

## CASE STUDIES

### CASE STUDY 3

#### BACKGROUND

#### ETHICAL CONSIDERATIONS IN HEALTH SERVICES RESEARCH IN DEVELOPING COUNTRIES:

(The details of this case study are based upon two papers from the published literature: Bang, Abhay T; Bang, Rani A; Baitule, Sanjay B; Reddy, M Hanimi; Deshmukh, Mahesh D. 1999. "Effect of Home-based Neonatal Care and Management of Sepsis on Neonatal Mortality: Field Trial in Rural India." *Lancet*. 354: 1955-1961. Bang, Abhay T; Bang, Rani A; Baitule, Sanjay B; Reddy, M Hanimi; Deshmukh, Mahesh D. 2001. "Burden of Morbidities and the Unmet Need for Health Care in Rural Neonates: A Prospective Observational Study in Gadchiroli, India" *Indian Pediatrics*. 38: 952-965. <http://www.indianpediatrics.net/sept2001/sept-952-965.htm>.)

Neonatal mortality accounts for nearly half of the global child mortality in developing countries. Sixty-three percent of newborns in developing countries are born at home, where it can be more challenging to respond to complications in pregnancy, labor and delivery, and in the neonatal period (0-28 days of life).

Despite the fact that the majority of neonates in developing countries are born and cared for in rural homes, the majority of available information regarding neonate morbidity and mortality is based on hospital data. Most health statistics related to neonates in rural settings have been collected unsystematically, usually whenever the health worker in the area arrives. Not only are there limited data regarding morbidity and mortality data from rural areas; there are even fewer data available regarding unmet healthcare needs. In preparation for designing a randomized, clinical trial to assess a neonatal care delivery program in a rural area, researchers conducted a prevalence study to determine the extent of the problem of neonatal morbidity and mortality in this region and to determine the extent of unmet need.

#### The Prevalence Study

The prevalence study was conducted in a rural district of a poor country. This district is extremely undeveloped; farming of rice and forestry are the main source of household incomes.

Government health services include a male and female paramedic worker for every 3000 people and a primary care Centre for every 20,000 people. No specialized neonatal care is available in the area. Private rural medical practitioners, herbalists, and magic healers are the main sources of care.

The purpose of the prevalence study was to estimate the number of existing neonatal *morbidity*s in this district, and what type of morbiditys, and also the number of neonatal *mortality*s in the last

year. In addition, investigators documented the number and proportion of neonates with various different indications for health care who had not yet received health care, as well as the number and proportion of infants with various, different indications for health care who *had* actually received such care. The rationale for this research was that, in order to plan for appropriate research and care in the region, it was critical to have estimates both of the burden of neonatal morbidities, as well as the unmet need for care. The majority of studies up to that time had focused on either single conditions or hospital based care.

The prevalence study was conducted in cooperation with a non-governmental organization (NGO) for community health care and research that has been working in the area for more than ten years. The study was conducted in 39 villages routinely served by the NGO. Community consent to conduct the prevalence study was obtained in each village from the village health worker (VHW). The VHWs were women who lived in the village, had 5-10 years of education and were willing to observe and collect data for the study. The VHWs were trained to “take history, observe the process of labor, examine newborns, and record the findings”. The VHW in each village observed all pregnant women periodically, observed the birth, and visited the neonates approximately every 3 days for the first 28 days of life (or until death, or until the mother and baby left the village—whichever occurred first). VHWs were trained to identify a number of maternal and environmental characteristics as well as neonatal symptoms.

The neonates received care according to their usual practice, including care from family members and the traditional birth assistants, care from government nurses and private doctors, if invited by the family. If a doctor recommended that a family take a baby to the hospital, the NGO working on the study offered to provide the ambulance service for transporting the sick baby, but the final decision was left to the family. Any care received, and the sources of care received, were recorded by the VHW.

One year was devoted to the prevalence study. During this year, VHWs observed neonatal health “with minimum interventions”. Of the 763 neonates observed during the year, 54.4% had indications for health care, according to the VHWs, including 48% suffering from high-risk health conditions. However, only 2.6% of the neonates with indications for healthcare were seen and treated by a doctor, and only 3 (0.4%) were hospitalised.

Forty (40) of the 763 neonates died during the year. Of the 40 neonates who died, 38 had been characterized as having high-risk health conditions. That is, approximately 10% of those characterized as having high-risk health conditions died. Of the three sick neonates who were hospitalized by the families, none of these died.

Important data on prevalence and incidence of neonatal morbidities and mortalities were learned, which proved helpful for designing an intervention study that followed.

### Questions:

1. Discuss the ethics of this prevalence study.
2. Investigators conducted this study in order to obtain a rigorous understanding of the background conditions, in order to plan high quality, responsive, and relevant interventions.  
Do you think the study could have been conducted any other way? Why or why not? What would the implications have been for the scientific findings? For the cost? What approach would you recommend?
3. Do your beliefs about the ethics of this study vary, depending on whether it was conducted by local health researchers vs. by U.S. or European researchers, in conjunction with local researchers? Why or why not?
4. What are you guessing was meant by the phrase “community consent was obtained in each village by the VHW”. Do you think this approach is appropriate? Should there be any other consent in addition? Instead? Why or why not?

### The Intervention Trial

The prevalence study indicated that this population of neonates suffered a significant disease burden and a substantial level of unmet healthcare need. One finding in the prevalence study was that almost 20% of neonates suffered from sepsis (a systemic infection, characterized by high fever and significant illness; many cases of sepsis lead to death). Investigators chose to focus their clinical trial on the prevention and treatment of sepsis and other neonatal morbidities in home-cared, rural neonates in the same population. Previous to this trial, there had been various studies confirming the effectiveness of home-based health workers identifying and treating health problems successfully, and reducing morbidity and mortality. Further, USAID, WHO, and the United Nations all have supported the training of local healthcare workers to provide additional services and care in impoverished areas.

Village health workers are known to provide a low cost and efficient means of improving health outcomes, at least for certain indications. Indeed, the highly successful WHO strategy of Integrated Management of Childhood Diseases (IMCI) relies heavily on identification of ill children

in the home through local health workers. No study of the use of local health workers had been conducted previously to reduce mortality from neonatal sepsis and other neonatal morbidities.

The intervention trial was designed as a randomized controlled trial with the 39 villages from the above prevalence study receiving intervention and 47 nearby villages, also in the “catchment district” of the NGO, that would serve as controls. The VHWs in the intervention villages received training in home-based management of neonatal conditions including birth asphyxia, premature birth and low birth weight, hypothermia, and breast-feeding problems, and they were trained to treat neonatal sepsis. After the first year, VHWs began educational programs for pregnant women to teach them about how to care for their own infants. In the control arm, VHWs were trained to collect data, going door to door during pregnancy, birth, and the first 28 days of the neonatal period, as in the intervention arm. They did not offer care or referral, however. The study was conducted for three years with the hypothesis that the intervention villages would see a 25% reduction in neonatal mortality by year 3.

The intervention study found a statistically significant 50% reduction in neonatal and infant mortality in the intervention villages ( $p < 0.001$ ). Treatment for sepsis by the VHW reduced mortality by almost 14% ( $p < 0.01$ ).

A few years after the completion of the above study, another researcher wants to replicate this study in another poor country that also has alarmingly high rates of neonatal morbidity and mortality. Given the published results from the study, above, and given that the concept of local health workers has been so well validated, is it justified to repeat the above study? On the other hand, what are the risks of *not repeating* the study? Why would a country want to replicate a study with its own people?

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