Integrating Results from Formative Phase Studies for Informing the Design of Intervention Studies on Neonatal Health in India

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Abstract

Background The millennium development goal (MDG) for India envisages reducing infant and child mortality by two-thirds between 1990 and 2015. Population-specific, systematic and comprehensive clinic-based strategies are required to reduce neonatal mortality at the national level. The present formative research is a step towards evolving operational strategies to improve infant survival by reducing neonatal morbidity and mortality in the country. It aims at prompt recognition, referral and treatment of sick neonates. It also seeks participation of the community and healthcare providers (a public-private mix) taking into consideration the existing resources and facilities addressing the diverse socio-cultural beliefs that influence the newborn care practices in various strata of the community.

Methods A multi-centric community-based study involving cross-sectional surveys and nested case-control designs was conducted in 10 districts from 9 different Indian states. Cross-sectional surveys were conducted to assess existing healthcare facilities and to assess health-seeking behaviour of various stakeholders. A case-control study nested in a cohort was conducted to identify the risk factors and to validate the verbal and social autopsy tools. A combination of standard qualitative and quantitative research methods was used for data collection purposes by trained research associates with stringent quality checks.

Findings From the cohort study of 10,420 pregnant women, the annual neonatal mortality rate was estimated to be 48.4 per 1,000 live births. The case-control study identified maternal characteristics

like age, low parity and diseases during pregnancy; neonate's characteristics like not crying immediately after birth, low birth weight, congenital anomalies, pre-term birth, non-vaccination, infections and small for date of birth; and community factors like unhygienic practices and no breast-feeding to newborn immediately after birth among the significant risk factors. The cross-sectional survey of health facilities found lack of nurses and midwives (37% in rural vs. 79% in tribal), lack of essential equipment and devices (22% in urban vs. 28% in tribal), lack of supplementary training to health workers in essential newborn clinical care (40% in urban vs. 53% in rural) and inadequate drug supplies (37% in rural vs. 50% in tribal) as barriers in offering effective antenatal and neonatal care services in peripheral rural and difficult-to-reach tribal settings. The cross-sectional study of stakeholders regarding knowledge and perceptions on neonatal health issues suggested community stakeholders have a good perception about common neonatal health problems like respiratory infections, fever and diarrhea, but lacked sensitivity to specific neonatal morbidities like asphyxia, sepsis, low birth weight and hemorrhagic diseases.

Interpretation Population-specific interventions need to be instituted, as perceptions and behaviour of stakeholders, the health facilities and the risk factors for neonatal mortality were found to vary among rural, tribal, urban slum and urban communities. Interventions for health behaviour modification and reduction of sepsis, asphyxia and low birth weight should be undertaken as the next phase of the study.

Introduction

Neonatal care in developing countries, where 96% of the global burden of neonatal death occurs, is practically non-existent (Bang et al. 1999). In India, as many as 1.72 million children die each year before reaching their first birthday, and of these, 72% die during the neonatal period. The millennium development goal (MDG) for India envisages reducing infant and child mortality by two-thirds between 1990 and 2015 (World Bank 2004).

Although a home-based neonatal care approach (Bang et al. 2001) was found effective in reducing neonatal mortality in a rural community in India, it was designed for specific morbidities. The said approach is yet to be replicated in other parts of the country on a larger scale because of certain inherent operational issues. For example, the approach requires provision of an additional community worker (*shishu rakshak*) at the village level, and clinicians are not yet motivated enough for administration by injection of gentamycin to the sick newborn by these untrained community workers. There is thus a need to further explore home-based and clinic-based strategies to reduce neonatal mortality at the national level.

Population-specific, systematic and comprehensive strategies are required to reduce neonatal mortality at the national level. The Neonatal Health Research Initiative (NHRI) is a comprehensive research endeavour funded by the United States Agency for International Development (USAID) in conjunction with the International Clinical Epidemiology Network (INCLEN Trust) to develop and test intervention strategies for neonatal health in India.

Formative research is a step towards developing intervention strategies to improve infant survival (Gittelsohn et al. 2006) and was thus the initial phase of the NHRI program. Steps considered vital for reducing neonatal morbidity and mortality in the country include prompt recognition, referral and treatment of sick neonates with participation of the community and healthcare providers. Strategies must take into consideration the existing resources and facilities and address the diverse socio-cultural beliefs that influence the newborn care practices in various strata of the community.

The objectives of the formative stage were (1) to identify risk factors for neonatal mortality, (2) to assess medical and social causes of neonatal deaths, (3) to assess the neonatal healthcare facilities, (4) to assess health-seeking behaviours of community stakeholders and (5) to recognize patterns for, determinants of and barriers in newborn care. These in turn would inform the development of intervention studies.

Methods

Study Design

Various multi-centre community-based studies were employed, including cross-sectional surveys, cohort studies and nested case-control studies (Rothman and Greenland 1998). Cross-sectional surveys studied selected healthcare facilities and identified stakeholders' health-seeking behaviour. A prospective cohort of pregnant women (in the 3rd trimester of pregnancy) was followed until one month after delivery for the purpose of studying neonatal deaths. Neonatal deaths occurring in the follow-up period constituted cases, and the family members were interviewed using verbal and social autopsy methodology. A random sample of mothers who delivered normal babies (weighing more than 2500 gm at birth) formed the group of controls. Thus, a nested case-control (approximately 1:2 ratio) study of pregnant women enabled identification of risk factors and validation of the verbal and social autopsy tools.

Study Setting

The cross-sectional surveys were conducted in 10 districts from 9 different Indian states, representing varied socio-cultural and geographical regions (see Figure 1 – map). Within each district, three blocks (geographic units covering a population of approximately 100,000 inhabitants) were randomly selected, one each from rural, urban and urban-slum areas. In addition, two sites (Bilaspur and Nagpur) also selected a tribal block each. For the nested case-control study, nine districts participated (Delhi did not) and one block per district was included.

Sampling Methods

For the cross-sectional surveys, a multi-stage, stratified sampling procedure was used, with block as the primary sampling unit. In the first stage, a single district per site was purposively selected from each participating state, taking into consideration feasibility and convenience. Participating states were those where a clinical epidemiology unit (CEU) or partner medical college (PMC) belongs. In the second stage, three blocks per district (plus two tribal blocks) were randomly selected within strata of block type (rural, urban, urban-slum), for a total of 32 blocks. Only one block per district was selected (at least two of each type of block) for the nested case-control study, given financial constraints, in following the expected large number of pregnancies in a four-month period.

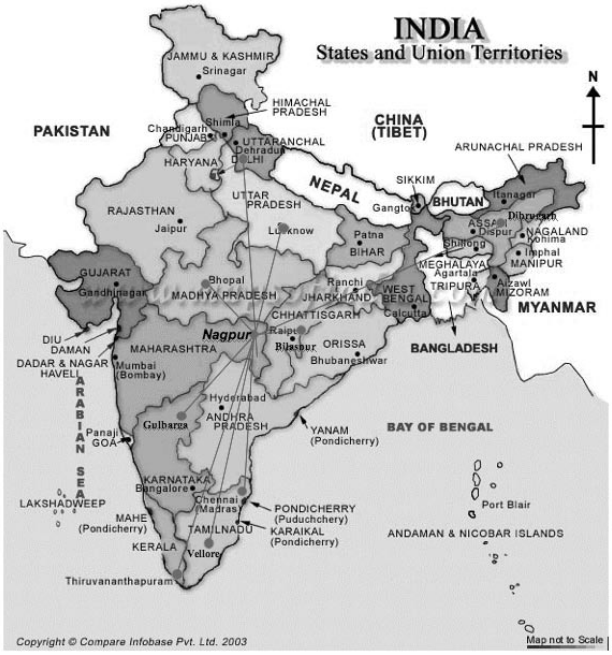
Sample Size

The cross-sectional healthcare facilities survey had a specified number of facilities (one private and one government) per block, and the stakeholders survey identified a specified set of individuals to interview within each block. Since the cross-sectional surveys were qualitative in nature, sample size considerations were only needed for the nested case-control study. All pregnant women in their third trimester in the sampled 10 blocks were recruited into the cohort study that was to yield the subjects for the nested case-control study, from 2002 to 2003. Based on a birth rate in India of 25 per 1,000 population per year, and on an annual neonatal mortality rate in India of 40 per 1,000 live births, we estimated 33 neonatal deaths to occur per block in a four-month period. Accounting for a 20% non-responder rate, we thus expected a total of 260 neonatal deaths for our study in the 10 selected blocks. A total of 250 cases and 491 controls were recruited. This provided at least an 82% power to detect odds ratios of 1.6 or higher in two-sided .05 significance tests, for moderate (35%) risk factor exposures in the control group.

Data Collection and Management

Data were collected by trained research associates in structured, pre-designed, pilot-tested study instruments, following stringent quality assurance procedures developed, monitored and evaluated by the Central Coordinating Office (CCO).

Figure 1. Location of NHRI study sites for data collection in the formative phase



Participating sites:
1. Nagpur, Maharashtra (Central Coordinating Office - CCO)
2. Bhopal, Madhya Pradesh
3. Lucknow, Uttar Pradesh
4. Vellore, Tamilnadu
5. Thiruvananthapuram, Kerala
6. Dibrugarh, Assam
7. Gulbarga, Karnataka
8. Chennai, Tamilnadu
9. Bilaspur, Chattisgarh
10. New Delhi

Qualitative data from the cross-sectional survey of healthcare facilities were gathered by tape recorded interviews from a single health worker per facility (n=62) and from five mothers or caretakers of sick neonates exiting from a physician consultation (n=306). In addition, an equipment check was conducted of each healthcare facility (n=61) and the skills of the interviewed healthcare worker in handling five sick neonates were observed (n=282).

Tape-recorded in-depth interviews of selected stakeholders – medical officers (n=94), village health nurses or multipurpose health workers (VHN/MPHW) (n=100), non-governmental organization (NGO) representatives (n=94) and mothers (n=270) – were done to assess healthcare-seeking behaviours in the selected blocks. The mothers were categorized into three groups: (a) women who had experienced neonatal illness or neonatal death in the last three months and sought some type of health care (n=100); (b) women who had not experienced neonatal illness or neonatal death in the last three months (n=100); (c) women who had experienced neonatal illness or neonatal death in the last three months, but did not seek any type of health care (n=70). In addition, five focus group discussions were conducted per district with: (i) women above 40 years who have grandchildren, (ii) husbands or grandfathers, (iii) women with a child less than six months of age, (iv) VHN/MPHW and (v) birth attendants. In all, data from 792 in-depth interviews and 50 focus group discussions were obtained.

The cohort studied yielded the subjects for the nested case-control study. A cohort of 10,420 pregnant mothers was recruited and followed until the outcome (i.e., neonatal death or live birth). All the neonatal deaths (n=250) were thoroughly investigated and subsequently subjected to verbal and social autopsy (Gray et al. 1989). These were tape recordings, subsequently transcribed. In addition to the qualitative data from the cases, we collected quantitative information from both cases and controls through standardized interview forms.

Statistical Analysis

Qualitative interview data from tape recordings were translated, transcribed and coded manually since they were in a variety of local Indian languages. Coded responses were analyzed descriptively with simple frequency distributions. Whenever multiple observations within a facility or by a health-care worker were taken, adjustments to the variance of estimated percentages were performed to account for the correlated nature of the data. For the nested case-control study, unadjusted odds ratios were initially calculated and then adjusted using the Cochran-Mantel-Haenszel chi-squared statistic to account for the 10 centre strata. Unconditional multiple logistic regression permitted examining the relative importance of various risk factors. All statistical analyses were performed with Stata (version 8.0, 2003).

Results

The survey of the existing healthcare facilities revealed that their geographic distribution is concentrated in urban and urban slum settings, with complete lack of facilities in tribal settings. Health facilities, particularly in rural and tribal settings, were not conveniently located in close proximity of the healthcare seekers (>80% of the facilities were located at >1 km from places of residence), and the facilities did not cater to the specific needs of the community. Approximately 55% of the facilities provided primary care, 40% secondary care and only 5% tertiary care. All three levels of healthcare services were only available in urban facilities, while tribal facilities completely lacked tertiary care. Although the private sector was well represented in urban settings, it was less visible and operational in rural and tribal settings.

Lack of nurses and midwives (37% in rural and 79% in tribal) and inadequate drug supplies (37% in rural and 50% in tribal) hampered the routine antenatal and neonatal care practices in peripheral rural and difficult-to-reach tribal settings. Health facilities in general had very limited capabilities to offer emergency and specialized neonatal healthcare services, due to lack of essential equipment and devices (approx. 22% in urban to 28% in tribal) and lack of supplementary training to health workers in essential newborn clinical care (approx. 40% in urban to 53% in rural).

The cross-sectional study of stakeholders, regarding knowledge and perceptions on neonatal health issues, suggests that the current status of antenatal care is inadequate and did not stand up to the expectations of the mothers. Community stakeholders have a good perception about common neonatal health problems like respiratory infections, fever and diarrhea, but lacked sensitivity to specific neonatal morbidities like asphyxia, sepsis and hemorrhagic diseases. Sensitivity was highest among urban and lowest among tribal stakeholders. Stakeholders did know some correct newborn care practices (e.g., measures for low birth weight babies) and the benefits of seeking newborn care at health facilities. However, the decision to seek care for newborns and pregnant mothers was taken mostly by husbands, particularly so in rural and tribal areas. Lack of time (40%) and family pressures (22%) were the decisive factors against seeking healthcare facilities in urban and slum areas, whereas lack of transportation (54%), lack of money (40%) and rumours about the health system (25%) were the main factors found in rural and tribal areas. The perceived level of satisfaction among the stakeholders was found to be very high in tribal settings (93%), but very low in urban settings (10%). The NGO representatives perceived the lack of awareness (33%) and lack of doctors or treatment facilities (23%) as the main reasons for non-seeking of newborn care services by rural and tribal communities. Urban and slum communities were found to have a better perception about good newborn care practices (e.g., early breast-feeding, colostrums feeding, improved

hygienic care), whereas rural and tribal communities practiced mainly bad newborn care practices (e.g., withholding early breast-feeding, no colostrums feeding, application of unhygienic things, immediate bathing and dressing of the baby).

Healthcare providers did have some knowledge and skills to provide basic healthcare to newborns (respiratory tract infections, diarrhea/dehydration, fever), but they lacked in specific clinical and managerial skills required to treat sick neonates (pneumonia, jaundice, signs/symptoms of sickness and low birth weight).

From the cohort study of 10,420 pregnant women, the overall neonatal mortality rate was estimated to be 48.4 per 1,000 live births per year. Table 1 presents the causes of mortality (note that a child can have multiple causes of death). Respiratory distress syndrome, low birth weight, birth asphyxia and neonatal sepsis complex were the four most common causes of mortality.

Table 1. Causes of neonatal deaths (n=250) in the cohort study of 10,420 pregnant women

Cause	%*
Respiratory distress syndrome	56.4
Low birth weight	48.5
Birth asphyxia	40.2
Neonatal sepsis complex	36.9
Pre-term baby	29.9
Congenital anomaly	12.4
Hypothermia	12.0
Jaundice	4.1
Diarrhea	2.5
Neonatal tetanus	2.5
Unknown	8.3
Unspecified	1.7

* Note that a child can have multiple causes of death

The nested case-control study odds ratios (unadjusted, stratified and adjusted) are presented in Table 2. All maternal, neonate and community factors studied were statistically significant at the 0.05 level in bivariate testing, adjusting for site with the M-H chi-squared statistic. Among the maternal factors, strongest relationships with caseness were seen for young age, low parity, illiteracy, toxaemia or diseases during pregnancy and difficulties during labour. The neonate's factors were in general stronger, with not crying immediately after birth, congenital anomalies, pre-term birth, low birth weight, non-vaccination, infections and small for date of birth being among the strongest risk factors. Finally, one of the strongest risk factors was to not be breast-fed immediately after birth, followed by unhygienic cord care practices. Most of these factors are highly correlated with each other, so that the relative importance of the factors was examined in multiple logistic regressions. The final model (presented) showed that the strongest risk factors were those associated with the neonate itself, with congenital anomalies the strongest, but with preterm and smallness for date very strong as well. Parity (maternal factor) and withholding of breast-feeding (community factor) were also importantly associated with being a case.

Table 2. Risk factors for neonatal mortality identified from the case (n=251) – control (n=591) study

	Bivariate analyses						Multivariate analyses		
	Crude			Stratified (Mantel-Haenszel)			Logistic Regression		
	OR	95%CI	p	OR	95%CI	p	OR	95%CI	p
A. Maternal factors									
Parity (nulli and primipara)	3.98	2.82–5.63	0.0001	4.06	2.90–5.70	0.0001	3.58	1.91–6.76	0.0001
Maternal Illiteracy	1.61	1.13–2.26	0.0054	1.66	1.18–2.35	0.0032	1.79	1.03–3.12	0.0381
Disease during pregnancy	3.11	2.13–4.53	0.0001	3.43	2.34–5.04	0.0001	2.22	1.34–3.98	0.0069
B. Neonate factors									
No cry immediately after birth	10.02	6.03–16.98	0.0001	9.37	5.76–15.2	0.0001	2.27	1.02–5.01	0.0459
Resuscitation	4.15	2.86–6.02	0.0001	5.96	3.87–9.14	0.0001	2.09	1.12–3.91	0.0211
Low birth weight	5.71	3.85–8.48	0.0001	6.41	4.25–9.66	0.0001	3.38	1.72–6.49	0.0001
Preterm	16.63	9.03–32.49	0.0001	17.16	9.34–31.52	0.0001	7.96	3.16–20.05	0.0001
Small for date	11.71	6.84–20.71	0.0001	11.65	6.66–19.73	0.0001	7.12	3.28–15.45	0.0001
Congenital anomalies	16.48	4.89–86.3	0.0001	16.59	4.98–55.28	0.0001	23.66	4.01–139.55	0.0001
Infections (ARI)	11.43	5.13–28.71	0.0001	12.13	5.28–27.88	0.001	6.42	1.98–20.78	0.0019
Non-vaccination	6.71	4.51–10.14	0.0001	9.69	6.15–15.29	0.0001	4.74	2.64–8.48	0.0001
C. Community level factors									
Unhygienic practices	1.46	1.04–2.08	0.0257	1.96	1.25–3.09	0.0016	1.97	1.01–3.86	0.0497
Withholding immediate breast-feeding	23.98	14.96–39.01	0.0001	22.36	14.17–35.28	0.0001	12.27	6.54–23.11	0.0001

Some stratum-specific variations were observed (as assessed by the test of homogeneity in stratified analysis) in neonatal care practices among the sites with respect to distribution of certain important factors like unhygienic practices, incorrect feeding practices, improper care of newborn with low birth weight and inadequate care for mother during and after delivery. This could be mainly attributed to low literacy status and ignorance of the caretakers, especially in rural and tribal communities.

The qualitative studies of verbal and social autopsies helped to understand the quantitative results and to design possible interventions. Mothers and relatives undergoing verbal autopsies were relatively more sensitive to respiratory distress syndrome, but more specific to congenital anomalies and prematurity.

Social autopsies identified a different set of factors related to neonatal mortality. Among these, we note delay in recognition (ranging from 76% in tribal to 94% in urban) and delay in seeking care for neonatal problems (ranging from 37% in urban to 80% in tribal), non-utilization of healthcare facility for treatment of neonatal illnesses (ranging from 41% in tribal to 87% in urban slum), non-involvement of mothers in decision-making actions related to neonatal health (ranging from 73% in urban to 97% in tribal) and unexplained or sudden deaths of newborn (ranging from 8% in urban

to 75% in rural). When compared to healthcare workers, mothers had reasonably high sensitivity (80%) and specificity (57%).

Table 3. Sensitivity and specificity of verbal autopsy in identifying various causes of death

	Sensitivity (%)	Specificity (%)
Respiratory distress syndrome	90	54
Low birth weight	84	65
Birth asphyxia	73	76
Neonatal sepsis complex	41	85
Pre-term baby	82	93
Congenital anomaly	66	96
Hypothermia	57	91
Sudden death	33	82
Neonatal tetanus	100	100

Discussion

Neonatal mortality in India is a major public health problem for the country and without a doubt, one of the most pressing problems to overcome (World Bank 2004). Strategies for addressing the problem can benefit from qualitative studies prior to undertaking intervention studies. Qualitative formative studies are increasingly playing an important role in developing quantitative and intervention studies (Mesko et al. 2003; Milligan et al. 2002). In rural Nepal, quantitative and qualitative components were used to describe the care-seeking practices and care of perinatal illnesses (Mesko et al. 2003). In order to design relevant interventions to improve prenatal care, one requires thoughtfulness, sensitivity and understanding of the specific circumstances of communities (Milligan et al. 2002). Such studies help in determining community specific issues that may present problems for late recognition of neonatal illness or delay in seeking medical treatment. For example, the urban slums in India have specific problems, such as inadequate perinatal care (Fernandez et al. 2003) and inequalities in the distribution and access to basic health services (Awasthi and Agarwal 2003; Kapoor et al. 1996), and these are major determinants of childhood mortality and morbidity. Rural areas of India face many of the same factors, but with slight variations such as poor use of primary care health services and inadequate antenatal care (Bhardwaj and Hasan 1993; Misra et al. 1993). Such differences may be important in the planning of intervention studies. In our studies, the distribution of the identified risk factors was found to vary among rural, tribal, urban slum and urban communities. Thus, stratum-specific interventions need to be instituted to address the issue of neonatal mortality, particularly focusing on the needs of the tribal and rural strata of the population. Different cultural practices by various religious and ethnic groups may also need to be considered when developing possible interventions.

In our case-control study, maternal characteristics were associated with neonatal mortality, but characteristics of the neonate (low birth weight, congenital anomalies and prematurity) and perinatal care practices (incorrect feeding practices, unhygienic cord care and non-vaccination) were much more important factors associated with mortality. The extent to which physical characteristics of newborns such as low birth weight and gestational age relate to neonatal mortality is well known (Tripathy et al. 2002; Kaushik et al. 1998; Sachar and Soni 2000). Maternal factors that make for a

high-risk pregnancy have also been recognized (Gupta et al. 1997; Sehgal et al. 2004). However, the multiple factors are highly correlated, confounded and interactive. Multivariate regression models may tease out some of these effects (Kost and Amin 1992), but integrating qualitative information is not a statistically clear-cut methodology.

The development of interventions is a complex activity, given the multiple factors and specific circumstances of different communities and populations. Hospital-based deliveries (Augustine and Bhatia 1994) may have different factors from home-based deliveries in rural communities (Bang et al. 2001). It is thus essential to contextualize the development of interventions in order to optimize their effectiveness. There have been several suggestions for interventions over the years, from training traditional birth attendants (Bhakoo and Kumar 1990) or women as healthcare providers (Shah 1989), conducting community-level educational outreach (Das et al. 1998), to the more recent home-based neonatal care and sepsis management program (Bang et al. 1999) and the national Integrated Management of Childhood Illnesses (IMCI) approach (Anand et al. 2004). From our qualitative studies, communities also recognized the importance of low birth weight, sepsis, respiratory distress syndrome, asphyxia, pre-maturity and hypothermia as perceived causes of neonatal deaths. Hence cause-specific interventions should be devised to reduce neonatal morbidity and mortality in the country. Since the verbal autopsy and social autopsy tools used in our study were sensitive and specific in recognizing neonatal health problems, they can be used by the health workers in the field to investigate medical and social causes of neonatal deaths.

Our healthcare facility survey identified similar problems of care as Biswas et al. (2004) in West Bengal. There is a need to take a fresh review of the existing healthcare facilities so as to make them more purpose-specific and effective in offering neonatal care services to the community by upgrading their capabilities in terms of resources like drugs, equipments, manpower and training. The stakeholders did not have very precise and accurate information on neonatal diseases, and many socio-cultural factors were found to influence the health-seeking behaviour of parents. Suitable behavioural interventions should be designed to bring in the behavioural change in caretakers and healthcare-providers, thereby leading to correct newborn care practices. These and other interventions are being planned and carried out in India currently under the auspices of the Neonatal Health Research Initiative, as India strives to address the millennium development goal (MDG) of reducing infant and child mortality by two-thirds between 1990 and 2015 (World Bank 2004).

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