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SEARCH's HBNC trial: towards a broader debate on the ethics of social intervention research

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Abstract

The SEARCH home-based neonatal care (HBNC) trial generated a heated debate amongst health activists, researchers and demographers in India upon its publication in the Lancet in 1999. More than a decade after the Lancet article, a new debate has been sparked, this time on the ethics of the study. Against this backdrop, we identify three key questions which require in-depth discussion. First, was the choice of the study design (cluster non-randomised control trial), appropriate given the circumstances relating both to the study site and the locale? Second, was it ethical not to offer any intervention to the control units given that a known treatment existed? Third, do contemporary research ethics guidelines satisfactorily address all the ethical issues related to the study design? This paper examines the first question. We draw three main conclusions from this critical appraisal of the HBNC trial. First, the study design of the trial is motivated by the paradigm of evidence-based programmes and policy formulation. Second, generally speaking, the HBNC study design passes the internal and external validity tests but raises important ethical questions. Third, these questions transcend the HBNC trial to apply to many other social and health interventions studies; as such, the HBNC trial should be studied as a paradigmatic case.

Introduction

The home-based neonatal care (HBNC) cluster non-randomised control trial conducted by the Society for Education, Action, and Research in Community Health (SEARCH), India, generated a heated debate amongst health activists, researchers and demographers in the country upon its publication in the Lancet in 1999. This debate, as one of us (SB) remembers, stemmed in part from criticism of the study's methodology and questions regarding the generalisability of its findings. A decade after the *Lancet* article, a new debate has been sparked, this time on the ethics of the study (1-3).

This new debate has followed the publication in 2007 of Lavery and collaborators' book, *Ethical Issues in International Biomedical Research: A Case Book* (4). In this edited volume, SEARCH's HBNC trial was used to illustrate ethical issues related to scientific validity. In their opening comments on the trial, Lavery and collaborators raised some key questions:

> ... was there sufficient scientific justification for randomizing the villages between the intervention and the control? Was it ethically permissible for the investigators not to treat those neonates in the control villages identified with sepsis during the study with effective treatment? Should a different research design have been used? If so, what design? Finally, does it matter that this study was being conducted by researchers from India and that it was not sponsored or conducted by researchers from developed countries? ... (4: 108).

This introduction to the case was accompanied by two commentaries written by Marcia Angell and Zulfiqar Bhutta. At the heart of Angell's critique of the case was scepticism about whether the ethical justification of the HBNC trial's study design was adequate. On the other hand, Bhutta's defence was grounded in: (a) the study's potential long-term, desirable public health implications if the intervention was proven effective; (b) the people-centred motivations of the researchers, that is, their long-term commitment not only to the disadvantaged population at the study site, but also to the fight against unacceptably high rates of poor neonatal outcomes globally; and (c) the contextual interpretation of research ethics principles, particularly those relating to 'standard of care'.

Against this backdrop, we identify three key questions which require more in-depth discussion. First, was the choice of the study design, a cluster non-randomised control trial, appropriate given the other circumstances relating to the study site and the locale? Second, was it ethical not to offer any intervention to the control units when a known proven treatment existed? Third, were there any ethical issues arising from the study design? If there are, do contemporary research ethics guidelines satisfactorily address the ethical issues related to the use of the cluster controlled trial design in social intervention research?

This paper focuses on the first question. Except for providing some initial insights into issues related to the standard of care, we leave the other two questions for another occasion, appreciating that they too warrant in-depth discussion, and we hope to pursue these issues subsequently in this journal.

There are a number of reasons for essaying an in-depth treatment of these three questions.

First, the various commentaries that have been published mark the key ethical issues relating to the case, and together they help convey the complexities involved. This debate therefore

seems to have matured and is poised for a move beyond the particular case to a generic discussion of the issues.

Second, a retrospective analysis of the HBNC trial will be challenging as the ethics discourse has evolved and standards of ethics are different, at least in certain respects, from those that existed when the trial was launched. For example the debate on standards of care and the use of placebo has evolved in the past decade, after HBNC's launch in the early 1990s. We hope that our critique will enable a broader debate on key research ethics issues such as standards of care and post-trial obligations in social interventions comparable to the HBNC trial. In this broader debate, we would like to harness the HBNC's potential as a paradigmatic case instead of targeting it for research ethics appraisal and critique.

Finally, this broader debate appears timely as there is a growing interest in designing and implementing social interventions in health in tune with the biomedical or clinical trial model, as has been used in the HBNC study. We draw upon many such studies in the arena of neonatal care in our paper. Such a trend is also visible in other fields. For example, researchers at the Poverty Action Lab (http://www.povertyactionlab.org), Massachusetts, USA, have been engaged in an assessment of social interventions using controlled trial designs in fields such as education, micro-financing, and health, in different contexts in the developing world. Interestingly, the use of the biomedical research model in social intervention research in India can be traced to, as far back as as the 1970s, to the Narangwal Project (5). One will also find such social intervention experimentation elsewhere in the world. These studies can be fraught with similar ethical questions as is evident from the debate that one such study (6) generated in the recent past.

This growing interest in modelling social interventions on biomedical research designs can be explained both by the demand for evidence-based scaling up of "successful" interventions and by the argument that developmental resources might not be optimally utilised in the absence of a systematic evidence base. If this is the case, an in-depth exploration of the three questions we raised earlier appears to be all the more relevant, useful and timely to appreciate the ethical tenability of studies of this genre.

In what follows, we present a critical appraisal of SEARCH's choice of study design in the HBNC trial. To do so, we reviewed the study designs used in other similar studies. We have also attempted to review whether control clusters in these other studies received any interventions or none at all, and the reasons for the researcher's decision. Based on our appraisal we conclude that, broadly speaking, the HBNC study design was appropriate and scientifically valid. Even so, the HBNC study raises research ethics questions, particularly relating to standard of care. These questions transcend this one study and are applicable to a wide range of social intervention research modelled on the biomedical research paradigm. These questions will require further in-depth exploration and a broader debate.

Appraisal of the choice of study design

We assessed the study design used by SEARCH, the cluster non-randomised controlled trial, using the criteria of 'internal' and 'external' validity. We use the notion of validity to convey appropriateness and suitability of a design to the research context and the research problem. In our case therefore, internal validity is an indication of whether SEARCH's choice of study design was justified by the study locale and the context of neonatal mortality in Gadchiroli and whether it enabled measurement of the experimental intervention's impact on neonatal health outcomes. External validity is judged according to whether comparable studies - in this case, those focusing on high neonatal mortality rates - addressed the issue by selecting a similar study design, in this case, the cluster non-randomised control trial or one of its variants.

1. Assessment of internal validity

Internal validity must be assessed on three counts: (a) the choice of a controlled design with no intervention in the control arm; (b) the choice of units of intervention (i.e. clusters vs. individuals) and (c) the method of assignment of units to the intervention or control arm (i.e. non-randomisation vs. randomisation).

a) *The choice of a controlled design with no intervention in the control arm*. We appraise two aspects of SEARCH's decision regarding controlled design: the choice of controlled trial design over other designs, and the decision to provide no intervention to control clusters. Overall, controlled trials (particularly if randomised) continue to enjoy a higher status than other designs do. In the case of the HBNC trial, the intervention tested was unconventionally simple, and, without a highly regarded type of study design, it might not have withstood the scepticism of policy makers and the wider community. So the SEARCH team's use of a control arm seems justified on these grounds. This view on the choice of a controlled trial design has been expressed before (7).

While other commentators such as Angell (8) have challenged this justification arguing that "there are really no surprises in these sorts of trials, and so they are not particularly 'persuasive to policy-makers' " (8:115), the results of the HBNC trial in fact suggest otherwise. The SEARCH researchers were able to report a 72% decrease in mortality, much more than the 25% difference that the study was expected to detect. The ability of the HBNC trial to demonstrate a reduction in neonatal mortality on such a scale played a crucial role in changing policies in India (3, 9). It also seems to have encouraged several other groups to pursue research in the field. Bhutta captures the study's importance with his statement: "The benefits of the study for the local people (in terms of improved neonatal survival) and its impact on national and global programmes for neonatal care have been enormous." (10: 117).

Regarding the decision to provide no intervention to controlled clusters we make two observations, drawing upon the reporting of the HBNC study by the SEARCH

researchers. First, SEARCH's reporting of the HBNC study in its first published paper (11) and later in a series of publications (12-14) describing the methodology, processes and impact of the HBNC trial did not state any specific rationale for its decision to provide no intervention to the control cluster which constituted the standard of care in this trial. We see that SEARCH's decision was twofold: a decision against the provision of state-of-the-art neonatal care requiring access to tertiary care facilities to the control clusters; and a decision to provide no intervention to the control clusters. Bang (9) referred to the Declaration of Helsinki Guideline 17 in response to criticism of the first decision. His defence has been grounded in the clear impracticality of providing state-of-the-art care even during the trial duration involving only a limited population. However, he and his colleagues have been silent about the rationale for the decision to provide no intervention whatsoever to the control clusters.

The second observation is that SEARCH reported (11, 12) that its action area - which included both experimental and control villages participating in in the HBNC trial - had been benefiting from broad-based healthcare related interventions by SEARCH since the year 1988. For example, between 1988 and the start of the study, SEARCH had already invested in educating adolescents in reproductive health; training male village health workers in primary healthcare and traditional birth attendants (TBAs) for pneumonia case management in children; and providing prenatal consultation and referral to tertiary care facilities outside the action area. However, the SEARCH researchers made no reference to these pre-trial interventions. Such accounting for pre-trial interventions would have allowed the HBNC trials to be designated as a two-stage trial design. Later in this paper, we present other studies with such innovatively altered controlled trial designs to compare with SEARCH's pre-study intervention. We argue that such innovative alterations can potentially contribute to enhancing ethics of a trial. Had these pre-trial interventions been accounted for within the HBNC trial design, then it is less clear if the HBNC trial would still have been considered as a trial providing no intervention to the control clusters.

b) *Opting to test the intervention at the cluster rather than the individual level*. The growing interest in evidence-based interventions - in health, nutrition, environment, education, and other aspects of development - that seek to guide policies and programmes has led researchers to explore the use of the cluster controlled trial (CCT) as opposed to the more conventional randomised controlled trial (RCT). In CCTs, the units under study are groups that existed before the beginning of the study. Some examples of such groups are communities (for interventions aimed at health-seeking behaviour); schools (for innovative pedagogies, or for drug or smoking prevention programmes); families (for nutrition interventions); and hospitals units (for health systems interventions).

The CCT design may be appropriate under certain circumstances. For instance, many interventions in public health operate at the group level and cannot be tested in a regular RCT. Two examples of such interventions would be vaccination to achieve herd immunity, and the treatment of infectious diseases such as tuberculosis (15-17). Other interventions unsuitable for testing with RCTs include those targeting the healthcare system as a whole or health practitioners in particular. In such instances, applying, or restricting the impact of the interventions to specific and randomised individuals is impractical. Similarly, interventions aimed at changing behaviours are largely impossible to randomise at the individual level, as information may be shared through communication channels that are difficult to control. Finally, the literature on the science of clinical trials lists a number of reasons that warrant the use of a CCT over a traditional RCT : it may be more efficient or convenient to conduct; it may foster investigators' cooperation; it could better help address ethical considerations; it can facilitate subject compliance, and it avoids "contaminating" the treatment group (18, 19).

In the case of SEARCH, the two key components of the HBNC intervention were: creating a village-level cadre of trained health workers; and educating mothers and grandmothers about the care of pregnant women and neonates. Both these components warranted the employment of an intervention at the cluster level to avoid the contamination of control units. It would have been hard, for example, to prevent educated mothers and grandmothers educated as part of the trial intervention from passing on their knowledge to others in their community. The conventional RCT design would not have offered the robust control comparator required to demonstrate efficiency. Additionally, the study would have posed serious ethical problems if trained female health workers (FHWs) did not respond to the neonatal care needs of specific families in a given village because those families happened to be assigned to the control arm of the study. By ensuring that all families in a given community were covered by the intervention under study, the researchers helped ensure that FHWs would not be put into heartbreaking, ethically problematic situations.

c) *Opting against randomisation*. The arguments in favour of randomisation are both epistemological and pragmatic. Abel and Koch state, "The first and most important argument is the eminent importance of balancing prognostic variables for evaluating treatment effects. Lack of balance in these variables is usually the main objection raised against non-randomised studies, for in these studies an adjustment is not possible for unknown prognostic variables." (20: 493) Although randomisation is often considered the gold standard, epistemologically sound non-randomisation can also be legitimised on the grounds of pragmatic constraints (20, 21). The SEARCH research team explicitly explained that it would be difficult to randomise villages. One concern related to denying care to "...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...". (12: S13). The team also stated that the possible

bias due to the non-randomised assignment was contained by the fact that the intervention and the control units had comparable socio-demographic profiles. It, therefore, seems that the SEARCH team's rationale for opting against randomisation was justified.

Broadly speaking then, our assessment of internal validity of the cluster non-randomised controlled trial design that SEARCH employed in the HBNC trial indicates that: (a) the use of controlled trial design was in consonance with the continuing trend to regard data generated through this design as superior to those generated by other means; (b) the choice of testing the intervention at the cluster level instead of the individual level was ethically and methodologically sound; and (c) SEARCH's choice of non-randomised allocation of villages to the intervention under investigation was epistemologically sound given the pragmatic constraints, and was ethically defensible, while the possible bias due to non-randomisation seems to have been contained. However, our appraisal does raise questions regarding the decision to provide no intervention to control clusters, that is, the decision regarding the standard of care, and the rationale behind it. We take this up in the discussion section later in the paper.

2. Assessment of external validity

To assess if SEARCH's choice of study design for the HBNC trial stands the test of external validity, we examined the study designs employed by other researchers testing interventions to improve neonatal health outcomes, with a particular emphasis on those targeting high neonatal mortality rates. Our review explored (a) whether neonatal care social intervention studies employed CCTs; (b) whether the study design of the HBNC trial was emulated or built upon in later research in neonatal care interventions; and lastly (c) whether control clusters in these studies received any interventions or none at all, and the reasons for these choices.

a) *Use of the cluster control trial design in neonatal social intervention studies*. Several recent intervention studies addressing unacceptably high neonatal mortality rates and conducted in various parts of the world have demonstrated researchers' increasing preference for CCTs (22-28). Haws and colleagues (29), in their meta-analysis of intervention studies for improving perinatal and neonatal health outcomes, identified 19 RCTs out of the 41 studies they reviewed that were reported between 1978 and 2005. Three of these 19 RCTs, or 7.3 per cent, are listed as cluster randomised controlled trials. Another meta-analysis of studies related to community-based interventions addressing neonatal health outcomes reported that 10 out of 13 trials (that is 77%), reviewed and conducted between 1998 and 2008 in South Asia and Africa, were CCTs (30). Two obvious limitations of this comparison are: the periods of reporting of studies that are included in meta-analyses overlap; and the likely different criteria for inclusion of studies in meta-analyses. In spite of these obvious limitations, the difference in percentage share of CCTs reflected in these two meta-analyses is noteworthy. It suggests that there might indeed be a trend towards favouring the CCT design in the field of social interventions for neonatal care. A more systematic review would confirm this.

b) *Influence of the HBNC trial on subsequent neonatal care social intervention studies*. The HBNC study is described as a benchmark and pioneering work in the neonatal care intervention literature. For example, Thea and Quazi (31) stated in a Lancet editorial that a study conducted in Sylhet, Bangladesh (32) had been built on the pioneering work of the SEARCH study. Similar to SEARCH's work, the population in the control arm of the Sylhet study used governmental facilities. Notably, Thea and Quazi regard the cluster randomised trial with a control arm as one of the strengths of the Sylhet research project. Similarly, Bhutta (10) and Bhutta and Sufi (33) have acknowledged the HBNC trial as a landmark study. Taken as a whole, then, it appears that the HBNC trial study design contributed significantly to the neonatal intervention research enterprise by facilitating the creation of evidence supporting a wide-range of home-based and community-based interventions - particularly in the contexts of less and/or ill-equipped healthcare systems. It seems reasonable to conclude that since many studies subsequent to the HBNC trial have replicated, adapted or built on its design to improve it, the design used by SEARCH was applicable to other contexts and locations characterised by high neonatal mortality.

c) *Approaches to control clusters*. We also reviewed the studies mentioned so far to analyse their approach to control clusters. We have noticed that, in most cases, control clusters received no intervention at all. When they received any interventions, they varied in their nature and scope - an observation that has also been supported by a systematic review of intervention studies aimed at addressing neonatal care and health (34). For example, we find the study by Azad and collaborators' (6) illustrative. In their study, they provided basic strengthening of health services and training to birth attendants to all clusters, while in the intervention cluster a facilitator convened 18 women's groups every month to support participatory action and learning for women, and to develop and implement strategies to address maternal and neonatal health problems.

The predominant trend in neonatal intervention research seems to have been to give no intervention to control clusters. More recently, however, researchers have used modified study designs allowing control clusters to benefit from some intervention. We find the work of Baqui and colleagues (32) illustrative. They tested two interventions (i.e. home-care and community-care) using a cluster randomised control trial. In yet another study, a six-country research initiative led by the First Breath Study Group, Carlo and collaborators (35) report the application of an innovative mixed study design in a two-stage intervention. In the first stage, the researchers applied a 'before and after' study design to assess an 'essential newborn care' intervention in all 96 clusters. This was followed by a second

stage, in which a CCT design was used to test a neonatal resuscitation programme. As mentioned earlier, given the fact that SEARCH had an on-going pre-trial intervention in its entire action area, the HBNC trial design could aptly be considered comparable to Carlo and collaborators' study design (35).

Broadly speaking, assessment of external validity of the CCT design that SEARCH employed in the HBNC trial indicates that: (a) there seems to be an increasing propensity towards the use of CCT - both randomised and non-randomised - designs in studies in neonatal care social interventions; (b) SEARCH's HBNC study design seems to have influenced the neonatal intervention research enterprise; and (c) researchers are exploring variations in the CCT study design. For instance, approaches to control clusters seem to vary; at least a few studies have attempted to offer some intervention in control clusters.

Discussion

Our critical appraisal, using the criteria we set out for assessment of 'internal' and 'external' validity of the choice of study design in the HBNC trial, shows that the study design met these criteria. We can, therefore, conclude that it was an appropriate choice and scientifically valid. We observed, as part of the outcome of the assessment of 'internal validity', that although SEARCH's choice of non-randomised allocation of villages (clusters) to the study intervention was criticised, it was scientifically sound on epistemological grounds and seems to have been ethically justified. Most importantly, it was transparently reported through their research writings (11-14), making it available for academic scrutiny. Also, at least a few other studies in neonatal care have reported the use of a cluster non-randomised controlled trial design, further supporting SEARCH's decision to use a non-randomised design. Similarly, the growing propensity towards employing the CCT design in social intervention research in the neonatal arena, together with indications that the HBNC study influenced neonatal care-related social intervention research, supports the 'external validity' of SEARCH's choice of this study design.

The other contentious aspect of the HBNC trial was the researchers' decision to provide no intervention to control clusters. This leads to the issues relating to the standard of care and exploitation of those in control clusters, As such, any further discussion on these aspects falls outside the scope of this paper. However, we take this opportunity to articulate some initial thoughts and to raise some introductory questions for further exploration. As we have noted earlier, researchers have begun to report studies using a CCT design in which control clusters received interventions (6, 32, 35). These variants of the CCT design partly address the ethical dilemma inherent in providing no intervention to control clusters, although researchers rarely articulated ethical concerns as a reason for employing these variations. Promisingly, these diverse study designs seem to meet current research ethics standards better, while maintaining the scientific rigour that is expected of the social intervention research enterprise as a global good. We thus expect these new methodological approaches to contribute to the evolving trends in neonatal care intervention research, in particular; and to social intervention research, in general.

On the other hand, we noted that the exchanges between critics of the trial and responding commentators remained anchored in the standard of care debate developed within the biomedical research context. In the biomedical research context, the use of placebo controls when a known effective treatment for the concerned health condition exists has evoked strong criticism (36, 37). The standard of care debate in international biomedical research that was triggered by the AZT trial in the late 1990s offers insights into various aspects of this issue, drawing upon international research ethics guidelines, such as the Declaration of Helsinki (38-41). However, there are diverse viewpoints regarding standard of care (38) and related key concepts such as equipoise which facilitates decision making on the appropriate standard of care in a particular trial (42-47). Furthermore, some bioethicists and commentators have argued against premising biomedical research (central to which is the relationship between researchers and research participants) on a medical care (central to which is the relationship between healthcare provider and patients) model while responding to claims of exploitation, particularly in placebo controlled trials in the international research context (47-49). Central to this argument is the need to distinguish between the obligations of researchers towards research participants from those of healthcare providers' towards patients. The obligation in the healthcare context is that of the 'duty to care' whereas in the biomedical research context it would be that of the 'Good Samaritan' type and differ in its scope as Hawkins (49) describes. She goes on to state that such a paradigm shift would allow responses to claims of exploitation in the context of placebo controlled trials and help determine their ethical permissibility. As such, all placebo controlled trials would not withstand the criteria of ethical permissibility as Hawkins suggests in this work. We will not be able to expand this further as it falls outside the scope of this paper.

However, given the growing interest in the application of experimental designs to social intervention research, it is evident that more in-depth and systematic engagement with the existing discourse on the standard of care and exploitation, developed within the context of global health research, is required. Some initial questions for such engagement would be: Is this existing discourse instructive enough for social intervention research? If so, are there any specificities of social intervention research that might be accounted for and factored in? For example, would the long-standing relationship between researchers and study communities, as in the case of the HBNC trial, affect the nature and scope of research ethics obligations, particularly to those in control units? Or, would there be a need to explore an alternative discourse specific to social intervention research? Also, we earlier noted that the controlled trial design, particularly the randomised controlled trial, continues

to be the gold standard in the 'evidence-based intervention' paradigm in biomedical sciences. A more fundamental question that warrants deliberation is: Does this design need to hold the same weight in social intervention research as it does in biomedical research, and what would be the moral force behind such a position? Are there alternative approaches to creating credible evidence that do not compromise on research ethics standards?

Limitations

We note one main limitation of our approach to appraising the choice of study design for the HBNC trial. The appraisal is based on the literature available in the public domain relating to the HBNC and other studies. There is no documentation in the public domain of the research ethics reviews and deliberations to which the protocol of the HBNC study was submitted. Had these been available, they might have provided us with better insights into the SEARCH team's decisions, making the debate better informed.

Conclusion

We draw three main conclusions from this critical appraisal of the HBNC trial. First, the study design of the trial was motivated by the paradigm of evidence-based programmes and policy formulation. This paradigm is inspired by the biomedical research model. Second, generally speaking, the HBNC study design passes the internal and external validity tests but not without raising important questions. These questions relate to the standard of care - the nature and scope of the intervention to be received by control clusters as comparators, and the ethical reasoning behind these choices. Third, these questions transcend the HBNC trial and apply to many other social and health intervention studies which have employed the biomedical research model. For instance, primary healthcare initiatives such as the Narangwal project in India suggest that the cluster non-randomised controlled trial design has been employed as early as in the 1970s in India. There are also a number of studies in neonatal care that have employed this design or its variants, but the HBNC trial appears to be one of the first such trials in neonatal care social interventions. It is a paradigmatic case and holds enormous educational value for the research community concerned with ethics in intervention research.

Joy Lawn, one of the internationally-known experts behind the 2005 series on neonatal survival in *The Lancet,* has been quoted (50) as saying that "at least 2.5 million newborn deaths each year are preventable by 'doing things which aren't rocket science' " - and these things include simple neonatal care interventions. With UNICEF estimating that 3.7 million neonates die every year around the world (51), efforts to implement effective neonatal care interventions, particularly of the HBNC type, remain of the highest priority.

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The SEARCH HBNC Trial at a glance

Background and the problem

- Nearly 5 million neonates die each year, 96% of them in developing countries. Neonatal mortality constitutes 61% of infant mortality and nearly half of child mortality in developing countries. The neonatal mortality rate varies from 5 per 1,000 live births in developed countries to 53 per 1,000 live births in the least developed countries.
- 63% of neonates in developing countries - 83% of neonates in rural India - are born at home. The standard advice is to hospitalise every ill neonate but hospitals with facilities for neonatal care are inaccessible and unaffordable for rural populations. The estimated cost of hospital-based neonatal care in India is very high. Further, parents may be unwilling to move ill neonates because of traditional beliefs. So those who arrive in hospital are generally seriously ill. Most neonatal deaths occur at home.
- The SEARCH HBNC trial was done in Gadchiroli, India, about 1,000 km from the Maharashtra state capital, Mumbai. This is an extremely underdeveloped district, with poor roads, communications, education, and health services. Government health services in the area comprise a male and a female paramedic worker for every 3,000 people and a primary health care centre with two physicians for every 20,000 people.
- Hence, to reduce neonatal mortality, ways to provide neonatal care at home, the SEARCH team considered, must be developed.

SEARCH and its work in the field area

SEARCH (Society for Education, Action, and Research in Community Health) is a non-government organization for community healthcare and research, established in 1986. Since 1988, SEARCH has trained and supported male village health workers and traditional birth attendants in the action area in the management of pneumonia in children. SEARCH runs other health programmes such as reproductive health education for adolescents, management by voluntary health workers of minor health problems, and consultation and prenatal care at a referral clinic outside the field research area.

The HBNC trial

- The HBNC field trial was conducted in the field areas (100 villages) of SEARCH. This comprised an action area of 53 villages and an adjacent control area of 47 villages. SEARCH had recorded 98% of all births and child deaths in the field research area.
- The intervention and control villages were not randomly selected for reasons of feasibility and other concerns such as the potential risk of having to deny care to those in need.
- The intervention and control blocks of villages were similar geographically, economically, socially, in availability of health services and in vital indices for the period 1991 to 1993. This, according the SEARCH team, was to keep the selection bias to the minimum.

The intervention in the experimental clusters

- The trial tested the hypothesis that a package of home-based neonatal care, including the management of sepsis (pneumonia, septicaemia, and meningitis) would reduce neonatal mortality in the experimental clusters by at least 25% in 3 years compared to the control area.
- Village women with 5-10 years of schooling were chosen as village health workers in 39 intervention villages from the total 53 where SEARCH has been active.
- Neonatal care was introduced in these villages in a stepwise manner from April 1995 to March 1998.
- In the first year female health workers (FHW) sought to estimate the natural incidence of neonatal morbidities and the need for care, and to plan for further intervention.
- In the second year, after a survey of 280 parents to know if they would seek care from FHWs if their neonate was sick, the FHWs were trained in home-based management of neonatal illnesses.
- In the third year, health education of mothers and grandmothers on the care of pregnant women and of neonates was added to the programme.
- The trial did not provide for any referral care to neonates apart from what was already available at government hospitals. The family was free to seek care from other sources as well.

The control clusters

- SEARCH did not provide training of TBAs and management of pneumonia in children in the control area; here, these tasks were done by the government health services.
- Owing to successful maternal immunisation against tetanus, neonatal tetanus was rare in both intervention and control areas.

Recording of births and deaths was done from 1993 to 98 by an independent set of workers in the intervention and the control areas. These workers collected information on neonatal events prospectively, and also undertook a house-to-house survey every six months.

(Based on: Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. Lancet. 1999 Dec 4;354(9194):1955-61).