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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]

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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).

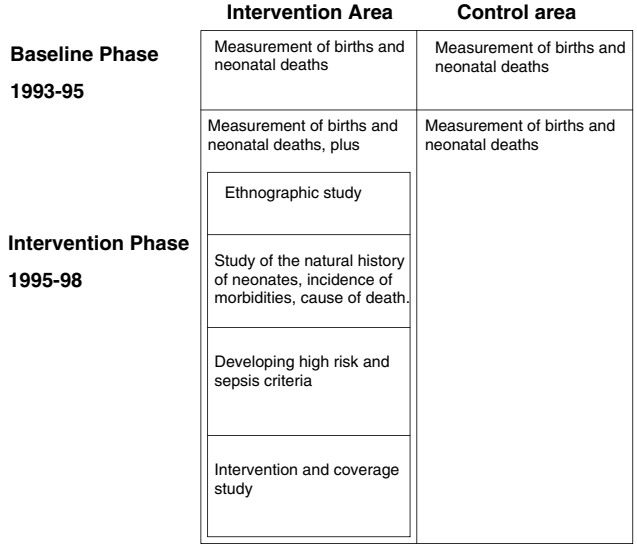

Figure 1. The study design of the field trial of home-based neonatal care in Gadchiroli.

SAMPLE SIZE[2]

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

$\alpha = 0.05$, two − tailed, $\beta = 0.2$

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

d = expected reduction = 25% of $0.07 = 0.0175$

P_1 = probability of death after interventions that is, $0.07 - 0.0175 = 0.0525$

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

$$q = 1 - P = 0.939$$

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

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

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

p = mortality due to neonatal sepsis expressed as proportion of neonatal mortality = 0.33

Expected reduction 40% = 0.13

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

= 209 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.

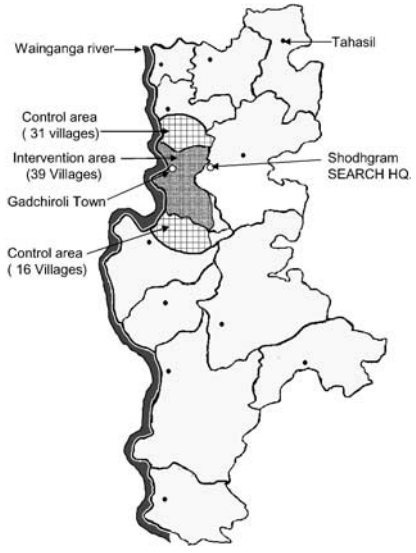

Figure 2. The field trial area in Gadchiroli.

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.

Activities	93-94	94-95	95-96	96-97	97-98	98-99
A. Baseline Phase						
Baseline data collection	—	—				
First review			X			
B. Intervention Phase						
i) Year 1 : training and observation to estimate morbidities and cause of neonatal deaths.			—			
ii) Second review.				X		
iii) Year 2 & 3 : Home-based management and monitoring				—	—	
C. Analysis and collection						
i) Analysis						—
ii) The final review						X
iii) National meeting						X

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 (1993–95) 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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