Community-Based Intervention Packages for Improving Perinatal Health in Developing Countries: A Review of the Evidence

Jessica Schiffman, BA, Gary L. Darmstadt, MD, MS, Siddharth Agarwal, and Abdullah H. Baqui, MBBS, DrPH, MPH

The Lancet Neonatal Survival Series categorized neonatal health interventions into 3 service delivery modes: “Outreach,” “Family-Community Care,” and “Facility-based Clinical Care.” Family-Community Care services generally have a greater potential impact on neonatal health than Outreach services, with similar costs. Combining interventions from all 3 service delivery modes is ideal for achievement of high impact. However, access to clinical care is limited in resource-poor settings with weak health systems. The current trend for those settings is to combine neonatal interventions into community-based intervention packages (CBIPs), which can be integrated into the local health care system. In this article, we searched several large databases to identify all published, large-scale, controlled studies that were implemented in a rural setting, included a control group, and reported neonatal and/or perinatal mortality as outcomes. We identified only 9 large-scale studies that fit these criteria. Several conclusions can be reached. (1) Family-Community Care interventions can have a substantial effect on neonatal and perinatal mortality. (2) Several important common strategies were used across the studies, including community mobilization, health education, behavior change communication sessions, care seeking modalities, and home visits during pregnancy and after birth. However, implementation of these interventions varied widely across the studies. (3) There is a need for additional, large-scale studies to test evidence-based CBIPs in developing countries, particularly in Africa, where no large-scale studies were identified. (4) We need to establish consistent, clearly defined terminology and protocols for designing trials and reporting outcomes so that we are able to compare results across different settings. (5) There is an urgent need to invest in research and program development focusing on neonatal health in urban areas. (6) It is crucial to integrate CBIPs in rural and urban settings into the already existing health care system to facilitate sustainability of the program and for scaling up. It is also important to evaluate the packages and to demonstrate the health impact of large-scale implementation. (7) Finally, there is a need for improving the continuum of care between home and facility-based care.

Semin Perinatol 34:462-476 © 2010 Published by Elsevier Inc.

KEYWORDS community-based, intervention packages, neonatal health, neonatal mortality, urban slums

Every year, an estimated 3.6 million infants die worldwide in the first month of life.$^1,2$ Approximately three-fourths of these deaths occur within the first week of life, and the majority are preventable through simple, low-cost interventions.$^3$ One-half or more of these deaths occur in the home.$^2$

The most common causes of neonatal mortality include a variety of infections (36%), prematurity (28%), and intrapartum-related neonatal deaths (“birth asphyxia”) (23%).$^2$ Maternal health during pregnancy and delivery are key determinants of neonatal deaths. In low-resource settings, where deliveries are commonly performed in the home, household practices are important determinants of mortality.$^1$ Therefore, to prevent the greatest number of neonatal deaths, we must focus our attention on prevent-
ing complications in the perinatal and neonatal periods in developing countries.

The current trend in developing community-based strategies for improving neonatal health in low-resource settings is to combine antepartum, intrapartum, and postnatal interventions into “packages” that can be integrated into the health care system. In this paper, we define a “package” as a bundle of 2 or more interventions and refer to the community-based intervention packages as community-based intervention package (CBIP). We are moving away from implementing single interventions into health care systems in a vertical manner because combining evidence-based interventions into packages with a common service delivery mode is generally more cost-effective than implementing a single intervention into the health care system. Even in weak health care systems, reaching high coverage with these basic packages can decrease neonatal deaths by an estimated 35% to 66%.3

The authors of the Lancet Neonatal Survival Series categorized the service delivery modes for neonatal health interventions into “Outreach,” “Family-Community Care,” and “Facility-based Clinical Care” (Fig. 1).3 The “Outreach” category describes services that meet the needs of a population and can be implemented periodically either in health facilities or in the community. Examples include immunization programs and routine antenatal care.3,4 The “Family-Community Care” category combines family-oriented and community-oriented services that are designed to complement the specific community’s social and cultural context.3 An important focus of Family-Community Care is to empower families and communities to practice healthy preventive behaviors and to demand services, such as care-seeking for illness. Another example of Family-Community Care is case management of neonatal illness by community-based workers (CBWs), including referral to health facilities for clinical care.3,5 The “Clinical Care” category describes facility-based clinical services, such as neonatal resuscitation, emergency obstetrical care, care of sick newborns, and care for very low birth weight infants. These services are performed by skilled clinicians and are most commonly delivered in clinics and hospitals.3

Figure 1 The Lancet Neonatal Survival Series Universal Evidence-based intervention packages organized by service delivery modes.4
Family-Community Care services generally have a greater potential impact on neonatal health than Outreach services, with similar costs.\(^3\) In a review article, Haws et al\(^4\) assessed the impact of intervention packages on neonatal health and found that studies that included Family-Community Care interventions were more likely to provide a continuum of care from pregnancy through the postnatal period than the other service delivery modes. CBIPs delivered through both the Outreach and Family-Community Care service modes were estimated to decrease neonatal mortality by 18% to 37%.\(^3\) Although Clinical Care services are generally more costly than the other service delivery modes, they are integral to substantially decreasing perinatal mortality beyond the effect that Outreach and Family-Community Care services can have alone.\(^3\)

On the basis of the principles for service delivery set forth in the Lancet Neonatal Survival Series,\(^3\) the objectives of this paper are (1) to systematically identify large-scale, controlled studies that test a CBIP with a primary focus on Family-Community Care interventions because they have a greater potential impact than Outreach and Clinical Care interventions, (2) to describe the positive and negative findings of the studies identified, and (3) to summarize the lessons learned. We also briefly describe urban models of health care as a comparison to the community-based models that have been implemented in rural areas.

**Methods**

**Literature Search and Selection of Trials**

We searched PubMed, the Cochrane Database of Systematic Reviews, and Google Scholar to identify all published, large-scale controlled trials or program evaluations carried out in a rural setting that implemented a CBIP and included a control group. Only studies that reported neonatal mortality rate (NMR) and/or perinatal mortality rate (PMR) as outcome variables were considered. We did not review trials that tested single interventions. We also did not consider trials with a primary focus on clinical care for neonatal infections, prematurity, intrapartum-related neonatal deaths (“birth asphyxia”), stillbirths, or hypothermia unless they were incorporated into a CBIP; these topics are covered in other articles in this series.\(^5-9\)

Combinations of the following key terms (among others) were used to search the databases: “neonatal mortality,” “neonatal health,” “perinatal mortality,” “perinatal health,” “community-based intervention,” and “birth outcomes.” We initially received 790 hits when performing a broad search. We narrowed our search to 108 citations that tested interventions for improving neonatal or perinatal health. Among these, 61 were studies that were not controlled trials or program evaluations that tested CBIPs (7 of these studies were controlled studies that tested single interventions), 8 were review articles or meta-analyses, 28 were not journal articles (books, presentations, reports, etc.), and 11 were controlled trials or program evaluations that tested CBIPs (one was an RCT but the trial was ongoing and the results are not yet published, another one was an RCT that did not report NMR or PMR). Although our primary focus was on identifying RCTs, we extended our search to include controlled trials that were not randomized and program evaluations that used a randomized or nonrandomized controlled trial design due to the scarcity of RCTs in the literature.

**Results**

We identified 10 large-scale, controlled studies that fit our search criteria.\(^3,10,11,14,16-19\) Because Bang et al 2005\(^17\) was a continuation of the Bang et al 1999\(^14\) study and the results reported in the 2005 paper were an updated version, we excluded Bang et al 1999 from our final list of large-scale controlled trials of CBIPs (Table 1).

**Design of the Studies**

We identified 9 studies published to date in which the authors evaluated CBIPs in a rural, developing country setting (Table 1). Five of the 9 studies were cluster RCTs.\(^10,11,12,13,16\) 2 were nonrandomized controlled trials.\(^17,18\) One program evaluation had a controlled, quasi-experimental design,\(^19\) and the final trial had a 2-part design; the first part used a before-after design and the second part used a cluster RCT design (Table 1).\(^13\)

**Comparing CBIPs by Service Delivery Mode**

Figure 1 groups the evidence-based interventions into the service delivery modes specified by the Lancet Neonatal Survival Series: Family-Community Care, Outreach Services, and Facility-based Clinical Care.\(^3,4\) Table 2 compares the 9 key studies across the Family-Community Care service delivery mode.

Only one study offered all the Family-Community Care strategies.\(^17\) This study also demonstrated the greatest reduction in NMR compared with the other studies that reported NMR as an outcome (Table 3). Baqui et al 2008\(^11\) (Bangladesh) came close to offering all the Family-Community Care strategies but did not include extra community-based care of low birth weight neonates. The remainder of the studies included some, but not all the Family-Community Care strategies. Few studies offered any of the Outreach or Clinical Care interventions listed in (Fig. 1) (not shown in Table 2). Baqui et al 2008 (India)\(^19\) and Darmstadt et al 2010\(^13\) offered tetanus toxoid immunization, an Outreach intervention, as part of the CBIP. Only 4,\(^11,13,18,19\) of the studies included promotion or distribution of folic acid supplementation during pregnancy; however, the supplements were not necessarily given periconceptually. None of the studies included any Facility-based Clinical Care interventions, except Baqui et al 2008\(^11\) (Bangladesh) provided limited support of government facilities to provide care for mothers and their newborns.

Some additional strategies not included in the Lancet’s list of universal evidence-based packages were also in-
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<th>Authors (Year), Location</th>
<th>Study Design</th>
<th>Intervention</th>
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<th>Positive Findings (Significant $P &lt; 0.05$), <em>NMR per 1000 Births</em></th>
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<td>Bang (2005), Gadchiroli, India (a continuation of the Bang 1999 trial)</td>
<td>Controlled trial, not randomized</td>
<td>Continued interventions from previous trial (Bang, 1999). The field trial of home-based neonatal care was started in 1993. 1995-1996: home visits consisted only of observations of neonatal morbidity, cases of death and treatment of neonatal pneumonia. 1996-1997: management of sick neonates was introduced as an intervention. 1997-1998: management of sick neonates was improved and health education was added.</td>
<td>Received usual care provided by local health system. NMR decreased from 62 (1993) to 25 (2003), which is a 70% decrease (95% CI 59-81%); Early NMR decreased by 64%, late NMR by 80%, SBR by 56%, and IMR by 57%. PNMR did not change. All reductions were significant at $P &lt; 0.001$ except SBR at $P &lt; 0.05$.</td>
<td>HBNC had no effect on PNMR. Control groups not randomly selected because of a lack of feasibility. The estimated number of deaths attributed to the various components of HBNC was based on a nested before-after comparison in the intervention arm (no control).</td>
<td>HBNC decreased the NMR by 70% and contributed equally to early and late NMR. SBR and PMR also decreased by approximately 50%. Most deaths (93.6%) were prevented due to sickness management. This reduction in neonatal mortality can be explained by the following components of HBNC: sepsis management (36%), supportive care of LBW neonates (34%), asphyxia management (19%), primary prevention (7%), and other (4%).</td>
<td>The only study that included all of the Family-Community Care components listed in Table 2. This study resulted in the greatest reduction in NMR, among the studies that reported NMR as an outcome. Most of the reduction in mortality was attributed to home-based management of sepsis, LBW neonates, and birth asphyxia.</td>
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<td>Baqui (2008), Sylhet, Bangladesh</td>
<td>Cluster randomized controlled trial</td>
<td>2 interventions over 30 mo: 1. Home-care arm: female community health workers identified pregnant women, made home visits during pregnancy to educate mothers and assess newborns on days 1, 3, 7 after birth, referred sick neonates to hospitals and provided treatment in homes. 2. Community-care arm: education and care seeking through group sessions held by female and male community mobilizers, no home visits included.</td>
<td>Received usual health services by government, NGOs, and private providers with additional government health-system strengthening, including refresher training for facility-level health providers to treat neonatal infections and provided supply of antibiotics. Last 6 mo of 30-mo period: NMR 29.2 (home-care arm), 45.2 (community-care arm), 43.5 (comparison arm); NMR reduced by 34% in home-care arm vs comparison arm (adjusted RR 0.66, 95% CI 0.47-0.93). No reduction in NMR in community-care arm vs comparison arm (RR 0.95, 95% CI 0.69-1.31).</td>
<td>Community Health workers attended &lt;5% of births because of a high workload, travel distances, and not receiving timely notification of births. Each female community health worker responsible for large population (18,000).</td>
<td>A home-care strategy that integrates preventative and curative newborn services reduced NMR by 34% and is an effective intervention to reduce neonatal mortality in communities with weak health care systems and high neonatal mortality.</td>
<td>Showed that home-care is more successful at decreasing neonatal mortality than a purely community-based model.</td>
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<td>Baqui (2008), Uttar Pradesh, India*</td>
<td>Controlled, quasi-experimental design</td>
<td>Intervention included prenatal, intrapartum, and postnatal components. <strong>Prenatal:</strong> home visits were made by auxiliary-nurse midwives, aganwadi workers (maternal and child health promotion workers), and change agents to provide counseling on preventive care, nutrition, preparedness for child birth, and health care use for complications; <strong>Intrapartum:</strong> families were encouraged to call auxiliary nurse-midwives or trained TBAs to attend delivery; <strong>Postnatal:</strong> CBWs visited families at home after birth to provide counseling on essential newborn care (thermal care, hygiene, and clean cord care), maternal and newborn danger signs, and health-care use; follow-up visits were made for sick, premature, or LBW newborns.</td>
<td>Received standard government health and integrated Child Development services.</td>
<td>The NMR decreased by 34% within the group of women who received a postnatal visit within 28 d (NMR 35.7, 95% CI 29.2-42.1) compared with the group who either received no visit (NMR 53.8, 95% CI 48.9-58.8) or only an antenatal visit (NMR 54, 95% CI 45.9-62.1); women who received a postnatal visit within 3 d of delivery had a 25% reduction in NMR compared with those who did not receive a visit.</td>
<td>Adjusted baseline NMRs did not differ between intervention (NMR 46.4, 95% CI 42-50.8) and comparison groups (NMR 45.8, 95% CI 40.6-51). Neonates who only received a visit by a CBW during the antenatal period did not have lower NMR (54, 95% CI 45.9-62.1) compared with those who did not receive a visit (53.8, 95% CI 48.9-58.8).</td>
<td>INHP with a newborn component increased coverage of antenatal and postnatal health promotion visits and improved some neonatal-care practices. Most of the improvement was in the antenatal period. Fewer than 1 in 4 neonates received a home visit during the first 3 d of life, which is when half of all neonatal deaths occurred. The program failed to reduce neonatal mortality but those women who received a postnatal visit within the first 28 d after birth were less likely to have their newborn die. Most of the reduction in NMR was most likely due to promotion of essential newborn care practices, including exclusive breastfeeding, thermal care, clean cord care, and referral of sick newborns. Simulation analyses showed that 30% program coverage with an antenatal visit and a postnatal home visit within the first 28 d can reduce NMR by 34% from baseline.</td>
<td>The first study to use multipurpose government health workers as part of a large-scale community-based neonatal health program evaluation to assess the impact on neonatal mortality.</td>
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<td>Bhutta (2008), Hala, Pakistan</td>
<td>Cluster controlled trial</td>
<td>Over the course of 2 years: LHWs received additional training in home-based newborn care, visited pregnant women twice during pregnancy, within 24 h after birth, and days 1,3,7,14, and 28 after delivery; LHWs were encouraged to link up with Dais (traditional birth attendants); Voluntary community health committees were created to work with and support LHWs—they organized group education sessions where LHWs used videos and visual aids to promote knowledge and behavior about maternal and newborn care.</td>
<td>Received services from government’s already existing LHW program, no attempt made to link LHWs with TBAs, all rural health center clinical staff were offered training in newborn care.</td>
<td>Reductions from baseline NMR from 57.3 to 41.3 (decreased by 28%); reduction in SBR from 65.9 to 43.1 per 1000 births (decreased by 34.6%).</td>
<td>LHWs not provided with injectable antibiotics. Because this was a pilot study, there were a small number of clusters. Lack of statistical analysis due to limitations of pilot study. Low retention rates of health-care staff.</td>
<td>Decreases in NMR and SBR indicate community health workers (LHWs and Dais) can be effective at implementing a community outreach intervention for improving neonatal health. A larger RCT is currently under way.</td>
<td>Focused on strengthening already existing primary care model centered on LHWs.</td>
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<td>Carlo (2010), 6 countries</td>
<td>First part (Essential Newborn Care Course): before-after design Second part (Neonatal Resuscitation Program): cluster randomized controlled trial</td>
<td>Used train-the-trainer model with local instructors who trained birth attendants from rural communities using the WHO essential newborn care (ENC) course which focuses on routine neonatal care, resuscitation, thermoregulation, breastfeeding, skin-to-skin care, care of the small baby, and common illnesses. After completion of the essential newborn care course, the clusters randomly assigned to the Neonatal Resuscitation Program received a 3 d course.</td>
<td>Before-after design: the control group was a cohort of women who did not receive training in the essential newborn care course (before the course was taught).</td>
<td>Decrease in SBR (RR 0.69, 95% CI 0.54-0.88, $P = 0.003$).</td>
<td>No significant reduction in neonatal death from all causes in first 7 d after birth (RR 0.99, 95% CI 0.81-1.22) or in the PMR; no significant reduction in rates of neonatal death in births in which attendants were trained in the Neonatal Resuscitation Program.</td>
<td>The NMR in the 7 d after birth and PMR did not decrease after essential newborn care training of community-based birth attendants, however the SBR was significantly decreased. Subsequent training in the Neonatal Resuscitation Program did not significantly decrease the NMR, PMR, or SBR.</td>
<td>Strengths include multicountry design, large sample sizes, use of local trainers to train birth attendants. The apparent effect of ENC on SBR may have been due to a misclassification error, which is a potential weakness of the study.</td>
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<td>Darmstadt (2010), Mirzapur, Bangladesh</td>
<td>Cluster randomized controlled trial</td>
<td>CHWs identified pregnancies through surveillance, made 2 antenatal home visits, attended the delivery when possible, made 3 postnatal visits on days 2,5,8 to promote preventative newborn care practices, referred sick neonates to local hospitals, and cared for neonates in the home if families refused to be referred (no injectable antibiotics were used).</td>
<td>Usual health services provided by government, NGOs, and private providers.</td>
<td>No evidence that the intervention reduced NMR.</td>
<td>Adjusted mortality hazard ratio in intervention arm at baseline was 1.02 (95% CI 0.80, 1.30) vs at end point was 0.87 (95% CI 0.68, 1.12) –results were not significant.</td>
<td>The intervention did not adequately address the risk factors for mortality in this population.</td>
<td>Baseline NMR was lower than that of other low-resource communities and therefore the causes of neonatal mortality were different. 60% of deaths from birth asphyxia and prematurity—neonatal sepsis contributed to a lesser extent. CHWs lacked the tools and skills needed to treat asphyxia and prematurity, attended &lt; 20% of home deliveries, and had only 18%-33% postnatal care coverage. Therefore, the level and cause-structure in the local population must be considered when developing the intervention.</td>
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<td>Kumar (2008), Shivgarh, India</td>
<td>Cluster randomized controlled trial</td>
<td>Two intervention groups over 16 mo: 1. Intervention group A: received preventative package of interventions for ENC, including birth preparedness, clean delivery and cord care, thermal care (skin-to-skin), breastfeeding promotion, and danger sign recognition. 2. Intervention group B: received the same ENC package as group A plus use of a liquid crystal hypothermia indicator (ThermoSpot).</td>
<td>Received usual governmental and NGO services.</td>
<td>NMR was reduced by 54% in intervention group A compared with control (NMR 0.46, 95% CI 0.35-0.60 and 52% in intervention group B compared with control (NMR 0.48, 95% CI 0.35-0.66).</td>
<td>This community-based intervention that primarily focused on behavioral modification within the sociocultural context led to a greater than 50% reduction in neonatal mortality. In addition, adding ThermoSpot to the intervention did not lead to a significant reduction in neonatal mortality.</td>
<td>Intervention was developed based on research that actively involved participation of community members throughout the research period. The study shows that it is possible to change behavior that produces positive outcomes and is scalable.</td>
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<td>Jokhio (2005), Sind, Pakistan</td>
<td>Cluster randomized controlled trial</td>
<td>TBAs were trained and given disposable delivery kits, referred women for emergency obstetrical care, and visited women at least 3 times during pregnancy (3, 6, 9 mo); LHWs supported the TBAs and recorded data; Teams of obstetricians held outreach clinics for antenatal care.</td>
<td>TBAs did not receive training and were not given delivery kits; LHWs enrolled and followed up with all pregnant women and made the normal monthly home visits; No outreach clinics were organized.</td>
<td>Cluster adjusted OR for perinatal death 0.70 (95% CI 0.59, 0.82) and neonatal death 0.71 (95% CI 0.62, 0.83); PMR was reduced by 30% and NMR by 29%.</td>
<td>Cluster adjusted OR for maternal mortality 0.74 (95% CI 0.45, 1.23) not statistically significant; The study was not powered to detect meaningful change in maternal mortality.</td>
<td>Training TBAs and integrating them into an already existing primary health care system was effective in decreasing perinatal mortality.</td>
<td>Small number of clusters of large size is a limitation of the study design. The use of disposable, safe delivery kits by TBAs was a unique component of the package. Goal of improving the existing primary health care system to make it sustainable and at low cost was also unique.</td>
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<td>Manandhar (2004), Makwanpur, Nepal</td>
<td>Cluster randomized controlled trial</td>
<td>Trained female facilitators from the local community supported groups through an action-learning cycle using participatory learning rather than instruction; They identified local perinatal problems and developed prevention strategies.</td>
<td>The authors only wanted to test the effect of the women’s group intervention so they provided health services strengthening activities in both intervention and control groups, including improvements in equipment for resuscitation and phototherapy, ENC training at all levels of the healthcare system, and basic newborn care kits distributed to CBWs.</td>
<td>NMR 26.2 in the intervention group compared with 36.9 in control group (adjusted OR 0.70, 95% CI 0.53, 0.94), reduced by 30%; Maternal mortality was also reduced (adjusted OR 0.22, 95% CI 0.05, 0.90), reduced by 78%.</td>
<td>Differences in literacy and poverty indicators between intervention and control groups (less poverty in intervention group); SBRs were similar in intervention and control groups.</td>
<td>An intervention in rural Nepal involving women’s groups led by a local female facilitator reduced neonatal mortality by 30%.</td>
<td>95% of groups remained active at end of trial without any financial incentives: This may indicate that the intervention is scalable. Interactive, participatory learning strategies using picture card games, stretcher schemes, and interactive learning during home visits were unique.</td>
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CBW, community-based worker; CI, confidence interval; ENMR, early neonatal mortality rate; IMR, infant mortality rate; INHP, Integrated Nutrition and Health Programme; LHW, lady health worker; NGO, nongovernmental organization; HBNC, home-based neonatal care; LBW, low birth weight; NMR, neonatal mortality rate; PMR, perinatal mortality rate; PNMR, postneonatal mortality rate; SBR, stillbirth rate; TBA, traditional birth attendants; WHO, World Health Organization; ENC, Essential Newborn Care.

*The Baqui et al 2008 (India) study is not a trial but a program evaluation. The other 8 studies in this table are trials.
cluded in Table 2. All nine studies had training sessions for community health worker (CHWs), and in all but two studies CHWs made antepartum, intrapartum, and/or postnatal home visits. Seven Clean delivery kits were distributed for use in the intrapartum period in six studies. Two studies used injectable antibiotics as part of home-based management of neonatal illnesses.

Comparing Studies by Impact on NMR and PMR

Table 3 compares the percentage reduction in NMR and PMR across all studies. It was found that Bang et al 2005 had the greatest reduction in NMR (70%) and PMR (56%).

Kumar et al 200810 had the second greatest decrease in NMR (54% in the intervention group without ThermoSpot) and PMR (41% in the intervention group without ThermoSpot). Three studies did not have a statistically significant decrease in NMR.15,13,19 Baqui et al 200819 (India) did not show a significant decrease in NMR overall, however, there was a 34% decrease in NMR among infants born to women who had received a postnatal visit within 28 days after birth (Table 3).

By using a before-after design to test the impact of training birth attendants in the World Health Organization

Table 3 Comparison of Percent Reduction in NMR and PMR Across 9 Key Controlled Studies

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<tr>
<th>Study</th>
<th>NMR (% Reduction)</th>
<th>PMR (% Reduction)</th>
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<td>Bang (2005), Gadchiroli, India</td>
<td>70</td>
<td>56</td>
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<tr>
<td>Baqui (2008), Sylhet, Bangladesh</td>
<td>34</td>
<td>Not reported</td>
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<tr>
<td>Baqui (2008), Uttar Pradesh, India*</td>
<td>34</td>
<td>Not reported</td>
</tr>
<tr>
<td>Bhutta (2008), Hala, Pakistan</td>
<td>28</td>
<td>34.6</td>
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<tr>
<td>Carlo (2010), six countries</td>
<td>Not significant</td>
<td>Not significant</td>
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<td>Darmstadt (2010), Mirzapur, Bangladesh</td>
<td>Not significant</td>
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<tr>
<td>Kumar (2008), Shivgarh, India†</td>
<td>54, 52</td>
<td>41, 38</td>
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<tr>
<td>Jokhio (2005), Sind, Pakistan</td>
<td>29%</td>
<td>30%</td>
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<tr>
<td>Manandhar (2004), Makwanpur, Nepal</td>
<td>30%</td>
<td>Not reported</td>
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</table>

*Percent decrease in NMR is reported for neonates who received a postnatal home visit within 28 d of birth. NMR remained unchanged when only an antenatal visit was received.
†The first number represents the % decrease in the intervention group that received essential newborn care, and the second number represents the % decrease in the intervention group that received essential newborn care and ThermoSpot.
(WHO) Essential Newborn Care (ENC) course, which included basic newborn resuscitation, Carlo et al 2010\textsuperscript{13} reported no significant decrease in PMR or NMR from all causes in the first 7 days after birth. They also did not find a significant reduction in NMR in births in which attendants were trained in the Neonatal Resuscitation Program (NRP), which provided more advanced training in neonatal resuscitation. However, they did find a significant decrease in the stillbirth rate (SBR) after training in ENC (relative risk 0.69, 95% confidence interval 0.54-0.88, \( P = 0.003 \)). This observed reduction in the SBR presents some methodological and interpretation challenges. As the authors note, baseline misclassification of some early neonatal deaths as a “stillbirth” may explain their observation of an apparent benefit of ENC on the SBR. It is anticipated that neonatal resuscitation training might increase early neonatal deaths if previously nonresuscitated “stillbirths” are resuscitated but subsequently die, but this was not observed. Thus, the reduction in stillbirth may be attributable to improved recognition and intervention for asphyxiated infants who would have otherwise been considered “stillborn”; however, this remains unclear. The lack of impact of NRP training was possibly because resuscitation was also included in ENC training.

**Role of CBWs**

In this article, we refer to community-based workers (CBWs) as an umbrella term that includes a variety of frontline workers with various levels of training and skills, including CHWs, traditional birth attendants (TBAs), Lady Health Workers (LHWs) in Pakistan, community mobilizers (who provide community mobilization activities but not home visits), and other community workers. All 9 studies included CBWs that were trained to carry out various tasks (Table 2); however, these tasks varied considerably across the studies.

CBWs often had multiple roles in the community and in the home. They were commonly literate women who were recruited from the community. Baqui et al 2008\textsuperscript{11} (Bangladesh) and Kumar et al 2008\textsuperscript{10} specifically recruited both female and male CBWs because they believed that men also played an important role as agents for improving newborn care. In some studies, CBW functions included identification of pregnant women and data collection, making antepartum, intrapartum, and/or postnatal home visits to promote behavior change, providing home-based case management of newborn illnesses, and holding group meetings in the community to promote healthy behaviors. Some CBWs also managed neonatal illnesses in the home by using injectable antibiotics.

TBA training was also an important component of some of the intervention packages. Training of TBAs in the Carlo et al 2010\textsuperscript{13} trial was the primary focus of the intervention package. TBAs first participated in the WHO Essential Newborn Care course and some of them subsequently participated in the Neonatal Resuscitation Program. In Jokhio et al’s study (2005),\textsuperscript{12} TBAs also made antenatal home visits and were trained to conduct clean deliveries using clean delivery kits. Although Jokhio et al found a statistically significant reduction in perinatal mortality, other studies have also shown that the benefits of training TBAs may not be compelling and that investment in providing such training may not be justified.\textsuperscript{20}

**Community Mobilization and Promotion of Care Seeking**

Six studies included community mobilization and all nine studies included behavior change communication (BCC) activities in their intervention packages (Table 2). The community mobilization and BCC activities varied widely across the studies and are discussed in detail in Kumar et al,\textsuperscript{21} along with interpretation of the differential impact of the approaches taken. In brief, 4 out of 6 studies that included community mobilization resulted in a statistically significant decrease in NMR. Baqui et al 2008\textsuperscript{11} (Bangladesh) did not find a significant decrease in NMR in the community-care arm compared with the control group, and Baqui et al 2008 (India) also did not find a significant reduction in NMR in women who received an antenatal visit but NMR did significantly decrease when women received a postnatal visit within 28 days of birth\textsuperscript{19} (Table 1). Individual and group health education sessions were held in the Bang et al 2005\textsuperscript{17} study with the goal of changing health behaviors and increasing care seeking. Mothers and grandmothers were educated about topics involving care of pregnant women and newborns. In the Bhutta et al study,\textsuperscript{18} the LHWs were supported by community health committees comprised of volunteers from the local communities. The committees held group education sessions every 3 months during which LHWs used flip charts and videos for health education. Adolescents, women of reproductive age, and elderly women attended the sessions.

An integral component of the community-care arm in Baqui et al\textsuperscript{11} (Bangladesh) was community mobilization, whereas in the home-care arm, the main strategy was home visits by CHWs. In both arms, male and female mobilizers held group meetings to educate the community about birth preparedness and newborn care. Female mobilizers held visits every 4 months, whereas male mobilizers held visits every 10 months. In the home-care arm, fewer female community mobilizers were included, and they held visits every 8 months. In addition, in the community-care arm, “community resource people” who were volunteers from the villages, identified pregnant women and encouraged them to attend the community meetings, seek antenatal care, and seek care if their newborns showed signs of illness.\textsuperscript{11}

Only one study focused on community mobilization as a primary component of its CBIP.\textsuperscript{16} Manandhar et al\textsuperscript{16} implemented a community mobilization strategy by using an action-learning cycle that was promoted by female facilitators trained in perinatal health issues. These facilitators held monthly meetings for women in the community. They encouraged active, participatory learning during the meetings by using strategies, such as stretcher schemes, production and distribution of clean delivery kits, and...
picture card games to educate the women about prevention and treatment of common problems during pregnancy and after delivery in the newborn. In the action-learning cycle approach, the intervention package was not predetermined, but was decided upon by the individual women’s groups.

In Shivgarh, Uttar Pradesh, India, behavior change management, which included community mobilization as one of its components, was the primary intervention strategy used. This approach included multilevel engagement, for example, household intervention through antenatal and postnatal home visitations, monthly participatory meetings with groups of newborn community stakeholders, and group-level folk song meetings with embedded messages. Community mobilization created a supportive environment to facilitate initiation and maintenance of behavior change. The intervention package was designed after conducting research within the community to identify common behaviors that placed the newborn at risk for key causes of neonatal morbidity and mortality (primarily infections and hypothermia), but were amenable to change. CHWs called Sahayaks were recruited from the local community and were the primary community mobilizers. Volunteers from the community, Saksham Kartas, were also important community mobilizers who helped to spread and sustain changes in behavior.

BCC for the promotion of care seeking is an integral component of the Family-Community Care delivery mode. Although implemented differently across the trials, some form of BCC was included in all the studies (Table 2). Promotion of care seeking, defined as any behavior or service that enabled or enhanced the ability of mothers or their newborns to receive skilled medical care during delivery or for obstetrical or neonatal complications, was commonly included. The most common form of care seeking was encouraging referrals to local health facilities (7 of the 9 studies; see Table 2) or instructing CBWs about the indications for referral. Manandhar et al also worked on strengthening the capacity of the health care system to handle referrals by improving equipment and providing training at all levels of the healthcare system. Similarly, Baqui et al (India) used the already-existing government health care system as a platform for implementing a CBIP in the context of a large-scale nutrition and health program, implemented by CARE-India. They provided further training for the auxiliary nurse-midwives and anganwadi workers and also recruited additional voluntary community workers called “change agents” to enhance the reach of the program. However, none of the studies included follow-up on referrals.

Although care seeking was an important component of the Darmstadt et al trial, there was no significant decrease in NMR after the intervention package was implemented, even though CBWs referred sick neonates to the local hospital and helped facilitate transport to the hospital. In the Kumar et al trial, no significant difference in care seeking was found in the intervention arm compared with the comparison arm, but NMR was substantially reduced. Based on the mixed results and lack of data to suggest that promotion of care seeking has an independent association with NMR or PMR, it is difficult to determine the impact that it has on the reduction in NMR.

**Lack of Cost-Effectiveness Data**

Only 3 of the 9 studies reported cost-effectiveness data. Bang et al reported that the cost of their intervention package was US$5.30 per neonate served. Baqui et al (Bangladesh) reported a lower cost per neonatal death averted for the home-care intervention arm (US$2995, including health systems strengthening costs) compared with that reported by Manandhar et al (US$4397, including health systems strengthening). These studies show that their packages are less than the cost-effectiveness threshold of US$14,872 per death averted and are thus highly cost-effective. It is important to emphasize that most of the studies reviewed did not report cost-effectiveness data, and those that did used varying methods.

**Integration of Intervention Package into Existing Health Care System**

Five of the studies in this series used the existing health care infrastructure as a platform for their intervention package, and strengthened aspects of the existing system in an attempt to decrease neonatal and perinatal mortality. Both Jokhio et al and Bhutta et al used the existing LHW Program, introduced by Pakistan’s Ministry of Health in 1994, as a foundation for strengthening the existing system. In the government system, LHWs are trained and paid to provide antenatal care, contraceptive advice, and immunizations. They do not receive training in delivering babies and there is minimal effort to link LHWs with TBAs.

In the Bhutta et al package, LHWs received additional training in home-based newborn care and made antepartum, intrapartum, and postnatal home visits. Unlike in the government program, the LHWs were directly linked with TBAs in the intervention package. The TBAs were also encouraged to attend a voluntary, 3-day training session, but the main focus of the program was on training the LHWs. Jokhio et al also used the LHW program as a platform for strengthening the existing system, but their focus was on training the TBAs to use clean delivery kits and to recognize the indications for referral of women for emergency obstetrical care. The TBAs also made 3 antenatal home visits, whereas LHWs played a minor role by supporting the TBAs and recording data. Both studies show that strengthening the existing primary health care system, without the use of injectable antibiotics or other expensive technologies, can decrease NMR and PMR; NMR decreased by 28% in the Bhutta et al trial and by 29% in the Jokhio et al trial.

Baqui et al (India) conducted an independent evaluation of a CBIP implemented in the context of a large-scale nutrition and health program, implemented by CARE-India (a nongovernmental organization, NGO) and the Indian government through the already existing government
health care system. They provided further training for the auxiliary nurse-midwives and *anganwadi* workers who were already making home visits to promote maternal and child health. They also recruited additional voluntary community workers called “change agents” to enhance the reach of the program and to also make home visits. This study did not result in a statistically significant reduction in neonatal mortality; however, the infants of women who received a postnatal visit within 28 days after birth did have a significantly lower risk of neonatal death (reduced by 34%).

**Discussion**

**Conclusions Based on Current Evidence**

The current trend in delivering community-based interventions for improving neonatal and perinatal health is to bundle single interventions into packages; we call these “Community-Based Intervention Packages” (CBIPs) in this article. However, we identified only 8 large-scale, controlled trials and 1 program evaluation that evaluated CBIPs and reported NMR and/or PMR as outcomes. The Baqui et al study in India was the only program evaluation that used a rigorous design and measured NMR. The finding of this evaluation (ie, lack of mortality impact) suggests that although technical interventions to substantially reduce newborn deaths are known, appropriate packaging and implementation of evidence-based interventions with high coverage and quality in large programs remains a challenge. No published studies were identified from Africa. Therefore, large-scale studies testing CBIPs in Africa are urgently needed, particularly health system effectiveness trials. We are also in need of research measuring the impact of successful CBIPs implemented at scale and integrated into the existing health care system.

Although there are a lack of data, particularly in Africa, there have been recent advancements in developing an evidence-based approach to bundling interventions. The Lives Saved Tool (LiST) is a cohort modeling modality used to estimate the impact of scaling up specific maternal, newborn, or child health interventions at the country, state, or district level (ideally using coverage data at the level of interest) on neonatal or child mortality. Although continually being updated, 19 community-based interventions have been identified as having a statistically significant reduction in NMR. The LiST model was validated by comparing actual changes in NMR to predicted changes in 4 studies in South Asia. LiST was shown to be a reliable tool for use by policymakers and program managers to identify and prioritize interventions that have the greatest impact on neonatal mortality in South Asia. However, the model does not yet enable cost-effectiveness modeling.

When comparing the key studies identified in this paper by service delivery mode, we see that most of the interventions implemented by all 9 studies were, by design, in the Family-Community Care delivery mode (Table 2). Only one of the studies included Clinical Care interventions, and only a few used Outreach interventions. These studies confirm that Family-Community Care interventions can have a substantial effect on neonatal and perinatal mortality; however, a mixture of all the service delivery modes, with continuity of care between homes and health facilities is ideal. For example, among the studies in this series, the primary link between care in the home and local health facilities was through referrals of sick newborns, although in some cases community-based activities also helped to promote antenatal care and institutional delivery, as described by Martines et al in this Seminars series. In one study, CHWs helped to facilitate transportation to the health facilities.

Several important themes were common across the studies. Many of the trials included community-mobilization strategies, health education, and behavior change communication sessions (in groups and in the home), care-seeking modalities, training of CHWs, and home visits during pregnancy and after birth. Although each of the studies had slight variations in how these intervention approaches were organized and implemented, they seemed to be integral to the success of the CBIPs. The key player facilitating these interventions was the frontline worker (CHW, TBA, community mobilizer, other community workers) in all the studies. For example, Bhutta et al focused on training LHWs and TBAs and on strengthening the existing primary health care system, whereas Manandhar et al focused on a community-mobilization strategy for which they trained facilitators to encourage participatory learning in group sessions in the community. Kumar et al used a strategy that used antenatal and postnatal home visits, and encouraged active participation in group meetings led by CHWs. A unique component of this strategy was the focus on a limited set of key behaviors, and multilevel targeting of the various actors and influencers in newborn care.

However, there remain several hurdles that must be overcome to establish a well-developed, evidence-based method of bundling interventions. First, there is a lack of consistent terminology and language. For example, we must develop well-defined and measurable definitions for terms, such as community mobilization, behavior change communication, and care seeking to make accurate comparisons across studies.

Second, a similar inconsistency exists in the reporting of outcomes. Many studies screened for inclusion in this review were excluded because they did not report NMR or PMR. However, even among the 9 key studies that met study inclusion criteria, not all of them reported both outcomes (Table 3). Some did not report the percentage reduction in NMR or PMR and others did not report 95% CIs. In the future, we recommend that NMR and/or PMR be reported as outcomes, as well as SBR and other indicators of maternal health, whenever possible.

Because the CBIPs did not include the same components across the 9 trials, it was difficult to compare the impact of the packages. Not all the interventions included in the packages
were evidence-based and the rationale for including some of the interventions was unclear. The interventions may have been bundled for reasons such as convenience or funding requirements. Furthermore, the concept of bundling evidence-based intervention packages is also relatively new, therefore these studies may not have been designed to take this into account. In addition, none of the studies tested the mortality impact of the individual interventions included in the packages.

**A Call for Attention to the Vulnerable Urban Newborn**

Although the focus of this work is on newborn health in rural settings, there is also an urgent need for investment in CBIPs targeting vulnerable newborns in poor, urban communities. We were unable to identify any urban trials of CBIPs.

More than 22 million births take place annually among the urban poor in low and middle-income countries (calculated using a crude birthrate of 22 per 1000 live births and a slum population of 1.1 billion). In many low- and middle-income countries, on the basis of reanalysis of Demographic and Health Surveys data, infant and neonatal mortality rates are considerably higher among the urban poor compared with national averages. Cities in developing countries, in particular, are growing at their edges. These peri-urban spaces are home to migrants who work in construction, trade and perform other petty jobs. Migrant housing communities are usually transitory, informal, and suffer vulnerabilities requiring special attention.

Newborn care in slum settings is suboptimal and scarcely documented. Although rural and urban population characteristics differ, organization of health services in most developing countries has revolved around rural systems. Hence, there is a need to systematically study the outcomes of urban-specific newborn interventions and tailor CBIPs and service delivery strategies to the specific urban setting. Neonates born in poor, urban settings are at high risk of death due to multiple risk factors. One clear example is the sharp disparity in attendance at delivery by trained medical personnel training in poor compared with nonpoor urban settings in most developing countries.

Providing a slum-based “mother” support system through women’s groups or through training of slum-based workers has the potential of (1) addressing the lack of family support, which is a common reason for home deliveries; (2) overcoming the notion that childbirth is a natural process, which creates resistance to changing typical delivery methods using unskilled attendants; (3) addressing the vulnerabilities of powerless individuals, such as migrant workers who do not have legal citizenship and who live in short-term housing where home deliveries are more common; and (4) encouraging care seeking, promoting safe and clean household practices, and supporting outreach services. In addition, encouraging slum-level health funds as a community risk pooling measure has the potential to reduce delays in seeking care by mitigating the need to undertake out-of-pocket expenditure on transportation, drugs, and other medical supplies.

Training of slum-based birth attendants is worthy of consideration in light of the substantial number of home deliveries in slums in developing countries. Findings pertaining to cord care, clean hands and other birth-related practices in urban slums from Mumbai, Dhaka, Nepal, and Indore suggest that practices during home deliveries in disadvantaged urban settlements is far from satisfactory and predispose the newborn to risks of infection.

In past decades, a greater emphasis has been placed on rural health, thus, urban areas of most developing countries lack a planned primary health care infrastructure. Multiple health providers administer health services without any coordination, leading to poor quality of services, as well as duplication of services in some areas, and undercoverage in others. The large and growing private health sector, with its fee-for-service structure, makes it unaffordable to the most vulnerable. In addition, the private sector is unregulated. Although NGOs and charitable organizations help fill in the gaps, the services they provide are often fragmented. Overall, there are very few instances when NGOs have provided a comprehensive package of maternal newborn and child health (MNCH) services. Furthermore, efforts to develop and evaluate innovative approaches to delivering comprehensive MNCH care to the urban poor have not been well documented.

Questions that future urban newborn health research should seek to answer include the following: (1) How can community-based support and action groups be effective in an often heterogeneous urban slum society to reduce neonatal mortality? (2) What approaches and strategies can ensure implementation of proven technical interventions in the urban context? (3) Could these interventions be augmented in urban areas with greater availability of medical and nursing personnel? (4) How can we engage the private sector and civil society organizations that have a presence in urban centers? (5) How can we involve the federal, regional, and city governments to influence policy changes? (6) Could individuals from disadvantaged urban communities be motivated to take ownership of local programs? (7) How can the challenging health needs of migrant populations be addressed?

**Recommendations for Future Investigation**

There is a striking need for additional, large-scale RCTs to test evidence-based CBIPs in developing countries, particularly in Africa. Several such studies are now underway but further investigation is needed. As a research community, we need to establish consistent, clearly defined terminology and protocols for designing trials and reporting outcomes so that we are able to compare results across different settings. The evidence-based universal packages originally defined in the Lancet Neonatal Survival Series, elaborated on by Haws et al and continually updated by the Child Health Epidemiol-
ogy Reference Group\textsuperscript{24} can be used as the “gold standard” for designing and testing packages or may be used as a platform for developing even more comprehensive CBIPs. LiST has incorporated at least 19 evidence-based interventions shown to have a statistically significant impact on neonatal mortality,\textsuperscript{23} but cost-effectiveness modeling is not yet available with this tool and such data from neonatal and perinatal health field trials are scarce.

In addition, there is an urgent need to invest in research and program development focusing on neonatal health in urban areas. Newborn care in urban slums in developing countries around the world is suboptimal. Furthermore, there are no published studies that provide data on the impact of CBIPs in the urban context.

It is also crucial to integrate the CBIPs in rural and urban settings into the already-existing health care system to facilitate sustainability of the program and for scaling up. As we have seen in 2 studies in this report,\textsuperscript{12,18} it is possible to strengthen the existing primary health care system without introducing additional high-cost technologies or interventions to see a substantial reduction in neonatal mortality.

Finally, there is a need for improving the continuum of care between home and facility-based care. To date, studies that have implemented CBIPs in rural settings have focused on referrals as the primary link between activities in the community and services in health care facilities. However, we need to develop additional linkages and strategies to simultaneously move families closer to clinical care, and to make clinical care available more peripherally in communities.\textsuperscript{37}

References

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