

## Online Supplementary Document

Sacks et al. Comprehensive review of the evidence regarding the effectiveness of community-based primary health care in improving maternal, neonatal and child health: 3. neonatal health findings

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Table S1. Summaries of studies using randomized control trials (RCTs) to assess neonatal community-based interventions			
Outcome measure	Author and year of publication	Population and study design	Results
<b>Nutritional status</b>			
Birth weight/low birth weight	Christian 2003 <b>S23</b>	The study sought to determine the effect of micronutrient supplementation on neonatal mortality. Designed as double blind cluster randomized control trial, intervention clusters were assigned to either five micronutrient supplement groups: 1) folic acid alone, 2) folic acid+iron, 3) folic acid+iron+zinc, or 4) multiple micronutrients. Control group received only Vitamin A. 4,130 pregnant women were enrolled in the study. Pregnant women received supplements through sector distributors. The study was conducted in Nepal.	The risk of low birth weight in the folic acid +iron supplements group was 16% lower than that of the Vitamin A only group 16 (RR: 0.84, 95% CI: 0.72-0.99). Compared to Vitamin A only group, the risk of low birth weight in the multiple micronutrients group decreased by 14% (RR: 0.86, 95% CI: 0.74-0.99). Folic iron supplementation alone however had no effect on birth weight. (RR: 1.00, 95% CI:0.88-1.15)
	Larocque 2006 <b>S46</b>	Implemented in Peru, the study examined the effect of antenatal mebendazole on low birthweight in a hookworm endemic area. The study enrolled 1042 pregnant women in a double-blind, randomized controlled trial. Women in the intervention group received 500mg of mebendazole and daily iron supplements. Control group received placebo plus iron supplements.	The proportion of low birth weight infants in the intervention and control clusters did not differ (8.1% vs. 8.7%, p=0.755). The proportion of very low birthweight infants however was significantly lower in the intervention than the control clusters (0% vs. 1.5%, respectively; p=0.007).
Small for gestational age	Christian 2003 <b>S23</b>	See Christian above	None of the micronutrient supplement combinations reduced small for gestational age. (RR ranged from 0.91 to 1.02, p=0.17)
Preterm birth	Christian 2003 <b>S23</b>	See Christian above	Micronutrient supplementation had no effect on preterm birth (RR ranged from 0.99 to 1.08, p=0.77).

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<b>Morbidity</b>			
Neonatal omphalitis	Mullany 2006 <b>S53</b>	The study was a cluster randomized trial to test the effect of CHX on neonatal mortality. 413 communities in Sarlahi, Nepal, were randomly assigned to one of three cord care regimens: 1) cleansing with 4.0% chlorhexidine (CHX) (4,934 infants), 2) cleansing with soap and water (5107), and 3) cleansing dry cord care (5082). The cord care group was the control group.	The risk of omphalitis was reduced by 32%-75% comparing the CHX vs. dry cord care clusters. The effect of CHX was greater in reducing severe omphalitis (Moderate or severe redness, IRR: 0.68 95% CI: 0.58–0.80, Severe redness with pus, IRR: 0.25, 95% CI: 0.12-0.53). Cleansing with soap and water had no effect on moderate to severe omphalitis (IRR1.01, 95% CI: 0.58–1.77).
	Soofi 2012 <b>S77</b>	The primary goal of the study was to examine the effect of CHX on neonatal mortality at the community level. The study design was a two-by-two cluster randomized trial and implemented in Sindh Province, Pakistan. 187 clusters, consisting of 9,741 newborn, were assigned to one of four groups: 1) 4% CHX (CHX) solution only, 2) CHX plus hand washing, 3) hand washing only and 4) hand washing with antiseptic (control group).	Compared to the control clusters, the incidence of omphalitis was reduced by 47% in the hand washing plus CHX clusters (RR: 0.53, 95% CI: 0.32–0.88); 37% in the hand washing only clusters (RR: 0.67, 95% CI: 0.48–0.93); and 56% in the CHX only clusters (RR: 0.44, 95% CI: 0.29–0.67).
Diarrhea/dysentery	Osendarp 2001 <b>S61</b>	The aim of the study was to test the effect of zinc supplementation during pregnancy on incidence of diarrhea and dysentery in infants at age 6 months. 420 Bangladeshi infants were enrolled in a double-blind, placebo controlled randomized control. In the intervention clusters (with 199 infants), pregnant women took 30mg of zinc beginning at 12 to 16 weeks. The control clusters (221 infants) received placebo.	Among children born low birth weight at birth, at age six months, there was a 16% lower risk of acute diarrhea and 64% lower risk of dysentery in the intervention compared to control clusters (for acute diarrhea: RR: 0.84; 95% CI: 0.72-0.98; for dysentery RR:0.36; 95% CI: 0.25-0.84).

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Acute respiratory infection	Datta 1987 <b>S27</b>	The study examined the feasibility and effect of training primary health care workers on management of acute respiratory infections among children born low birth weight. The study design was a two-stage, cluster randomized design. 21 villages in Haryana, India were assigned to intervention (i.e. training on recognition and treatment of acute respiratory infections) and 16 to control. 199 low birth weight infants were born in the intervention clusters and 211 in the control clusters.	The case fatality (per 100 attacks) of acute respiratory infection among low birth weight neonates was 35% lower in the trained primary health care workers arm than the control arm (8.7 deaths per 100 attacks vs. 24.6 per 100 attacks; although paper does not report 95% CI) ( $p < 0.01$ )
<b>Mortality</b>			
Neonatal mortality rate			
	Azad 2010 <b>S9</b>	This stratified, cluster-randomized trial in three rural districts of Bangladesh aimed to assess the effect of facilitator-led support groups, traditional birth attendant training and health system strengthening on neonatal mortality over the 3 year study period. Outcomes were monitored for 36,113 births.	Adjusted NMR in intervention clusters was lower than comparison areas (33.9 per 1000 live births vs. 36.5 per 1000 live births, respectively); (RR: 0.93; 95% CI: 0.80-1.09).
	Bang 2005 <b>S13</b>	This field trial was conducted in Gadchiroli, India. 39 villages were assigned to an intervention group and 47 to a control group. The goal of the study was to determine the effect of a home-based neonatal health package delivered through traditional birth attendants on neonatal mortality. The control group received standard care. The intervention included training of birth attendants and treatment of pneumonia and minor illness.	Neonatal mortality rate (NMR) in the intervention area was reduced by 70% (% Change: 70, 95% CI: 59-81) and the absolute difference in NMR between the intervention and comparison area was 44 deaths per 1000 live births.

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<b>Outcome measure</b>	<b>Author and year of publication</b>	<b>Population and study design</b>	<b>Results</b>
	Baqui 2009 <b>S14</b>	The trial assessed effect of timing of first postnatal home visit by lady health workers on neonatal mortality. 24 administrative units in Sylhet, Bangladesh were randomly assigned to either home care, community care, or comparison arm. Pregnant women in the home care intervention group received visits from female health workers on day 1, 3, and 7 postpartum. Analysis was restricted to the home care group and included 9,211 live births were enrolled in the study.	The risk of neonatal mortality was reduced by 67% in those who received a visit on day one than those who received no visit, among those who survived the first day (Adjusted hazard ratio (HR): 0.33, 95% CI: 0.23-0.46). Among those who survived the second day, the risk of neonatal mortality was reduced by 64% in those who received a visit on the second day compared to those who did not receive a visit. (HR:0.36, 95% CI: 0.23-0.55)
	Bhutta 2008 <b>S20</b>	The study examined the feasibility of using lady health workers and traditional birth attendants in rural Pakistan to deliver a package of community-based intervention for improving perinatal care. A total of 315 villages, spread across eight village clusters in Pakistan were randomly assigned to intervention and comparison groups (four cluster per group). The intervention package included provision of essential maternal and newborn care practices, community education group sessions, and partnership between lady health workers and local traditional attendants at delivery. The total population of the villages were 138,000.	In the intervention clusters, neonatal mortality rate declined by 28% compared to control clusters (Mantel-Haenszel RR: 0.72, 95% CI: 0.56–0.91).
	Bhandari 2013 <b>S19</b>	The trial assessed the effect of an integrated management of neonatal and childhood illness (IMNCI) on neonatal and infant mortality. Intervention included community health worker training and health system strengthening. Implemented in India, 18 clusters were assigned to either intervention or control. 29,667 and 30,813 births occurred in the intervention and control, respectively.	The risk of neonatal mortality was 20% lower in the intervention compared to the control clusters (HR: 0.80; 95% CI: 0.68-0.93).

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<b>Outcome measure</b>	<b>Author and year of publication</b>	<b>Population and study design</b>	<b>Results</b>
	Colbourn 2013 <b>S24</b>	The study evaluated the effect of participation in a women's participatory group intervention (CI) at a community level combined with facility-based quality improvement intervention (FI) on maternal, perinatal and neonatal mortality. The study design was a two-by-two factorial cluster randomized controlled trial. Clusters were assigned to one of four groups: control (17 clusters, 4912 births), FI only (15 clusters, 5335 births), CI only (15 clusters, 5080 live births), and FI and CI (14 clusters, 5249 live births). The study was implemented in three districts in Malawi.	The odds of neonatal mortality in the combined FI and CI intervention group was 22% lower than that of the control clusters (OR: 0.78, 95% CI: 0.60-1.01).
	El-Arifeen 2012 <b>S30</b>	The objective of the study was to test the effect of cord cleansing with CHX on neonatal mortality in rural Sylhet, Bangladesh. The study used parallel cluster randomized trial design. 29,760 newborn infants born were randomized into three groups: multiple-cleansing, single cleansing, and dry cord care (control arm). Each intervention was delivered by a community health worker.	Neonatal mortality in the single-cleansing group was reduced by 20% (RR: 0.80; 95% CI: 0.65–0.98) compared to the dry cord care group. There was no effect of multiple cleansing on neonatal mortality. (RR: 0.94; 95% CI: 0.78-1.14).
	Fottrell 2013 <b>S33</b>	The study explored the effect of coverage of participatory women groups on neonatal mortality, using a cluster-randomized control design. 18 villages in Bangladesh were randomized to intervention (women's groups) and control groups. The intervention included 840 women's groups and 17,940 live births.	The risk of neonatal mortality in the intervention areas was 38% lower than that of the control clusters (RR: 0.62; 95% CI: 0.43-0.89).
	Kirkwood 2013 <b>S44</b>	Implemented in Ghana, and designed as cluster randomized trial, 49 zones were assigned to control clusters and 49 to an intervention cluster (home-visits by a community based surveillance volunteer during pregnancy and 3 days postpartum). A total of 16,329 live births were included in the study. The goal of the study was to determine if home-visits during pregnancy and postpartum contribute to reduction in neonatal mortality.	Home visits by community-based surveillance volunteers had no effect on neonatal mortality (RR: 0.78, 95% CI:0.56–1.08)

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<b>Outcome measure</b>	<b>Author and year of publication</b>	<b>Population and study design</b>	<b>Results</b>
	Kumar 2008 <b>S45</b>	The objective of this study was to determine the impact of a community-based behavior change management on neonatal mortality. The study design was a cluster-randomized control trial. 39 villages in Uttar Pradesh, India, were assigned to one of these three groups: 1) essential newborn care practices, or 3) liquid crystal hypothermia indicator (ThermoSpot) plus essential newborn care practices 2) control (usual government and non-government services).	The risk of neonatal mortality in the clusters that received the ThermoSpot intervention was 52% lower than that of the control clusters (RR: 0.48, 95% CI: 0.35-0.66). The clusters that received essential newborn care alone had a 54% lower risk of neonatal mortality compared to that of control clusters (RR: 0.46, 95% CI: 0.35-0.60).
	Lewycka 2013 <b>S47</b>	This was a factorial, cluster-randomized trial of 48 clusters in rural Malawi of community groups and peer counselor home visits. Community groups used Community Action Cycles focused on maternal and child health. Outcomes were monitored on mortality and exclusive breastfeeding for 26,262 births.	Stratified, adjusted analysis shows a 41% reduction in neonatal mortality (OR: 0.59; CI: 0.40-0.86) in areas with community groups only. NMR was not assessed for areas with peer counselor visits only.
	Manandhar 2004 <b>S50</b>	This was a randomized trial with pair-matched clusters of facilitator-led women's groups focused on "perinatal problems" in rural Nepal. Birth outcomes were monitored in a cohort of 28,931 women over 3 years, of whom 8% participated in groups.	The neonatal mortality rate was lower in intervention than comparison clusters (26.2 per 1000 live births vs. 36.9 per 1000 live births) (adjusted OR: 0.70; CI: 0.53-0.94). Stillbirth rates were similar in both clusters.
	Memon 2015 <b>S51</b>	The study implemented a community-based perinatal and newborn care intervention in Gilgit-Baltistan Province, Pakistan. It was designed as a quasi-experimental study. 20 villages with 16,802 households were assigned to the intervention group and 20 villages with 18,659 households to the control group. The intervention was a preventive newborn care package (early initiation of breastfeeding, recognition of danger signs, and delayed bathing).	The odds of perinatal mortality comparing the intervention to control site was reduced by 38% (OR: 0.62, 95% CI: 0.56-0.69). There was a 42% reduction in the odds of neonatal mortality in the intervention compared to the control villages (OR: 0.58, 95% CI: 0.48-0.68).
	More 2012 <b>S52</b>	The study was a cluster-randomized trial of facilitator-supported 24 intervention and 24 comparison settlements in urban Mumbai, India. Vital statistics were recorded for 18,197 infants over 3 years.	The neonatal mortality rate higher in the intervention arm (OR: 1.48, 95% CI: 1.06-2.08).

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	Mullany 2006 <b>S53</b>	See Mullany 2006 above	There was no statistically significant effect of CHX on neonatal mortality, though there was a 24% reduction comparing the CHX group to the dry cord care group (RR:0.76, 95% CI: 0.55-1.04)
	Persson 2013 <b>S66</b>	The study tested the effect of local community groups that included local health care staff and politicians on maternal and newborn indicators, using a cluster randomized control design. 44 communes in Quan Ninh province, Vietnam, were randomly allocated to an intervention group and 46 to a control group. The analysis included 22,561 births.	The odds of neonatal mortality rate was reduced by 49% in the intervention communes compared to the control communes (OR: 0.51, 95% CI: 0.30-0.89).
	Tielsch 2007 <b>S81</b>	The study was a community-based placebo controlled cluster randomized trial. The objective was to test the effect of cleansing neonates with wipes that contained CHX on neonatal mortality. The study was carried out in Sarlahi District, Nepal. A total of 8,650 and 8,880 live births were born in the intervention and control clusters, respectively. Newborns in the intervention clusters were cleansed with wipes that contained CHX.	Cleansing with infant wipes with CHX had no effect on neonatal mortality (RR: 0.89, 95% CI: 0.72-1.10).
	Sloan 2008 <b>S76</b>	The study examined the effect of community-based kangaroo mother care on neonatal mortality in rural Bangladesh. As a cluster randomized control trial, 21 divisions were assigned to a community-based kangaroo care intervention and 21 to a control group. The study enrolled 4165 live births. Each newborn was followed for 30-45 days.	Community-based kangaroo mother care had no effect on neonatal mortality (OR: 1.06, 95% CI: 0.76–1.47).

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	Soofi 2012 <b>S77</b>	See Soofi 2012 above	Compared to the hand washing with antiseptic soap group, there was a 36% reduction in neonatal mortality in the CHX plus hand washing group (RR: 0.64, 95 % CI: 0.39–1.06), 26% reduction in the CHX only group (RR: 1.23, 95% CI: 0.50-1.08). Handwashing only had no effect on neonatal mortality (RR: 1.08, 95% CI: 0.79-1.48). In a factorial analysis (CHX vs. no CHX), neonatal mortality was 38% lower in the CHX than the no CHX group (RR: 0.62, 95% CI: 0.45-0.85).
	Tripathy 2010 <b>S83</b>	Using a cluster-randomized design, this study aimed to assess the impact of facilitator-led women’s groups on neonatal mortality for 19030 births over a 3 year period in two states in rural India.	NMR was 32% lower in intervention clusters (adjusted for clustering, stratification, and baseline differences) (OR 0.68, 95% CI 0.59-0.78) during the 3 years, and 45% lower in years 2 and 3 (0.55, 0.46-0.66).
Early neonatal mortality rate	Shankar 2008 <b>S73</b>	This double-blinded cluster-randomized trial implemented in Lombok, Indonesia, aimed to determine the effect of maternal multiple micronutrient supplementation on fetal loss and infant death. The study consisted of 262 clusters and enrolled 31,290 pregnant women. The intervention group received multiple micronutrients. Control group only received iron and folic acid (IFA).	Multiple micronutrients supplementation in pregnant women had no effect on early neonatal mortality (RR: 0.90, 95% CI: 0.76–1.06)
Perinatal mortality rate	Bang 2005 <b>S13</b>	See Bang 2005 above	Perinatal mortality rate in the intervention cluster was reduced by 56% (% change: 56, 95% CI: 44-68) between baseline and endline. Absolute difference in perinatal mortality rate between intervention and control group was 38 deaths per 1000 live births.



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	Bhutta 2008 <b>S20</b>	See Bhutta 2008 above	Following the intervention, perinatal mortality rate in the intervention clusters at baseline decreased by 34.5 deaths per 1000 live births (P<0.05). In the control clusters, perinatal mortality rate increased by 6.9 deaths per 1000 live births between baseline and endline assessments.
	Colbourn 2013 <b>S24</b>	See Colbourn 2013 above	The odds of perinatal mortality was reduced by 16% in the clusters implementing both FI and CI interventions compared to the control clusters (OR:0.84, 95% CI:0.72-0.97)
	Jokhio 2005 <b>S39</b>	The study examined the effect of training traditional birth attendants and giving them clean disposable delivery kits on perinatal and maternal mortality in Pakistan. Three sub-districts were randomly assigned to an intervention group and four sub-districts to a control group. The study design was a cluster randomized controlled trial. 10,114 and 9184 pregnant women were enrolled in the study in the intervention and control sites, respectively.	The odds of perinatal death was 30% lower in the sub-districts with trained traditional birth attendants than the control sub-districts (Cluster-adjusted OR 0.70, 95% CI: 0.59-0.82).
	Kumar 2008 <b>S45</b>	See Kumar 2008 above	Compared to the control group, perinatal mortality was 42% lower in the essential newborn care arm (RR: 0.58, 95% CI: 0.44–0.77) and 33% lower in the essential newborn care plus ThermoSpot arm (RR: 0.67, 95% CI: 0.49–0.93).
	More 2012 <b>S52</b>	See More 2012 above	The stillbirth rate was non-significantly lower in the intervention arm (OR: 0.86, 95% CI: 0.60-1.22). Extended perinatal mortality did not differ between arms (OR: 1.19, 95% CI: 0.90-1.57).
	Shankar 2008 <b>S73</b>	See Shankar 2008 above	Multiple micronutrients supplementation in pregnant women had no effect on perinatal mortality (RR: 0.90, 95% CI: 0.79–1.03).

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Infant mortality	Benn 2008 <b>S18</b>	Using data collected from a randomized-control trial of Vitamin A supplementation conducted in Guinea Bissau, the study tested the effect of oral polio vaccine on infant mortality. A total of 4345 normal birth weight infants were enrolled, 962 of which received oral polio vaccine (OPV).	The effect of OPV on infant mortality were different in boys and girls. Among boys, the risk of infant mortality was reduced by 63% (Mortality Rate Ratio: 0.37, 95% CI: 0.18-0.73), comparing those who received OPV at birth to those who did not. Among girls, receipt of OPV was not associated with infant mortality (Mortality Rate Ratio: 1.14, 95% CI: 0.70–1.89).
	Sloan 2008 <b>S76</b>	See Sloan 2008 above	Community-based kangaroo mother care had no effect on infant mortality (OR: 1.04, 95% CI: 0.77–1.40).
	Shankar 2008 <b>S73</b>	See Shankar 2008 above	Infant mortality was 18% lower in the multiple micronutrients group than the control group (RR: 0.82, 95% CI: 0.70–0.95).
Low birth weight-specific mortality rate	Sloan 2008 <b>S76</b>	See Sloan 2008 above	The odds of very low birth weight-specific mortality rate was reduced by 63%, comparing the community-based kangaroo mother care group to control clusters (OR: 0.37, 95% CI: 0.16–0.85).
	Tielsch 2007 <b>S81</b>	The study was carried out in Sarlahi District. A total of 8650 and 8880 live births were born in intervention and control clusters respective. The study was a community-based placebo-controlled, cluster randomized trial. After birth, newborns in the intervention group were cleansed with infant wipes that contained cholohexidine.	Among newborns born low birth weight, there was a 28% reduction in neonatal mortality in the intervention relative to the control group (RR: 0.72, 96% CI: 0.55-0.95).
RR: Risk ratio or rate ratio OR: Odds ratio IRR: Incident rate ratio			

## Appendix S2.

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