

Original Article

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

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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.

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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.

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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 VHVs 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

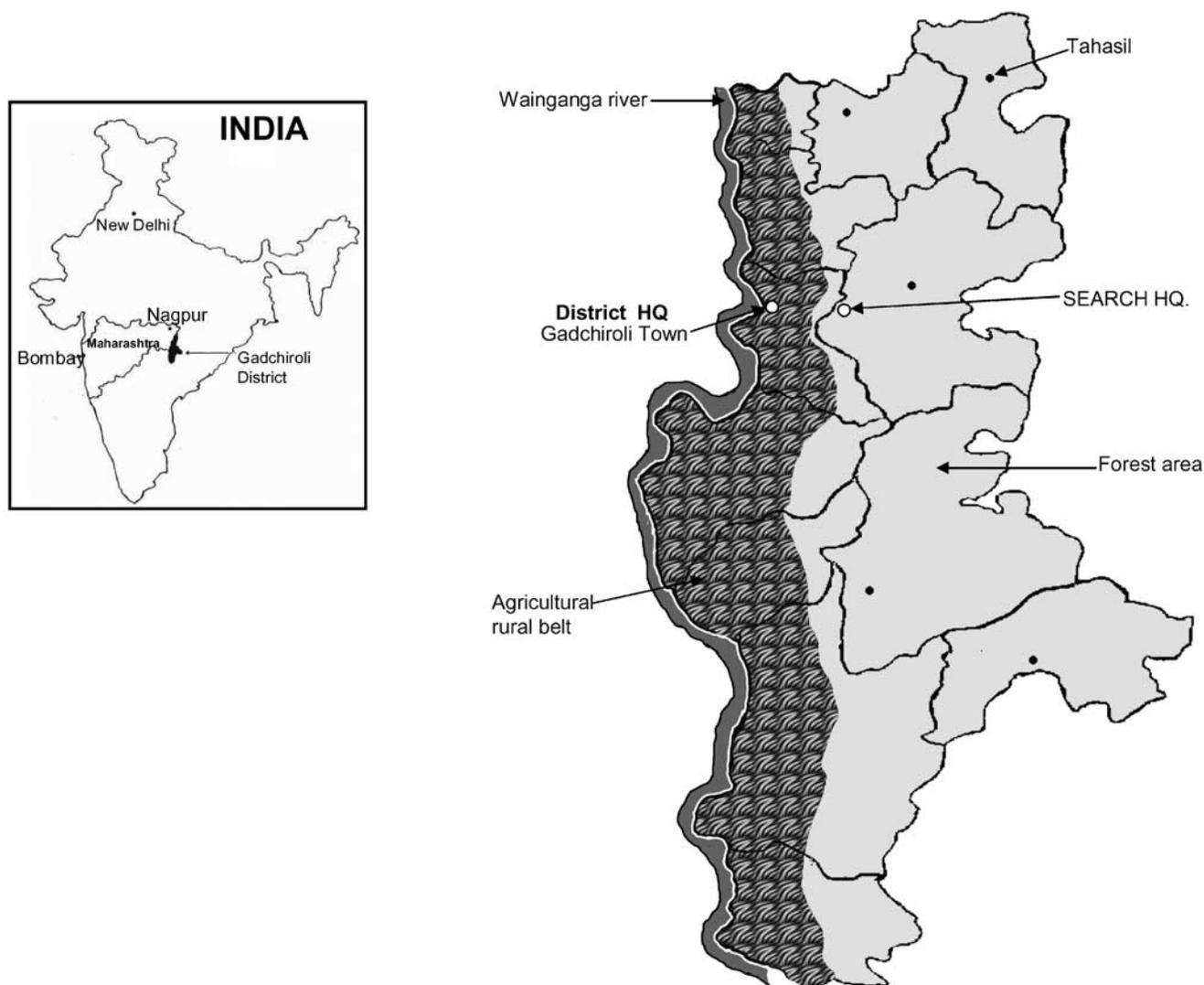


Figure 1. (a) The Maharashtra state. (b) Gadchiroli district.

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	%	
<i>Population</i>	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	—	
<i>Rural–urban distribution</i>			
Rural	718,445	91.3	61.3%
Urban	68,565	8.7	38.7%
<i>Proportion of 0 to 6 population — total</i>	—	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	
<i>Literacy — in population aged 7 and above: total</i>	—	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 state²⁴ (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.

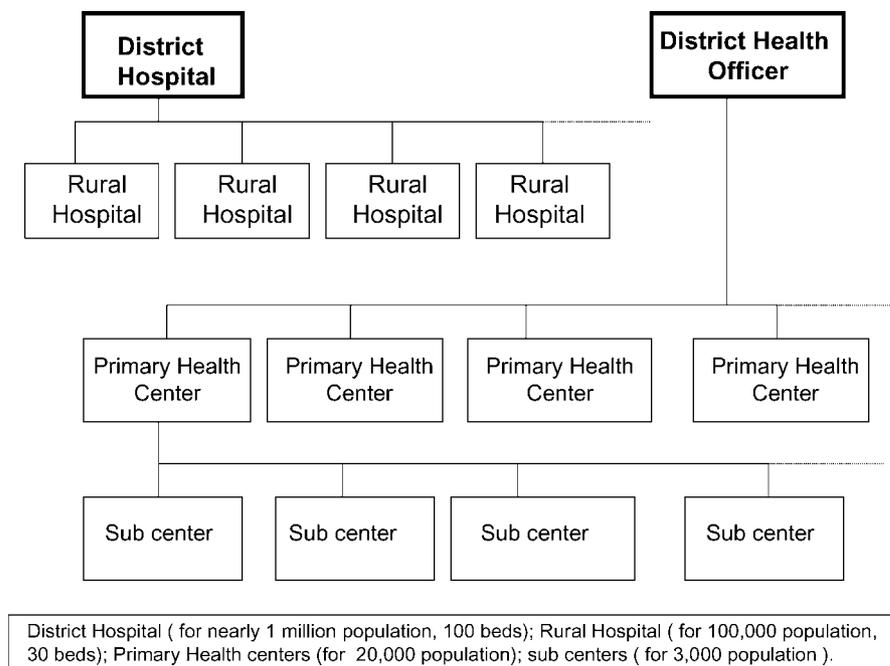


Figure 3. Government health services.

Box 1 The Community Health Action and Research Approach of SEARCH

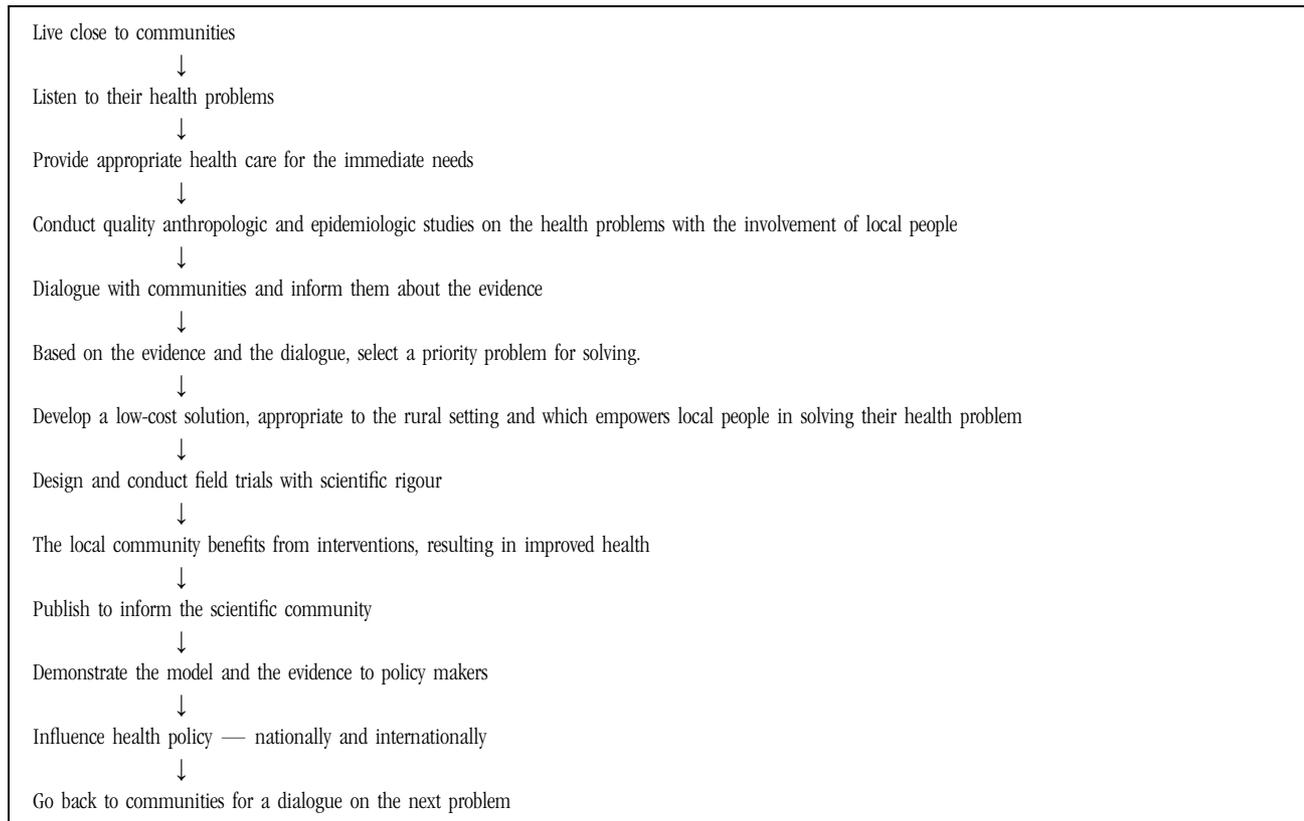


Figure 4. Shodhgram.

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 interven-

tions 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
<ol style="list-style-type: none"> 1. A community-based study of the prevalence of gynecological morbidities and reproductive tract infections 2. Trained the traditional birth attendants (TBAs) 3. A reproductive health clinic 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} 	<ol style="list-style-type: none"> 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 them²⁷ 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 SEARCH²⁸ 3. Services in clinic included antenatal examination, treatment of gynecological infections, abortion and family planning services, and management of infertility
B. Studies and interventions on Child Mortality	
<ol style="list-style-type: none"> 6. A vital statistics surveillance system was developed in an area of 102 villages in the agricultural western part of the district 7. The verbal autopsy method was further developed³³ 8. A field trial of case management of childhood pneumonia in an intervention area with 58 villages and a control area with 44 villages 9. A simple device, named "breath counter," was developed 10. Treatment of neonatal pneumonia with cotrimoxazole by these workers 	<ol style="list-style-type: none"> 6. The vital rates were first estimated in 1988. The infant mortality rate was 121 per 1000 live births 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. (i) Study of local beliefs and practices <ol style="list-style-type: none"> (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. To assist TBAs in making a correct diagnosis of pneumonia³⁵ 10. Both the cause-specific mortality rate for neonatal pneumonia and the neonatal mortality rate decreased¹⁷
C. Alcohol and Social Policy	
<ol style="list-style-type: none"> 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 12. A deaddiction therapy center and a village-based deaddiction and preventive education approach were started (1994) 	<ol style="list-style-type: none"> 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

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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