while the proportion of neonates with weight gain <300 g during neonatal period declined significantly. These changes can improve neonatal health, especially by improving immunity, reducing hypoglycaemia and hypothermia, and increasing weight gain. Evidence of such an effect in the form of reduced incidence of infections and hypothermia was seen in the third year (Table 1).

The increase in breastfeeding most probably occurred due to the effective health education and practicing supervised breastfeeding in the presence of VHW. Active support by the TBA was crucial for this change to occur. Evidence of these changes was seen in the knowledge and behaviour of mothers (Tables 3 and 4).

Table 2 provides data on some interventions that show increased coverage from 1995 to 1998. These might explain some of the observed effect on morbidities. Coverage of some interventions was not recorded, especially those provided by TBAs. Antenatal care at a referral clinic can improve pregnancy outcomes, but information on the coverage of this was not recorded. However, these interventions have been present since 1989 and are unlikely to have made a difference in neonatal morbidities in 1997 to 1998.

In comparison to the traditional beliefs and practices recorded qualitatively at the baseline (Panel 1), a different picture was found in 1997 to 1998 (Table 3): a mean of 78.7% of mothers gave correct answers to the 10 questions asked 2 weeks after the health education in group, indicating a high rate of retention. The proportion of correct practices — either self reported or observed — was high, which can explain some of the decrease in morbidities. Care seeking for sick neonates (87.2%), and correct care of preterm, LBW babies (88.1%) should result in better survival. Health education did not seem to influence the practices of hand washing before feeding and consuming iron–calcium tablets, which remained at low levels.

One would expect that improved maternal knowledge and practices, increased coverage of HBNC interventions and reduction (though modest) in the incidence of LBW suggesting improved dietary intake by mothers — these should cause improvement in maternal health as well. In fact, we did observe a significant reduction in the incidence of maternal morbidities in these mothers, to be reported separately.

Table 3 Evaluation of Mothers' Knowledge and Behaviour in the Last Year of Intervention (1997–98)
(% Mothers with Correct Response, $n = 726$)

Knowledge	(%)
1. Mother should eat adequately	84.4
2. Preparedness for delivery	78.7
3. Hand washing is necessary	84.4
4. Delivery room should be clean	85.0
5. Which neonates are high risk	67.6
6. Danger signals in baby when the VHW should be called	77.3
7. How to keep baby warm	78.0
8. Preterm, LBW babies not to be bathed daily	74.5
9. What is the illness if baby breathes fast or has chest indrawing	80.2
10. What should be done to ensure weight gain in baby	77.3
Total (mean)	78.7
Behaviour	(%)
1. Mother eating full meals during pregnancy*	93.9
2. Mother sought medical/ANC care during pregnancy*	39.1
3. Mother consumed iron/calcium tablets during last trimester of pregnancy*	11.8
4. Mother eating full meals after delivery*	78.9
5. The delivery and baby room was clean†	75.8
6. Proper care taken to keep the baby warm†	96.0
7. Mother washed hands before feeding†	7.7
8. Mother's nails were clipped†	92.4
9. Mother held baby properly for breast feeding†	96.0
10. Mother cared properly for preterm, LBW baby†	88.1
11. VHW was called if baby was sick†	87.2
Total (mean)	69.7

*As reported by mother.
†Observed by VHW/supervisor.

Even after making allowance for the possibility that the baseline beliefs and behaviours may have already departed from the traditional beliefs, the level of correct knowledge and practices recorded in 1997 to 1998 was very high. In view of the known difficulties in changing the traditional beliefs and human behaviours by health education,[18] *what could explain these high levels?* We believe that the following factors may be responsible:

1. The credibility of the providers of education. The therapeutic role of VHWs in treating sick neonates and the support by TBAs who had a decisive power in determining the practices probably played an important role.
2. Health education messages, targeting the specific audience and the local beliefs and practices and containing culturally appropriate appeal (such as, ''Every baby in the womb is Lord Krishna, and you are the Mother Yashoda. Will you starve the Lord Krishna growing in your womb?'').
3. The high coverage of health education, 66 and 76% (Table 2, points 14 and 15) repeated four times (thrice by home visits and once in group).
4. Health education followed by home visits by the VHWs and the physician with demonstration, practice, persuasion and problem solving.
5. Visible results in the form of improved survival[9] and decreased illness.

Our methods of health education match with the ''Social Cognitive Theory'' developed by Bandura and others.[19] Our approach addressed the group as well the individuals, it provided the enabling feeling of self-efficacy to mothers, and it was linked with experience rather than mere information.

How does this study compare with other experiences of reducing neonatal morbidities? Earlier studies have reported reduction in the incidence of a single morbidity such as birth asphyxia, hypothermia or tetanus with the help of TBAs, or tetanus toxoid immunization.[20–22] ''Kangaroo care'' improved the survival of preterm, LBW babies;[23] and breastfeeding improved immunity.[24,25] High-calorie supplementary food to mothers decreased the proportion of LBW.[17] Putting eye ointment at birth decreased the incidence of conjunctivitis.[26] The package of HBNC, as practised in the Gadchiroli trial, and the observed effect on morbidities, is in consonance with the known effect of these interventions. However, *the distinctive feature of the HBNC approach is that it combined multiple interventions in a package and decreased multiple morbidities by a large margin.*

Recently, Manandhar and colleagues reported on a field trial in Makwanpur, Nepal. The interventions included health education and mobilisation of rural women for better practices and care seeking. The authors report improvement in various process indicators, and 30% reduction in the NMR, and 69% reduction in maternal mortality.[27] This report supports our experience in Gadchiroli.

We cannot single out any one intervention in HBNC that reduced the neonatal morbidities. The simultaneous presence of multiple interventions in the package of home-based neonatal care probably had a synergistic effect. Thus, the reported increased food intake by mothers, increased breastfeeding, better thermal care, clean practices or early detection and treatment of infections together produced multiple effects, enhancing the total positive effect. Since almost all interventions in the HBNC were based on standard medical practice and, together, have yielded good results at low cost, individual trials of each component intervention may not be necessary. However, the total approach of HBNC should be repeated to examine its feasibility in different settings and effectiveness when scaled. Success of the HBNC approach in a smaller area is only the first step. Replicating these methods on larger scale without a loss of coverage or quality is a challenge to the program managers.

Table 4 Seasional Variation in the Incidence of Neonatal Morbidities in Gadchiroli: 1995–1996 vs 1997–1998

Type of morbidity	1995–1996 ($n = 763$)				1997–1998 ($n = 913$)			
	Percent incidence by season				Percent incidence by season			
	Rainy ($n = 330$)	Winter ($n = 274$)	Summer ($n = 159$)	p*	Rainy ($n = 419$)	Winter ($n = 299$)	Summer ($n = 195$)	p*
Preterm	10.7	10.3	7.9	NS	11.5	8.0	10.8	NS
Birth weight <2000 g	11.7	8.2	9.9	NS	7.6	5.4	7.7	NS
Birth weight 2000–2499 g	35.4	34.6	27.0	<0.15	26.7	31.8	26.2	NS
Mild asphyxia	15.2[a]	13.5[b]	13.6[c]	NS	6.6[d]	8.1[e]	10.4[f]	NS
Severe asphyxia	4.6[a]	2.7[b]	8.7[c]	<0.06	2.9[d]	1.2[e]	3.7[f]	NS
Delay in breastfeeding	10.6	8.0	8.8	NS	0.0	0.0	0.0	NS
Feeding problems (total)	18.2	12.4	18.9	<0.10	11.0	8.4	10.3	NS
Hypothermia	14.8	21.5	13.8	<0.05	3.3	3.7	4.1	NS
Neonatal sepsis	17.6	17.2	15.7	NS	9.1	7.4	7.2	NS
Upper respiratory symptom	16.1	29.9	11.3	<0.001	9.8	14.4	9.2	NS
Diarrhoea	5.2	5.8	5.7	NS	1.2	2.0	2.6	NS
Unexplained fever	10.3	5.5	23.9	<0.001	3.6	1.0	14.4	<0.001
Umbilical infection	20.3	26.3	7.5	<0.001	1.9	1.7	2.6	NS
Bacterial skin infection	9.7	17.2	5.7	<0.001	2.6	2.7	3.1	NS
Conjuctivitis	13.9	13.9	6.3	<0.04	1.0	1.3	1.5	NS

*χ^2 test 2×3.
VHW did not attend all deliveries. Hence, asphyxia was observed in total 570 out of 763 neonates in 1995–1996 and 772 out of 913 neonates in 1997–1998: a, 244; b, 223; c, 103; d, 350; e, 259; f, 163.

The high baseline level of morbidities (1995 to 1996) enabled the interventions to produce a large effect. However, a high proportion (42%) of LBW neonates, or the traditional nature of the community with low levels of female education and health care, worked in the opposite direction, making any improvement difficult — and that much more remarkable. Hence, we expect this approach to produce favourable results elsewhere as well.

The 62% reduction in the NMR caused by the HBNC may be attributed partly to the reduced incidence of morbidities, and partly to the reduced case fatality due to the treatment of morbidities, as we have reported earlier.[9] In a subsequent paper, we have tried to diaggregate and quantify these two effects on the NMR.[28]

SIGNIFICANCE

Apart from reducing neonatal and perinatal mortality, the HBNC in the Gadchiroli trial reduced a broad range of neonatal morbidities. These outcomes add to the value of the approach. It revealed that health education of mothers, training of VHWs and TBAs, and frequent home visits to identify and care for sick neonates can change neonatal care practices in a traditional community, reduce infections, care-related morbidities and the seasonal increase in morbidities. This approach was found to be feasible and effective in one of the most deprived areas of India. Developing the methods to scale this approach is the next challenge.

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Original Article

Is Home-Based Diagnosis and Treatment of Neonatal Sepsis Feasible and Effective? Seven Years of Intervention in the Gadchiroli Field Trial (1996 to 2003)

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OBJECTIVES:

To further evaluate our earlier findings on the feasibility and effectiveness of home-based management of neonatal sepsis by analysing 7 years data (1996 to 2003) from the field trial in Gadchiroli, India.

STUDY DESIGN:

Neonates in 39 villages were monitored by trained village health workers (VHWs) from 1995 onwards. In 1996, we trained VHWs to diagnose sepsis by using a clinical algorithm and provide domiciliary treatment using intramuscular gentamicin and oral co-trimoxazole. Health records for all neonates were kept by the VHWs, checked by field supervisors, and computerized. Live births and neonatal deaths were recorded by an independent vital statistics collection system. We evaluated the feasibility and effectiveness of this approach.

RESULTS:

During September 1996 to March 2003, VHWs monitored 93% of all neonates in 39 villages ($N=5268$). As compared to 552 cases of sepsis diagnosed by computer algorithm, VHWs correctly diagnosed 492 cases (89%). Parents agreed to home-based treatment for the majority of infants (448, 91%), refused treatment in 31 (6.4%) cases, and hospitalized 13 infants (2.6%). VHWs treated 470 neonates with antibiotics, that is, 8.9% of all neonates in community. Of 552 cases diagnosed by computer, VHWs correctly treated 448 (81.2%) and gave unnecessary treatment to 22/470 (4.7%) of treated neonates. The case fatality (CF) was 6.9% in treated cases vs 22% in untreated or 16.6% in the pre-intervention period ($p<0.001$). Home-based treatment resulted in 67.2% reduction in %CF among preterm and a 72% reduction among LBW neonates.

CONCLUSIONS:

Home-based management of neonates with suspected sepsis is acceptable to most parents, safe, and effective in reducing sepsis case fatality by nearly 60%. With proper selection, training, and supervision of health workers, this method may be applicable in areas in developing countries where access to hospital care is limited.

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INTRODUCTION

Neonatal infections are a major cause of morbidity and mortality worldwide. The World Health Organisation estimates that, globally, 32% of the estimated four million neonatal deaths each year are caused by infections, including sepsis, pneumonia, diarrhea, and tetanus.[1] Another global review of neonatal infections estimated that annually there are approximately 29 million neonatal infections (including 800,000 cases of sepsis and 130,000 cases of meningitis) and as many as 1.5 million neonatal deaths due to infections.[2] In Gadchiroli, India, we have studied clinical sepsis among home-based neonates in 39 villages since 1995. In our studies, the term 'sepsis' includes neonatal sepsis, pneumonia, and meningitis. In a cohort of 763 neonates prospectively observed in 1995 to 1996, we estimated the incidence of clinically suspected sepsis to be 17.0 % and the case fatality (CF) without interventions to be 18.5%.[3,4] Moreover, sepsis was the primary cause in 52.5% of neonatal deaths.[5,6]

The management of sepsis by trained village heath workers (VHWs) is one of the interventions in the home-based neonatal care package in the field trial in Gadchiroli.[5] Promising early data (1996 to 1998) on 71 cases suggested that VHWs could identify and manage neonates with suspected sepsis in the home setting, resulting in improved survival. This initial experience raised the possibility that managing neonatal infections in the community may be an intervention with broad applicability. Since then, three new field trials of community-based management of sepsis in neonates have been started in India and Bangladesh.

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We have continued the home-based interventions and monitoring in the Gadchiroli field area to date. In the current paper, we present the data and experience up to March 2003.

RESEARCH QUESTIONS

To evaluate the feasibility and effectiveness of home-based management of neonates with suspected sepsis, we asked seven questions:

1. Is it possible to monitor neonates in their community and identify suspected sepsis cases? This was evaluated using five indicators: (i) The proportion of neonates in community visited by VHWs (% coverage). (ii) The proportion of neonatal sepsis cases correctly identified (true positives), using the diagnostic guidelines given to VHWs as the gold standard. (iii) The proportion missed (false negatives). (iv) The proportion overdiagnosed (false positives). (v) The proportion correctly considered not having sepsis (true negatives).
2. What proportion of parents agree to hospitalization of neonates with suspected sepsis? What proportion accept home-based treatment by the VHWs? What proportion refuse both?
3. What proportion of neonates in community are treated for suspected sepsis?
4. How effective is home-based management in reducing case fatality in neonates with sepsis, including neonates with varying risk based on gestational age, birth weight and postnatal age (day of life)?
5. Can VHWs safely administer intramuscular injections (antibiotics and vitamin K) to newborns?
6. What are the difficulties faced by VHWs?
7. Is home-based management acceptable to the medical community, both local and national? Is it ethical?

METHODS

Data Sources

We have previously described the area, study design, methods of data collection, and the interventions in the field trial.[5,7] The data reviewed in this paper come from six sources:

(1) Maternal and neonatal health records completed by the VHWs during home visits. The date of onset of the last menstrual period was recorded from the history given by the woman at the time of registering her pregnancy, usually in the fourth month of pregnancy. The period of gestation was estimated at birth from this information. The birth weight was recorded by VHWs, usually within 6 hours after birth, by weighing the baby using a 0 to 5 kg spring balance (Salter). This printed record also included a sepsis monitoring form. From 1995 to 1998, we used six clinical criteria based on 12 signs/symptoms to diagnose presumed sepsis. In 1998, we slightly modified the diagnostic schema [seven criteria; 10 signs/symptoms (Box 1)]. The current monitoring form is given in Appendix A. Clinical sepsis was defined by the simultaneous presence of two or more criteria. Records were completed by VHW's during home visits. All neonates were visited eight times on days 1, 2, 3, 5, 7, 15, 21, and 28. High-risk neonates (birth weight <2000 g, preterm birth or difficulty in feeding on the day of birth) received additional visits on days 4, 6, 9, 13, 18, and 24 since August 1998 to date. Beginning in 2002, we reduced the number of visits to six, on days 1, 2, 3, 7, 15, and 28, to the rest of the neonates (considered low risk). If parents inform the VHW that the baby is sick, additional home visits are made.

(2) Sepsis treatment records completed by VHWs for the cases of neonatal sepsis diagnosed and treated. These records included diagnostic criteria present on various days and data on treatment and progress.
These two records were reviewed by a visiting field supervisor approximately every 15 days and verified by visiting the family. In an earlier study, we found that data recorded by VHWs showed 92% agreement with parallel observations by a visiting physician.[3] Four possible complications of antibiotic injections were specifically looked for: (i) cellulitis or abscess at the site of injection, (ii) hemorrhage at the site of injection, (iii) decreased tone and movement in the limb suggesting nerve injury, (iv) skin rash indicating possible drug allergy.

(3) Records of the supplies provided to VHWs.

(4) The field diaries maintained by the field supervisors. These provided additional clinical data, as well as the difficulties faced and community reactions.

Box 1 Clinical criteria used to diagnose neonatal sepsis*

A. Criteria used in 1995 to 98

1. Previously normal cry became weak/stopped or previously normal baby became drowsy/unconscious or previously normal sucking became weak or stopped.
2. Baby cold to touch or fever (skin temperature >99°F)
3. Skin infection or umbilical infection
4. Vomitting or diarrhea or abdominal distension
5. Respiratory rate ≥ 60
6. Grunt or chest indrawing

B. Criteria used in 1998 to 2003

1. Previously normal cry became weak/stopped
2. Previously normal baby became drowsy/unconscious
3. Previously normal sucking became weak/stopped
4. Baby cold to touch or fever (>99°F)
5. Skin infection or umbilical infection
6. Abdominal distension or vomiting
7. Grunt or chest indrawing

*Simultaneous presence of any two or more criteria in a neonate denoted sepsis.

(5) Meetings with VHWs, supervisors, and physician every 2 months to discuss qualitative experiences and the difficulties experienced by VHWs.
(6) Vital statistics surveillance in the study area, conducted by independent field workers and supervisors. Previously, we reported that 98% of births and child deaths were recorded by this system.[5]

Recorded data are entered onto the computer within 30 days of collection and analyzed every 6 months. A computer algorithm was written to identify cases of sepsis using the diagnostic criteria and the data in the neonatal records and sepsis monitoring forms. The incidence of sepsis was estimated from these diagnosed cases. The proportion of neonates with sepsis correctly diagnosed by VHWs (true positive), diagnoses missed by the VHW (false negative), or over-diagnosed (false positive) were estimated by comparing the VHW's sepsis diagnosis and treatment records with the cases identified by the computer algorithm of sepsis. The total live births and neonatal deaths were provided by the vital statistics surveillance. We calculated the number of vitamin K injections given from the newborn forms, and the number of gentamicin injections from the sepsis treatment forms. These were regularly matched with the supplies given to VHWs to ensure the proper use of medicines and syringes.

Home-based interventions in the field trial in Gadchiroli have been previously reported.[5] Interventions relevant to sepsis management are presented in Box 2.

Box 2 Interventions for the home-based management of neonatal sepsis

- Health education of mother and family about the five danger signs in baby. If any one of these appeared, they should immediately seek care from the VHW.
  Danger signs:
  1. Reduced sucking
  2. Drowsy or unconscious
  3. Baby cold to touch
  4. Fast breathing
  5. Chest indrawing
- VHWs monitored all neonates by making repeated home visits and recorded presence or absence of defined signs/symptoms (see appendix).
- VHWs were trained to diagnose sepsis if two or more of the signs/symptoms were simultaneously present in the baby.
- For neonates diagnosed with clinical sepsis, the VHW:
  1. Informed parents of the illness, and the threat to newborn's life.
  2. Advised parents to immediately take the baby to hospital, then the VHW offered treatment at home and obtained a written informed consent form.
  3. Maintained normal body temperature and breastmilk feeding of the baby.
  4. Administered antibiotics:
     - Gentamicin injected intramuscularly in the antero-lateral aspect of baby's thigh. The dose of gentamicin was 10 mg per day for 10 days for pre-term babies with birth weight <2500 g, and 15 mg per day for 7 days to full-term babies or to those with birth weight ≥2500 g. Gentamicin was given divided in two daily doses, except for a period (June 1998 to January 2001) during which it was given in once a day dosing.
     - Syrup co-trimoxazole (sulphamethoxazole 200 mg+trimethoprim 40 mg per 5 ml) 1.25 ml twice a day for 7 days.
  5. Made daily home visits to baby under treatment to administer antibiotics and record progress.
- If baby did not improve in 24 hours or if baby did not take feeds/medicines orally, or if baby was persistently hypothermic, referral to hospital was again advised.
- Recorded the outcome.

The Choice of Antibiotics

In the absence of bacterial culture and sensitivity reports, the antibiotics recommended for treating neonatal sepsis in developed countries are parenteral ampicillin and gentamicin.[8,9] This combination covers a broad spectrum of organisms that cause neonatal sepsis, including *Escherichia coli*, Klebsiella, *Streptococcus pneumoniae, Staphylococcus aureus*, Group B Streptococcus and *Hemophilus influenzae*. In the absence of community-based data on the organisms causing neonatal sepsis in Gadchiroli, we used our community-based data regarding organisms colonizing the maternal reproductive tract of rural women in Gadchiroli.[10,11] Of 280 maternal genital bacterial isolates, 93% were sensitive to co-trimoxazole, 95% to gentamicin, and 100% were sensitive to at least one of these.

For this study we chose to use parenteral gentamicin and oral co-trimoxazole (rather than parenteral ampicillin). We have previously studied the use of co-trimoxazole for pneumonia in children, including neonates, in this area[11] and reported a 40% reduction in pneumonia-specific mortality rate in neonates in the intervention area. Moreover, co-trimoxazole can be administered orally. Thus, based on this background and the recommendations of the advisory group of pediatricians, we chose injection gentamicin and oral co-trimoxazole as the antibiotic combination for treating suspected sepsis. The dose and the duration of antibiotic administration are described in Table 9.

Syringe and Needle

Gentamicin is available in India in only one strength, 40 mg/ml. As neonates in our trial needed very small doses (5 or 7.5 mg twice a day), we used disposable insulin syringes and needles to enable VHWs to accurately dispense the proper dose. These syringes, marked for insulin at 40 U/ml, match exactly with the available strength of gentamicin, and allow precise measurement of the gentamicin dose. The small needle available with the insulin syringe ensures that the needle does not penetrate too far into neonate's thigh. Disposable syringes and needle reduce the risk of infection.

VHWs were asked to store all used syringes without washing them in a plastic box, and return these to the field supervisor. An account of syringes supplied and returned was maintained and checked with the number of neonates treated to prevent any unaccounted use to give unnecessary injections by VHWs.

Training and Supervision

We trained VHWs in stages. In 1995 they were trained to take history, examine a mother and newborn, and record data. They monitored the neonates in their village during one year (April 95 to March 96). In May 1996, we taught VHWs to give intramuscular vitamin K. When they had given 10 injections to newborns in their village in the presence of the field supervisor without any error, they were certified to give injection vitamin K independently on the day of birth. In July –August 1996, we trained VHWs to diagnose and treat sepsis (Tables 8 and 9). They were repeatedly assessed by simulated exercises and retrained, until performance was deemed satisfactory. Beginning in September 1996, we permitted them to diagnose and treat sepsis as per guidelines. Communities were informed of this new intervention, and mothers and families were given health education to recognize danger signs and seek care from the VHW. As a VHW was likely to diagnose and treat a case of sepsis only once or twice each year, continued training and drills with assessment were made in the supervisory visits and in the bi-monthly review meetings to help retain her skills. Close field supervision of VHWs, continued training, education of community and families about sepsis management, and regular uninterrupted supplies were maintained.

Communication with Medical Community

We informed and explained this intervention by visiting local private doctors. Senior pediatricians, neonatologists, and public health professionals of national standing were involved in this trial as members of an external advisory committee which met at the field site in 1995, 1996, and 1998. The committee reviewed our data, advised us about interventions, assessed the quality of training for VHWs, and gave ethical clearance.[5,7] The study director (AB) presented the findings of the trial at the annual national conferences of the Indian Academy of Pediatrics (IAP) and the National Neonatology Forum (NNF) of India. A national workshop was jointly organized by the IAP, NNF, UNICEF, and SEARCH in 1999 at the project headquarters to study the findings of the trial and discuss its significance for national policy. A consensus statement was issued on this approach by the national workshop.[12] The second national workshop was organized on 31 March 2003 at the project headquarters.[13]

Consent and ethical clearance. All neonates with suspected sepsis were advised hospitalization. If parents did not agree to it, a written consent from all families was taken before treatment at home. An external advisory committee gave ethical clearance.

RESULTS

A total of 5796 live births were recorded in 39 intervention villages from April 1996 to March 2003. Of these, 169 neonates died (neonatal mortality rate (NMR) 29.1/1000 live births). Additionally, 123 neonates from other areas were transiently in the intervention villages and were monitored by VHWs. Thus, in total 5919 neonates were present during 1996 to 2003 in the intervention villages. VHWs visited 5510 of these neonates, giving a service coverage of 93.1%.

From September 1996, when sepsis management was started, to March 2003, 5268 neonates were visited by the VHWs. Based on the data recorded by VHWs, the computer algorithm identified 552 neonates with sepsis, giving an incidence of sepsis of 10.5%. Of these 552 cases of sepsis, the VHWs correctly diagnosed 492 (89.1%). The ability of the VHWs to diagnose sepsis in comparison to the computer algorithm is presented in Table 1.

The yearly incidence of sepsis and the proportion of sepsis cases treated by VHWs is presented in Table 2. Both the incidence of sepsis and the percent treated by VHWs increased over the first few years of the study. In the last year recorded, 93/751 infants (12.4%) were diagnosed by computer algorithm and 86 of these (92.5%) were actually treated by the VHWs.

The gestational age distribution of the 552 cases was: term (462, 83.7%) and preterm (<37 weeks; 86, 15.6%). Among preterm infants, 61 (71% of all preterm infants) were 35 to 36 weeks, nine (10.5%) were 33 to 34 weeks, and 16 (18.6%) were <32 weeks gestation. Gestation was not recorded in four (0.7%) neonates. The distribution of birth weights was: 2500 g or more, 256 (46.4%) and LBW (<2500 g) 293 (53.1%). Among LBW infants 187 (63.8% of all LBW infants) were 2000 to 2499 g; 51 (17.4%) were 1750 to 1999 g; 29 (10%) were 1500 to 1749; and 26 (9%) were <1500 g. Birth weight was not recorded for three (0.5%) newborns.

Table 1 Diagnosis of Sepsis by the Trained VHWs in Comparison to Computer Algorithm

		Computer algorithm		
	Diagnosis	Sepsis	No sepsis	Total
VHW	Sepsis	492	22	514
	No Sepsis	60	4694	4754
	Total	552	4716	5268

Table 2 Number of Diagnosed* and Treated cases of Sepsis in Different Years

Time Period	Total neonates in community	Neonates diagnosed as sepsis*	Incidence (%)	Neonates treated by VHW†	% of cases treated
September, 1996 to March, 1997	443	34	7.7	18	52.9
April, 1997 to March, 1998	913	77	8.4	53	68.8
April, 1998 to March, 1999‡	669	69	10.3	60	87.0
April, 1999 to March, 2000	898	93	10.4	76	81.7
April, 2000 to March, 2001	829	105	12.7	84	80.0
April, 2001 to March, 2002	765	81	10.6	71	87.7
April, 2002 to March, 2003	751	93	12.4	86	92.5
Total	5268	552	10.5	448	81.2

*Diagnosed by computer algorithm.
†Village health worker.
‡Diagnostic criteria slightly modified to give more sensitivity from this year (see Box 1).

Table 3 Clinical Features in Neonates with Sepsis (1996 to 2003)* ($n = 552$)

Clinical features	Present in	
	n	%
Diagnostic criteria†		
Cry weak or stopped	316	57.2
Sucking reduced or stopped	375	67.9
Baby became drowsy or unconscious	212	38.4
Baby was cold to touch or had fever‡	311	56.3
Vomiting or abdominal distension	204	37.0
Grunting or chest retraction	334	60.5
Skin pustules or umbilical infection	90	16.3
Other clinical features		
Fast breathing ($\geq$60 per minute)	240	43.5

*Clinical features recorded during entire neonatal period.
†Simultaneous presence of any two criteria resulted in the diagnosis of sepsis.
‡Skin temperature >99°F.

Table 4 Feasibility of Home-Based Sepsis Management

Indicator	No./total	%
Screening for sepsis		
Coverage (% neonates visited by VHWs)	5510/5919	93.1
VHW's diagnosis compared to computer diagnosis		
True positive (Sensitivity %)	492/552	89.1
True negative (Specificity %)	4694/4716	99.5
False positive	22/514	4.2
False negative	60/552	10.9
Parental acceptance		
Agreed to hospitalise	13/492	2.6
Agreed to home-based treatment	448/492	91.1
Refused both	31/492	6.3
Proportion of total neonates in community treated by VHWs for sepsis	470/5268	8.9

Our method of diagnosing sepsis required at least two diagnostic criteria to be present simultaneously in a neonate. The clinical features present in 552 neonates with suspected sepsis are presented in Table 3. All infants had more than two diagnostic criteria, with a mean of 3.3 criteria. The most frequently recorded signs/symptoms were sucking reduced or stopped; grunting or chest indrawing (retraction), and cry became weak or stopped. For all infants with presumed sepsis, the age at diagnosis ranged from 1 to 28, with a mean of 11.1 days. For those who died with a diagnosis of sepsis, the mean age at the time of death was 7 days, and the mean age at diagnosis was 5.3 days. There was a relatively short time interval between sepsis diagnosis and death.

The feasibility of home-based diagnosis and treatment as evaluated is presented in Table 4. The vast majority of infants (93.1%) were visited by VHWs. The VHWs were likely to (89.1%) accurately diagnose a case of clinical sepsis (as defined) and only missed 10.9% cases or overdiagnosed 4.2% patients (as compared to diagnosis by computer algorithm). Of the 492 patients diagnosed by the VHW to have presumed sepsis, parents agreed to and were able to hospitalize only 13 infants (2.6%), but agreed to home-based treatment for almost all infants (91.1%). Of note, in 31 cases (6.3%), parents refused both home and hospital care. Thus, the total number of neonates treated as sepsis by VHWs (true cases treated + false positives) was 470, that is, 8.9% of the neonates in the intervention area.

Table 5 Effect of Sepsis Case Management on Case Fatality in Gadchiroli (1996 to 2003) ($n=552$)

Treatment	Live births	Sepsis diagnoses	Deaths	% Case fatality	p-value	
Before training of VHWs* in treatment (April 1995 to August 1996)†	1005	163	27	16.6	<0.02 (before vs. after)	<0.001 (before vs. untreated)
After training of VHWs (September 1996 to March 2003)	5268	552	53	9.6		
Treated by VHWs	—	448	31	6.9	<0.0001 (treated vs. untreated)	
Untreated by VHWs	—	91	20	22.0		
Diagnosis missed by VHWs	—	60	15	25.0		
Parents refused treatment	—	31	5	16.1		
Hospitalized‡	—	13	2	15.4		

*Village health worker.
†Pre-intervention period.
‡Referred by VHW or self referral by parents, some received initial dose of antibiotics given by VHWs.

Table 6 Effect of Sepsis Management on the Case Fatality in Neonates by Gestation and Birth Weight (September 1996 to March 2003) (Total Sepsis Deaths: 53)

	Sepsis cases untreated* ($n=91$)			Sepsis cases treated by VHW† ($n=448$)				
Risk group	Cases	Deaths	% CF‡	Cases	Deaths	% CF‡	% Reduction in CF‡	p-value
Estimated gestational age								
<32 weeks	6	6	100.0	10	4	40.0	60.0	<0.03
33 to 34 weeks	3	2	66.7	6	2	33.3	50.0	<0.41
35 to 36 weeks	16	2	12.5	45	2	4.4	64.4	<0.28
Total preterm	25	10	40.0	61	8	13.1	67.2	<0.02
Full term	66	10	15.2	383	22	5.7	62.1	<0.02
NR§	0	0	—	4	1	25.0	—	—
Birth weight								
<1500 g	12	9	75.0	14	4	28.6	61.9	<0.05
1501 to 1749 g	7	2	28.6	21	4	19.0	33.3	<0.48
1750 to 1999 g	7	2	28.6	43	5	11.6	59.3	<0.26
2000 to 2499 g	24	5	20.8	159	11	6.9	66.8	<0.05
Total LBW	50	18	36.0	237	24	10.1	71.9	<0.001
≥2500 g	41	2	4.9	208	7	3.4	31.0	<0.46
NR§	0	0	—	3	0	0.0	—	—

*Untreated = Village health worker missed the diagnosis (60)+parents refused treatment (31).
†Village health worker.
‡Case fatality.
§Not recorded.

Home-based treatment of presumed neonatal sepsis was very effective at reducing sepsis-related deaths (Table 5). In the pre-intervention period, 16.6% of newborns with a diagnosis of clinical sepsis died. By contrast, in the post-intervention period 6.9% of those who were treated died as compared to 22% of those who were untreated (either because of missed diagnosis or parental refusal of treatment).

The effect of home-based management on the case fatality in untreated and treated neonates categorized by estimated gestational age and by birth weight is shown in Table 6. Case fatality (CF) for

Table 7 Effect of Treatment on the Case Fatality in Neonatal Sepsis by the Day of Life (1996 to 2003)

	Untreated				Treated by VHWs*				
Day of diagnosis	Diagnosed	%	Deaths	% CF†	Diagnosed	%	Deaths	% CF†	% Reduction in CF†
1 to 4 days	42	46.2	15	35.7	125	27.9	21	16.8	52.9‡
5 to 7 days	9	9.9	1	11.1	54	12.1	5	9.3	16.2
1st week	51	56.0	16	31.4	179	40.0	26	14.5	53.8‡
2nd week	11	12.1	1	9.1	114	25.4	2	1.8	80.2
3rd week	16	17.6	3	18.8	96	21.4	3	3.1	83.5‡
4th week	13	14.3	0	0.0	59	13.2	0	0.0	—
2 to 4 weeks	40	44.0	4	10.0	269	60.0	5	1.9	81.0‡
Total	91	100.0	20	22.0	448	100.0	31	6.9	68.6§

*Village health worker.
†Case fatality.
‡$p<0.05$.
§$p<0.0001$.

both treated and untreated infants was inversely related to estimated gestational age and birth weight — that is, the risk of death decreased with increasing gestational age and birth weight. Home-based management resulted in a significant reduction in the CF for both term (62.1% reduction) and preterm infants (67.2% reduction) and for those who were under 2500 g birth weight (71.9% reduction). Of note, although home-based management resulted in a 31% reduction in the CF for infants over 2500 g birth weight, this finding was not statistically significant, probably because of the already low CF for this group without treatment.

The effect of home-based management compared by age at diagnosis in those who were treated and those who were untreated (diagnosis missed or parents refused treatment) is presented in Table 7. The younger the newborn, the higher the CF. For all age groups, CF was higher in the group who were untreated. Home-based treatment significantly reduced the risk of death for neonates with both an early (first week of life) and later diagnosis of neonatal sepsis.

VHWs gave 4793 injections of gentamicin. They also gave 5069 injections of vitamin K. To date, we have not identified any neonate with injection-related complications, including infection at the injection site, hemorrhage, nerve injury, or allergic rash. We have not maintained a record of the needle injuries to VHWs. However, the prevalence of HIV-positive Elisa test in pregnant women attending the women's clinic of SEARCH in the adjacent area was less than 0.1% during this period.

The difficulties expressed by VHWs in the review meetings or observed in supervisory visits included:

1. Not able to visit a neonate due to lack of information about its birth or arrival from outside. This was more common when mothers moved to parents' home for delivery a few days before delivery.
2. Parents not informing VHWs about development of a danger sign or symptom on a non-visit day.
3. VHW misinterpreting the clinical criteria, especially when the baby was sick from birth due to asphyxia or prematurity.
4. Natural variations in the respiratory rate in a newborn, causing difficulty in correctly counting and recording respiratory rate.
5. Despite advice from the VHWs, parents refusing to take a seriously ill neonate to hospital or refusing treatment.
6. Apprehension about the possibility of death especially when treating a preterm baby of < 32 weeks gestation, or a LBW baby <1500 g, because the treatment by VHW could be blamed for death.
7. Maintenance of oral feeding and body temperature in neonates <32 weeks or <1500 g often became difficult.
8. Parents or other families in village making request to VHW to give other medicinal injections as well.

Apart from the initial surprise and skepticism in the local medical community about a VHW treating neonatal sepsis with injection gentamicin, we did not experience any opposition. The professional leadership, including the members of the external advisory group and the national office bearers of organizations such as the IAP and NNF of India, actively engaged in discussions and decisions, and approved of this approach. The national workshops passed unanimous resolutions supporting this approach.[12,13]

DISCUSSION

This analysis covering 7 years of data from the Gadchiroli trial shows that it is feasible to screen neonates in a community with 93% coverage and to identify the suspected cases of sepsis with estimated 89% sensitivity as compared to the guidelines.

The majority of parents (91.1%) accepted home-based management, and most (97.4%) refused to go to hospital. VHWs treated in total 8.9% of all neonates in community as suspected sepsis. Home-based management of sepsis, with gentamicin and co-trimoxazole, reduced the CF significantly in all risk groups assessed (gestation, weight, and day of life). Overall, CF reduced from 16.6 to 6.9% in the treated neonates. No complications of injections to neonates was recorded. The local and national medical community was highly supportive of this approach.

In many parts of the world, most births and neonatal deaths occur at home. In areas that are far from health-care facilities or when families are unable or refuse to leave their homes and villages for care, creative approaches to the delivery of health care are needed. Earlier studies in Gadchiroli suggested that trained VHWs could identify sick newborns in their homes and were able to treat neonates with presumed sepsis and pneumonia appropriately and in a timely manner, thus reducing neonatal mortality. This study extends our earlier studies, confirms the earlier findings, and presents a new evidence about feasibility, acceptance, and problems.

Infections (primarily neonatal sepsis, pneumonia, and meningitis) have been reported to be the major causes of neonatal death in many developing countries.[1,2] Untreated, neonatal infections can very quickly result in serious illness and death. They are potentially preventable causes of neonatal mortality.

In this study, VHWs used strictly defined clinical criteria to diagnose presumed sepsis in a setting where there was no laboratory to make a definitive microbiologic diagnosis. We have selected these diagnostic criteria to be able to identify all potentially fatal cases of sepsis. We acknowledge that our criteria may overdiagnose sepsis (false-positive cases). We have evaluated[14] that, using these criteria, nearly 10% neonates in rural Gadchiroli would be identified as sepsis (the yield). The ability of these trained health workers to make a diagnosis of clinical sepsis was very similar to that of a computer-based algorithm using the same criteria, confirming that it is possible to train women with limited formal education and no prior medical or nursing education to examine newborns and to decide if they are ill or not. Of note, using this computer-based comparison, VHWs missed a diagnosis of presumed sepsis in only 11% cases and only 4% of the treatment was unnecessary treatment.

The major finding of this study is that home-based treatment of presumed sepsis with intramuscular gentamicin and oral co-trimoxazole was able to markedly reduce the CF rate. While 16.6% of infants with presumed sepsis died in the pre-intervention period and 22% of those who were untreated (missed diagnosis or refused treatment) during the intervention period died, only 6.9% of those who were treated by VHWs died. Although the risk of death was greatest in neonates who were preterm and/or of low birth weight, there was a similar reduction in %CF among both term and preterm infants who were treated in the home. The preterm neonates included in this study were of 28 to 37 weeks gestation. A neonate born before 28 weeks is not considered viable in India.[15] Nearly three-fourths of the LBW neonates were full term, but intrauterine growth restricted neonates, most of them with birth weight >1500 g. Although early neonatal sepsis occurring in the first week of life had the highest CF, there was a significant reduction in CF for home-based treatment throughout the neonatal period.

A potential criticism of this approach is that diagnostic criteria are based upon nonspecific signs and symptoms that may reflect a number of pathologic neonatal conditions, in addition to sepsis (including surfactant-deficient respiratory distress of the premature infant and hypoxic–ischemic encephalopathy of the term infant). Therefore, neonatal sepsis may have been overdiagnosed in the intervention sites. However, because of the high risk of death in untreated sepsis, an accepted principle in the management of neonatal sepsis even in developed countries is to treat on the slightest suspicion of infection. Remington and Klein reported that in the neonatal nurseries in Boston, 6.5% neonates were treated with antibiotics for suspected sepsis, though of those treated only 6% turned out to be culture positive.[9] Moreover, despite possible concerns about accuracy of the diagnosis, the home-based treatment by VHWs in our study did result in a significant reduction in CF in treated cases and, as reported earlier, in the all-cause NMR by 62%.[5]

The importance of health education for mothers and families in the community must be emphasized. Despite recommendations by VHWs, the majority of families refused to take their neonates to hospital for care. Although families accepted home-based care, VHWs were concerned that parents did not always inform them about a sick infant on a non-visit day and thus treatment was delayed for some infants. Obviously, there is a great scope for improvement in parental-care-seeking behavior.

Although we were concerned about potential problems in allowing a VHW to give intramuscular injections to a sick neonate, including complications of injections and unnecessary or excessive use of injections, none of these occurred during the 7 years study period. This evidence suggests that, with proper training, motivation, supervision, and community education, potential hazards can be avoided.

A major concern about home-based care is whether it is ethical to allow a VHW, rather than a doctor, to diagnose and treat a potentially fatal disease such as neonatal sepsis. Ideally, all such neonates should be hospitalized, evaluated by a highly specialized medical team and treated. However, the ideal conditions do not exist in the real world. In areas where hospitals are not accessible, or where hospitals do not have facilities to care for a sick neonate or when parents cannot or do not want to hospitalize a sick neonate, not to treat a life-threatening condition may be considered unethical. Use of injections by nonphysicians has already been accepted and widely practiced in immunization programs or in situations such as self-administration of insulin by insulin-dependent diabetic patients. The risk of death and hence the urgent need to treat is greater in the case of a neonate with sepsis in a rural home.

Although the local medical community was initially skeptical about the ability of VHWs to treat sick infants with antibiotics (especially injectable antibiotics) in the home, they did not oppose the program and became great supporters once the success of the intervention was established. Furthermore, national opinion leaders and decision makers (such as the successive national presidents of the IAP and the NNF) have actively supported this innovative approach.[12,13]

The unresolved issues for further research are: (1) improving methods of family education for recognition of sick neonate and better care seeking, (2) making gentamicin available in Uniject device which can be easily administered, (3) choice of antibiotics which can be administered orally, (4) interventions to prevent early-onset sepsis because it contributes most of the remaining sepsis deaths in Gadchiroli, (5) in the cases with fatal outcome, the mean duration of treatment before death was only 1.7 day. Earlier initiation of treatment will further improve the survival.

Significance

The success of the Gadchiroli trial in reducing sepsis-related neonatal mortality in a community setting with limited resources is promising for other developing countries. This intervention is currently being adapted to other settings in India and elsewhere in the developing world. If successful in replicating the findings in Gadchiroli, these studies will have broad public health implications for the prevention of neonatal mortality in developing countries.

Such innovations are not new. The history of public health in developing countries shows similar examples wherein hospital-based treatment of dreaded infections was simplified and substituted by home-based treatment. Domiciliary treatment of tuberculosis, oral rehydration therapy for cholera and other watery diarrhea, and community-based management of pneumonia in children are some such successful innovations. These have saved more lives than many other costly treatments. A similar change might occur in the public health approach to the management of neonatal infections in developing countries.

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Appendix A: The neonatal sepsis monitoring form in Gadchiroli

Mother's name: *Godavari Patil* Village: *Khursa* Worker's name: *Kusum Gadpayale*

Which of the following signs are present? [Mark **'Y']**

	Days														Other days
	2	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**12**	**15**	**18**	**21**	**24**	**28**	
1. Previously normal cry became weak or stopped															
2. Previously normal baby became drowsy or unconscious										Y					
3. Previously normal sucking became weak or stopped										Y					
4. Mother feels that baby is cold to touch or has fever						Y	Y	Y	Y	Y					
5. Skin or umbilical infection (pus or abscess)															
6. Abdominal distension or consecutive 3 feeds led to vomiting															
7. Grunt or chest indrawing															
Total no of criteria present (On a given day)						1	1	1	1	3					

Out of above 7 criteria, simultaneous presence of two or more criteria indicate sepsis: ☐

If 'Yes' go to sepsis management form.

Original Article

Low Birth Weight and Preterm Neonates: Can they be Managed at Home by Mother and a Trained Village Health Worker?

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OBJECTIVE:

Observations on a cohort of neonates in the preintervention year of the field trial of home-based neonatal care (HBNC) in rural Gadchiroli, India, showed that preterm birth and low birth weight (LBW), <2500 g, constituted the most important risk factors. Owing to a limited access to hospital care, most neonates were managed at home in the subsequent intervention years. The objective of this paper is to evaluate the feasibility and effectiveness of managing LBW and preterm neonates in home setting.

DESIGN:

We retrospectively analyzed data from the intervention arm (39 villages) in the HBNC trial. Feasibility was assessed by coverage and by quality (19 indicators) of care. Effectiveness was evaluated by change in case fatality (CF) and in the incidence of comorbidities in LBW or preterm neonates by comparing the preintervention year (1995 to 1996) with the intervention years (1996 to 2003).

RESULTS:

During 1996 to 2003, total 5919 live births occurred in the intervention villages, out of whom 5510 (93%) received HBNC. These included 2015 LBW neonates and 533 preterm neonates, out of whom 97% received only home-based care. The coverage and quality of interventions assessed on 19 indicators was 80.5%. The CF in LBW neonates declined by 58% (from 11.3 to 4.7%, $p<0.001$), and in preterm neonates, by 69.5% (from 33.3 to 10.2%, $p<0.0001$). Incidence of the major comorbidities, viz., sepsis, asphyxia, hypothermia and feeding problems, declined significantly. Preterm-LBW neonates without sepsis (270) received only supportive care — CF in them decreased from 28.2 to 11.5% ($p<0.01$), and those with sepsis (53) received supportive care and antibiotics — CF in them decreased from 61 to 13.2% ($p<0.005$). Supportive care contributed 75% and treatment with antibiotics 25% in the total averted deaths in preterm-LBW neonates. The intrauterine growth restriction (IUGR)-LBW neonates without sepsis (1409) received only supportive care — the CF was unchanged, and 181 with sepsis received supportive care and antibiotics — the CF decreased from 18.4 to 8.8% ($p<0.05$). Treatment with antibiotics explained entire reduction in mortality in IUGR neonates. In total, 55 deaths in LBW neonates were averted by supportive care and 35 by the treatment with antibiotics.

CONCLUSIONS:

Home-based management of LBW and the preterm neonates is feasible and effective. It remarkably improved survival by preventing comorbidities, by supportive care, and by treating infections.
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INTRODUCTION

Low birth weight (LBW), defined as a birth weight <2500 g, is indisputably a very important indirect cause of death in neonates the world over. Globally, between 40 and 80% of neonatal deaths occur among LBW neonates. The World Health Organization estimates that 16% of neonates, or nearly 20 million, are born LBW each year. The highest incidence is observed in South Asia, where an estimated 31% of neonates are born LBW, contributing 11 million, a little more than half, of the world's LBW neonates.[1]

LBW is caused by intrauterine growth restriction (IUGR), short gestation or both. The incidence of preterm birth (<37 completed weeks of gestation) is fairly similar worldwide, generally ranging between 7 and 16% of total births and, according to WHO estimates, is the direct cause of 24% of neonatal deaths. In South Asia, IUGR is responsible for nearly two-thirds of all LBW neonates.[1]

Attempts to prevent LBW or preterm births in populations have been largely ineffective. This is one of the most challenging and frustrating problems in public health. Kramer[2,3] and, more recently, Ramakrishnan and Neufeld,[4] have reviewed the results of various interventions, including food and micronutrient supplements. In spite of occasional promising results, such as high-energy supplementation in the Gambia trial,[5] large-scale trials and meta-analyses have shown very little effect on the incidence of LBW.

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LBW and preterm birth were major problems in Gadchiroli. A cohort of 763 neonates born in 39 villages was studied in the preintervention year (1995 to 1996) of the field trial of home-based neonatal care (HBNC) in Gadchiroli, India.[6,7] The distribution of neonates by birth weight and period of gestation in the preintervention year, percent case fatality (CF) and the proportion of deaths contributed are presented in Table 1. Nearly 42% neonates were LBW, with a mean 11.3% CF. Of the total neonatal deaths, 90% occurred in the LBW neonates. The 9.8% of neonates were born preterm, experienced high (33%) CF and they accounted for 62.5% of total neonatal deaths. Table 1 also shows that the CF in neonates with birth weight >2500 g was 0.2%, in IUGR neonates it was 4.4% and in preterm neonates it was 40.3%.

The estimated population attributable risk (PAR) of death in this cohort was 0.74 for preterm birth and 0.55 for IUGR. However, analysis of deaths by associated morbidities also revealed that CF was low in LBW or preterm neonates without other associated morbidities. The CF progressively and steeply increased with the number of comorbidities, viz., sepsis, asphyxia, hypothermia and feeding problems, complicating the LBW or preterm birth.[8] We also estimated that PAR for sepsis was 0.55; for asphyxia 0.35; for hypothermia 0.08 and for feeding problems 0.04. Based on this analysis and practical common sense, we proposed that if LBW and preterm births cannot be prevented, an alternative approach could be to manage them by preventing and treating comorbidities. We hypothesized that by using this approach, the HBNC would substantially improve neonatal survival including the survival of LBW or preterm neonates.[8]

Table 1 The Baseline Incidence and CF in Different Birth Weight and Gestation Strata and Percent of Total Deaths (1995–1996, $n = 763$, deaths $= 40$)

Characteristic	% Incidence	% CF	Proportion of total deaths (%)
(a) Birth weight (g)[$]			
≥2500	54.7	0.2	2.5
< 2500	41.9	11.3	90.0
2000–2499	32.2	3.7	22.5
1500–1999	8.0	29.5	45.0
<1500	1.7	69.2	22.5
Not recorded	3.4	11.5	7.5
Preterm LBW*,†	8.6	40.3	62.5
IUGR‡ LBW†	34.9	4.4	27.5
(b) Gestation (weeks)[$]			
≥37	88.2	2.1	35.0
<37	9.8	33.3	62.5
35–36	6.0	21.7	25.0
33–34	2.4	33.3	15.0
<33	1.4	81.8	22.5
Not recorded	2.0	6.7	2.5
Preterm ≥2500 g†	1.4	0.0	0.0
Preterm <2500 g†	8.6	40.3	62.5

[$]a and b are the two classifications of the same 763 neonates.
*Low birth weight.
†Denominator 725 neonates because of missing gestation or birth weight data in some.
‡Intrauterine growth restriction.

The objective of this paper is to evaluate the feasibility and effectiveness of HBNC in the management of LBW or preterm neonates in the Gadchiroli field trial, and to explain the effect.

METHODS

The area, study design, data collection, preintervention morbidities and the HBNC interventions have been described elsewhere.[7–13] Here we shall only describe the relevant salient points.

Home Visiting

Resident women with 5 to 10 years of school education were selected, usually one each in 39 intervention villages (total population 39,312) and trained as village health workers (VHWs). Each VHW registered the pregnant women in her village, usually in the 4th month of pregnancy. Using a cultural calendar, she determined the date of the onset of last menstruation by asking the history, and calculated the expected date of delivery. Most of the women delivered at home, with delivery conducted by traditional birth attendants (TBA). The VHW also attended the delivery. On the day of birth, she determined the period of gestation based on the expected date of delivery that she had earlier calculated and recorded. Less than 37 weeks of gestation was called preterm birth. She recorded all information on a printed mother–neonate record.

The VHW weighed the newborn, usually within 1 to 6 hours after birth. When she was not present at birth, she visited and weighed the baby almost always within 24 hours. She used a spring balance (Salter) of 0 to 5 kg range with a discriminatory power of 25 g. The instrument was adjusted and corrected for the "zero error" every time the weight was measured and was tested for accuracy once in 3 months by weighing the standard weights. In case of hospital delivery, she used the birth weight recorded in hospital.

Based on the data on a cohort of 763 neonates in the preintervention year, we identified the presence of any one or more of the following as predictors of the risk of neonatal death: birth weight <2000 g, gestation <37 weeks, or baby not taking feeds on the first day.[13] Such high-risk neonates received more care from VHWs.

The VHW revisited the mother and neonate on days 2, 3, 5, 7, 15, 21 and 28. The visits to "high-risk" neonates were increased starting in 1999, with additional visits on days 4, 6, 9, 12, 18 and 24. The baby was weighed every week, and finally on day 28. The total weight gain during the neonatal period was calculated from these observations. Weight gain <300 g during the neonatal period was defined as ''inadequate weight gain'' because it predicted a risk of death in the 2nd month of life.[6]

Apart from the visits on the fixed days, VHWs made additional visits on any other day if the parents informed her that their baby was sick. The neonates were monitored by the VHWs until day 28 or until the mother and baby left the village or the baby died, whichever was earlier.

Interventions

The interventions for the management of LBW and preterm neonates are described in Box 1.

A supervisory physician (SBB) made visits to each village and to each neonate once in 15 days. He checked and corrected the records, the findings and the care given by the VHW and the family. From 2001, two VHWs were promoted to become field supervisors, with the physician overseeing their work.

From 1999, we introduced three additional measures: (1) The VHWs were introduced to kangaroo mother care[14] and were asked to teach it to mothers if the baby was hypothermic in spite of the HBNC. (2) An evaluation form was introduced to evaluate the HBNC care to each neonate, to be completed by the supervisor on the 28th day. (3) The VHWs were advised to refer to hospital (government hospital or SEARCH hospital) any neonate with sepsis who did not respond to treatment with antibiotics within 24 hours,

Box 1 Interventions in the home-based management

1. *Health education*: To all mothers
   - In group: All pregnant women in a village received 2 hours group health education, once in 4 months.
   - Individually (45 minutes) given by VHW using a flip chart twice during pregnancy, and on the second day after delivery.
   - The families with a high-risk neonate (preterm or birth weight <2000 g or difficulty in feeding on the first day) received a printed pamphlet and instructions for special care.
2. *Thermal care*:
   - Encouraged to use baby clothes and head wears.
   - All high-risk or the hypothermic neonates (axillary temperature <95°F), after initial warming by heated cloth, were covered in a blanket and put in sleeping bag.
   - Families were advised not to bathe high-risk or hypothermic neonates at least till 7th day.
   - The room was kept heated by fire.
3. *Breast feeding*:
   - Early initiation of breastfeeding within 6 hours after birth and exclusive breastfeeding.
   - The VHW educated mother by assisting in proper position, and attachment.
   - She managed breast problems (engorged breast or insufficient milk) by encouraging continued and repeated breastfeeding, and if necessary, by extracting breast milk and feeding with a spoon. VHWs were given a special traditional Indian spoon (*palade*), which has a long beak and facilitates feeding a baby who does not suck vigorously.
   - High-risk babies were given 2-hourly breast or spoon-feeding.
   - If mother had insufficient milk, breast milk was supplemented by boiled cow milk.
   - A breastfeeding monitoring form was introduced from the year 2000 for the babies who had problems in breastfeeding
4. *Prevention and management of infections*:
   - Hand washing by mothers.
   - Avoiding contact with persons with manifestations of infection.
   - Cleanliness of clothes and the hygiene in delivery room.
   - Putting tetracycline ointment in the eyes of every neonate at birth.
   - Cord care by keeping it clean, dry and applying gentian violet (1%).
   - Skin care — by keeping skin clean and dry.
   - Treating skin infections (pyoderma, intertrigo) with gentian violet.
5. *Management of neonatal sepsis*:
   - All neonates were monitored for the signs of sepsis. Sepsis was diagnosed by VHWs clinically, by using specific criteria.
   - Treatment with two antibiotics.
   - Supportive care (i.e. home visits, advice, thermal care and assistance in breast feeding)
   - If parents refused treatment with antibiotics, the baby received only supportive care.
6. *Vitamin K injection, 1 mg to all neonates*
7. *Referral*:

Those neonates whose feeding or temperature could not be maintained in spite of the home-based interventions, or those with sepsis who did not respond within 24 hours of starting antibiotics were to be referred to the hospital. However, it was up to the parents to act upon this.

any neonate who was persistently hypothermic in spite of home-based care or could not be breastfed or spoon-fed at home.

The interventions and the results up to March 31, 2003 are included in this analysis.

Analysis

The HBNC interventions were introduced incrementally from April 1996 and the full package from 1997. A computer algorithm applied clinical definitions to the data on newborns collected by the VHWs. The incidence of various comorbidities was estimated from these.

A separate vital statistics surveillance system, evaluated to be 98% complete, recorded all births and neonatal deaths in the 39 intervention and the 47 control villages.[9,11] The proportion of neonates born in 39 villages who were covered by the HBNC was estimated by comparing their number with the live births registered by this system. The estimated number of neonatal deaths was also based on the information collected by this system.

Figure 1 is a flow diagram showing different categories of neonates, and the type of care they received in different years of the trial.

Without our planning for it, a before–after and concurrent comparison was available in this trial. Some LBW and preterm neonates had received only supportive care, while some had received supportive care plus antibiotics (Figure 1). Their CF in the preintervention period (1995 to 1996) and in the intervention years (1996 to 2003) was available. To estimate the contribution of supportive measures (home visiting, breastfeeding, thermal care, Vitamin K, health education) and of the treatment with antibiotics in reducing CF, we compared the reduction in CF separately for the IUGR-LBW and the preterm-LBW neonates with sepsis and without sepsis, and estimated the absolute reduction in the CF. (a) The reduction in CF in neonates without sepsis or in neonates with clinical sepsis but who did not receive antibiotics was considered as the effect of the supportive measures. (b) The reduction in CF in LBW and preterm neonates with sepsis who received antibiotics was considered as the effect of supportive measures + antibiotics. The supportive measures being common in both groups, the net difference in the two reductions (a and b) was estimated as the effect of antibiotics.

χ^2 test with Yate's correction was used for estimation of significance.

Ethical Review

An external group of pediatricians, neonatologists and public health management experts advised and reviewed the study at three points in time and gave ethical clearance. Written consent was taken from the parents of the neonates with sepsis for home-based management.

RESULTS

In the preintervention year, 763 neonates in 39 villages were studied. Their distribution by birth weight and period of gestation

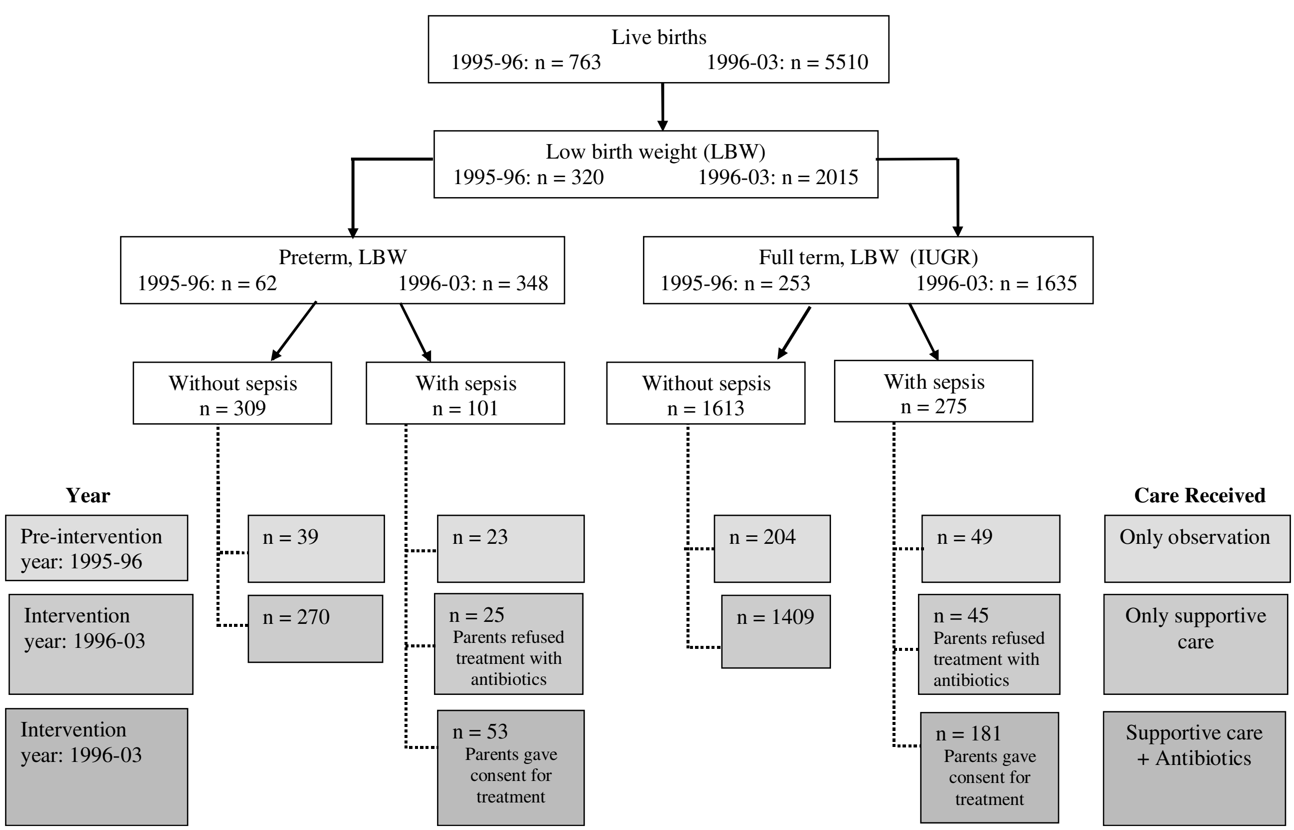

Figure 1. Low birth weight neonates and different types of care received (1995 to 2003).

and the CF in different strata are presented in Table 1. The number of neonates and their mean birth weight (in parenthesis) in different gestational groups was as follows: <32 weeks, 11 (1484 g); 33 to 34 weeks, 15 (1742 g); 35 to 36 weeks, 46 (2188 g); 37 to 38 weeks, 189 (2416 g); 39 to 40 weeks, 302 (2549 g) and >40 weeks, 162 (2613 g).

During the 7 years of intervention, 5919 live births occurred in the 39 intervention villages. The coverage of neonates by HBNC, the proportion detected LBW or preterm and the proportion of LBW or preterm who received home-based management are presented in Table 2. Out of the neonates born, 93% received HBNC, and 97% of the LBW/preterm babies were managed at home.

Number of neonates in different categories and the type of care they received in different years is presented in Figure 1.

Starting in 1999, the coverage and quality of home-based care to each neonate was evaluated on various indicators. The 19 indicators of the interventions or practices relevant to the management of LBW/preterm neonates and their coverage are presented in Table 3. Coverage of most of the indicators was in the range of 80 to 100%; it was <50% on three indicators: hand washing by mother, use of kangaroo care and advising referral.

The effectiveness of HBNC interventions in preventing LBW or preterm birth was evaluated by the change in the incidence of these two problems and has been reported elsewhere.[15] The incidence of preterm birth during different years from 1995 to 2003 remained almost constant, at nearly 10%. The incidence did not vary significantly in any of the gestation substrata as well.

Mean birth weight increased from 2472 g in 1995 to 1996 to 2584 g during 2000 to 2003 (+112 g), and the incidence of LBW decreased from 41.9 to 35.2%, a net decrease of 16%, which was highly significant. The change was distributed in all birth weight strata. The change in the mean birth weight and reduction in the incidence of LBW occurred mostly in neonates with IUGR. The incidence of IUGR (<2500 g and >37 weeks) decreased from 34.9% in 1995 to 1996 to 28.4% in 2000 to 2003.

The effect of home-based management on CF is presented in Tables 4 and 5. In preterm neonates (Table 4), the mean CF decreased by 69.5%, the highest decrease being in the 35 to 36 weeks group. In the <33 weeks group, in spite of a decrease, the CF remained high at 45%. In LBW neonates (Table 5), CF decreased by 58%. The decrease was most pronounced (67%) in neonates 2000 to 2499 g. The CF reached very low (1.2%), in neonates 2000 to 2499 g, but in the <1500 g group, it remained high, at 40%, in spite of a 42.2% decrease.

Further explanation of the improved survival of LBW/preterm neonates was sought in three effects: the incidence of comorbidities, the effect of managing sepsis with antibiotics and the effect of supportive care in LBW neonates.

Table 2 Coverage of Home-Based Care (1996–2003)

	No.	%
Total live births	5919	—
Home delivery	5387	91.0
Neonates provided home-based care	5510*	93.0
Birth weight measured	5454†	99.0
Identified as low birth weight	2015	36.9
Gestation determined	5429	98.5
Identified as preterm	533	9.8
LBW/preterm‡ neonates	2199	39.9
LBW/preterm‡ neonates hospitalized/received referral care	62	2.8
LBW/preterm‡ neonates received only home-based care	2137	97.2

*Some of the hospital born neonates returned to the villages and provided home-based care.
†Birth weight on hospital born neonates became available from hospital records.
‡Low birth weight or preterm or both.

Table 3 Coverage and Quality of Selected Home-Based Interventions for the Management of LBW/preterm* Neonates: 1999–2003 (total neonates = 3245, LBW/preterm* neonates = 1219)

	Indicators of care or practice	%†
1.	Health education twice in pregnancy and once after delivery	95.5
2.	VHW‡ present at delivery	75.4
3.	Correct identification of high-risk§ baby	94.8
4.	Gave high-risk baby care pamphlet to family	95.8
5.	Proper thermal care by family	97.5
6.	Care for hypothermia properly provided by VHW	92.9
7(a).	Initiation of breastfeeding within 1 hour¶	60.7
7(b).	Initiation of breastfeeding within 6 hours¶	94.8
7(c).	Initiation of breastfeeding within 24 hours¶	99.9
8.	Feeding problems managed by VHW	95.4
9.	Babies not sucking advised referral by VHW	48.3
10.	Does mother hold baby properly while feeding?¶	98.1
11.	Did mother wash hands before feeding?¶	19.5
12.	Were mother's nails clipped?¶	95.8
13.	Did parents call VHW within 24 hours, when baby had health problems?¶	68.9
14.	Did VHW diagnose sepsis correctly?¶	94.0
15.	Did VHW treat sepsis correctly?¶	95.3
16.	If necessary‖, Kangaroo care method used?¶	12.5
17.	Weight measured each week for four weeks¶	86.9
18.	Weight increased by more than 300 g in 28 days¶	84.9
19.	Second month high-risk baby correctly diagnosed	84.4
	Mean of 19 indicators	80.5

*Low birth weight or preterm or both.
†The relevant denominator used varies for different indicators.
‡Village health worker.
§Preterm or <2000 gm or breastfeeding problem on the first day.
¶Among low birth weight or preterm or both cases.
‖If a LBW or preterm neonate was persistently hypothermic.

Table 4 Effect on CF in Different Gestational Groups: 1995–2003

Gestation period (weeks)	% CF						% Change 1995–1996 to 2000–2003	p
	1995–1996		1996–2000		2000–2003			
	(Deaths = 40, n = 763)		(Deaths = 78, n = 3165)		(Deaths = 50, n = 2345)			
Full term (≥37)	(14/673)	2.1	(43/2813)	1.5	(26/2083)	1.2	−40.0	NS
Preterm (<37)	(25/75)	33.3	(31/307)	10.1	(23/226)	10.2	−69.5	<0.0001
35–36	(10/46)	21.7	(9/218)	4.1	(5/162)	3.1	−85.8	<0.0002
33–34	(6/18)	33.3	(7/52)	13.5	(3/31)	9.7	−71.0	<0.05
<33	(9/11)	81.8	(15/37)	40.5	(15/33)	45.5	−44.4	NS
Not recorded	(1/15)	6.7	(4/45)	8.9	(1/36)	2.8	−58.3	NS
Total	(40/763)	5.2	(78/3165)	2.5	(50/2345)	2.1	−59.3	<0.0001

NS = nonsignificant.

Table 5 Effect on CF in Different Birth Weight Groups: 1995–2003

Birth weight	% Case fatality						% Change (1995–1996 to 2000–2003)	p
	1995–1996		1996–2000		2000–2003			
	(Deaths = 40, n = 763)		(Deaths = 78, n = 3165)		(Deaths = 50, n = 2345)			
≥2500 g	(1/417)	0.2	(14/1925)	0.7	(9/1514)	0.6	+147.9	NS
<2500 g	(36/320)	11.3	(59/1190)	5.0	(39/825)	4.7	−58.0	<0.0002
2000–2499 g	(9/246)	3.7	(18/943)	1.9	(8/658)	1.2	−66.8	<0.0300
1500–1999 g	(18/61)	29.5	(17/196)	8.7	(17/132)	12.9	−56.3	<0.0100
<1500 g	(9/13)	69.2	(24/51)	47.1	(14/35)	40.0	−42.2	NS
Weight not recorded	(3/26)	11.5	(5/50)	10.0	(2/6)	33.3	+188.9	NS
Total	(40/763)	5.2	(78/3165)	2.5	(50/2345)	2.1	−59.3	<0.0001

NS = nonsignificant.

Improved survival of preterm and LBW neonates was accompanied by a reduction in the incidence of comorbidities (Figures 2 and 3). In the LBW neonates, the incidence of sepsis, asphyxia and hypothermia decreased significantly. The incidence of feeding problems decreased by a smaller margin and was not significant. In the preterm neonates, the incidence of all four comorbidities decreased by almost half.

Effect of supportive care and of supportive care + treatment with antibiotics on CF in preterm-LBW neonates without sepsis and with sepsis is shown in Figure 4a. Similarly, the effect on CF in IUGR neonates is shown in Figure 4b. Among preterm-LBW neonates without sepsis, supportive care alone resulted in a significant reduction in CF. By contrast, supportive care alone did not result in a significant reduction in CF among preterm-LBW neonates with sepsis. In this group, CF was significantly reduced, from 61 to 13%, in those who received treatment with antibiotics + supportive care. Similar pattern was observed for the LBW-IUGR neonates as well.

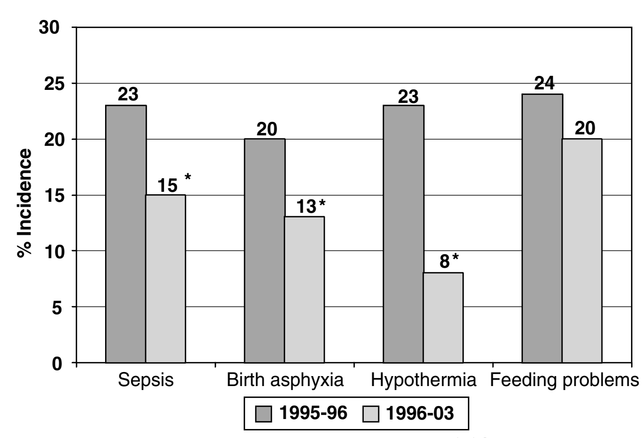

Figure 2. Effect on the incidence of comorbidities in low birth weight neonates: 1995 to 1996 vs 1996 to 2003.

As shown in Figure 1, different groups received different care in different years. The effect on CF of only supportive care, and of

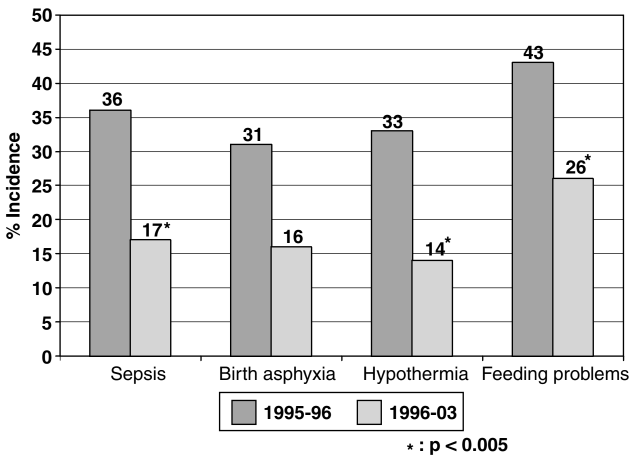

Figure 3. Effect on the incidence of comorbidities in preterm neonates 1995 to 1996 vs 1996–2003.

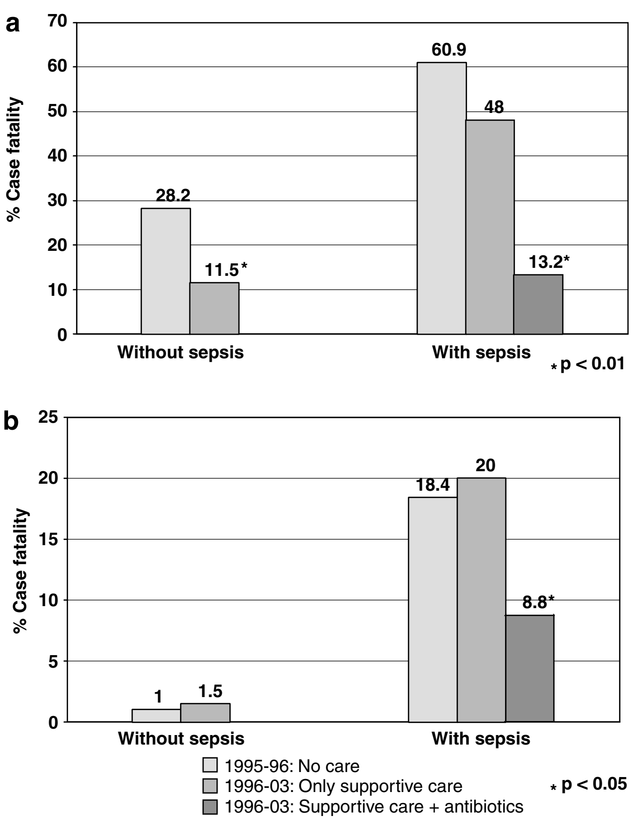

Figure 4. Effect of supportive care and treatment with antibiotics on CF among the low birth weight neonates: (1995 to 2003). (**a**) Preterm, low birth weight neonates and (**b**) full term, low birth weight (IUGR) neonates.

supportive care plus antibiotics, is presented separately for the preterm-LBW and the IUGR-LBW neonates in Table 6. Based on the absolute reduction in %CF, we have also disaggregated the effect of antibiotic therapy from the effect of supportive care. It is estimated that supportive care to all preterm-LBW neonates prevented total 55 deaths, accounting for 75% of the reduction in mortality; and the treatment with antibiotics contributed 25% of the total reduction. However, in the IUGR-LBW neonates, supportive care did not contribute to the reduction, and all prevented deaths (17) were attributed to the effect of treatment with antibiotics in IUGR neonates with sepsis.

The mean weight gain in LBW neonates during the neonatal period (1 to 28 days) did not show improvement; it was 566 g in 1995 to 1996, and 549 g during the intervention years (1996 to 2003). In preterm neonates, these values were 436 and 475 g, respectively.

DISCUSSION

In the 7 years of interventions in the field trial in rural Gadchiroli, 5510 newborns were managed at home, including 2015 LBW and 533 preterm neonates. With a resident VHW in each village, it was feasible to assess the neonates at birth and to identify LBW or preterm neonates and manage them at home with high coverage and quality. We observed no change in the incidence of preterm births and a modest (16%) but significant reduction in the incidence of LBW, mostly IUGR. On the other hand, the home-based management reduced the CF by nearly 60% for LBW and by nearly 70% for preterm neonates. Thus, the majority of the LBW or preterm neonates born in rural Gadchiroli could be effectively managed at home. A small proportion would still need referral.

Based on the preintervention data, we proposed a hypothesis that if the incidence of LBW/preterm could not be prevented, survival could still be improved by prevention/management of comorbidities, especially infection, in the LBW/preterm neonates.[8] The results of this study support this proposition. This is in line with the principles of managing LBW/preterm neonates in hospital. The essential approach is to prolong survival by preventing comorbidities and ensuring initiation of respiration at birth as well as feeding, warmth and protection from infection. We have applied the same principles in the home setting by training a VHW and mothers, with highly promising results.

Three factors explained the reduction in CF. First, there was a substantial decline in the incidence of comorbidities such as sepsis, asphyxia, hypothermia and feeding problems. Second, treatment with antibiotics in suspected sepsis contributed all of the observed decline in CF in the IUGR-LBW neonates, while in the preterm-LBW neonates, antibiotics therapy for the suspected sepsis contributed 25%, and third, the supportive care contributed 75% of the observed reduction in deaths in preterm LBW neonates. Overall, supportive care (home visiting, breastfeeding, thermal care) averted 55 deaths and treatment with antibiotics averted 35 deaths in LBW neonates.

This is a before–after comparison between the preintervention and the intervention years without an untreated control group. It would be unethical to detect LBW/preterm neonates in the control area and do nothing for them. However, we monitored the NMR

Table 6 CF in 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	NS	12	48.0	<0.005‡	12.9	3
With sepsis	1996–2003	Antibiotics+supportive care	53	244		7	13.2		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%)

Group	Year	Intervention	Neonates	Mean gestation (days)	*p*	Deaths	% CF	*p*	Absolute reduction in % CF*	Deaths prevented in 1996–2003†
(2) *Full term, 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	NS	9	20.0	<0.05‡	−1.6	0§
With sepsis	1996–2003	Antibiotic+supportive care	181	275		16	8.8		9.6	17
Total	—	—	—			—	—	—	—	17

Deaths prevented by treatment with antibiotic = 17
Deaths prevented by supportive care = 0
Percent contribution of antibiotics to total number of prevented deaths = 17/17 = 100%

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

and the IMR in the control area. As reported elsewhere, the NMR and IMR in the control area remained unchanged during the years of interventions.[16] As LBW and prematurity are the most important determinants of the NMR and the IMR, we can assume that the incidence and mortality due to LBW/preterm was unchanged in the control area and, hence, the observed changes in mortality in the intervention area can be attributed to the HBNC interventions.

Was the estimated gestation period correct? The period of gestation was estimated by VHWs on the basis of history given by pregnant women. The estimated mean duration of gestation remained consistent (276 days) during the different years (not presented). The mean birth weight progressively increased with the increase in the period of gestation (results: text). Moreover, a pronounced effect of the degree of prematurity was seen on CF (Table 4). These facts indirectly validate the estimated period of gestation. The early recording (usually in the 4th month of pregnancy) of the date of last menstruation by the VHWs who were women from the same village and culture may be one possible explanation of relatively reliable estimation of the period of gestation in our study.

No change occurred in the incidence of preterm birth. This is consistent with the conclusion drawn by the reviewers of various other intervention trials.[17] Generally, no effective intervention to prevent preterm birth is yet available.

The only preventive intervention against LBW was health education during pregnancy to overcome the voluntary ‘‘eating down'' prevalent in Gadchiroli[11] as well as in South Asia.[18] The mean birth weight increased by 112 g and the incidence of LBW declined by 16%, entirely due to reduction in the incidence of IUGR. Since no food supplements were given during this trial, the observed decline in the incidence of LBW suggests that nutrition education during pregnancy may have partly overcome the ''eating down'' practice. However, we did not measure the dietary intake in pregnancy and hence cannot test this.

Tables 2 and 3 show the feasibility of providing various HBNC interventions at a high coverage. This demonstrates the high acceptance by families and the potential of service delivery by VHWs. However, a few indicators, such as hand washing by mothers, referral to hospital or kangaroo mother care showed low coverage. The kangaroo mother care method has been reported to successfully reduce morbidities and CF in LBW/preterm neonates.[1,14] However, a recent review concluded that the quality of studies was unsatisfactory, and there is no conclusive evidence to recommend it.[19] Moreover, it has so far been used only in hospitals. We did not find good acceptance in our population (Table 3). A community-based trial in Bangladesh is currently underway (N. Sloan, personal communication).

In all, 2.8% LBW/preterm neonates (62/2199) received referral/hospital care (Table 2). CF in these 62 neonates was 22.6%.

Comparison with Other Experiences

In our study, the main change occurred in CF, which decreased by nearly 60 to 70%. It occurred in all birth weight or gestational strata, although by varied margins (Tables 4 and 5). How do these results compare with experiences elsewhere?

In an earlier field trial of detection and management of high-risk neonates in villages near Pune, India, LBW or preterm neonates were managed by better care at home and by referral.[20] Although the authors do not present separate data on the CF in the neonates managed at home, the CF in the LBW neonates (<2500 g) during the intervention period was reported to be 16% and in preterm neonates (<37 weeks) to be 35%. In comparison, CF in the Gadchiroli trial was much lower, that is, 5% for LBW and 10% for preterm. These differences were probably due to the treatment of infections by VHWs and relatively well-developed methods of health education and home-based management in the Gadchiroli trial.

In a feasibility trial conducted in rural north India nearly two decades ago, the LBW infants having suspected pneumonia were treated with oral penicillin. The CF in the intervention area was reported to be 8.7 vs 24.6% in the control area, and a 20% reduction in infant mortality rate was recorded. However, the study group included infants up to the age of 1 year, and the difference in the study and the control area was not significant.[21]

Comparison with the outcome of neonatal care in hospitals is difficult. Hospitalized neonates are likely to be selectively sicker. However, neonates born by hospital deliveries are less likely to be a selected population. A national database from 17 hospitals in India reports on nearly 50,000 hospital born neonates in the year 2000, among whom the NMR was 30 per 1000 live births and 33% of neonates were LBW,[22] very similar to the proportions among the neonates in Gadchiroli trial during intervention. The reported CF in different birth weight strata was also comparable (Table 7).

Although the effectiveness of the HBNC package in Gadchiroli in reducing the CF is satisfactory, nonetheless, a selected high-risk neonates had a high case fatality and needed hospitalization. These were:

1. <33 weeks gestation (CF 45.5%).
2. <1500 g birth weight (CF 40%).
3. LBW/preterm neonates whose feeding or body temperature could not be maintained at home.
4. LBW/preterm with sepsis who did not respond to treatment with antibiotics.

Similarly, although CF declined, the mean weight gain during days 1 to 28 did not substantially increase in either LBW neonates (566 vs 549 g) or preterm neonates (436 vs 475 g). These findings suggest the need for better strategies to feed preterm and LBW neonates.

Further research on home-based management of LBW/preterm neonates should focus on the application of the kangaroo mother care method in home settings, improved techniques of feeding in homes and developing a model of first-referral-level neonatal care for managing neonates who cannot be managed by HBNC. Apart

Table 7 Case Fatality in LBW Neonates in Hospitals in India and in Gadchiroli Trial

	National database (year 2000)*		Gadchiroli trial (2000–2003)	
Birth weight (g)	*n*	CF (%)	*n*	CF (%)
<1500	1,832	40.8	35	40.0
1500–1999	3,662	7.5	132	12.9
2000–2499	10,899	2.0	658	1.2

*National Neonatology Forum of India: National Neonatal Perinatal Database.[22]

from ensuring their survival, their weight gain in neonatal period needs to be improved so that they enter into the postneonatal period with less risk of death.

SIGNIFICANCE

The LBW and preterm births are associated with most of the mortality and a major proportion of morbidity in the neonatal period, and the importance of their prevention is undisputed. However, as long as we do not have effective methods of primary prevention, then secondary prevention, that is, case management and to increase the survival, is the practical option. The overwhelming effect of supportive care and treatment with antibiotics on mortality and morbidities observed in this trial suggests that the current situation of lack of care at home for needy neonates must change.

The significance of the results of this study is underscored by the fact that globally nearly 20 million LBW neonates are born each year, and that hospital-based care is not available to most of them. The cost of hospital-based care for LBW or preterm neonates is prohibitively high. In South Asia, where nearly one-third of neonates born are LBW, such a large load — nearly 11 million LBW neonates — can be possibly managed only by home-based care. We report the time inputs and cost required for providing HBNC elsewhere.[23]

This paper reports the efficacy of the HBNC approach in 39 villages. However, the major challenge is to provide such care on larger scale, as a part of the regular health services. Methods for scaling need to be developed, and effectiveness of HBNC in the health services setting need to be tested. We discuss this challenge in more detail elsewhere.[23]

IUGR-LBW babies are usually born in families who are poor and marginalized. Access to hospital is particularly difficult for these families. Thus, the LBW neonates represent probably the most disadvantaged and vulnerable group even within underdeveloped countries. The approach of home-based management can be a major step toward equity.

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Original Article

Management of Birth Asphyxia in Home Deliveries in Rural Gadchiroli: The Effect of Two Types of Birth Attendants and of Resuscitating with Mouth-to-Mouth, Tube-Mask or Bag–Mask

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OBJECTIVES:

To evaluate the effect of home-based neonatal care on birth asphyxia and to compare the effectiveness of two types of workers and three methods of resuscitation in home delivery.

STUDY DESIGN:

In a field trial of home-based neonatal care in rural Gadchiroli, India, birth asphyxia in home deliveries was managed differently during different phases. Trained traditional birth attendants (TBA) used mouth-to-mouth resuscitation in the baseline years (1993 to 1995). Additional village health workers (VHWs) only observed in 1995 to 1996. In the intervention years (1996 to 2003), they used tube-mask (1996 to 1999) and bag-mask (1999 to 2003). The incidence, case fatality (CF) and asphyxia-specific mortality rate (ASMR) during different phases were compared.

RESULTS:

During the intervention years, 5033 home deliveries occurred. VHWs were present during 84% home deliveries. The incidence of mild birth asphyxia decreased by 60%, from 14% in the observation year (1995 to 1996) to 6% in the intervention years ($p<0.0001$). The incidence of severe asphyxia did not change significantly, but the CF in neonates with severe asphyxia decreased by 47.5%, from 39 to 20% ($p<0.07$) and ASMR by 65%, from 11 to 4% ($p<0.02$). Mouth-to-mouth resuscitation reduced the ASMR by 12%, tube–mask further reduced the CF by 27% and the ASMR by 67%. The bag–mask showed an additional decrease in CF of 39% and in the fresh stillbirth rate of 33% in comparison to tube–mask (not significant). The cost of bag and mask was $13 per averted death. Oxytocic injection administered by unqualified doctors showed an odds ratio of three for the occurrence of severe asphyxia or fresh stillbirth.

CONCLUSIONS:

Home-based interventions delivered by a team of TBA and a semiskilled VHW reduced the asphyxia-related neonatal mortality by 65% compared to only TBA. The bag–mask appears to be superior to tube–mask or mouth-to-mouth resuscitation, with an estimated equipment cost of $13 per death averted.
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INTRODUCTION

The World Health Organization (WHO) estimates that globally, between four and nine million newborns suffer birth asphyxia each year. Of those, an estimated 1.2 million die and almost the same number develop severe consequences.[1] The WHO also estimates that globally, 29% of neonatal deaths are caused by birth asphyxia.[2] In addition, a sizable proportion of stillbirths are caused by asphyxia. Wiggleworth's classification of perinatal deaths equates fresh stillbirths with birth asphyxia,[3] and this was validated by a prospective study in the UK.[4] Thus, birth asphyxia or perinatal asphyxia is a huge global problem with fresh stillbirth, neonatal death and long-term neurodevelopmental problems as its main serious outcomes.

Ellis and Manandhar, based on a literature search of published studies from 20 developing countries in the previous 15 years, estimate that 24 to 61% of perinatal mortality was attributable to asphyxia. The cause-specific perinatal mortality rate associated with asphyxia was generally between 10 and 20 per 1000 births.[5]

Perinatal asphyxia can result from inadequate supply of oxygen immediately before, during or just after delivery. Apart from fetal hypoxia, conditions such as prematurity or congenital anomaly can also result in a failure to establish adequate breathing at birth and manifest as ‘‘asphyxia’’. In the field setting in developing countries intrapartum monitoring or the finer clinical observations at birth, such as heart sounds, heart rate or presence of umbilical arterial pulsation, are not available on home-delivered neonates. In

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such situation, it is impossible to classify or diagnose the cause in a neonate depressed at birth. One practical solution to this problem is to use the term ''birth asphyxia'' for the clinical condition of failure to initiate or maintain regular breathing at birth and hence requiring resuscitation. This does not relate to the cause. The outcome can be (i) a freshstill birth, or a severely asphyxiated neonate who is not resuscitated and hence counted as ''fresh stillbirth'', (ii) an asphyxiated live neonate who can subsequently die during neonatal period (asphyxia-related mortality), (iii) survive with neurological disability or (iv) survive as a normal infant.

The estimated incidence of the problem depends upon how it is defined and measured. The Apgar score is the common method used in hospitals. For the community setting, the National Neonatology Forum of India has suggested, ''gasping and ineffective breathing or lack of breathing at one minute after birth''[6] and it has been equated with an Apgar score of three or less.[7] Almost all available estimates of asphyxia in home-delivered neonates used retrospective inquiry to the family about the description of the events at birth.[8,9] The validity of such estimates is doubtful.

In what is probably the first ever prospectively observed epidemiologic study of home deliveries and neonates in the community, we found the incidence of mild birth asphyxia to be 14.2% and of severe asphyxia to be 4.6% in the observational year, 1995 to 1996 in the field trial of the home-based neonatal care in Gadchiroli, India.[10,11] Mild and severe asphyxia were mutually exclusive categories. Mild asphyxia was defined as no cry, or breathing absent or slow, weak or gasping, at 1 minute after birth. Severe asphyxia was defined as breathing absent or slow, weak or gasping at 5 minutes after birth. (See Table 1 for the incidence and the mortality associated with asphyxia in this year.) The case fatality (CF) in mild asphyxia was low, and it was not associated with the risk of mortality (relative risk (RR), 0.5) but severe asphyxia had an RR of 8.0. The primary cause of death was assigned by an independent neonatologist. The asphyxia-specific mortality rate (ASMR) was 10.5/1000 live births when the NMR was 52/1000 live births in 1995 to 1996.[12]

We have also estimated the population attributable risk of asphyxia in Gadchiroli in 1995 to 1996 to be 0.35, next only to preterm birth (0.74), intrauterine growth restriction (0.55) and sepsis (0.55).[13]

The field trial of home-based neonatal care in Gadchiroli included management of birth asphyxia as a part of the package of home-based interventions. The interventions were introduced against a background of the morbidity and mortality described above and were continued from 1996 through 2003. The objectives of this article are:

1. To evaluate the effect of the home-based management of birth asphyxia. We selected the following indicators for evaluation:
   - (i) Proportion of home deliveries in which the trained village health worker (VHW) was present.
   - (ii) Incidence of birth asphyxia — mild and severe;
   - (iii) CF in severe asphyxia;
   - (iv) ASMR;
   - (v) fresh stillbirth rate (SBR).
2. To compare the effectiveness of the two sets of birth attendants, only traditional birth attendant (TBA) and the TBA plus VHW, and the three methods of resuscitation used in the field trial, namely, mouth-to-mouth breathing by the TBAs, tube and mask used by trained VHWs, and bag and mask used by trained VHWs.

The comparisons were made before–after (1995 to 1996 vs 1996 to 2003) for the most part. For a few outcomes, it was with the concurrent control area.

MATERIALS AND METHODS

The area, available health care, study design, and data collection methods in the field trial of home-based neonatal care have been earlier described.[10,14–16] Here we describe only the salient points in relation to the measurement of indicators and the management of birth asphyxia.

Data collection

SEARCH (Society for Education, Action and Research in Community Health) had selected an intervention and a control

Table 1 Birth Asphyxia in 1995–1996: The Baseline

	Incidence		Case fatality		RR	Mortality rate
	Cases/neonates	%	Deaths/cases	%		
Mild asphyxia*	81/570	14.2	3/81	3.7	0.5	—
Severe asphyxia†	26/570	4.6	10/26	38.5	8.0	—
Asphyxia specific mortality rate/1000 live births	—	—	—	—	—	10.5

*At 1 minute after birth, no cry, or the breath was absent or slow, weak or gasping.
†At 5 minutes after birth, the breath was absent or slow, weak or gasping.
RR = relative risk of death.

area in the Gadchiroli district, India, in 1988, and established a vital statistics surveillance system by using male VHWs and male field supervisors.[15,17] Trained field supervisors conducted "verbal autopsy" by visiting families where there had been the death of a child or a stillbirth. The criteria for diagnosing cause of death by verbal autopsy and the results of the cause of death have been published.[17,18] This verbal autopsy was continued until 1999, when it was stopped. Because nearly 95% births occurred at home, attended by TBAs, we had trained the TBAs in the intervention villages in 1988 in safe and hygienic home delivery, and in mouth-to-mouth resuscitation of babies who failed to cry or breathe at birth.[17,19]

The field trial of home-based neonatal care was conducted in this area from 1993 to 1998. During 1993 to 1995 only the baseline vital statistics were collected in 39 intervention and 47 control villages in which TBAs conducted most of the deliveries. In 1995 to 1996, female VHWs were trained in the intervention area. They attended home deliveries conducted by the TBAs in their villages and observed newborns at 1 and at 5 minutes after birth, and by making eight subsequent home visits.[11,14] They recorded the data about pregnancy, delivery and newborn on a mother–newborn printed record that was checked in the field by a visiting physician.

To determine the causes of deaths in children, the verbal autopsy was continued in the intervention and the control areas from 1988 to 1999. The ASMR was estimated from these data. In addition, from 1995, the prospectively observed mother–newborn records of the neonatal deaths in the intervention area were reviewed by an independent neonatologist (VK Paul, Department of Pediatrics, All India Institute of Medical Sciences, New Delhi) who assigned the most probable primary cause of death.[12] The ASMR was estimated from these data. The method used to estimate the ASMR (verbal autopsy or neonatologist) was specified.

The data from the records of neonates observed by the female VHWs were computerized. Using the definitions described in the Introduction section, a computer algorithm diagnosed mild and severe birth asphyxia.[10,11]

Stillbirths were recorded by the vital statistics surveillance system as well as by the female VHWs who attended home deliveries and were verified by supervisors by visiting the family. Stillbirth was defined as a birth (completed 28 weeks gestation) in which the fetus did not breathe or cry or show movement of chest or limbs at birth. The weight of the stillborn fetus was not measured. The VHWs observed and recorded the stillborn fetus as "fresh" or "macerated" from 1996 onwards. Using our definition, a "fresh stillbirth" could include an intrapartum fetal death or a severely asphyxiated neonate who did not cry or breathe, and who could not be resuscitated, and hence was considered as a fresh stillbirth. Due to this definition, the intervention of resucitation at birth could theoretically reduce the fresh SBR.

Using these data in the intervention area, the incidence of birth asphyxia (mild or severe), ASMR based on the birth asphyxia as the primary cause of death, and fresh SBR were estimated only in the intervention villages. These three estimates were not possible in the control area in the absence of prospectively observed data. The fresh SBR was estimated from 1996 to 2003.

Interventions

Different interventions during different periods and the available indicators are shown in Figure 1. Most home deliveries were attended by the TBAs. The VHWs were resident women of the village, with 5 to 10 years of schooling. After initial training and 1 year of observing home deliveries and neonates without intervention (1995 to 1996) they were trained in how to manage a baby at birth and how to manage those who did not cry or breathe at birth by following an algorithm (see Box 1). The training was given in a 3-day workshop, followed by review, practice and assessment in the next workshop 2 months later. Since the occasion to deal with an asphyxiated baby and the need for resuscitation occur only infrequently, their skills were kept up by way of drills practiced on dummy dolls every 2 months. From 1996, the VHWs took charge of newborns from the TBAs. The VHW cleaned immediately the mouth of the newborn and dried the skin with a clean cloth, diagnosed birth asphyxia and managed as shown in Box 1.

Box 1 Diagnosis and Management of Asphyxia by VHW

1. Be present at the time of birth.
2. Be prepared to face an asphyxiated baby in any delivery, but especially if the delivery is prolonged, obstructed or if the liquor is thick and green.
3. Record the exact time of birth. Start counting time.
4. Place baby on a clean cloth on a flat surface.
5. Clean the nose and mouth with a clean gauze.
6. Clean and dry the skin of the baby with a soft cloth.
7. At 60 seconds (1996 to 1999), or at 30 seconds (from 1999) examine the cry and respiration
   If both are present and vigorous — normal.
   If any one of the following is present: no cry or no breathing or weak breathing/gasping; diagnose as asphyxia and perform further steps.
8. Clean mouth, throat and nose with mucus extractor.
9. If baby did not yet cry/breathe, clamp and cut the umbilical cord.
10. Place the baby on a flat surface, with a folded cloth under shoulders to extend the neck.
11. Open the mouth. Place the mask on mouth and nose.
12. Ventilate lungs (tube and mask (1996 to 1999) or bag and mask (1999 to 2003)) 30 to 40 times a minute. Observe the chest expansion.
13. Stop and observe for spontaneous breathing once every minute.
14. Record the breathing at 5 minutes.
15. Stop ventilating either when the baby starts breathing spontaneously or if no breathing even at 15 minutes — declare as stillbirth.
16. Record all events, findings and outcome.
17. If a neonate was asphyxiated and ventilated at birth, consider it as a "high-risk" neonate and visit more frequently.

Period	Worker	Intervention / Equipment	Indicators available
1988 - 95	**TBA***	Cleaning of mouth **Mouth to mouth** resuscitation	1. ASMR$,based on verbal autopsy (1988- 99)
1995 - 96	**TBA** + VHW #	TBA as above VHW only observed and recorded	1. As above 2. Incidence of asphyxia 3. % Case fatality 4. ASMR$, based Primary cause of death
1996 - 99	**VHW** + TBA	An algorithm of how to manage birth asphyxia Cleaning face, drying skin with a cloth. Resuscitation started at 1 minute with **Tube and mask**	1 , 2 , 3 , 4 5. Fresh still birth rate
1999 - 03	**VHW** + TBA	Same algorithm Cleaning face, drying skin with a cloth. Resuscitation started at 30 seconds with **Bag and mask.**	2, 3, 4, 5.

* : Traditional birth attendant.
# : Village health worker.
$: Asphyxia specific mortality rate.
Note : The underline indicates the worker who managed asphyxia at birth, and the method/instrument used for resuscitation.

Figure 1. Management of birth asphyxia in different periods during 1988 to 2003, in Gadchiroli.

Equipment

The VHWs used room air for ventilation. The mucus extractor was of plastic, with a mucus trap and was disposable (Romson, India).

The tube and mask were made of silicon rubber, and had a safety valve to prevent excessive pressure (Phoenix, Chennai, India). Masks of two sizes were given to the VHW to be used according to the size of the baby. The price of the tube and mask was $10. Bag and mask (Phoenix, Chennai, India), of a size 280 ml, and with a price of $20 also had a safety valve. No drugs were used in resuscitation.

We introduced health education from 1997, provided by the VHW, to individual pregnant woman by using a flip chart and by way of the group health education session. The messages included need for antenatal check up and birth preparedness.

To encourage a VHW to be present during home delivery, she was paid by SEARCH an incentive ($1.00), if the TBA and the family confirmed her presence at the birth to the supervisors. VHWs could remain present in some of the hospital deliveries as well. From 2000, the government encouraged institutional delivery, and introduced a financial incentive of $15.00 if the woman delivered in a government institution (health subcentre manned by a nurse-midwife or in a hospital). The incentive money was paid to the family.

Private rural medical practitioners (usually unqualified) or nurses were often called by a family to ‘‘treat’’ the woman in labour. The ‘‘treatment’’ most often involved administering intravenous saline and oxytocics. Even in such cases, the actual delivery was conducted by a TBA and the neonate managed by a VHW.

Analysis

All data, vital statistics, mother–newborn records and treatment records, verbal autopsy reports were computer entered. They were analyzed by SPSS-PC + (Version 3) and Epi info (Version 5). The χ^2-test with Yate's correction was used for estimating the significance.

Consent and Ethical Clearance

Community consent was obtained from all 39 intervention villages in the form of a signed resolution. Every family was free to refuse the visit and the care provided by a VHW. An external advisory committee gave ethical clearance and monitored the trial.[14]

RESULTS

The intervention area included 39 villages in Gadchiroli, with a total population of 38,998 in 1994.

The number of deliveries, place of delivery and type of attendant at delivery in the intervention villages during 1995 to 1996 (without active intervention) and during 1996 to 2003 (with active interventions of home-based neonatal care) are presented in Table 2. Nearly 89 to 95% of deliveries were at home, almost all of them conducted by TBAs. The proportion of institutional deliveries increased from 5 to 10% during intervention period because of the incentive money offered by the government for institutional delivery. This increase occurred from the year 2000, and it may explain the proportion of caesarian deliveries increasing from 0.5 to 2%. The presence of a VHW at delivery also increased from 78 to 84%. The doctors called during home delivery were invariably unqualified private doctors who quickened the delivery by giving oxytocics.

The estimated incidence and mortality due to asphyxia in the intervention area during the year 1995 to 1996 are presented in Table 1. The incidence of mild asphyxia was relatively high, but it did not show association with risk of death. Severe asphyxia showed high CF (38%) and high association with the risk of death (RR 8.0). Out of the NMR of 52 per 1000 live births, 10.5, that is, approximately 20% was ascribed to asphyxia by the neonatologist. This became the preintervention baseline.

The effect of home-based neonatal care on the incidence of birth asphyxia during the 7 years of intervention is shown in Table 3. The incidence of mild asphyxia declined progressively and markedly but that of severe asphyxia did not change.

The effect of interventions on mortality indicators is presented in Table 4. Since mild asphyxia had no association with the risk of death, it was omitted. The table shows that the CF declined by nearly 50% ($p<0.07$) and the ASMR by 65% ($p<0.02$).

The comparison of the CF, ASMR and fresh SBR during the three types of resuscitation methods employed during different years is presented in Table 5. The ASMR declined significantly and equally with the tube and mask and the bag and mask. The CF and fresh SBR were substantially (though not significantly) less with the bag and mask as compared to

Table 2 Type of Delivery and the Attendance at Birth in the Intervention Area

	1995–1996		1996–2003	
	Number	%	Number	%
Total deliveries	782	—	5651	—
Live births	763	—	5510	—
Type of delivery (%)				
Institutional*	43	5.5	586	10.4
By caesarian section	4	0.5	71†	2.1†
Home	739	94.5	5033	89.1
Not recorded	0	0.0	32	0.6
Home deliveries conducted by TBA	680	92.0	4874	96.8
VHW present in home deliveries	574	77.7	4218	83.8
Doctor called at the time of home delivery	181	24.5	1269	25.2
Doctor gave injection at the time of home delivery (oxytocics)	171	23.1	1068	21.2

*Hospital, but during 1996 to 2003 also included health subcentres.
†Out of 3335 deliveries on which these data were available.
TBA = traditional birth attendant; VHW = village health worker.

Table 3 Effect of Home-Based Neonatal Care on the Incidence of Birth Asphyxia (Before–After Comparision in the Intervention Area)

	Incidence %				% Change 1995–1996 to 2000–2003	p
	Managed by TBA	Managed by VHW				
	1995–1996	1996–1998	1998–2000	2000–2003		
Mild asphyxia*	14.2	8.4	5.9	5.7	−59.9	<0.0001
Severe asphyxia†	4.6	2.4	3.7	4.9	+6.5	NS

TBA = traditional birth attendant; VHW = village health worker.
*At 1 minute after birth, no cry, or the breath was absent or slow, weak or gasping. From the year 1998, the observation was made at 30 seconds, instead of at 1 minute.
†At 5 minutes after birth, the breath was absent or slow, weak or gasping.

Table 4 Effect of Asphyxia Management by Different Workers on Case Fatality and Mortality Rate due to Asphyxia (Before–After Comparision in the Intervention Area)

	TBA 1995–1996	VHW 1996–2003	% Change	*P*
Severe asphyxia* % C.F. (deaths/neonates)	38.5 (10/26)	20.2 (34/168)	−47.5	<0.07
Asphyxia specific mortality rate† (deaths/neonates)	10.5 (8/763)	3.6 (20/5510)	−65.4	<0.02

TBA = traditional birth attendant; VHW = village health worker; C.F. = case fatality.
*At 5 minutes after birth, the breath was absent or slow, weak or gasping.
†Based on the primary cause of death assigned by neonatologist.

Table 5 Before–After Comparision of Three Methods of Resuscitation in the Intervention Area

	TBA$ Mouth-to-mouth 1995–1996 1	VHW£ Tube and mask 1996–1999 2	VHW£ Bag and mask 1999–2003 3	% Change 1 vs 2	% Change 1 vs 3	% Change 2 vs 3
Case fatality in severe asphyxia (%)	38.5	28.3	17.2	−26.5	−55.3*	−39.2
Asphyxia-specific mortality rate†/1000 live births	10.5	3.5	3.7	−66.7*	−64.8*	+5.7
Fresh SBR‡/1000 births	NR	18.4	12.4	—	—	−32.6[a]
Asphyxia mortality + freash still births/1000 births	—	21.9	16.0	—	—	−26.9

$TBA = traditional birth attendent;
£VHW = village health worker.
*$p<0.05$.
†Primary cause of death, assigned by neonatologist.
‡Still birth rate.
NR = not recorded.
[a] = $p<0.09$

the tube and mask. The CF difference between mouth-to-mouth resuscitation and the tube and mask was 26.5 (not significant), while with bag and mask it was 55.3% and significant. The fresh SBR was less with bag and mask as compared to tube and mask by 32.6%, and the difference was near significant. Thus out of the three mortality indicators, the tube and mask effectively reduced one while the bag and mask reduced all three.

This was an uncontrolled, before–after comparison between 1995 to 1996 and 1996 to 2003. Moreover, the effect of training the TBAs in mouth-to-mouth resuscitation could not be assessed in this comparison because they were trained earlier. However, it was assessed by comparing the ASMR based on the cause of death assigned by verbal autopsy — in both the intervention and the control area (Table 6). The cause assignment included multiple causes, that is, more than one cause was assigned to death, if more than one morbidity was present. Hence the ASMR are higher than in earlier tables when only a single primary cause was used. The comparison with the control area shows the effect of training TBAs in mouth-to-mouth resuscitation (11.7% reduction) and of VHWs using tube and mask (41.8% reduction) in the intervention area. The reduction is insignificant with mouth-to-mouth but highly significant with tube and mask. The verbal autopsy was stopped in 1999, so we cannot compare by this method the effect of bag and mask.

To assess the risk factors associated with the residual problem of asphyxia in the intervention phase, odds ratios (ORs) of severe asphyxia and fresh stillbirth were estimated for some of the risk factors on which we had collected data. These are presented in Table 7. The OR for these two considered together (A + B in Table 7) was high for preterm birth (3.8), twin delivery (3.5), low birth weight (1.8) and bad obstetrical history (1.5). It was also high (3.0) for injection (mostly oxytocics) given by private doctor during home delivery.

Discussions with VHWs revealed that they invariably preferred bag and mask because of the following difficulties with the tube and mask: (a) it was difficult to resuscitate for up to 15 minutes using tube and mask during which the worker is required to blow 30 to 40 times/minute. (b) They needed to continuously bend forward for 15 minutes, which was uncomfortable. (c) They could not be sure whether the blowing pressure was correct, especially as the fatigue set in.

Table 6 Effect on Birth Asphyxia as a Cause of Death Assigned by Verbal Autopsy* (1993–1999)

Year	Interventions	Intervention area			Control area			% Difference (control–intervention)
		Live births	Asphyxia deaths	Asphyxia SMR†	Live births	Asphyxia deaths	Asphyxia SMR†	
1993–1995	TBA mouth-to-mouth	1999	56	28.0	2271	72	31.7	−11.7
1995–1996	TBA+VHW presence	1016	25	24.6	1074	40	37.2	−33.9
1996–1997	VHW Tube and mask	804	15	18.7	940	22	23.4	−20.1
1997–1998	VHW Tube and mask	979	11	11.2	1108	39	35.2	−68.2
1998–1999	VHW Tube and mask	729	11	15.1	910	28	30.8	−51.0
1996–99	Three intervention years	2512	37	14.7	2958	89	30.1	−51.2**

Effect of TBA training in mouth-to-mouth resuscitation = (31.7−28.0) = 3.7 (11.7%)
Effect of VHW training+tube and mask = (28.0−14.7)−(31.7−30.1) = 11.7 (41.8%**)

*More than one cause is assigned to many deaths, and death counted in each cause. Hence, the rates are higher.
†Asphyxia specific mortality rate/1000 live births, based on verbal autopsy.
TBA = traditional birth attendant; VHW = village health worker.
**$p<0.001$.

Table 7 Risk Factors Associated with the Remaining Problems of Asphyxia (1996–2003)

Risk factor	Severe asphyxia (A) OR* (95% CI)	Fresh still births (B) OR* (95% CI)	For A+B OR* (95% CI)
Preterm birth (<37 weeks)	2.6 (1.8–4.0)	6.4 (4.0–10.2)	3.8 (2.8–5.1)
Low birth weight (< 2500 g)	1.8 (1.3–2.5)	—	1.8 (1.3–2.5)
Prolonged labour (>24 hours)	1.1 (0.4–2.7)	0.8 (0.2–2.5)	1.0 (0.5–2.0)
PROM (>24 hours)	1.6 (0.4–5.6)	0.4 (0.02–2.9)	0.9 (0.3–2.8)
Twins	2.5 (0.8–7.4)	4.5 (1.3–13.3)	3.5 (1.5–7.9)
Bad obstetrical history (stillbirth/neonatal death)	1.2 (0.8–1.9)	2.0 (1.2–3.5)	1.5 (1.1–2.1)
Injection given by private doctor (oxytocics)	2.6 (1.9–3.6)	3.7 (2.4–5.8)	3.0 (2.3–3.9)

*: Odds ratio.

DISCUSSION

In this study, the home-based neonatal care interventions were introduced in rural Gadchiroli, where >90% of deliveries occur at home. The interventions included training a literate village woman, the VHW, to attend the delivery along with the TBA, and to take care of the neonate at birth including resuscitating if required. The interventions by the trained VHW reduced the asphyxia related mortality, the CF by nearly 50% and the ASMR by 65%, in comparison to management by a TBA alone. The incidence of mild asphyxia also reduced by 60%, but its importance cannot be judged because mild asphyxia was not associated with risk of death. The incidence of severe asphyxia did not decrease. This was understandable in view of the fact that the trial did not include any major obstetrical interventions, and the emphasis, almost entirely, was on immediate diagnosis and management of asphyxia. This could also be because some of the prevented fresh stillbirth may manifest as severe asphyxia.

The trial was not designed to compare different methods of resuscitation. But a comparison over different time periods suggests that for such home-based resuscitation, the bag and mask was more effective and acceptable to the care provider. Tube and mask was equally effective in reducing the ASMR, but the bag and mask was more effective in reducing the CF and fresh SBR, and it was easier for the VHWs to use. Mouth-to-mouth resuscitation by TBAs was the least effective. To further reduce the incidence and mortality due to asphyxia, better obstetrical care in the indicated deliveries and preventing the unnecessary use of oxytocics by unqualified doctors during home deliveries may be useful.

Based on this evaluation, we conclude that home-based interventions provided by a trained VHW present at birth, in addition to a TBA, were effective in reducing deaths due to asphyxia. The bag and mask appears to be more effective equipment for resuscitation.

There are several limitations of this evaluation. The total effect of asphyxia manifests in the form of CF, fresh stillbirths, and neurodevelopmental consequences. We have complete data on deaths (CF and ASMR), data on fresh SBR only from 1996, no data on neurodevelopmental effects. Hence, the evaluation is mostly possible only on CF and ASMR.

This was not a controlled trial of asphyxia management, and hence most of the evaluations are made by before–after comparison. It would be ethically impossible to observe asphyxia at birth but not intervene in the control group. The opportunity of observing without intervention was available only in the year 1995 to 1996 in the intervention area before the VHWs were trained in management of birth asphyxia, which provided the unique data on observing the natural incidence and fatality due to asphyxia. Hence, results of subsequent interventions have to be compared with the estimates in 1995 to 1996. As many other factors such as the maturation of the skills as the experience increases, or the introduction of other interventions, can also change the outcome indicators, the before–after comparisons are a less reliable evidence.

However, a controlled comparison is available of the ASMR based on the cause of death assigned by verbal autopsy for the baseline (1993 to 1995), observation (1995 to 1996) and intervention (1996 to 1999) periods (Table 6). Such comparison shows net 11.7% difference in the ASMR between the intervention and the control areas during 1993 to 1995. This difference is attributed to the earlier training of TBAs in mouth-to-mouth resuscitation in the intervention area. A 41.8% reduction in the ASMR due to training of VHWs and use of tube and mask was detected. The verbal autopsy was stopped in 1999, and hence we do not have results during 2000 to 2003 when the bag and mask was introduced.

The effect of mouth-to-mouth resuscitation by TBAs assessed by comparing the ASMR in the intervention and the control area in 1993 to 1995 (Table 6), as showing a difference of 11.7%, must be understood with two qualifications. The method of verbal autopsy has never been validated in neonates. The TBAs in the control area also had received training in the government program.

Community-based field studies of birth asphyxia suffer from imprecision because the diagnostic definition of asphyxia and the measurement are fraught with enormous difficulties.[20] The presence of a trained observer at the time of home delivery, clinical assessment of the neonate at 1 and 5 minutes, exact measurement of time in the presence of that emergency, the impossibility of subsequently counter checking the correctness of the recorded data, distinguishing asphyxia from other causes of failure to breathe at birth, the ethical impossibility of having a control group — all make such field studies very challenging. Hence, relatively imprecise measurements, estimates and evaluations are inherent limitations.

We have used a simple clinical definition by observing the neonate at 1 and 5 minutes. This definition has been validated in the hospital setting.[7] We changed the timing of the first observation from at 1 minute to 30 seconds starting in 1999. This change, if at all, should result in increased incidence of mild birth asphyxia. Hence, the reduced incidence of asphyxia during the intervention years cannot be explained by the change in the definition. However, earlier initiation of resuscitation may improve the outcome such as the % CF in severe asphyxia observed with the bag and mask.

CF and ASMR are based on deaths — a definite, verifiable event. This study shows a large and significant decrease in these two rates. The reduction in mortality may be caused by resuscitation at birth and by the subsequent supportive care of such neonates as high-risk babies (Box 1).

Can the observed effect in reduction in mortality be explained by some other changes? A small increase in the proportion of institutional deliveries and caesarian section deliveries occurred during the intervention period (Table 2). This was entirely after 1999 (yearwise data not presented), due to an incentive scheme introduced by the government in 2000 to unselectively encourage institutional deliveries. But that does not explain the reductions in the CF and ASMR (Table 4), which were entirely based on the home deliveries observed by VHWs or the reduction in ASMR observed during 1996 to 1999 (Tables 5 and 6). Moreover, the increase in hospital deliveries is very marginal. Hence, the observed reduction in asphyxia-related mortality is attributable to the home-based interventions.

There are few studies with which the results can be compared. A meta-analysis of the evaluations of training of TBAs has estimated the net reduction to be 8% in the perinatal mortality rate and 11% in the ASMR.[21] Our estimated reduction in the ASMR due to training of TBAs is comparable, 11.7% (Table 6). We cannot use the perinatal mortality rate to evaluate the effect of the interventions against asphyxia because our intervention package of home-based neonatal care included many other interventions to affect the neonatal mortality during days 1 to 7 that contributes to the perinatal mortality rate.

In a field trial of training of TBAs in rural North India, the effect of advanced training, including equipping with bag and mask, was compared with that of mouth-to-mouth resuscitation. The CF was less by 20% in the group with bag and mask, and the ASMR in the two groups was 6 per 1000 and 19 per 1000.[22,23] Our results on ASMR are of comparable magnitude, but on CF we found much more reduction: by 55%. In our experience, literate VHWs can observe and record better, as compared to the illiterate TBAs who cannot count or record. VHWs can be better trained to follow an algorithm (Box 1). Moreover, TBA + VHW makes for a better team to manage mother and neonate at that critical moment of birth.

The main limiting factors for implementation are the cost of training and equipment, and rarity of use. Tube and mask ($10.00) was cheaper than bag and mask ($20.00). An average TBA in our area conducts 5 to 20 deliveries, and a VHW attends 20 to 25 deliveries per year. With the incidence of mild asphyxia less than 6% (Table 3) the need for using resuscitation equipment may arise once or twice in a year. Hence, the utilization rate is relatively low.

In the subsequent article,[24] we have estimated that the home-based interventions in the Gadchiroli trial averted 31 asphyxia related neonatal deaths in 39 villages during 1996 to 2003. (If bag and mask were used from the beginning of intervention, probably more deaths would have been averted.) In addition, bag and mask averted six fresh stillbirths per 1000 births (Table 5), therefore, would have averted additional 30 stillbirths during 1996 to 2003. Assuming one bag and mask per village (no need to replace the equipment has been experienced so far) the cost of the bag and mask was estimated to be $13 per averted death (fresh stillbirths + asphyxia related neonatal deaths). The cost of training and remuneration to VHWs as well as the outcome such as averting neurological consequences are not taken into calculation.

However, a more difficult but crucial prerequisite is to ensure the presence of a trained worker at the time of home-delivery. In spite of creating a full-time paid cadre, called an 'auxiliary nurse-midwife' one per 5000 population, in the entire country nearly 15 years ago, the national program in India has reported presence of this worker during only 15% of home deliveries.[25] A VHW being a resident woman from the same village is more likely to attend home deliveries. VHWs attended 84% home deliveries in Gadchiroli trial (Table 2). Choice of equipment will be effective only if the worker is present at birth.

Nearly 60% reduction in the incidence of mild asphyxia is an effect of the presence of two birth attendants, TBA + VHW, instead of one, and the resultant immediate drying, tactile stimulation and cleaning of throat. This reduced the need for resuscitation with tube or with bag to nearly to 6% (incidence of mild asphyxia) in the last 5 years of interventions. However, it is unlikely to have any effect on mortality because, to begin with, the mild asphyxia was not associated with an increased risk of death (Table 1).

In the postintervention scenario, the risk factors associated with the severe asphyxia or fresh stillbirth (Table 7) were all presumably obstetrics related. The unnecessary practice of administering oxytocics was clearly associated with three-fold risk of these events. As the prolonged labour did not show increased risk of birth asphyxia in this cohort, it did not act as a confounder causing a spurious association between the use of oxytocics and birth asphyxia. This harmful practice needs immediate attention.

CONCLUSIONS

This study demonstrates a significant effect of home-based neonatal care on mortality due to asphyxia. To deliver such an intervention, it is necessary to form a team of a semiskilled VHW with the TBA, so that each home delivery is attended not by a TBA alone but by two birth attendants. For resuscitating an asphyxiated baby in such setting, bag and mask appears to be more effective than tube and mask or mouth-to-mouth breathing, and more convenient to use. The estimated cost of bag and mask was $13 per averted death.

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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.

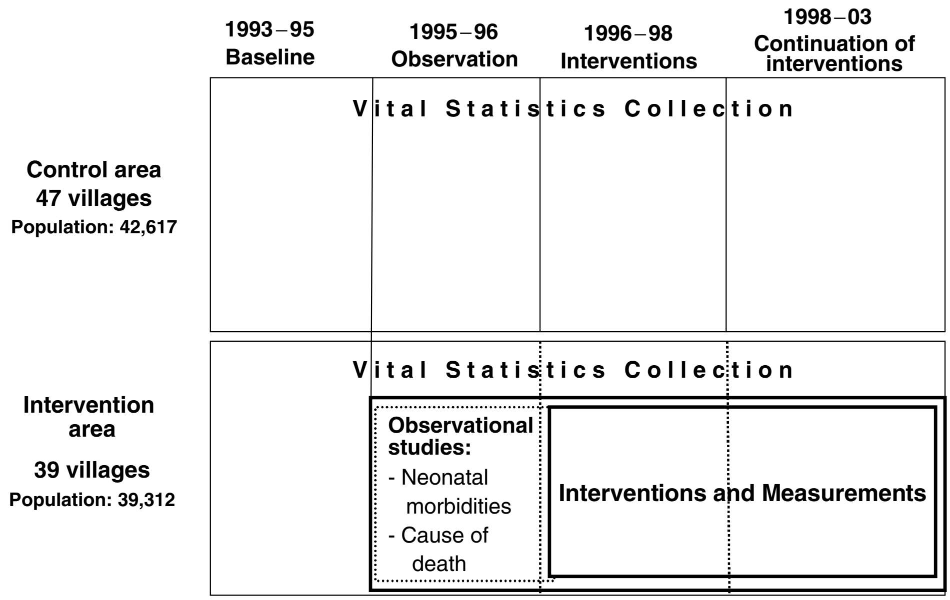

Figure 1. Study design.

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

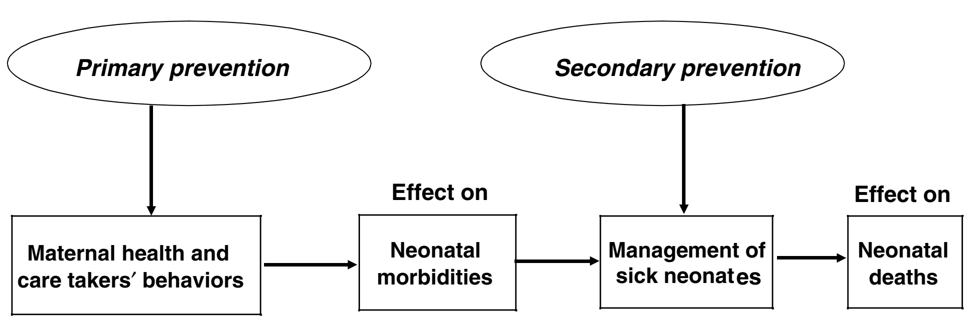

Figure 2. Neonatal health and the interventions.

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.

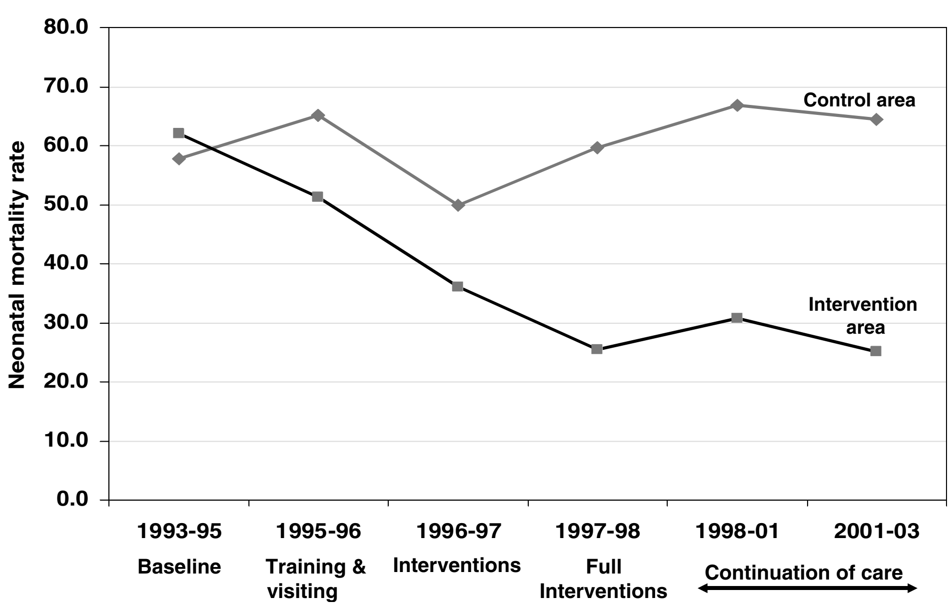

Figure 3. Neonatal mortality rate in intervention and control areas: 1993–1995 to 2001–2003.

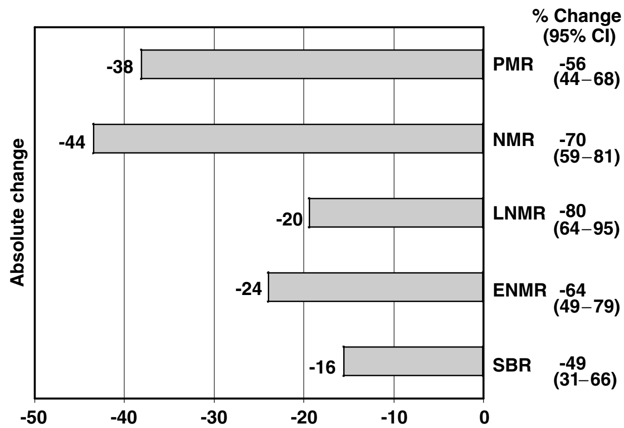

Figure 5. Effect of home-based neonatal care: absolute difference between the intervention and control area and percent change in different mortality rates.

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.

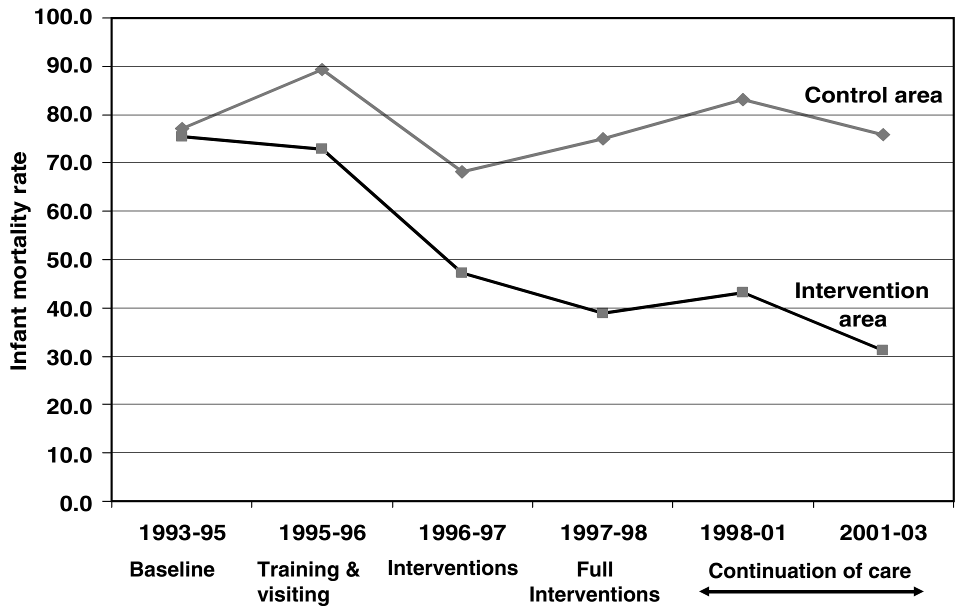

Figure 6. Infant mortality rate in intervention and control areas in Gadchiroli: 1993–1995 to 2001–2003.

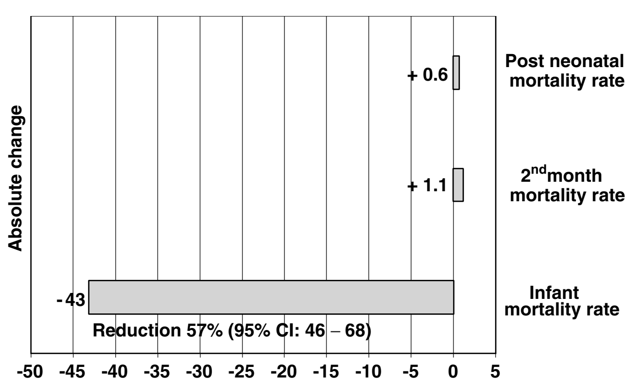

Figure 7. Effect of home-based neonatal care: absolute difference between the intervention and control area and percent change in different mortality rates.

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-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 ($n=1415$)			
Cause	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	NS	12	48.0	<0.005¶	12.9	3
With sepsis	1996–2003	Antibiotics+supportive care	53	244		7	13.2		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%)

Group	Year	Intervention	Neonates	Mean gestation (days)	p	Deaths	%CF*	p	Absolute reduction in %CF†	Deaths prevented in 1996–2003‡
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	NS	9	20.0	<0.05¶	−1.6	0‖
With sepsis	1996–2003	Antibiotic+supportive care	181	275		16	8.8		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.

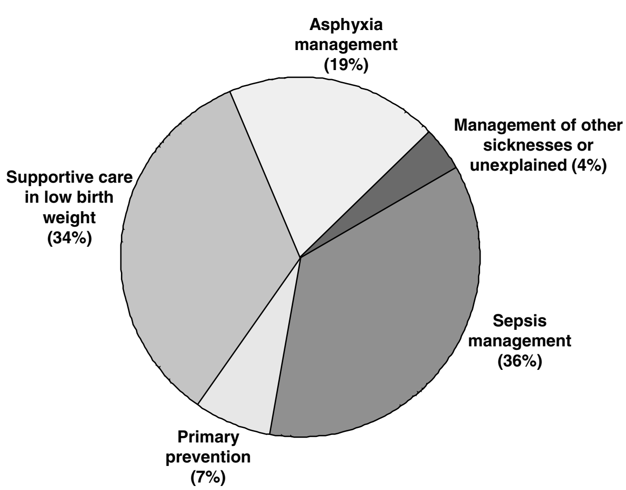

Figure 8. Proportion of neonatal deaths prevented by different components of home-based newborn care: 1996 to 2003 (total deaths prevented = 161).

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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Original Article

Home-Based Neonatal Care: Summary and Applications of the Field Trial in Rural Gadchiroli, India (1993 to 2003)

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Hanimi M. Reddy, PhD

High levels of neonatal mortality and lack of access to neonatal health care are widespread problems in developing countries. A field trial of home-based neonatal care (HBNC) was conducted in rural Gadchiroli, India to develop and test the feasibility of a low-cost approach of delivering primary neonatal care by using the human potential available in villages, and to evaluate its effect on neonatal mortality. In the first half of this article we summarize various aspects of the field trial, presented in the previous 11 articles in this issue of the journal supplement. The background, objectives, study design and interventions in the field trial and the results over 10 years (1993 to 2003) are presented. Based on these results, the hypotheses are tested and conclusions presented. In the second half, we discuss the next questions: Can it be replicated? Can this intervention become a part of primary health-care services? What is the cost and the cost-effectiveness of HBNC? The limitations of the approach, the settings where HBNC might be relevant and the management pre-requisites for its scaling up are also discussed. The need to develop an integrated approach is emphasized. A case for newborn care in the community is made for achieving equity in health care.
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I shall give you a talisman. When you are in doubt, or when the self becomes too much in you, bring before your eyes the weakest, most wretched and miserable human being that you ever saw, and ask yourself that the step you contemplate, "Will it reduce his misery? Will it reduce his helplessness?" You will get your answer.

Mahatma Gandhi

BACKGROUND

The Global Problem

A high neonatal mortality rate (NMR) in developing countries accounts for nearly two-thirds of infant mortality. Annually, four million neonatal deaths, and about the same number of stillbirths, occur globally, 98% of them occur in developing countries.[1,2] One of the reasons is a lack of access to health care. The neonatal period is inadequately addressed by national and international health programs in developing countries. (The same is true for the corresponding post-partum period in maternal health-care programs.[3]) Referral of sick neonates is recommended in most guidelines for field workers[4–6] but usually not practiced due to lack of accessible facilities and unwillingness of families to take neonates out of the home.[7–9] Most neonatal deaths in developing countries therefore occur at home.[1]

Management of bacterial infections in neonates (sepsis/pneumonia), which account for 31% of neonatal mortality,[10] is most often not included in community health programs. In fact, infections offer greater possibility for effective intervention because technology (antibiotics) is available. But simple methods for providing the benefits of antimicrobial therapy to neonates with serious infections have not been readily available in the field.[11]

The Local Situation

Gadchiroli district in the Maharashtra state in India is a very poor, least developed rural agricultural area, with low female literacy and a limited access to health services (Figure 1). Society for Education, Action and Research in Community Health (SEARCH), a local non-governmental organization, had worked during 1986 to 1993 on women's reproductive health in rural Gadchiroli, training of traditional birth attendants (TBAs), and had conducted a field trial of the community-based management of pneumonia in children.[11,12] These activities provided a field base as well as community acceptance for SEARCH.

The baseline situation[13] in 39 intervention villages of SEARCH in a 2-year period (1993 to 1995) is presented in Table 1.

To study the traditional beliefs and practices about newborn care, we held focus group discussions with mothers and grandmothers (1995). These revealed a severe lack of information about neonatal care and a large number of taboos and harmful practices. Health care was almost never sought for sick neonates. Families had a helpless, fatalistic outlook towards neonatal survival. We found a large scope for health education and for empowering mothers and families by way of new knowledge and skills.[13]

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

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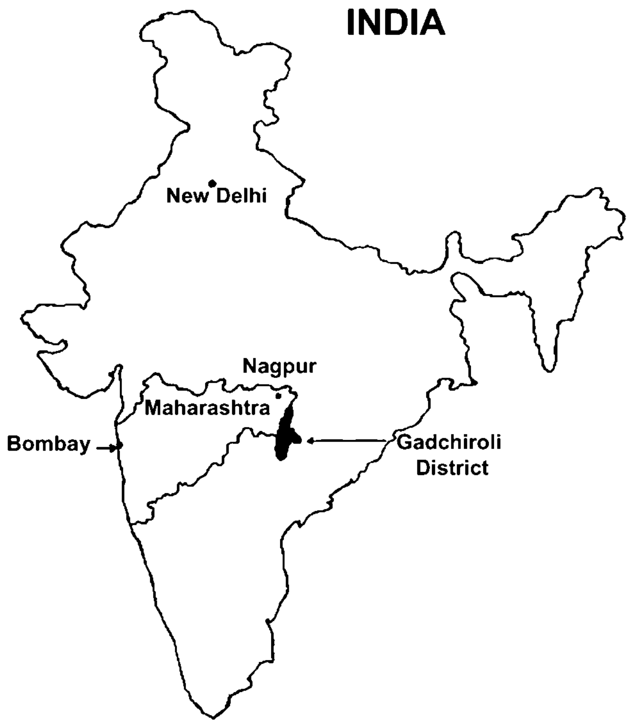

Figure 1. India, Maharashtra and Gadchiroli.

On this background we planned the field trial of home-based neonatal care (HBNC) in Gadchiroli.

Table 1 Baseline Situation in the 39 Intervention Villages in Gadchiroli

Characteristics	
Population (1994)	39,312
Occupation: agriculture	90%
Electricity at home	29%
Female literacy	38%
Primary health centers (managed by a doctor)	4
Health subcenter (managed by auxiliary nurse midwife)	16
Birth rate* (1993–95)	25.4
Neonatal mortality rate† (1993–95)	62.0
Infant mortality rate† (1993–95)	75.5
Perinatal mortality rate‡ (1993–95)	68.3
Proportion of deliveries at home§ (1993–95)	95%

*Per 1000 population.
†Per 1000 live births.
‡Per 1000 births.
§Mostly conducted by traditional birth attendants (TBA).

AIM OF THE STUDY

To develop a HBNC package that provides low-cost, primary neonatal care by using the human potential available in villages, and thereby, to reduce neonatal mortality and to improve neonatal health.[13]

The main hypotheses

1. It is possible to develop a home-based care package, and it will reach at least 75% of the neonates in the community and 60% of the neonates with sepsis.
2. The HBNC package will reduce the NMR in the intervention villages by at least 25% and the sepsis-specific NMR by at least 40% in three years.

STUDY DESIGN AND TIMEFRAME[13]

Adjacent blocks of villages in Gadchiroli, where SEARCH had been working since 1988, were selected as the intervention and the control areas in 1993 (Figure 2). A vital statistics surveillance system was already in operation in both areas. The census and the baseline phase (1993 to 1995) revealed that the populations in the two areas were similar on socio-economic and demographic characteristics, availability of health care and the vital rates such as the birth rate, NMR, perinatal mortality rate (PMR) and the infant mortality rate (IMR).[13]

After the baseline phase, we observed the neonates in the 39 intervention villages for one year (1995 to 1996). This cohort study provided unique observational data and insights into the health of the neonates in rural community which we have presented in three articles.[14–16]

STUDIES ON NEONATES IN RURAL GADCHIROLI

Neonatal Morbidities

We prospectively observed a cohort of 763 neonates in 39 villages (1995 to 1996) by way of a trained worker making eight or more home visits during the neonatal period.[14]

A high incidence of LBW (42%), clinical sepsis (17%), preterm births (9.8%), severe birth asphyxia (4.6%), hypothermia (17%) and breast-feeding problems (16%) was detected. In total, 48.5% of the neonates had high-risk morbidities (those associated with case fatality (CF) >10%). The burden of morbidity was a mean 2.2 morbidities per neonate. In all, 54% neonates needed medical attention. However, only 2.6% neonates received medical care, 0.4% were hospitalized.

New hypothesis. Many morbidities showed strong seasonal and day-wise variation probably due to inadequate protection from the environment. We developed a new hypothesis that better home-care will prevent the neonatal morbidities that showed a seasonal and temporal increase.

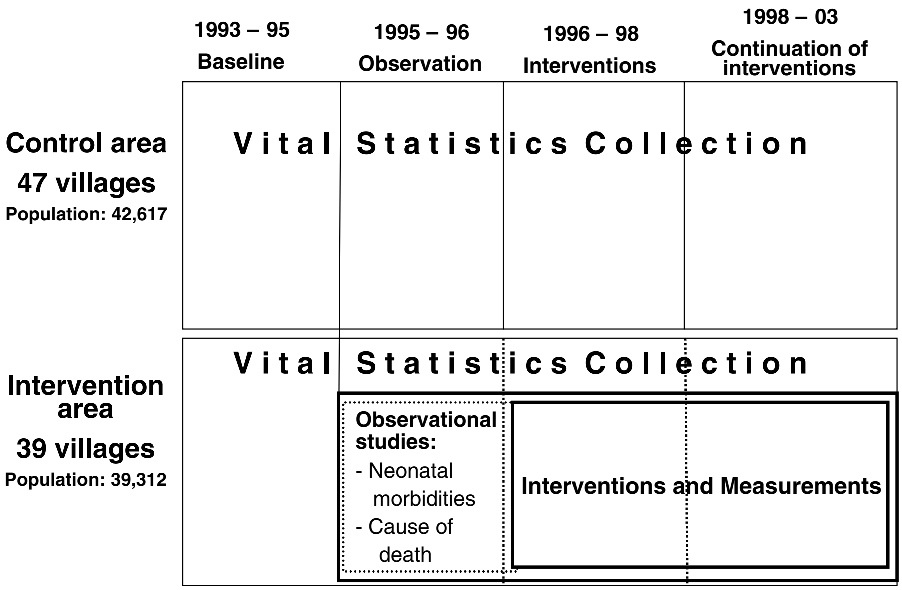

Figure 2. Study design of the field trial of HBNC in Gadchiroli.

Primary Cause of Death

An independent neonatologist assigned the primary cause of death, based on the prospectively observed records of 40 neonatal deaths in the cohort of 763 neonates observed in the community (1995 to 1996).[15]

Primary causes of death were the following: sepsis/pneumonia 52.5%; birth asphyxia 20%; prematurity 15%; hypothermia 2.5%; other and unknown 10%.

These data suggest that infection management is a high priority.

Contribution of Multiple Morbidities to Neonatal Deaths, and a Strategy for Intervention

The single primary cause assigned to each death may be arbitrary, and it does not take into account the contribution of simultaneous presence of multiple causes.[16] Hence, we performed a multi-causal analysis of the morbidities and deaths recorded in the cohort of 763 neonates with 40 deaths (1995 to 1996) in 39 villages.The main findings are presented in Box 1.

Significance: Preterm birth and IUGR are ubiquitous components, but usually not sufficient to cause death. Most neonatal deaths occur due to a combination of preterm birth or IUGR with other co-morbidities, especially infection.

New hypothesis: Though the preterm births or IUGR cannot be prevented in a population, neonatal deaths can still be reduced by a strategy of prevention or management of co-morbidities. The order of priority is sepsis, asphyxia, hypothermia and feeding problems. Prevention and/or management of infections will reduce neonatal mortality by 40 to 50%.

DEVELOPMENT OF THE TOOLS FOR HBNC

Based on the baseline, ethnographic and observational data, we developed various methods for the HBNC. These included:

1. a simple and validated method of screening on the day of birth and identifying the neonates at high risk of death;[19]
2. a simple and validated clinical method for identifying neonates with suspected sepsis;[20]
3. algorithms for the home-based management of birth asphyxia, LBW or preterm babies and of sepsis;[21–23]
4. methods of health education to mothers/families for the adoption of better mother-newborn care practices;[24]
5. selection of a village health worker (VHW), a resident literate woman in each village, as the provider of HBNC. A systematic method of selecting the appropriate woman as a VHW was developed;
6. a curriculum and the method of training VHWs (36 days of classroom training spread over a period of 12 months) including practicum periods in the community;
7. a mechanism of cooperation with TBAs;
8. a mix of social recognition, job satisfaction and performance-based remuneration to motivate the VHWs for a high level of performance.

EFFECTIVENESS OF HBNC INTERVENTIONS (1996 TO 2003)

The HBNC interventions were provided in 39 intervention villages. Though the training of VHWs, home visits and observations began during 1995 to 1996, the active interventions were introduced during 1996 to 1998. Subsequently, they were continued during 1999 to 2003 (Figure 2). The interventions in the HBNC package[25] are presented in Box 2 and Figure 3.

The effects of the interventions on morbidities and mortality were carefully monitored. We have presented these in four articles,[21–24] which we summarize here.

Box 1 Why do neonates die in rural Gadchiroli

1. Population attributable risks, that is the proportion of deaths in a population which can be attributed to a cause, and hence, will be averted if that cause is removed,[17,18] for the major morbidities were the following: (Since these causes overlap, the attributable risks of death also overlap.)

Preterm birth	0.74
Intra-uterine growth restriction (IUGR)	0.55
Sepsis	0.55
Birth asphyxia	0.35
Hypothermia	0.08
Feeding problems	0.04

2. Although pre-term birth was present in 63% of deaths and IUGR in 28% of deaths (and low birth weight (LBW) <2500 g in 90% of deaths), these alone, in the absence of other co-morbidities, were present in only 10% of the deaths.
3. The percent CF steeply increased with the mean number of morbidities per neonate. Most (83%) of deaths occurred in neonates with at least two or more morbidities. Thus, deaths occurred due to morbidity combinations.
4. The most common morbidity combinations and the proportion of deaths caused by these overlapping combinations were:

Preterm+sepsis	35%
IUGR+sepsis	22.5%
Preterm+asphyxia	20%
Preterm+hypothermia	15%
Preterm+feeding problems	12.5%

5. The CF in LBW alone or in suspected sepsis alone was low, but when these two occurred together, the CF increased up by 6 to 18 times.
6. Estimated excess deaths caused by sepsis, over and above LBW, was 44% of the total deaths.

Box 2 Home-based Neonatal Care: The Intervention Package

1. Selection and training of a village health worker in each village.
2. Ensuring cooperation of community, TBA and the health services.
3. Making a list of pregnant women in community, and updating it regularly.
4. Health education:
   - Group health education: using audio-visuals and group games.
   - To individual mother, by home visiting, twice during pregnancy and once on the second day after delivery.
   - To mothers of high-risk neonates.
5. Attending delivery, along with the TBA.
   - Encouraging the family and the TBA for referral when necessary.
   - Taking charge of the baby immediately at birth.
   - Assessment, and if necessary, management of asphyxia by following an algorithm, and using bag and mask.
6. Initiation of early and exclusive breast feeding, and supporting/teaching mother to breast-feed successfully.
7. Injection vitamin K1 mg, on the day of birth.
8. Thermal care of the neonate.
9. Assessing for high-risk status. If present, extra care.
10. Repeated home visits (8–12) during neonatal period to ensure breast-feeding, thermal care, hygiene, and to monitor the baby for any infection — superficial or systemic (sepsis).
11. Early diagnosis and treatment of neonates with sepsis, including administration of two antibiotics — co-trimoxazole and gentamicin.
12. Home-based care of LBW or preterm neonates.
13. Weekly weighing, problem solving, advising and helping mother.
14. Referral when necessary.
15. Supervision (twice in a month), support, supplies, records, performance-linked remuneration and continued training to VHWs.
16. Vital statistics and HBNC service data monitoring.

Figure 3. Home-based neonatal care in action.

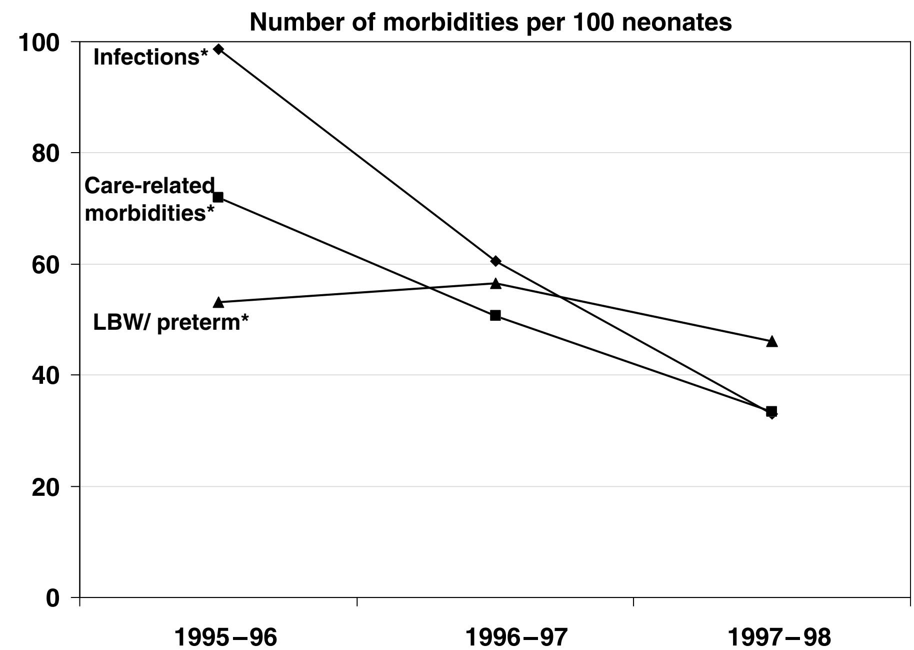

Figure 4. Reduced burden of neonatal morbidities.
Infections*: Neonatal sepsis, pneumonia, umbilical sepsis, skin infection, conjunctivitis, unexplained fever, diarrhea and upper respiratory syndrome. Care-related*: Mild and severe asphyxia, breast-feeding problems, hypothermia and inadequate weight gain in 0 to 28 days (<300 g). LBW/preterm*: LBW, preterm.

Effect on the Incidence of Neonatal Morbidities

We estimated the effect on the incidence of neonatal morbidities by comparing the incidence in early (1995 to 1996) vs. later (1997 to 1998) years of intervention (Figure 4).[24]

- The mean number of morbidities/100 neonates decreased by nearly 50%.
- Infections, the care-related morbidities and the seasonal increase in morbidities showed large and significant reductions.
- The incidence of LBW decreased by 16%; preterm births did not change.

The possible explanation for the reduction in the incidence of neonatal morbidities was the high proportion of mothers with correct knowledge (79%) and behaviors (70%) in 1997 to 1998. The incrementally increasing score of interventions in 3 years and the decreasing incidence of morbidities showed a dose–response relationship.

Home-based Management of LBW and Preterm Neonates

The VHWs assessed 93% of the 5919 neonates born in 39 villages, and provided home-based management to 97% of the detected LBW or preterm neonates.[21] A comparison of the observation year (1995 to 1996) with the intervention years (1996 to 2003) revealed that:

- CF in 2015 LBW neonates declined by 58% (from 11 to 5%, $p<0.001$), and in 533 preterm neonates by 70% (from 33 to 10%, $p<0.0001$) (Figure 5). The CF declined in all grades of severity of LBW or prematurity, though it remained relatively high in <1500 g and <33 weeks.
- The incidence of major co-morbidities, viz., sepsis, asphyxia, hypothermia and feeding problems declined.

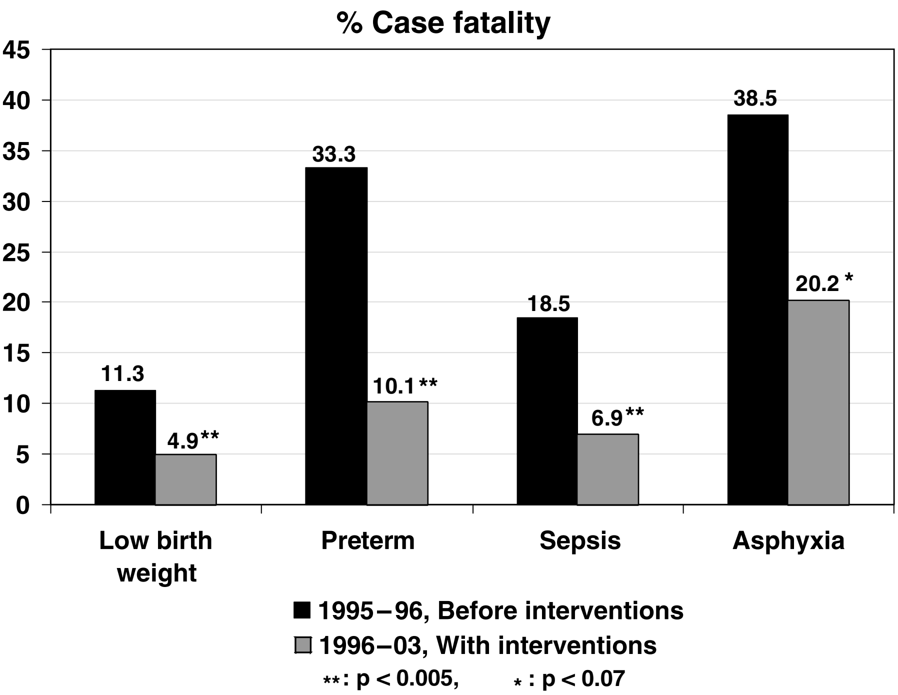

Figure 5. Effect of home-based newborn care on CF in life-threatening morbidities (1995 to 1996 vs 2001 to 2003).

- The deaths averted among the LBW neonates were explained as 55 deaths averted by supportive care and 35 by treatment with antibiotics.

Neonatal Sepsis

In 1996 to 2003, the VHWs monitored 93% of the 5919 neonates in 39 villages by frequent home visits.[22] Out of the 552 cases of suspected sepsis diagnosed by the computer algorithm, the VHWs correctly diagnosed 492 (89%) cases of suspected sepsis.

- Parents opted for home-base management in 91% of the diagnosed cases, refused any treatment in 6.3% and agreed to hospitalize in 2.6% of cases. The VHWs treated a total of 470, that is, 9% of all neonates in community as suspected sepsis, out of which 448 were correct diagnoses. Thus, they correctly diagnosed and treated 81% (448/552) of the total sepsis cases in the community. In the last two years (2001 to 2003), this proportion was 90%.
- The CF in the 448 treated cases was 6.9%, as against 22% in the untreated or 18.5% in the pre-treatment year, April 1995 to March 1996 (p<0.0001) (Figure 5).
- The CF in LBW sepsis cases declined by 72%, and in preterm sepsis cases by 67%.
- The sepsis-specific NMR decreased by 90%.

Birth Asphyxia

- The VHWs were present for 84% of the 5033 home deliveries and, in team with TBAs, managed the neonates at birth.[23]

Comparison of the observation year (1995 to 1996) with the intervention years (1996 to 2003) revealed that:

- ○ The incidence of mild asphyxia decreased by 60% (from 14 to 6%, p<0.001)
- ○ CF in severe asphyxia decreased by 47.5% (from 39 to 20%, p<0.07) (Figure 5).
- ○ Asphyxia-specific NMR decreased by 60%, from (11% to 4%, p<0.02).

Resuscitation with bag and mask appeared to be more effective in reducing CF and fresh stillbirths than tube and mask or mouth-to-mouth resuscitation.

IMPACT ON NEONATAL AND INFANT MORTALITY

The baseline NMR, IMR and the stillbirth rate (SBR) were similar in the control and intervention areas.[13,25,26] We estimated the impact of HBNC by comparing the change in the NMR and IMR in the intervention and the control areas during 10 years — from the baseline (1993 to 1995) to the last 2 years of intervention (2001 to 2003) (Figures 6 and 7).

- The NMR in the intervention area decreased from 62 to 25. The reduction in comparison to the control area was by 70% (95% CI 59 to 81%).
- The reduction in the NMR was contributed by the reduction in both the early NMR (24 points) and the late NMR (20 points).
- The SBR decreased by 49% (95% CI 31 to 66).
- The PMR decreased by 56% (95% CI 44 to 68).

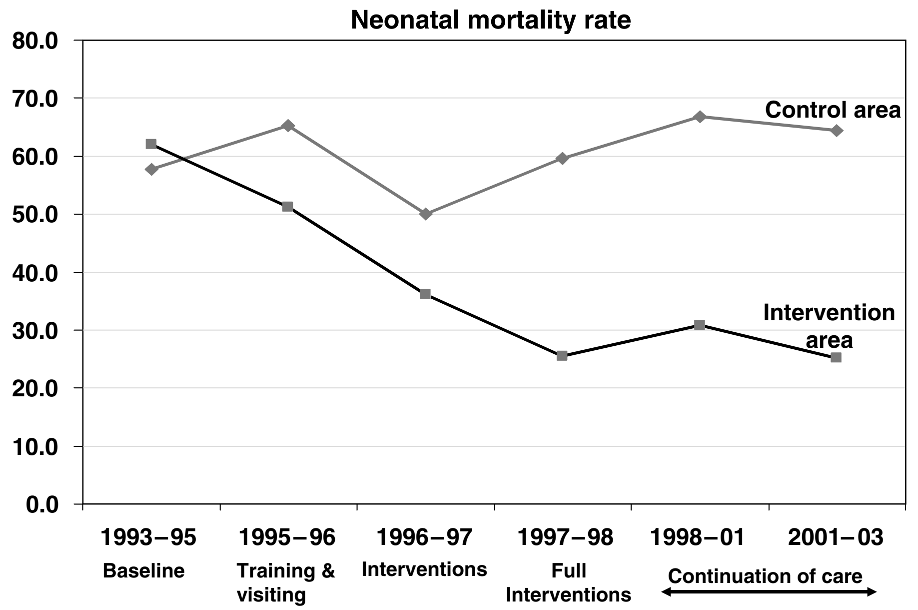

Figure 6. NMR in the intervention and control area: 1993 to 2003.

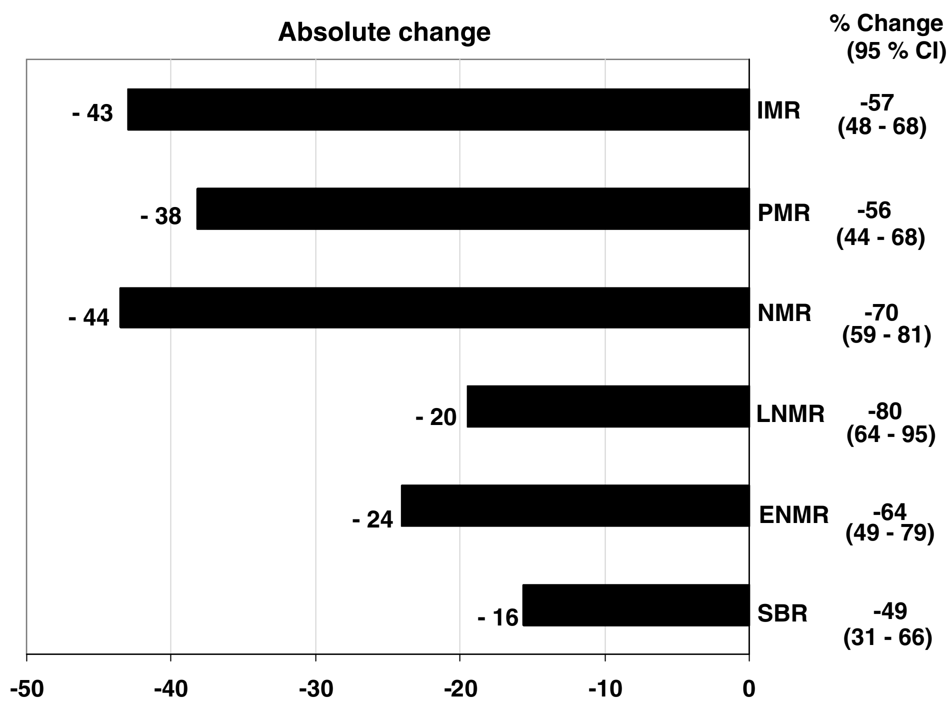

Figure 7. Effect on mortality rates: net reduction.

- The IMR declined from 76 to 31. In comparison to the control area, the reduction was by 57% (95% CI 46 to 68%).

THE PATHWAYS OF ACTION AND THE ATTRIBUTABLE CONTRIBUTION

The VHW acts through health education for behavior change, supporting the home-based care and management of sick neonates (Figure 8). We estimated the contribution of different components of HBNC interventions. The reduction in the NMR was attributable to various component interventions, in a proportion shown in Figure 9.[26]

HYPOTHESES TESTED

The field trial was started with two hypotheses, and two more were developed based on the data on neonatal health collected in the

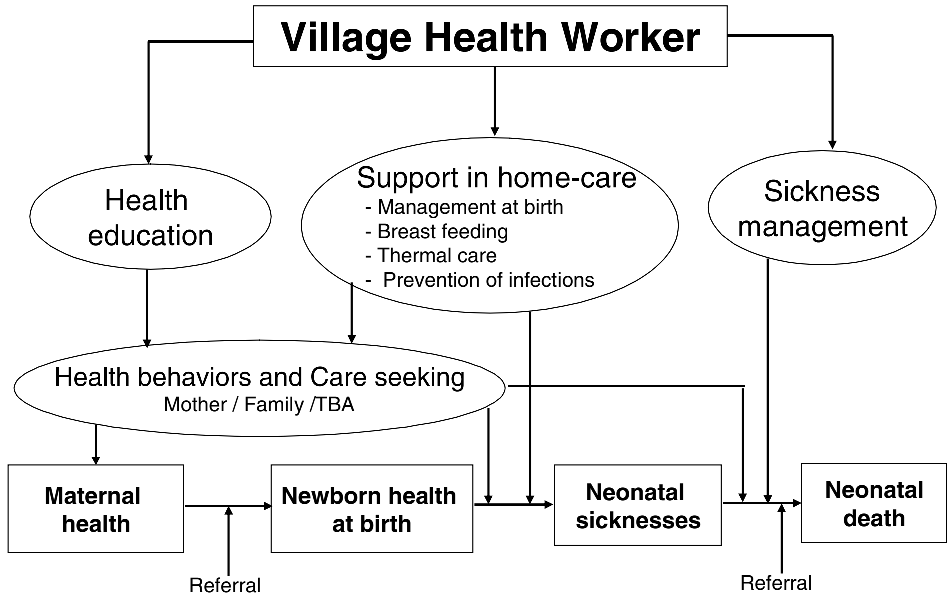

Figure 8. Pathways of action of the home-based neonatal care.

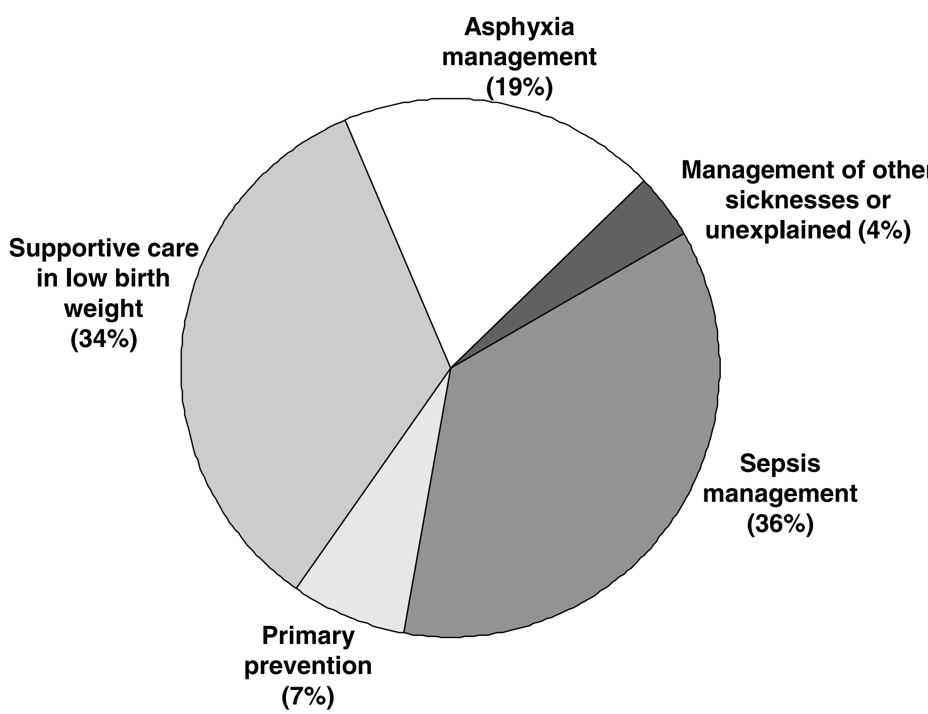

Figure 9. Proportion of neonatal deaths prevented by different components of home-based neonatal care (1996 to 2003) (total deaths prevented = 161).

observation year. The results of testing the hypotheses are presented in Box 3.

CONCLUSIONS

We conclude that in a poor, malnourished and semi-literate population such as in rural Gadchiroli, characterized by near-complete absence of access to neonatal health services, high incidence (42%) of LBW neonates and high NMR (62) and IMR (76), it was possible to provide HBNC to most (93%) neonates in the community, to reduce neonatal morbidity load (by 50%), to reduce neonatal mortality (by 70%) and finally, to reduce the IMR (by 57%) to a level of around 30, the goal of the National Population Policy of India to be achieved by the year 2010.[27]

Box 3 Hypotheses tested in the field trial

Hypothesis	Results
1. It is feasible to develop an HBNC intervention package that will cover 75% of neonates in the intervention area, and 60% of neonates with sepsis.	In all, 93% neonates received HBNC, including 84% attended at birth. An estimated 81% neonates with suspected sepsis were correctly diagnosed and treated by VHWs.
2. The NMR will decrease by 25% and sepsis-specific NMR by 40% in three years.	The NMR decreased by 62% in the third year (1997 to 1998) and by 70% in 2001 to 2003. The sepsis-specific NMR decreased by 76% in 1997 to 1998 and by 90% in 2001 to 2003.
3. Neonatal morbidities showing strong seasonal variation indicate inadequate protection. With the HBNC, the seasonal increase will disappear and the incidence of morbidities will substantially decrease.	The incidence of 17 morbidities decreased by a mean 50%, and the significant seasonal increase originally observed in six morbidities became insignificant except for fever in the summer.
4. Even if the incidence of LBW and preterm birth cannot be reduced, the HBNC will increase the survival of the LBW and preterm neonates by preventing or managing the co-morbidities.	The incidence of LBW decreased by 16% and that of preterm births was unchanged. During the 7 years of interventions, the incidence of co-morbidities in LBW or preterm neonates decreased, and the management of sepsis and other morbidities was feasible. As a result, the CF in LBW neonates decreased by 58%, and in preterm neonates by 70% ($p<0.001$).

THE COST AND THE COST-EFFECTIVENESS OF HBNC

(1) ***Time inputs***: Based on a time-motion study of 36 VHWs (3062 days of observations) in different seasons in a year, we estimated that the time spent by a VHW (approximately one per 1000 population) for the delivery of the HBNC package was as follows:

1. Time spent per day: 1 hour 23 minutes
2. Time per mother-neonate: 15 hours 39 minutes
3. Time per sepsis case managed: 10 hours 16 minutes

This was a unipurpose worker introduced for an intervention trial. If an existing worker such as a community health worker (CHW) is trained to deliver the HBNC, some of the overlapping tasks (maintenance of population register, preparing the list of pregnant women, health education, treatment of minor illnesses) will not need be duplicated.
Therefore, for such a multipurpose CHW, the additional time required for providing the HBNC to a population of 1000 was estimated to be 65 minutes per day.

(2) ***The cost of the HBNC package***: estimated in the Gadchiroli trial in 2001 to 2003 is presented in Table 2. The costs were calculated after removing the research-related costs. (The proportion of time spent by the VHWs and supervisors on the service component in HBNC vs research component was assessed from the detailed time-input study mentioned above.)

The distribution of the annual recurring costs was as follows:

(i) Personnel 70% (VHW 37%, TBA 9%, supervisors 22%, others 2%).
(ii) Transport 9%.
(iii) Medicines and supplies 9%.
(iv) Support 12%.

The recurring cost per mother-newborn ($6) is equivalent to the wages of 5 to 6 days for a female agricultural laborer in the Gadchiroli area.

These cost estimates are higher than those we published earlier for the year 1997 to 1998.[25] The main reasons for this are the increase in prices over the last 5 years (from 1997 to 1998 to the prices in 2002 to 2003) by nearly 30% and a reduction in the birth rate by nearly 20%, resulting in a smaller number of newborns served per VHW.

(3) ***Cost for India***: With these costs, the estimated cost of a program like this for the whole of India (population 1 billion) will be the nonrecurring cost of $155 million (in 2002 to 2003 prices), and the annual recurring cost of $118 million. These estimates do not take into account the administrative cost of program development in a large system, nor the savings due to adding the activity onto ongoing health services. Moreover, a proportion of population in India, especially the urban middle class, may not need the HBNC.

(4) ***Comparison of cost-effectiveness*** (Table 3): The $7 cost of saving one disability-adjusted life year (DALY)[28] by HBNC is much less compared to the cost of other interventions, as estimated by the WHO-CHOICE project, cited in Table 3. The main reasons for this are: (a) the high baseline level of NMR in Gadchiroli, (b) a

Table 2 Cost and Cost-Effectiveness of Home-Based Neonatal Care in Gadchiroli (2001 to 2003) (1 US$ = 45 Indian Rs.)

		Nonrecurring costs (2002 to 2003 prices*) US$	Annual recurring cost[†] (US$)
1	Cost per village[‡]	Training: 89.1	
		Equipments: 65.9	
		Total: 155.0	117.8
2	Per capita cost[§]	0.14	0.11
3	Cost per mother-newborn served	0.89[¶]	6.06[‖]
4	Cost per death averted**	21.1[¶]	129.4[††]
	Total (nonrecurring + recurring)	150.5	
5	Cost per DALY[§§] saved	0.96	5.82
	Total (nonrecurring + recurring)	6.78	

*Wholesale prices in India (base: 1993 to 1994), http://eaindustry.nic.in/pib.htm.
[†]Basis, 2001 to 2003 accounts, converted into annual cost.
[‡]39 villages.
[§]Population in 2002 to 2003 = 43, 397.
[¶]Non-recurring cost was spread over 8-years period (1995 to 2003).
[‖]Mean 758 live births per year during 2001 to 2003.
**Averted neonatal deaths+averted still births.
[††] 71 deaths averted during 2001 to 2003, that is, 35.5 per year.
[§§]Death of a neonate = 21.9 DALYs lost, estimated by the formula given by Murry CJL, in Murry and Lopez, WHO, 1994.[28]

highly effective HBNC intervention package that reduced the NMR and SBR by a large margin, (c) the community-based strategy of providing care, which reduces the cost as compared to services by professionals or in hospital and (d) the cost-effectiveness of HBNC is based on a smaller research study.

The question, however, is, will the cost and the effectiveness remain the same when scaled up? The cost per unit service should decrease due to economies of scale and due to integration with other services, but at the larger scale in a regular service program, the effectiveness also may decrease.

LIMITATIONS OF THE HBNC APPROACH IN THE GADCHIROLI TRIAL

The trial was conducted in Gadchiroli with its particular geographic, rural and cultural characteristics by an organization (SEARCH) which had developed a service base and earned the trust of the local population. Many of the interventions were developed in response to the local situation and need. Hence, the HBNC package and the results in Gadchiroli are, to some extent, limited by the specific context.

1. The approach was developed and tested in a rural area with very limited access to health services. Most (95%) deliveries occurred at home. Sick neonates were rarely taken to hospitals (0.4%), or to a doctor (2.3%).[14] The care gap, felt need, and the acceptance by the populations in other types of areas (urban slums, rural areas with better access) may vary. This is being tested in another project underway (ANKUR).

Table 3 Comparison with the Cost-Effectiveness of other Child Survival Interventions at 95% Coverage*

Ranking	Intervention	Cost per DALY saved ($)
1	Home-based neonatal care	7
2	Zinc fortification	14
3	Zinc supplementation to children	47
4	Case management of pneumonia in children	86
5	Oral rehydration therapy	194
6	Vitamin A fortification	237
7	Vitamin A supplementation to children	2137
8	Growth monitoring and supplementary food to undernourished infants	8235

*World Health Organisation (WHO-CHOICE Cost-effectiveness analysis results 2000) for South-East Asia Region.
Http://www3.who.int/whosis/cea/cea_data_process.cfm? path = evidence, cea, cea_r.... 21 July 2004.

2. Its efficacy has been shown in a population with high baseline levels of NMR and IMR. The baseline proportion of neonates with LBW was high (42%) and the morbidity load, especially the incidence of infections, too was high. The effect may vary with the baseline levels of morbidity and mortality.
3. In this trial, a new unipurpose VHW was introduced for delivering the HBNC. Similarly, the study was conducted by a non-government organization (NGO) outside the health

services system. How to integrate the HBNC approach into the routine health services and add the responsibility of delivering HBNC to the current job description of existing field workers is yet to be evaluated. We, at present, do not know how much drop in effectiveness may occur when, from the research mode, the HBNC will enter into the program mode.

4. The HBNC approach requires intensive training of VHWs (36 days) and field supervision (once in 15 days) to deliver a good quality care at home.
5. The work of a VHW involves some critical technical tasks such as resuscitating an asphyxiated neonate with bag and mask or managing a sepsis case with injection of gentamicin. Medical opinion and the national guidelines in each country may have reservations in accepting these advanced roles.
6. The HBNC intervention package evolved and was delivered by an interactive research team. The motivation and quality of managers will influence the outcome at other places.

The Gadchiroli trial shows a potential path. However, many operational issues need to be considered and tested in the field before this approach can be successfully scaled into a program.

IN WHICH SETTINGS IS HBNC ESPECIALLY RELEVANT?

1. Where the IMR is more than 30. HBNC has a proven record of reducing it to below 30. It is worth noting that Sri Lanka reduced its IMR down to the level of 15, despite having only 50 NICU beds in the entire country.[29] This was done mostly by a decentralized health care system reaching almost every mother and newborn.
2. Where a significant proportion of deliveries occur at home.
3. Even in settings with a higher proportion of institutional deliveries, the mother and the neonate are discharged within 48 hours and, hence, they need home-based post-natal and neonatal care.[3]
4. Where medical care to neonates is not available or not affordable or not acceptable to families. These could be rural areas, hilly and tribal areas and the urban slums.
5. Where marginalized population groups exist in relatively better developed areas.

Majority of the population in India or most developing countries belong to one or more of these catagories.

ISSUES FOR FURTHER RESEARCH

(1) Possible improvizations in HBNC, such as:
- Use of oral antibiotics for treating sepsis.
- Gentamicin delivered by way of the Uniject device (PATH, Seattle).
- Nutritional management of LBW neonates for better weight gain.
- Home-based kangaroo mother care for management of preterm or LBW neonates in HBNC.

(2) Developing referral linkages, especially for management of <1500 g or <33 weeks neonates.
(3) HBNC in urban slums (being tested in the ANKUR project).
(4) Integration of HBNC into existing maternal and child health programs or child nutrition and development programs such as the Integrated Child Development Scheme (ICDS) in India.
(5) Innovative approaches for the delivery and sustainability of HBNC.

BEYOND THE FIELD TRIAL: INTEGRATION INTO HEALTH PROGRAMS

Newborn health is rapidly emerging as a global health priority.[1] The home-based newborn care, or any newborn care for that matter, cannot be run in isolation, as a vertical program. How can the HBNC be integrated into the ongoing local, national and international health programs? There are multiple points of potential synergy and opportunities for integration.

1. Maternal Health and Reproductive Health

The HBNC approach in Gadchiroli was built upon the background of a high burden of gynecological[30] and maternal[31] morbidity, and a community-based activity of women's reproductive health.[11,32] The importance of maternal health and maternal care to neonatal health is too obvious to be emphasized. Now, it seems that the converse may also be true. We unexpectedly found that the HBNC interventions in the Gadchiroli trial resulted in a 49% reduction in maternal morbidities. This effect was highly significant ($p<0.005$) and showed a clear dose–response relationship with the mean score of interventions in HBNC. The need for emergency obstetrical care also decreased by 31% ($p<0.005$) (Bang et al, unpublished data).

This effect probably operated through health education, changes in maternal behaviors, the presence of a new semi-skilled VHW at delivery, improved practices of TBAs, continued support to the mother during the post-partum period and better care seeking. HBNC may offer the potential to fill the current gap of post-partum care — a period during which 61% of maternal deaths in developing countries occur.[3,33] Thus, the HBNC and the Safe Motherhood may be complementary approaches.

A recent publication of the cluster randomized trial in Makwanpur, Nepal, supports this view. It reports that awareness generation and mobilization of rural women for better health care resulted in significant reduction in neonatal and maternal mortality.[34]

2. Child Health

Current international programs such as the IMCI do not cover the neonatal period,[6] yet that is where the maximum risk of death is concentrated. The clinic-based approach of IMCI is inappropriate for neonatal care because the family is usually unwilling to take a sick newborn out of the home for medical care. The HBNC approach overcomes these two gaps.

There are several other potentially synergistic points between a child health program and HBNC: (i) Both can be delivered in the community by the same worker. (ii) Many skills required for the treatment of a sick child and a neonate are common (weighing, measurement of respiratory rate and temperature, breast-feeding, health education and use of antibiotics). (iii) The gains of HBNC may not be completely retained if the saved neonates subsequently die during later years of childhood because of other infections such as pneumonia, diarrhea.[35] An IMCI or child health program can prevent these deaths. In the Gadchiroli trial, the post-neonatal mortality did not increase.[26] The reduction in the NMR by 44 points was almost completely reflected in the reduction in the IMR by 43 points. This was probably because the HBNC was introduced in the intervention area over and above an already existing community-based management of childhood pneumonia and diarrhea.[11,12]

Such an incremental effect of pneumonia case management since 1988, followed by the HBNC since 1995 in the 39 intervention villages in Gadchiroli, is seen in Figure 10. The IMR in the last reported year (2002 to 2003) had decreased to 26.5. Thus, the IMR decreased by six points per year during 15 years.

3. Millennium Development Goal and the National Goal: It is meaningful that the resultant IMR in Gadchiroli is less than 30, which is precisely one of the goals of the National Health Policy and the Population Policy of India,[27] to be achieved by the year 2010. HBNC offers a possible approach to achieve that goal. The Millennium Development Goals also include reducing child mortality by two-thirds by 2015.[36] The feasibility and applicability of the HBNC approach can be tested in other developing countries for achieving this ambitious goal.

4. Health Services: Driven by the needs of the individual disease control programs, health services have been overstretched, creating a void of care at the community level. There are multiple vertical programs vying with each other for priority, without any health worker in the community to deliver them. A gross shortage of trained manpower for delivering health programs in developing countries, and the need to strengthen the health systems, has been recently identified as high priority.[37,38] Developing a new VHW or CHW for delivering the HBNC can meet the needs of many programs such as IMCI, polio immunization, AIDS control, DOTS, malaria control — to name a few.

The daily workload of providing HBNC for a unipurpose worker in Gadchiroli was approximately one-and-a-half hours, and, for a multi-purpose worker, it was estimated to be approximately 1 hour. Community-based delivery of various health programs through one CHW may improve the coverage and the compliance of many health interventions, reduce costs by sharing them and will strengthen the health services by providing the currently missing presence in community. The gains of integrating two health interventions into one at the community level have been earlier

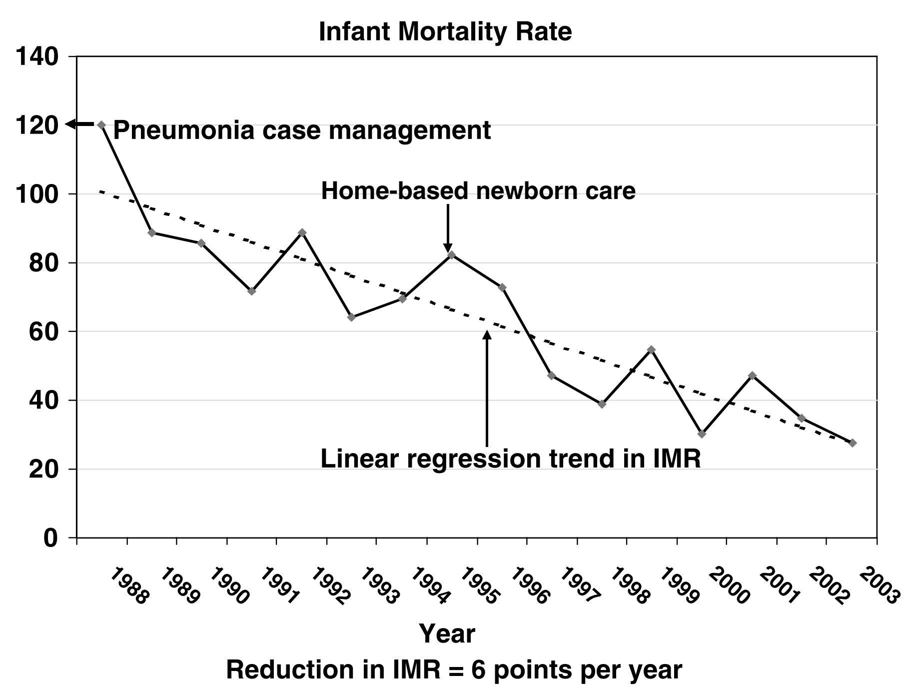

Figure 10. The infant mortality rate in Gadchiroli. Effect of pneumonia case management and the home-based neonatal care in the 39 intervention villages (1988 to 2003).

shown by the field trials of health care and nutrition, and of health care and family planning in Narangwal, India.[39]

However, a lot of groundwork and operations research will be necessary before this potential of integrating the HBNC into health services is realized.

ESSENTIAL INGREDIENTS FOR SUCCESSFUL REPLICATION

The coverage, quality and effectiveness of HBNC in the Gadchiroli trial were high. On looking back, the following ingredients are considered crucial for this achievement:

1. ***Community Consultation***: Neonatal care was not a high priority for the adult males who usually articulate community needs. Moreover, due to their past experience, families had a fatalistic outlook towards the survival of newborns. Hence, a wider consultation with community members, including women, to sensitize them to the need and the possibilities of the new intervention of HBNC, was necessary.

2. ***Selection of VHWs***: This was probably the single most important decision for ensuring success at the community level. A nationwide CHW program in India failed nearly two decades ago and was finally stopped. The major causes were selection of inappropriate persons as CHWs (mostly males) and poor training. The method of selecting VHWs in Gadchiroli involved setting eligibility criteria, wide publicity and community involvement to get the maximum number of eligible candidates, personality testing of the candidates, objective evaluation and, finally, testing in the field. This intensive method of recruiting yielded satisfactory results — high performance of VHWs and a <10% dropout rate in 8 years.

3. ***Training***: In the training strategy and the curriculum that we developed, a new, literate woman from a village required a minimum 36 days of training, spread over a period of 12 months. This gave her the opportunity to learn in small doses (3 days in each month) and to practice the incrementally learned new skills in community (in which about two births occur every month) under the guidance of a visiting field supervisor. This ensured a good quality of training; moreover, she was trained in the setting where she would be working. The community became the ground for learning clinical and communication skills.

4. ***Supervision***: Intensive field supervision (once in 15 days in this trial) was essential for onsite training and ensuring quality performance. Supervision was viewed as an extension of training and support.

5. ***Performance-linked remuneration***: Families, at least for now, were unwilling to pay for the services to the newborn. Hence, the VHW had to be financially supported. Her remuneration was kept marginally more than the wages she might earn as an agricultural laborer in the same number of hours. This ensured that the rural elites did not vie for the job, but at the same time, ordinary village women found it attractive to take up this new job.

We divided her total expected remuneration into approximately one-third as a fixed monthly payment (retention price) and two-thirds linked to her performance. A scale of payment using the work output and the quality of work was developed. We found this to be very effective in providing motivation as well as in ensuring good performance.

6. ***Motivation***: Apart from the remuneration, the new skills and a new role, the recognition that these give her in her community, the respect which she gets from her supervisors and her program managers and, finally, the emotional gratification she gets by helping other mothers and newborns in her own community are powerful motivators.

7. ***Acceptance and utilization***: HBNC covered 93% of neonates in the intervention area in Gadchiroli. The VHW could be present for 84% of the home deliveries. Most families were willing for management of sick neonates, including of LBW, preterm neonates and those with sepsis, to take place at home. The crucial elements for high acceptance were:

(i) An unserved area in which 95% of deliveries occurred at home. (However, even in the areas with a higher proportion of hospital deliveries, most of the post-partum/neonatal period is spent at home. Therefore, HBNC might be needed even in such areas.)
(ii) Selection as the VHW of a woman acceptable to the community.
(iii) 24-hour availability of the VHW.
(iv) Cooperation of the TBA who was made to feel not threatened but supported by the arrival of an *additional* hand.
(v) The curative role of the VHW, and the reduced CF. Treatment of minor illnesses in adults, management of pneumonia and diarhoea in children, management of birth asphyxia with bag and mask, administration of injection vitamin K to neonates and management of neonatal sepsis, LBW or preterm babies and other problems gave the VHWs good credibility. Without these, she would be powerless.

REPLICATION AND IMPROVIZATION INITIATIVES IN SOUTH ASIA

(i) In two national workshops (1999 and 2003), the national leadership of pediatricians and neonatologists in India endorsed the HBNC approach and recommended its wider application.[40,41]
(ii) Replication through NGOs at seven sites in Maharashtra — the project ANKUR. This trial is testing two operational questions. First, is HBNC acceptable and effective in different types of settings such as the rural, tribal and urban slums, including areas with higher proportions of hospital deliveries and lower levels of the IMR? Second, can

HBNC be delivered through the NGO sector? After the baseline study for 2 years, the training has been completed, and interventions introduced in 2003. The early results are promising.

(iii) Development of the training curriculum, manuals and health education material for training in HBNC has been completed by SEARCH, Gadchiroli. The evaluation of the training in seven different field sites showed that 92% of the trained CHWs scored >70%. As a result, the training has been now standardized.

These two projects (ii and iii) are supported by the Saving Newborn Lives Initiative, Save the Children, USA and the Bill & Melinda Gates Foundation.

(iv) Replication through government health services is a major research issue. A field trial (2003 to 2007) by the Indian Council of Medical Research at the behest of the Ministry of Health and Family Welfare, Government of India, is field testing the HBNC approach in five states in India, using the intervention package and training developed in the Gadchiroli trial.

(v) The new 5-year national project, Reproductive and Child Health (RCH-II) of the Government of India (2005 to 2010) includes introducing the HBNC approach in a substantial part of the country.

(vi) The IMCI program in India is being modified to include a HBNC component using a similar approach and has become an ''IMNCI'' that is, Integrated Management of Newborn and Child Illnesses.[42]

(vii) New field trials have been launched to test the feasibility, replicability, and sustainability of HBNC in communities in Bangladesh, Malawi, Nepal and Pakistan.

BEYOND THE OLD BOUNDARIES, A NEW ROLE

Management of a high-risk or sick neonate is usually considered a difficult and specialized job. Though theoretically sound and well meaning, this position may result in a ''touch-not a neonate'' mindset among health workers. The Gadchiroli trial shows that by using the method of task analysis, the complex job of neonatal care can be broken down into a series of smaller, simpler tasks and the VHWs can be trained to successfully undertake these tasks.

This new role involves some unconventional tasks, such as the management of birth asphyxia with bag and mask, administering injection vitamin K, management of LBW babies, clinical diagnosis of sepsis using specific criteria and managing sepsis with two antibiotics, including the administration of gentamicin. With proper training and supervision, these tasks can be done well in home settings by a VHW as demonstrated in this trial.

A trained VHW is not a skilled birth attendant, but she is also not an illiterate traditional attendant. She may be called ''a semi-skilled attendant''. The evidence in this trial shows that by teaming up with TBA, mother and family, the VHW can provide neonatal care, improve neonatal survival, and, as described earlier, also improve maternal health in unserved areas.

THE TALISMAN FOR EQUITY IN HEALTH CARE

We began this chapter with a quote, ''the talisman'', by Mahatma Gandhi. A neonate in developing countries undoubtedly is that weakest human being, its care the ultimate test of equity, human justice and health care.

Four million neonates die every year, most of them at home. If they cannot reach health services, the health services must reach out to them. The evidence from the Gadchiroli field trial suggests that such reaching out is possible.

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