Research Plans and Progress


WORLD HEALTH ORGANIZATION (WHO)

Hans Troedsson, Jose Martines, Jelka Zupan

Research and implementation of programs to improve perinatal and neonatal health are carried out by a broad collaboration of clusters at the WHO. Most activities are centered in the Family and Community Health cluster, but research and development activities also occur in the Health Technology and Pharmaceuticals cluster, the Sustainable Development and Healthy Environments cluster (nutrition), and Communicable Diseases cluster. The Tobacco-Free Initiative, a cabinet project, also seeks to improve perinatal health by reducing smoking during pregnancy. Major strategies to develop and adapt evidence-based guidelines for detection and treatment of clinical conditions are done through Integrated Management of Pregnancy and Childbirth (IMPAC) and Integrated Management of Childhood Illness (IMCI).

Research and development activities to improve facility-based care of pregnant women and their infants currently focus on field testing and validation of IMPAC guidelines; revision of IMCI young infant guidelines;\(^4\) managerial tools for strengthening access to and quality of the health care system; development of simpler, effective treatments of neonatal infections and follow-up of infants at risk.

Community-based research and interventions seek to: improve home care and care seeking; provide linkages with the community and support for women with special needs; early initiation of exclusive breast-feeding; prevention of MTCT of HIV through feeding; and maximize the benefits of IMCI feeding counseling.

Specific research activities to improve infant feeding in settings of high prevalence of HIV infections include: assessing the influence of infant feeding patterns on MTCT, infant morbidity, and mortality; identifying feasible and practical ways of improving the quality and safety of replacement feeding; determining how best to ensure that the transition period between exclusive breast-feeding and no breast-feeding carries a minimum risk of HIV transmission, nutritional, and psychological risks for infant and mother; examining the role of mastitis in HIV transmission through breast milk and how to minimize such problems; and assessing the effects of infant feeding recommendations for HIV-infected mothers on general population behaviors related to breast-feeding.

One study on care seeking and adherence to treatment for neonatal illness has recently been completed in a periurban cohort in New Delhi, India. WHO researchers found that 60% of deaths occurred within 24 hours of recognition of illness, 40% of caregivers did not seek outside care, and 70% of care was sought from private providers. Half of those private providers had no formal medical education, and failed to refer 70% of the newborns that eventually died. Lastly, less than half of caregivers followed referral recommendations. Further work is currently in progress to understand the barriers to care seeking for young infants and develop interventions to improve it.

SAVE THE CHILDREN’S SAVING NEWBORN LIVES (SNL) INITIATIVE

Gary L. Darmstadt, Anne Tinker, Judith Moore

Save the Children’s SNL Initiative, sponsored by the Bill and Melinda Gates Foundation, has launched a global program of maternal and newborn health care designed to improve newborn health and survival through increased and sustained use of healthy newborn practices, and improved and expanded policies and programs addressing newborn health. Goals SNL expects to achieve include:

- improved and expanded implementation of proven newborn health interventions;
- adaptation and replication of promising models of newborn care in the community;
- advanced state-of-the-art in newborn care;
- enhanced knowledge and understanding of newborn health among policy makers, program managers, donors, and the general public;
- help in mobilizing global resources for newborn health; and
- expansion of in-country capacity to plan, implement, and evaluate newborn health programs.

The initiative intends to deliver essential services during the antenatal period, during labor and delivery, immediately after birth, and during the first weeks of life (Figure 6). It focuses on community delivery of services, and provides a link between Safe Motherhood and Child Survival Programs. Interventions that SNL promotes as essential during the antenatal period include tetanus toxoid immunization, nutritional supplements such as iron and folic acid, treatment of maternal infections, and counseling on birth preparedness, breast-feeding, and recognition of signs of maternal complications. Essential interventions at the time of delivery include skilled health care and the presence of a skilled birth attendant, hygienic delivery, recognition and management of birth asphyxia, and further counseling on signs of maternal as well as neonatal illness. In the time immediately following birth, priority interventions include drying and wrapping the newborn, treatment to prevent ophthalmic infections, and immediate exclusive breast-
feeding. Postnatal contact soon after birth, which is particularly lacking in the community in many developing countries, is emphasized. Routine care in the weeks after birth includes further counseling on breast-feeding, temperature maintenance, and clean umbilical cord care. Special care will also be given to mothers and infants with signs of severe illness, particularly infections, and infants suffering from birth asphyxia or with LBW.

SNL’s activities will be greatest in focus countries where the need for quality services is the greatest (Table 4), where there is the potential for achieving demonstrable results, and where opportunities exist to work with strong local partners. In addition to program implementation in focus countries, SNL will also create strategic partnerships with India and South Africa, and establish program learning activities in Vietnam, Ethiopia, Indonesia, and Guatemala.

SNL research priorities are to devise better ways of implementing proven interventions and to advance the state-of-the-art in newborn care. SNL will design, adapt, and evaluate community-based models of maternal and newborn care, and, through formative research on household practices and care seeking, identify specific targets for behavior change and devise and evaluate communications strategies to enhance healthful behaviors. SNL will develop and adapt the positive deviance inquiry for newborn care. This model, as applied to perinatal and neonatal health, seeks to identify women and their families who, despite limited resources, have achieved successful pregnancies and given birth to healthy infants and maintained their health during the neonatal period. The behaviors and practices that contribute to their success will be identified and encouraged within the community to improve pregnancy and neonatal outcomes. Other activities include further refinement of the verbal autopsy instrument for determining perinatal and neonatal deaths;\textsuperscript{46,47} epidemiological research to inform WHO’s Global Burden of Disease; and development of improved strategies for recognizing and managing infections and birth asphyxia at the community level.

### UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) — CHILD HEALTH RESEARCH (CHR) PROJECT

**Ruth Frischer**

The USAID has a long history of conducting applied and operational research as well as implementing development programs internationally. USAID’s CHR Project sponsors research to improve perinatal and neonatal health outcomes and improve child health worldwide through cooperative agreements with WHO’s Department of Child and Adolescent Health and Development; Boston University; the ICDDR,B: Center for Health and Population Research, Bangladesh; the International Clinical Epidemiology Network (INCLEN) Trust; and the Johns Hopkins Bloomberg School of Public Health. The CHR currently sponsors over 30 ongoing research projects to improve perinatal, neonatal, and young infant survival and seeks to narrow the gap between research and implementation. A great deal of its research is designed to inform and refine the UNICEF—WHO IMCI approach, which is now implemented in over 81 countries.

Recent perinatal and neonatal projects completed by CHR include: WHO’s Young Infant Study, which surveyed for the pathogens causing most neonatal deaths;\textsuperscript{48} a study that reduced mortality in small-for-gestational-age infants by 66% with zinc supplementation;\textsuperscript{49} validation of the verbal autopsy tool for use in neonates;\textsuperscript{46,48} documentation of barriers to care seeking in neonatal illness; and a study that examined fetal growth retardation as a risk factor for early mortality.

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<th>Newborn Health Indicators for SNL Focus Countries</th>
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Ongoing projects are focused on: refinement of the recognition and management of serious illness in neonates; community-based care of neonatal infections; topical application of skin barrier-enhancing emollients as a strategy to prevent infections in preterm infants; and evaluation of packages of obstetric and neonatal care practices.

USAID — BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL (BASICS) II

Indira Narayanan

BASICS II is the flagship child survival program financed by USAID and administered by the Partnership for Child Health Care. BASICS II is a global project working in 16 countries, charged with achieving the greatest possible country-level impact on major threats to child health and providing technical leadership in policies and programming and carrying out operational research. BASICS II focuses on four Technical Focus Areas (TFAs) that promise the greatest reduction in mortality, specifically effective and sustainable child immunization, nutrition and growth promotion, integrated approaches to child health, and perinatal and neonatal health. The above are linked with cross-cutting areas such as social mobilization, training and performance improvement, private sector, and NGO partnerships. BASICS is also looking into developing and testing an integrated holistic package for child survival. In the latter initiative, to ensure that newborn health receives the necessary focus, a lifecycle or age-related approach is being explored. Regarding the perinatal/neonatal TFA, since this is a relatively new area in international health, advocacy has been a priority area at all levels including incorporation within all the activities noted below and at presentations at various forums and a congressional briefing.

Other areas of work at the global level include development of tools for capacity building such as a manual on basic/essential newborn care for health workers (with MNH and other partners) and technical support in the development of a manual for care of the sick newborn (WHO and MNH). BASICS II has also collaborated with the working group of maternal neonatal tetanus (UNICEF), the interagency working group on malaria and pregnancy, and with WHO for developing a protocol for identification of the sick young infant as a preliminary to including the neonatal period in the IMCI strategy.

At the regional level, in collaboration with WHO (Southeast Asia Regional Office), BASICS is developing a regional initiative involving 10 Southeast Asian countries commencing with a situational analysis and a regional workshop. Goals include intercountry exchange of information and tools, networking, and advocacy for promoting newborn health and donor involvement. In the LAC region, BASICS is publishing and disseminating a neonatal bibliography with the Pan American Health Organization.

At the country level, BASICS II is working at the community and household level to identify and test approaches that promote community participation/mobilization, individual and household behavior change, and community-based management strategies. The BASICS II approach promotes preventive essential newborn care with emphasis on proven effective interventions, such as maternal tetanus toxoid, anemia control, intermittent preventive therapy for malaria in pregnancy where applicable, presence of skilled health care at birth, temperature maintenance, early and exclusive breastfeeding, and cord and eye care. BASICS II is also examining approaches for detection and provision of care to sick newborn through behavior change, identification of problems, early referral of sick babies, and strategies to train community-based personnel appropriately. Behavior change and community mobilization approaches will also be used to promote better newborn health care practices and improved care-seeking behavior. BASICS II is involved in programs including operational research for newborn health in Senegal, El Salvador, India, and Honduras.

JOHNS HOPKINS AND THE ICDDR,B

Robert E. Black, Abdullah H. Baqui, Shams El Arifeen

USAID’s CHR Project and Bangladesh Mission and Save the Children’s SNL are sponsoring researchers from the Johns Hopkins Bloomberg School of Public Health and the ICDDR,B Centre for Health and Population to design and implement a package of community-based interventions to reduce neonatal mortality by 40% (relative to communities receiving standard care) in two Bangladeshi districts. The project, with multiple partners including the Government of Bangladesh, private organizations, and NGOs, intends to reduce early deaths by training health workers to deliver packages of essential obstetric and neonatal
health services. The primary aims of the study are to: improve newborn care and recognition and management of serious infections in neonates by mothers and trained first-line health workers, and evaluate the impact of a package of obstetric and neonatal care practices including management of serious neonatal infections by first-line health workers, either in the home or at community clinics, on neonatal mortality rates. The secondary goals are to evaluate impact on cause-specific neonatal mortality rates due to sepsis and determine the cost-effectiveness of home care and clinic care models.

With three study arms (home-based care, clinic care, and standard care), the trial intends to follow the outcome of nearly 10,000 pregnancies and births. In addition to delivering essential services, the project also intends to educate women and their families on the signs of serious illness, and use various communication strategies to encourage change in general health and nutrition, care giving, and care-seeking behaviors.

During home visits, community health workers will advise women to go for antenatal care and tetanus immunizations, assist traditional birth attendants with labor and delivery; and promote early newborn care including breastfeeding initiation and thermal control. The clinic care arm of the project seeks to identify and refer mothers with pregnancy complications, and provide early neonatal care.

If the intervention is successful, project investigators will, locally, encourage and assist the NGOs and the Government of Bangladesh to continue with services; nationally, disseminate project findings and advocate for policy change; and internationally, publish and disseminate findings due to their global implications.

NIH–NIHGlobal Network

Susan Meikle
The NICHD, in collaboration with other NIH Institutes and the Bill and Melinda Gates Foundation, have started a Global Network for Women’s and Children’s Health Research (Global Network). The purpose of the Global Network is to establish an innovative and flexible research network that will be responsive to the most critical existing and emerging health needs and public health problems of women and children around the world. Through competitive cooperative agreements, international multidisciplinary teams of investigators will work collaboratively to improve health, and to prevent premature disease and death among women and children, primarily in developing countries. Initial efforts will focus on safe pregnancy and birth outcomes, within the broader context of women’s and young children’s health.

The Global Network will increase and enhance opportunities for scientific linkages, interaction, knowledge development and transfer, and collaborative partnerships between US investigators and institutions and their foreign counterparts. It also is intended to strengthen and expand the global infrastructure for women and children’s health research.

Extremely high levels of maternal, fetal, and infant morbidity and mortality often occur despite the existence of effective interventions for prevention or treatment. In some instances, the results of studies have not been translated into feasible interventions for resource-poor settings where the burden of these conditions is the greatest. In other cases, feasible interventions have been developed, yet are relatively ineffective, or basic knowledge or understanding still is inadequate. It is increasingly clear that economic investment in early intervention or prevention is sound and that, in some situations, relatively inexpensive health interventions can have enormous impact. Establishment of a global network of linked US and developing country scientists and institutions will help facilitate high-quality, sustainable collaborative research that will address many of these problems and issues.

NIH–FOGARTY INTERNATIONAL CENTER’S INTERNATIONAL MATERNAL AND CHILD HEALTH RESEARCH AND TRAINING PROGRAM (IMCHRT)

Jeanne McDermott
The IMCHRT of the National Institutes of Health’s Fogarty International Center is a complementary and closely related program to the NIH–NICHD Global Network for Women’s and Children’s Health Research. It is designed to increase scientific expertise in maternal and child health in developing countries; to support collaborative research training between US-based and foreign scientists; and to establish or strengthen research and prevention centers of excellence in the home countries of trainees. Awards are usually, but not exclusively, given to current NIH grantees with a proven record of quality research and results, and who propose research that is relevant in a developing country setting.

The grants can be used for predoctoral and postdoctoral training and short-term training activities to support building capacity for laboratory support and program evaluation; strengthening capacity for testing and counseling, program management, and administration; and ensuring future local leadership of projects. These grants fund training to support ongoing collaborative research in the country.

Seven IMCHRT grants were funded in 1999 for a period of 5 years. These grants were awarded to provide training to support the following research: the role of human papilloma virus in the transmission of HIV, perinatal transmission of HIV, premature rupture of membranes, preeclampsia, the effects of malaria in pregnancy, neonatal host defenses, early child development, and nutrition. Four more grants were awarded in 2001, which will fund training to support research examining the role of nutrition and fetal growth, prevention of birth defects — particularly cleft lip and palate, diagnosis and treatment of perinatal sepsis, and strategies to modify provider behavior change, focusing on labor and delivery care.
**THE ICDDR.B AND CORNELL UNIVERSITY**

**Shams El Arifeen**

Infants born with LBW suffer from extremely high rates of morbidity and mortality from infectious diseases, and are underweight, stunted, or wasted beginning in the neonatal period through childhood. In Bangladesh, a recent study has shown that LBW doubled the neonatal mortality rate in periurban settings. LBW is also associated with impaired immune function, poor cognitive development, and high risks of developing acute diarrhea or pneumonia. Up to 45% of the children born in Bangladesh are afflicted with LBW, and almost half of the infant deaths could be prevented if LBW were eliminated. Those LBW infants who survive have little chance of fully reaching their growth potential. Moreover, evidence now shows that adults born with LBW face an increased risk of chronic diseases including high blood pressure, noninsulin-dependent diabetes mellitus, coronary heart disease, and stroke in adulthood.

To combat the scourge of LBW in Bangladesh, a team of scientists from The ICDDR.B and Cornell University has designed a maternal nutritional supplementation trial to reduce or prevent intrauterine growth retardation. The trial will provide food supplements to Matlab women earlier than the existing National Nutrition Program, and give supplementation to all women — not only women with body mass index measurements of below 18.5 — as prescribed by the current program.

Another purpose of the trial is to test whether a multiple micronutrient supplement (MUMS) can reduce maternal anemia more effectively than iron–folate supplementation alone, and whether improved maternal hemoglobin status leads to an increase in infant birth weight. Women will be randomized to one of three treatment arms: one providing 60 mg of iron and 400 μg of folic acid; one providing 30 mg of iron and 400 μg of folic acid; or one giving the UNICEF’s MUMS (Table 5).

The researchers hypothesize that women receiving both the early food supplements and the MUMS will have babies with higher birth weights than women enrolled in one of the other combination treatment groups.

The trial will also test the power of counseling to increase the duration of exclusive breast-feeding. Although breast-feeding is universal in Matlab, exclusive breast-feeding rates are quite low and need to be increased for optimal infant health. Women will be randomized to one of two groups: one receiving messages about general infant care and health, and another receiving counseling only about the benefits of exclusive breast-feeding. This part of the project is modeled after previous successful attempts to increase breast-feeding in the community.

The study will also attempt to determine the social and cultural determinants of intervention utilization and impact on outcomes; the cost-effectiveness of the intervention; and the impact of treatment of bacterial vaginosis (BV) on preterm birth rates. It will also use ultrasound-based measurement of fetal growth to estimate the timing of effect and degree of impact assessment.

**GLOBAL NETWORK FOR PERINATAL AND REPRODUCTIVE HEALTH (GNPRH)**

**Vinod K. Paul**

The GNPRH has created a network of seven institutions in Asia, Latin America, Europe, and the US to examine the relationship between preterm birth and maternal carriage of group B Streptococcus (GBS) and BV. With two sites in Thailand (Bangkok and Khon Kaen), and sites in Burma, The Philippines, Zimbabwe, Columbia, Ireland, and the US, the study intends to determine the prevalence of BV and GBS in women between 20 and 32 weeks’ gestation; compare rapid tests to gold standard techniques (optical immunoassay for GBS and clinical exam followed by vaginal pH for BV); and standardize the diagnosis of BV with the use of a teaching atlas and central laboratory.

As of October 2000, 1196 women had been recruited for the study. According to preliminary results, 16% of women had experienced a previous preterm birth. The rates of pH-diagnosed BV (i.e., pH ≥ 4.5) varied widely among study sites, from as high as 70% in Harare, Zimbabwe, to as low as 20% in Dublin, Ireland (Figure 7). Ten percent of women had some GBS colonization and 4.6% had heavy GBS colonization, although the rates varied widely between study sites (Figure 8).

**INSTITUTE OF CHILD HEALTH — MOTHER AND INFANT RESEARCH ACTIVITIES (MIRA)**

**Anthony Costello, Dharma S. Manandhar, David Osrin**

Despite ongoing programs to improve the health of mothers and children, Nepal’s child and infant mortality rates remain high. The under-five mortality rate is 100/1000 live births, infant mortality rate is 72/1000, and the neonatal and perinatal mortality rates each top 5%. Because of rural Nepal’s difficult terrain, there is little access...
to hospital or secondary care facilities, and over 90% of all births take place at home attended by an unskilled provider, often a relative. In addition, widespread poverty and low social status for women contribute to high fertility rates and fatalistic acceptance of infant and neonatal deaths. The major causes of newborn illness are birth asphyxia, LBW, and sepsis.

In 1992, the Institute of Child Health in London established the MIRA Group to improve perinatal health in Nepal. Since that time, MIRA has sponsored research on perinatal and neonatal health; provided training for doctors and nurses on advanced neonatal life support; provided training for health workers on neonatal care in the community; and hosted international workshops stressing perinatal care in the community and perinatal audits in health facilities.

One research activity, cosponsored by DFID, WHO, and USAID’s CHR Project, is to provide community-based, participatory health care in the Makwanpur District situated approximately 7 hours southwest of Kathmandu. Twenty-nine thousand married women of reproductive age were randomized into one of 24 intervention or control groups. Each intervention group has a female facilitator who supports the mother’s groups in identifying and prioritizing maternal and neonatal health problems, and assisting in identifying possible solutions to the problems. The mother’s groups also plan, implement, and monitor the progress of the intervention. This community participatory approach helps to improve awareness of problems and knowledge of the signs of illness, and also increases the demand for better health services.

The intervention also strengthens the health system by developing training materials and training health personnel, and by conducting perinatal audits to determine the outcome of each pregnancy and birth referred to the health center. It also assists in providing essential equipment and appropriate drugs, and by improving communication between the health center and the mother’s groups.

Another MIRA study, about to begin in Janakpur, Nepal, seeks to improve birth weights and prolong gestation by providing pregnant women with micronutrient supplements in the third trimester. The study also hopes to reduce perinatal mortality and examine the effect of nutrient status and immune function.

The Institute of Child Health has also recently founded the International Perinatal Care Unit, and is planning activities in Bangladesh, China, Nepal, South Africa, Tanzania, and Zambia.

KINTAMPO (GHANA) HEALTH RESEARCH CENTRE — PERINATAL INTERVENTIONS RESEARCH

Paul Arthur

The Kintampo Health Research Centre was established in Ghana in 1994 for field and epidemiological studies in collaboration with the London School of Hygiene and Tropical Medicine. The area covered by the center includes four districts and approximately 600,000 population. The center’s largest current project, The Obaa-pavita Project, examines the effects of weekly, low-dose vitamin A on maternal mortality. When the project is completely enrolled, 120,000 women will be under monthly surveillance for pregnancy, pregnancy outcomes, morbidity, and mortality. All infants will be followed at 14 and 42 days, and at months 2, 6, and 12. Interviews, home visits, and hospital records will also provide estimates of perinatal and neonatal mortality and morbidity, and infant illness and death.

Through information, education, and communication campaigns, the Obaa-pavita project will provide care for high-risk mothers and their newborns, strategies for perinatal and neonatal care, and a trial of hygienic delivery kits. Project staff will train health workers to identify sepsis and will refer all cases to a mobile health monitor who will administer treatment in the home. The project also hopes to offer risk factor analysis to explore or confirm relationships between antenatal exposures and birth outcomes; validate instruments for measuring perinatal and neonatal morbidity and mortality; and evaluate perinatal interventions.
NEONATAL HEALTH RESEARCH IN PAKISTAN — THE HALA PROJECT

Zulfiqar A. Bhutta

Since the early 1950s, the infant mortality rate in Pakistan has decreased by 50%, from 178 to 90 deaths per 1000 live births, and the neonatal mortality rate has declined by almost 60%, from 94 to 55 per 1000. However, since the mid-1970s, the rate of decline in early deaths has stagnated (Figure 9), progress stymied by the lack of programs to specifically target deaths in this age group. Furthermore, maternal mortality remains unacceptably high at 380/100,000. Estimates of perinatal deaths in the community range from 55 to over 80/1000 live births, with most of these deaths occurring in the first week of life.

Infections, birth asphyxia, and LBW or preterm birth are the major causes of neonatal death in rural Pakistan, where a traditional birth attendant attends to most deliveries. Most neonatal infections appear to be acquired from the environment rather than directly from the mother, and more than half of all serious sepsis infections are caused by Staphylococcus species, Streptococcus pneumoniae, and Escherichia coli. Other pathogens causing sepsis in the community include Klebsiella sp. and Enterobacter sp. — probably due to high rates of fecal contamination in the environment.

The high rates of LBW and preterm births (up to 26% of neonatal mortality) in Pakistan are fueled by widespread malnutrition in women and children under 5 years of age. Moreover, the rates of stunting and wasting in children, and maternal anemia have remained virtually constant for the last 35 years (Figure 10). One large-scale, community-based project under development aims to improve perinatal and neonatal outcomes in the Hala and Mattiari districts by providing high-risk referral and domiciliary resuscitation to asphyxiated newborns, and by providing care for LBW infants. Baseline indicators and outcomes will be recorded in almost 450 villages in Hala and adjoining Mattiari talukas, and compared with outcomes from a similar number of villages from nonintervention clusters in the same area. Health system issues, which will be addressed by the project, include strengthening of the referral pathways and secondary care centers; training of midwives, nurses, and doctors; and training of community health workers and TBAs to deliver the basic care package. Central to the design of the project is the development of community participation in the intervention by an innovative community education and mobilization program.

LBW infants will be given special care. To prevent infections, caregivers will delay bathing and vernix removal, provide oil massage and swaddling and hygienic cord care. Attention will be given to hand washing with antiseptic soap and environmental hygiene. Early and exclusive breastfeeding with colostrum administration will be encouraged, and infants will be watched for early signs of serious illness.

As part of Phase 1 of this project, baseline surveys of caregivers and perinatal and newborn care practices in health facilities in Hala and Mattiari have been completed. In addition, an extensive evaluation of perinatal and neonatal mortality has been conducted using standardized verbal and social autopsies. Pilot interventions of bag and mask resuscitation, thermoregulation and hypothermia prevention, and maternal nutritional interventions are underway, and the main cluster randomization is expected to run from 2002 to 2005.

INDIAN COUNCIL FOR MEDICAL RESEARCH: MULTICENTRE STUDY ON HOME-BASED MANAGEMENT OF YOUNG INFANTS (0–60 DAYS) IN INDIA

Vinod K. Paul, NC Saxena

Over 1.2 million newborns die each year in India. A new multicenter trial in Bihar, Orissa, Uttar Pradesh, Rajasthan, and Maharashtra states hopes to reduce mortality in infants under 60 days of age by delivering a package of home-based interventions. Each rural site consists of two interventions and one control community with a population of about 60,000 each. A village-based worker will deliver the intervention, which includes care at birth, care for both normal and LBW babies, identification of infants with infections, and health education to mothers and their families. The study is being developed by the Indian Council for Medical Research in collaboration with the
government of India. It will also have partnership with local health providers and a strong component of community participation. The primary goal is to reduce neonatal mortality by 50%. Secondary goals of the project are to estimate the incidence and case fatality rates of major morbidities in young infants, to determine the utilization of services provided by community newborn care workers, and to estimate the cost of implementing the package of interventions.

All newborns will receive resuscitation if necessary; counseling to promote hygienic umbilical cord care, and immediate and exclusive breastfeeding, prevention of infections, immunization; and growth monitoring at regular visits throughout the first 2 months of life. In addition, their caregivers will be urged to follow healthy newborn care practices and to curb harmful ones. LBW infants will receive extra thermal control, breast milk from a spoon if unable to latch on, and more frequent home visits than normal-weight children. Women in the last trimester of pregnancy, their mothers-in-law, and other family members will be educated on birth preparedness and clean delivery procedures, prevention of infection, the importance of early and exclusive breast-feeding, routine newborn care, and early detection of complications. All infants will be regularly evaluated during home visits using simple signs of illness and, if necessary, treated for localized infections and sepsis. Serious infections will be referred to a health facility. If the caregivers refuse referral, a treatment of oral cotrimoxazole and injectable gentamicin will be administered at home.

There will be three arms of the study. In one arm, a new village-level worker, namely, the Community Newborn Worker (CNW), will deliver the intervention. In the second arm, the Anganwadi Worker (AWW) will deliver the interventions. The third will be the control arm. The study will provide information on which model is more effective, sustainable, and affordable to deliver newborn care in the community.

The CNWs will be selected from the intervention communities, will have completed basic education, have some experience as a mother and possibly as a TBA or health provider, and have permission from their husbands and families to work. AWWs are existing village-level workers in the Integrated Child Development Services. They provide health and nutrition education, nonformal education, and supplementary nutrition. The target groups are other family members. The CNWs will be trained in the skills required to deliver the interventions and will receive an honorarium based on their performance in conducting clean deliveries, home visitation, and identifying and treating or appropriately referring sick infants.

The intervention will establish communication of CNWs or AWWs with traditional birth attendants and auxiliary nursing midwives. There will be a close link with the health system. Community participation will be encouraged at all stages of the intervention through individual and group meetings, and IEC activities. Community members will be consulted on selection of CNWs and offered educational sessions on newborn care.

**REDUCING INFANT MORTALITY IN MIDDLE-INCOME SETTINGS: PROJECT PLANS FOR PELOTAS, BRAZIL**

Elaine Albernaz, Cesar Victora

A great deal is known about reducing neonatal and infant mortality in low-income settings with very high death rates due to infectious diseases. In middle-income settings, such as Pelotas, Brazil, where the infant mortality rate is only 20/1000, new methods are needed to further reduce the death rate (Figure 11).

In Pelotas, over 70% of all infant deaths are in the neonatal period, and there are seven times as many deaths in poorer families than in richer ones. Furthermore, since 1983, the number of infants born with LBW has remained constant at 9% of all births (but more than 50% of all infant deaths) and the proportion of preterm births has increased slightly from 5.6% to 7.5%.

Now, researchers from the Federal University of Pelotas are seeking funding to introduce a set of interventions aimed to reduce neonatal mortality by 25% in the next 5 years. In Southern Brazil, over 95% of women receive antenatal care, and 99% of births and 97% of all infant deaths occur in hospitals, so efforts will focus on training of health professionals and monitoring the quality of care they provide. Specifically, the intervention will provide: increased physician attendance for low-income births, postnatal care for all infants by pediatricians, and improved care for preterm and LBW babies. The project will also provide intensive care for high-risk neonates, and at discharge, community health workers who will counsel caregivers on appropriate newborn care practices, including exclusive breast-feeding, will visit these infants at home.

At the facility level, four hospitals will be supported for certification as “Baby-Friendly”, and the IMCI strategy will be implemented at 40 health clinics in Pelotas City. Using information on mortality and malnutrition in each neighborhood, facilities will be prioritized to provide IMCI. Hospitals will also be subject to an ongoing perinatal audit to examine newborn deaths, and to determine how the deaths could have been prevented. The Pelotas Department of Health will also be expanded to provide continuous surveillance of all births, which will allow researchers to monitor the impact of quality and coverage of antenatal and newborn health services on neonatal mortality. The project will be evaluated, and results disseminated to assist in prioritizing further interventions to reduce infant mortality.

![Image](image-url)