

# Results From Recent Research

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## HOME-BASED NEONATAL CARE IN GADCHIROLI, INDIA

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A field trial of home-based neonatal care (HBNC) interventions took place in Gadchiroli, India (Maharashtra State), from 1993 to 1998, and was highly successful in reducing perinatal, neonatal, and infant mortality.<sup>59</sup> In the 3 years of intervention, there was a 71% reduction in perinatal mortality and a 62% reduction in neonatal mortality compared with the control area. At the same time, the infant mortality rate decreased by 45% (Figure 12). Total maternal morbidity was also dramatically reduced by approximately 25%. This project has inspired other groups to attempt to replicate or adapt the model of community-based care, and to address issues of cost-effectiveness and scale prior to the intervention being implemented on a state or national level.

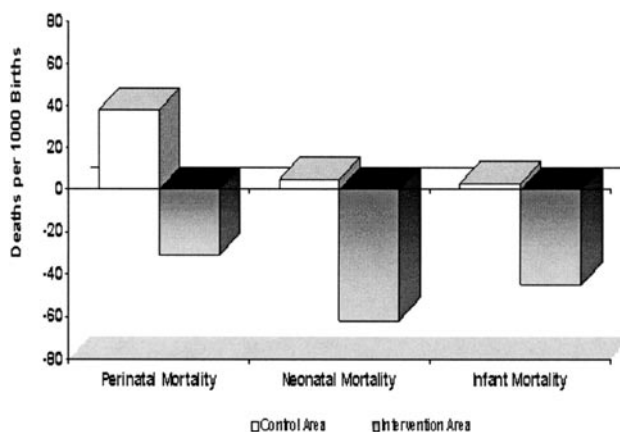
The study took place in 39 intervention and 47 control villages with approximately 40,000 people in each group. A baseline period lasted from 1993 to 1995, and an intervention phase of 3 years followed in 1995 to 1998. The intervention was incrementally introduced. In year 1, only home visits were made for observation with very little intervention. In year 2, 85% of newborns were visited in the home and management of sick infants was added to each visit. In year 3, the home visit coverage increased to 93%, with managed care of sick infants, and health education of mothers through group meetings at a rate of about 70%.

Driving this intervention's success was a cadre of well-trained and supervised female village health workers selected from the local female population. Each village health worker was between 20 and 40 years old with 5 to 10 years of schooling, and was trained to keep lists of pregnant women, keep a mother's health record, observe the process of labor, identify and manage asphyxiated newborns, and record birth weight. The health workers also made follow-up visits at regular intervals and on days of sickness, at which time they took medical histories and conducted examinations. Using treatment kits costing less than \$30, they managed cases of birth asphyxia, hypothermia, breast-feeding problems; provided special care to LBW neonates; and identified and treated sepsis and superficial infections. Community health worker reinforced their knowledge and skills through monthly training classes. A physician visited each village every 15 days to supervise the health workers, and found 92% agreement between their findings and those of the workers'. Economic incentives were given for good performance, and deductions from the wages were

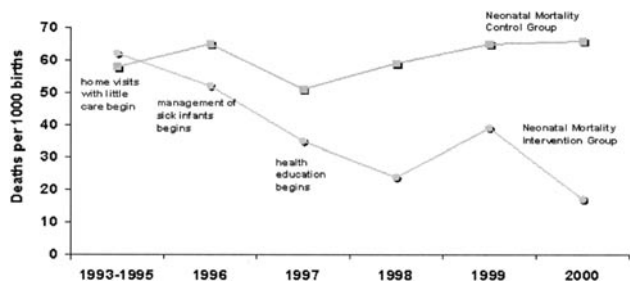
made if workers did not attend deliveries, or collected data of substandard quality.

Since the major cause of death was neonatal sepsis, a simple and effective method of management was needed. After determining basic patterns of antimicrobial resistance in the intervention area based on a study of vaginal isolates from women of reproductive age in the community, the village health workers were instructed to treat sepsis with injections of gentamicin and oral cotrimoxazole for 10 days in preterm infants and for 7 days for all other children. Although it is somewhat controversial for home-based workers to give injections, the village health workers have given over 7000 injections (5000 injections of vitamin K and 2000 injections of gentamicin) since 1996 without a single major complication. This treatment regimen began in the second intervention year (1996). After implementation, case fatality from presumed sepsis fell from 16.5% to 2.8%. Interestingly, all-cause neonatal mortality began to fall in the first intervention year when only home visits and observation were introduced (Figure 13).

Since 1998, the Gadchiroli project has continued to use data to develop a set of simple signs to diagnose which neonates are most likely to die with sepsis. The signs are for use by both health workers and caregivers, and if any one sign is detected, it is recommended that the infant should receive further evaluation. Treatment should be started if any two of the following signs/symptoms are present at the same time: baby's cry became weak or abnormal or stopped; baby stopped sucking or mother felt that sucking definitely became weak or reduced; baby became drowsy or unconscious; temperature more than 99°F (37.2°C) or less than 95°F (35.0°C); pus in skin or umbilicus; diarrhea or



**Figure 12.** Decline in perinatal, neonatal, and infant mortality—Gadchiroli, India 1993–1998.



**Figure 13.** Decline in neonatal mortality— Gadchiroli, India 1993–1998.

persistent vomiting or distension of the abdomen; grunting or severe chest indrawing; respiratory rate 60 or more per minute in a quiet baby even after two counts.

Several projects are currently in baseline survey or in planning, which will use methods developed in Gadchiroli to bring home-based care to much larger groups of people in India, Bangladesh, and Pakistan — as described in previous sections of this report. The Society for Education, Action and Research in Community Health (“SEARCH”) in Gadchiroli, India, has conducted and published studies on (1) burden of neonatal morbidity in home-cared rural neonates and, (2) a new intervention package called HBNC and its effect on neonatal mortality.

With the support of Saving Newborn Lives, SEARCH has planned two new projects.

- (1) Replicating the HBNC approach at seven sites in the Maharashtra State in India. This is a field trial in a population of 92,000. The baseline mortality data collection has been completed (1998–2001), and the training for intervention is planned in 2001 to 2002. The trial will be over in 2005 and will demonstrate the effect as well as the methods and cost of replicating HBNC.
- (2) Developing training, education, and advocacy material on home-based newborn care. SEARCH will be training seven NGOs in Maharashtra as well as five teams from the five states in India by developing the training modules and material for community level workers as well as their trainers. A Training and Resource Center on HBNC is to be developed in Gadchiroli for assisting others in India and developing countries.

In addition to adapting training and service delivery methods to a larger population, these projects will also attempt to integrate themselves into existing community development programs. Another issue that the NGO project will face is how differing levels of social development (rural, urban slum, and tribal) will affect acceptance and results of this model. Because in the follow-on projects, Gadchiroli methods of home-based care will be delivered to larger groups of people, a smaller mortality reduction is to be expected. One projection of results for the NGO trial is that home-based care will reach 75% of all births, the intervention will reduce neonatal

mortality by 30% in a before/after comparison, and perinatal mortality will be reduced by 25%.

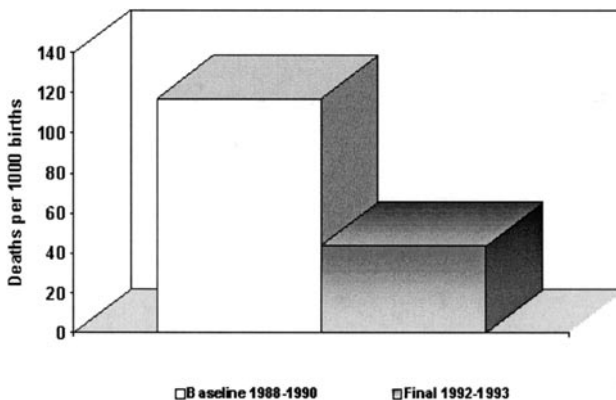
## COMMUNITY ORGANIZATION AND PERINATAL OUTCOMES IN BOLIVIA: THE WARMI PROJECT

### Lisa Howard-Grabman

An intervention to improve maternal and child health was conducted in the remote Inquisivi Province of Bolivia — a place with limited access to modern medical facilities. The intervention reduced perinatal mortality by 67% by initiating and strengthening women’s organizations, developing women’s skills in problem identification and prioritization, and training community members in safe birthing techniques (Figure 14).

The demonstration project, sponsored by a partnership among Save the Children, Mothercare (John Snow with support from USAID), and the local NGO Centro Interdisciplinario de Estudios Comunitarios (CIEC), ran from 1990 to 1993, and was followed by the National Warmi Project from 1995 until the present.<sup>60</sup> In addition to reducing early infant deaths, the Warmi Project also increased the number of women participating in women’s organizations from 42% to 86%, the proportion of women receiving prenatal care, and the number initiating breast-feeding on the first day after birth from 25% to 50%. The most significant contribution of the Warmi Project, however, was the development of a new methodology of reproductive health care and education. Key points of the new methodology were:

- participatory planning at the community level to identify obstetric and perinatal health problems and potential solutions;
- continuous training and education of health care staff and families;
- developing a “dialogue of knowledge” between indigenous and biomedical perspectives to negotiate improved health practices; and
- an emphasis on women’s participation and empowerment to raise women’s status.



**Figure 14.** Decline in perinatal and neonatal mortality— Warmi Project: Inquisivi Province, Bolivia 1988–1993.

The Warmi Project — named for the Aymara word for “woman” — established the “Community Action Cycle” process in communities that were geographically and culturally isolated, had little or no formal health care, no family planning services, and where husbands and other family members traditionally attended births. Infanticide was also reported in the community, and was most common in homes with a large number of children or in poor families with very few resources. The initial “autodiagnosis” phase allowed women to identify and prioritize problems based on their experiences, and to assist in the planning of interventions to improve problems. Initially, only women were engaged in discussion about problems in the community, but later husbands and other community members were invited to join the planning process. Part of the success of the Warmi Project was due to the timing of community participation. Because only women were involved in the early stages, their voices and opinions were not lost in the crowd. Including men in the later stages gave the intervention the support of the entire community, and virtually eliminated male hostility and opposition to the project as is common in many rural communities.

Actions taken by the community and program staff included: training birth attendants, offering tetanus immunizations to women of reproductive age, ensuring clean birthing surface and hygienic cord care, antibiotic eye drops, immediate breast-feeding, and thermal control of young infants. Over one-third of women prioritized too many children as a major problem, and they mandated project staff to ask a local NGO to come in and provide family planning services. Community funds and agreement with truck drivers were also established to provide transportation to women who needed care at secondary health facilities.

Over time, the radius of the project widened, mainly through personal contacts of participants who shared their experiences with other women. Agreements were also established with nearby hospitals and clinics so that women requiring specialized medical attention could seek care in those facilities. Many residents of Inquisivi were poor, spoke primarily the Aymaran or Quechuan dialects, and avoided seeking care at secondary health facilities because of insensitive or abusive treatment. The Warmi Project linked with the San Gabriel Hospital in La Paz to strengthen ties between Inquisivi and the referral hospital.

Another aspect of the Warmi Project's success is cultural sensitivity to existing birthing and healthcare practices. All project participants learned about traditional practices, and beneficial or benign practices were respected. When harmful practices were identified, project staff negotiated “new” or “improved” practice standards. Quarterly review and evaluation with the project team health providers and community members also contributed to Warmi's success. When interventions did not proceed as planned, community members were encouraged to assist in the analysis of problems and in planning possible

solutions. Steps were also taken at the beginning of the project to ensure sustainability. For example, the project linked with organizations providing economic development and literacy education, and joined forces with the local government and institutions that would continue project activities at the end of the demonstration period. In addition to continuing in Inquisivi since 1995, the Warmi methodology has been extended to hundreds of other Bolivian communities, and has been adapted for use in trials in Peru, Ecuador, Guatemala, Nicaragua, India, Nepal, and Zambia.

## GLOBAL REVIEW OF NEONATAL INTERVENTION TRIALS

**Zulfiqar A. Bhutta, Gary L. Darmstadt, Babar Hasan, Chitra Krishnan**

A global review of community-based perinatal and neonatal practices is currently underway to evaluate the effectiveness of interventions in community settings by evaluation of individual studies and pooled information. Using meta-analyses registered in the Cochrane Collaboration database, and a literature review of over 6000 research publications and program reports, the researchers reviewed studies which reported on interventions prior to birth, during labor and delivery, and in the postnatal period. Examples of perinatal interventions in the pooled analysis included: maternal nutritional supplementation; pharmacological treatments such as antibiotics, antimalarials, and vaginal chlorhexidine; and maternal vaccination. Interventions during labor and delivery focused on management of asphyxia, training of birth attendants; and examination of postnatal practices included care of the umbilical cord, postasphyxia care, breastfeeding, thermoregulation, micronutrient supplementation, and early detection of illness. Interim results are reported below.

A pooled analysis of 13 studies examining the effects of balanced high-energy protein supplementation of pregnant women was located in the Cochrane library.<sup>61</sup> This analysis found that food supplementation is generally associated with a modest increase in fetal growth of about 25 g, and no decrease in preterm birth. Food supplementation was, however, associated with a significant reduction in the risk of small-for-gestational-age births (OR 0.64; CI 0.53–0.78) and a significant reduction in stillbirth and neonatal mortality — based on a subset of three studies. In addition, four community-based studies also showed reduced stillbirth and neonatal mortality rates with protein–energy supplementation.<sup>62</sup>

The Cochrane collaboration yielded a meta-analysis of seven studies that examined the effect of maternal zinc supplementation on pregnancy outcomes.<sup>63</sup> The pooled dataset showed that zinc reduced preterm birth, but data were insufficient to evaluate other birth outcomes. Other community-based studies completed after this meta-analysis have demonstrated that zinc supplementation reduced preterm births and LBW<sup>64</sup> and that incidences of diarrhea

and dysentery, respiratory infection, and impetigo were reduced in children born to supplemented mothers — and that this effect was greater in LBW infants.<sup>65</sup> Zinc supplementation has also been shown to reduce mortality by 66% in small-for-gestational-age infants.<sup>49</sup>

A meta-analysis of iron supplementation trials in the Cochrane collection showed no effect on pregnancy outcomes,<sup>66</sup> but the studies contributing to the data pool came primarily from developed world settings where maternal anemia is uncommon. Three studies from rural settings in the developing world showed that iron supplementation reduced the incidence of LBW and increase weight at birth, but these results were not significant.<sup>67,68</sup> Conversely, iodine supplementation in the very iodine-deficient environment of China's Xinjiang province substantially reduced neonatal mortality.<sup>69</sup>

The effect of maternal vitamin A supplementation with and without multivitamins (B1, B2, B6, niacin, B12, folic acid, vitamins C and E) on pregnancy outcomes was tested in 1075 HIV-infected women in Tanzania.<sup>70</sup> This study found that vitamin A alone had no effect on birth outcomes, but multivitamin supplementation decreased the risk of LBW by 44%, severe preterm birth by 39%, and small-for-gestational-age birth by 43%. The Nepal Nutrition Intervention Project did show, however, that maternal mortality could be reduced by 44% with weekly oral vitamin A and/or beta-carotene supplementation.<sup>71</sup>

The Cochrane meta-analysis on routine use of antimalarials in pregnant women found that they resulted in lower rates of severe maternal anemia and greater than average birth weight in infants — and that these effects tend to be higher in women bearing their first child.<sup>72</sup> However, no differences in perinatal and neonatal mortality were detected in studies of prophylaxis in all parity groups. Researchers then identified eight community-based studies testing the effects of prenatal malaria prophylaxis on birth outcomes. These studies showed increased birth weight, lower (but not statistically significant) LBW rates, and nonsignificant trends towards reduction in perinatal mortality, stillbirth, neonatal mortality, and infant mortality.

A meta-analysis of 13 studies favoring the use of antibiotics to treat asymptomatic bacteruria found that treatment reduced preterm birth and LBW rates.<sup>73</sup> When data were pooled from studies examining the use of antibiotics to reduce preterm birth, no effect on neonatal outcomes was observed.<sup>74</sup> Moreover, there was a possible trend towards increased perinatal mortality with the use of this treatment; therefore, this can no longer be recommended as a standard treatment to delay early delivery. When membranes were ruptured prematurely, the analysis showed that antibiotic treatment clearly prolonged pregnancy, but had no effect on neonatal mortality or morbidities, and possibly increased perinatal mortality.<sup>75</sup> Data on antibiotic treatment for bacterial vaginosis are lacking from developing world settings, although work is underway to fill in these gaps. Two studies which evaluated vaginal and newborn skin cleansing with

chlorhexidine were identified.<sup>76,77</sup> Although more research is required in this area, preliminary conclusions are that it does seem to have a significant impact on neonatal infectious outcomes.

In the developing world, untrained TBAs perform most of the deliveries. Some studies have shown that when TBAs are trained, there is a trend towards reduced neonatal mortality, but training quality and coverage must be carefully controlled if it is to positively affect birth outcomes.<sup>78</sup> Studies of resuscitation in the developing world are few, but available data suggest that the two methods — mouth-to-mask and bag-to-mask — produce comparable outcomes in asphyxiated infants.<sup>79</sup> No other community-based studies on asphyxia management were available from developing countries to add to the evaluation, underlining the urgent need for further studies.

In the Kangaroo Mother Care (KMC) method, a well preterm infant, wearing only a diaper, is placed between the mother's breasts in skin-to-skin contact, instead of being placed in an incubator. This method has been shown to have many benefits. The Cochrane meta-analysis of three studies on KMC stated that: "Although KMC appears to reduce severe infant morbidity without any serious deleterious effects reported, there is still insufficient evidence to recommend its routine use in LBW infants.<sup>80</sup> Well-designed, randomized, controlled trials of this intervention are needed." Other studies examined by the Global Review team were of poor data quality, and all were facility-based, but did show a trend towards reduced infant morbidity. Again, community-based studies are needed to further evaluate the effects of KMC.

Eight studies were identified regarding effects of breast-feeding and counseling for breast-feeding for infection control. One of them, a pooled analysis from Brazil, The Gambia, Ghana, Senegal, Pakistan, and The Philippines, showed clearly that those neonates who were not breastfed had a higher mortality rate.<sup>81</sup> Another conclusion of the Global Review was that women who were counseled regularly were observed to exclusively breastfeed more frequently.

Which improvements in a health system would provide the largest decline in neonatal mortality? One study in the Karur District, Tamil Nadu, India, instituted a high-risk antenatal health care program. It found that the proportion of newborns with LBW was lower, and mean birth weight was higher for children of women receiving the high-risk care than for women in standard Tamil Nadu Government Hospital care or controls.<sup>82</sup> Preventable perinatal and neonatal morbidity were lower in the high-risk care group. Several small studies that focused on training community-based caregivers to recognize illness in newborns, and refer them to a hospital or health facility, have tended to reduce neonatal and or perinatal mortality. Likewise, the Gadchiroli project and other projects like it have produced promising results, indicating that carefully trained and supervised village health workers can recognize and treat neonatal illnesses

and produce a positive impact on newborn morbidity and mortality.<sup>59</sup>

This Global Review of Perinatal and Neonatal Health interventions has shown that there are disparate but promising data on the potential benefits of community-based interventions in the prevention and reduction of perinatal and neonatal morbidity and mortality. From available data, the most effective interventions appear to be those including aspects of maternal care and involving trained caregivers; and those that provide maternal energy/protein supplementation, micronutrient supplementation, treatment of

maternal infections, and trained attendants and strengthened referral pathways.

Any intervention package for domiciliary or community-based newborn care must also be based on a firm understanding of the determinants and pathways of care-seeking behaviors. In order to improve compliance and referral outcomes within current health systems, such packages must include components of physician/caregiver education at all levels and provision of basic facilities for maternal and newborn care.