Effect of the Newhints home-visits intervention on neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial

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Summary

Background In 2009, on the basis of promising evidence from trials in south Asia, WHO and UNICEF issued a joint statement about home visits as a strategy to improve newborn survival. In the Newhints trial, we aimed to test this home-visits strategy in sub-Saharan Africa by assessing the effect on all-cause neonatal mortality rate (NMR) and essential newborn-care practices.

Methods The Newhints cluster randomised trial was undertaken in 98 zones in seven districts in the Brong Ahafo Region, Ghana. 49 zones were randomly assigned to the Newhints intervention and 49 to the control intervention by use of restricted randomisation with stratification to ensure comparability between interventions. Community-based surveillance volunteers (CBSVs) in Newhints zones were trained to identify pregnant women in their community and to make two home visits during pregnancy and three in the first week of life to promote essential newborn-care practices, weigh and assess babies for danger signs, and refer as necessary. Primary outcomes were NMR and coverage of key essential newborn-care practices. Analyses were by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00623337.

Findings 16 168 (99%) of 16 329 deliveries between November, 2008, and December, 2009, were livebirths; the status at 1 month was known for 15 619 (97%) livebirths. 482 neonatal deaths were recorded. Coverage data were available from 6029 women in Newhints zones; of these 4358 (72%) reported having CBSV visits during pregnancy and 3815 (63%) reported having postnatal visits. This coverage increased substantially from June, 2009, after the introduction of new implementation strategies and reached almost 90% for pregnancy visits by the end of the trial and 75% for postnatal visits. The Newhints intervention significantly increased coverage of key essential newborn-care behaviours, except for four or more antenatal-care visits (5975 [76%] of 7859 *vs* 5988 [74%] of 8121, respectively; relative risk 1·02, 95% CI 0·96–1·09; p=0·52) and baby delivered in a facility (5373 [68%] *vs* 5539 [68%], respectively; 0·97, 0·81–1·14; p=0·69). The largest increase was for care-seeking, with 102 (77%) of 132 sick babies in Newhints zones taken to a hospital or clinic compared with 77 (55%) of 139 in control zones (1·43, 1·17–1·76; p=0·001). Increases were also noted in bednet use during pregnancy (5398 [69%] of 7859 *vs* 5135 [63%] of 8121, respectively; 1·12, 1·03–1·21; p=0·005), money saved for delivery or emergency (5730 [86%] of 6681 *vs* 5525 [80%] of 6941, respectively; 1·09, 1·05–1·12; p<0·0001), transport arranged in advance for facility (2496 [37%] *vs* 2061 [30%], respectively; 1·30, 1·12–1·49; p=0·0004), birth assistant for home delivery washed hands with soap (1853 [93%] of 1992 *vs* 1817 [87%] of 2091, respectively; 1·05, 1·02–1·09; p=0·001), initiation of breastfeeding in less than 1 h of birth (3743 [49%] of 7673 *vs* 3280 [41%] of 7921, respectively; 1·22, 1·07–1·40; p=0·004), skin to skin contact (3355 [44%] *vs* 1931 [24%], respectively; 2·30, 1·85–2·87; p=0·0002), first bath delayed for longer than 6 h (3131 [41%] *vs* 2269 [29%], respectively; 1·65, 1·27–2·13; p<0·0001), exclusive breastfeeding for 26–32 days (1217 [86%] of 1414 *vs* 1091 [80%] of 1371; 1·10, 1·04–1·16; p=0·001), and baby sleeping under bednet for 8–56 days (4548 [79%] of 5756 *vs* 4291 [73%] of 5846; 1·09, 1·03–1·15; p=0·002). There were 230 neonatal deaths in the Newhints zones compared with 252 in the control zones. The overall NMRs per 1000 livebirths were 29·8 and 31·9, respectively (0·92, 0·75–1·12; p=0·405).

Interpretation The reduction in NMR with Newhints is consistent with the reductions achieved in three trials undertaken in programme settings in south Asia. Because there is no suggestion of any heterogeneity (p=0·850) between these trials and Newhints, the meta-analysis summary estimate of a reduction of 12% (95% CI 5–18) provides the best evidence for the likely effect of the home-visits strategy delivered within programmes in sub-Saharan Africa and in south Asia. Improvements in the quality of delivery and neonatal care in health facilities and development of innovative, effective strategies to increase coverage of home visits on the day of birth could lead to the achievement of more substantial reductions.

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Introduction

Every year 3·3 million babies die within the first 28 days of life (the newborn or neonatal period); newborn deaths account for 41% of all child deaths in developing countries.[1,2] Another 3·2 million babies are stillborn.[3] Effective interventions could prevent most of these deaths.[4] The challenge is to identify strategies that can be implemented feasibly in the short term to ensure that newborn babies have access to these life-saving interventions. In 2009, WHO and UNICEF issued a joint statement calling on all governments in low-income and middle-income countries to implement home visits for newborn babies.[5] In particular, they recommend three visits during the first week of life to promote essential newborn care, examine newborn babies for danger signs and treat or refer them as appropriate, and counsel the family about danger signs and the importance of prompt care-seeking for the newborn baby.

See Online for appendix

This strategy was based on results from four proof-of-principle studies in south Asia (appendix pp 1–2) showing that home visits for promotion of essential newborn-care practices and treatment or referral of sick babies can reduce the neonatal mortality rate (NMR) by 30–60%. These studies were a non-randomised comparison in Gadchiroli, India,[6,7] cluster randomised controlled trials in Shivgarh, India,[8] and Sylhet, Bangladesh,[9] and a pilot study in Hala, Pakistan.[10] Since the joint statement was issued, effects on NMR have been reported in three cluster randomised controlled trials of interventions delivered in a programme setting that included home visits (appendix pp 1–2). The results of these trials in south Asia showed substantially lower reductions in NMR than did the proof-of principle trials: Projahnmo2 in Mirzapur, Bangladesh[11] (13% reduction), Hala, Pakistan[12] (15% reduction), and an assessment of the integrated management of the newborn and childhood illnesses programme in Haryana, India[13] (9% reduction).

We present findings from the Newhints[14] cluster randomised controlled trial, which was designed to test the effect of the home-visits strategy in Ghana delivered by the existing community-based surveillance volunteers (CBSVs). The underlying hypotheses were that CBSVs could be trained to make home visits during pregnancy and the first week of life to promote essential newborn-care practices and assess and refer sick newborn babies, they would achieve a high coverage of the Newhints home visits, these visits would lead to improved essential newborn-care practices and increased access to care for sick newborn babies, and this strategy would save newborn lives. The primary objectives were therefore to assess the effect of the Newhints intervention on all-cause NMR, and essential newborn-care practices including care-seeking.

For the **trial protocol** see http://www.trialsjournal.com/content/11/1/58

Methods

Newhints was a cluster randomised controlled trial; the clusters were CBSV supervisory zones. It was undertaken in seven predominantly rural districts in the Brong Ahafo Region, Ghana: Kintampo North, Kintampo South, Nkoranza North, Nkoranza South, Tain, Techiman, and Wenchi. The trial area comprised 98 supervisory zones, each with eight to 12 CBSVs; 49 zones were randomly assigned to the Newhints intervention and 49 to the control group (appendix p 3). Detailed information about the methods has been reported previously.[14]

Participants

The trial included all pregnancies that ended in a livebirth or stillbirth between November (the month after which Newhints training was completed), 2008, and December, 2009, and data for pregnancies, births, and deaths gathered through the surveillance system established for the ObaapaVitA trial[15] of vitamin A and maternal mortality and continued for the Newhints trial were used. The surveillance consisted of home visits to all women of reproductive age (15–45 years) every 4 weeks by an independent group of resident research fieldworkers. In July, 2009, because of budget constraints, this frequency was reduced to visits every 8 weeks and restricted to women who were pregnant and infants. This was estimated to be sufficient to achieve the required sample size for livebirths.

Informed consent was sought from all women for permission to use their surveillance data for evaluation in the Newhints study, and from any women who moved into the area during the course of the trial. Surveillance fieldworkers read an information sheet and consent form to the women in the local language and checked their understanding. Agreement was indicated by signature or other imprint on prepared consent forms. Women were assured of their right to refuse consent without it affecting their continuation in the surveillance or receipt of any community or health services. None of the women refused to participate. Additionally, in the intervention zones, the CBSVs, as per usual practice, obtained permission to make home visits to pregnant women and those who had delivered recently.

The trial protocol was approved by the ethics committees of the Ghana Health Service, Kintampo Health Research Centre, and London School of Hygiene and Tropical Medicine. The trial was overseen by the trial steering committee and data monitoring and ethics committee. The trial steering committee had 12 external members, chosen to facilitate dissemination and uptake of any findings within Ghana and to provide technical support; members included key policy makers from the Ghana Health Service at national and regional levels, national WHO and UNICEF representatives, and advisers with expertise in obstetrics, demography, statistical methods, clinical trials, and health services research. It was attended by representatives from the participating district health management teams and funding organisations. The data monitoring and ethics committee had five members with expertise in cluster randomised trials, obstetrics, newborn health, maternal health, and community medicine.

Randomisation and masking

Meetings were held in each district in November, 2007, to introduce the Newhints trial and explain the proposed randomisation process to all the CBSVs and obtain their cooperation and support. Computer-generated restricted randomisation was then done in a one-to-one ratio by an independent epidemiologist using stratified sampling to ensure balance within districts and the four large towns; it was restricted to ensure comparability between intervention and control zones with respect to NMR (difference of less than two per 1000 livebirths), percentage of deliveries in a health facility (<2·5%), and percentage of deliveries in a private facility (<2·5%) by use of available surveillance data in each of the 3 years before the trial planning started (2004–06).

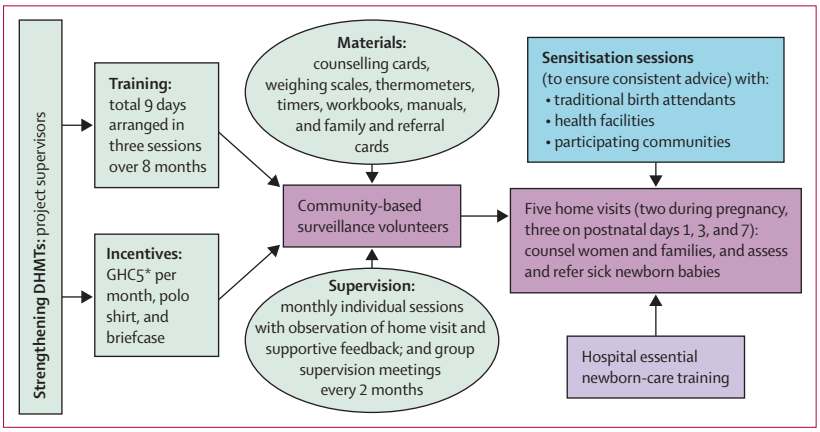

Figure 1: **Newhints integrated intervention package**
DHMT=district health management team. *GHC1 was roughly equal to US$1 during the trial.

Interventions

Newhints is an integrated intervention package (figure 1), based on extensive formative research[16] and developed and implemented in close collaboration with the district health management teams of the trial districts. The core component was training the CBSVs in the 49 intervention zones to identify pregnant women in their community and to undertake two home visits during pregnancy and three visits after birth on days 1, 3, and 7. Other components are outlined in figure 1; more detail including the content of each visit can be found in the trial protocol.[14] All pregnant women and newborn babies living in the Newhints zones were potential recipients of the home visits, in addition to the routine maternal and child health care that was available to them.

More than 400 CBSVs were trained for a total of 9 days in three phases over 8 months from March to October, 2008; all intervention communities had at least one trained CBSV. Phase one occurred in March; for 3 days, CBSVs underwent training to identify pregnant women and newborn babies, and to counsel and solve problems relating to key essential newborn-care behaviours. In phase two, which took place in June and July, 2008, CBSVs were trained over 4 days to weigh newborn babies, check them for danger signs, and if necessary refer them. Community-wide meetings were then organised by the district health management and Newhints teams during July and August, 2008, and chaired by the community chiefs. Their purpose was to introduce the importance of newborn care to the community; explain the rationale, content, and structure of the Newhints intervention; discuss the importance of community support for its success; and present the trained CBSVs with their Newhints polo shirt, briefcase, and certificate. In phase three, in October, 2008, CBSVs had refresher training for 2 days with a focus on the newborn assessment procedures. All Newhints materials, including training manuals and counselling cards, can be found on the internet site.

An additional set of implementation strategies to improve coverage of both home and supervisory visits were introduced between February and May, 2009; these included monthly tally sheets for supervisors to record supervisory visits made to CBSVs, introduction of repeat home visits to enable supervisors to observe CBSVs in action, group meetings with CBSVs about how coverage could be improved, introduction of compound registers for CBSVs to complete for their catchment areas, and recruitment of 47 new CBSVs for areas with heavy workloads.

Pregnant women and newborn babies living in the control zones continued to benefit from the routine maternal and child health care available, which consisted of antenatal clinics, access to free facility delivery, postpartum checkups, infant welfare clinics, and routine CBSV activities for outreach maternal and child health and immunisation clinics. They also benefited from the hospital essential newborn-care strengthening and sensitisation activities that covered all health facilities in the trial area. Women in all zones had free access to the National Health Insurance Scheme; exemption of registration and premium fees for pregnant women was introduced in July, 2008. Enrolment entitled women to six antenatal visits, delivery care (including complications), two postnatal visits, and care of the newborn baby up to age 3 months. All providers of maternity care services, including mission and private facilities, could participate in the National Health Insurance Scheme.

Outcomes

The primary mortality outcome was all-cause NMR (per 1000 livebirths), which includes all deaths that happen in the first 28 days of life. Secondary outcomes were age-specific and cause-specific NMRs; the most important was the NMR after day 1 (days 2–28). The NMR after day 1 was important because Newhints does not target birth asphyxia, an important cause of deaths on day 1, and to avoid any difficulty in distinguishing between early neonatal deaths and postpartum stillbirths by use of

For **Newhints materials** see http://newhints.lshtm.ac.uk

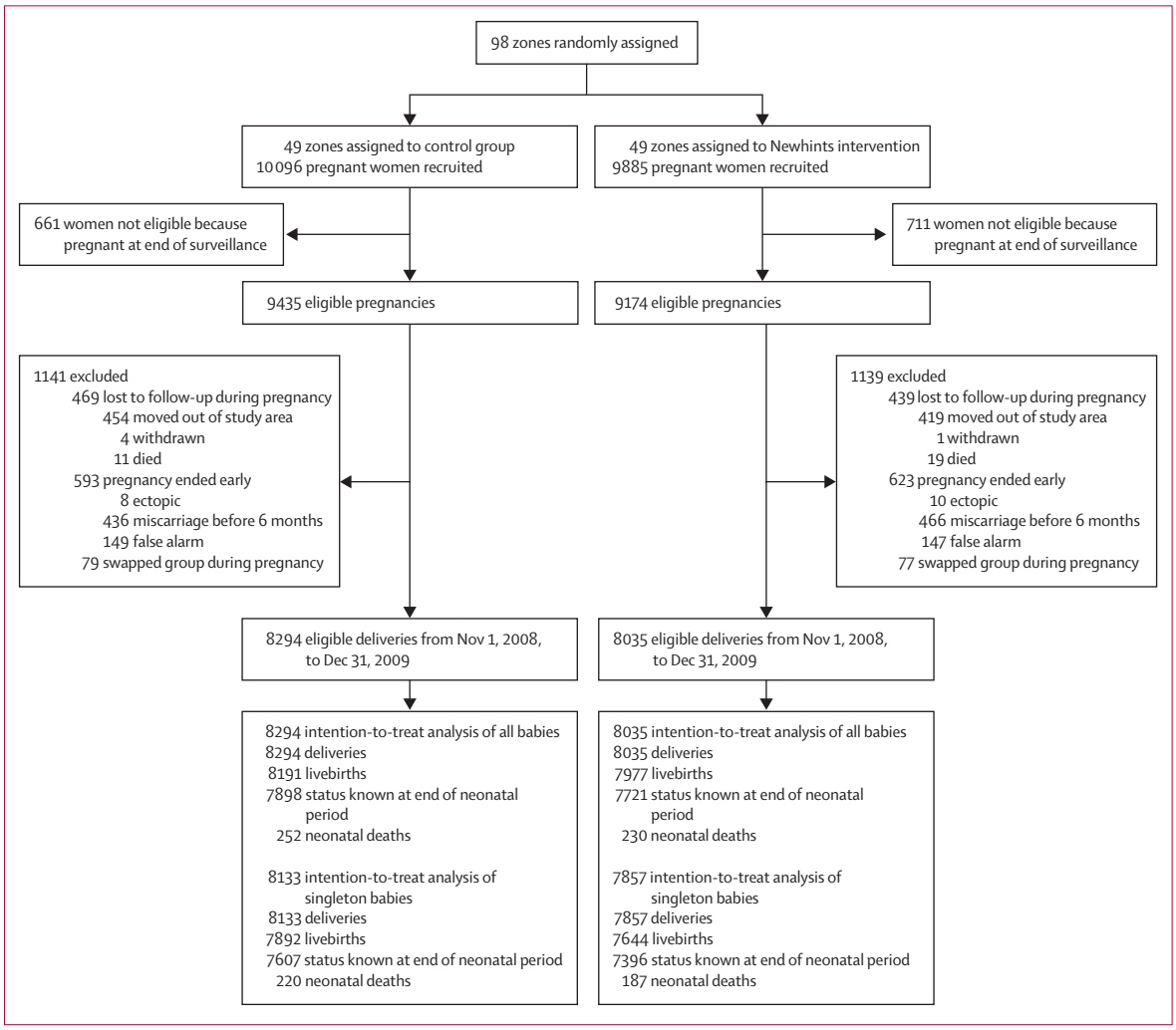

Figure 2: **Trial profile**

data from verbal post mortems. All mortality outcomes were calculated with the inclusion and exclusion of twins because twins are much more likely to be premature and to die, and twinning rates are higher in Ghana than in south Asia where the other trials have been done.[17]

The primary behaviour outcomes were the percentages of mothers practising the Newhints recommended behaviours. The data were extracted from the birth form administered at the first surveillance visit after birth; the form included questions about the pregnancy, delivery, and newborn-care practices promoted by Newhints. The denominator used for the outcome depended on the timing of the recommended practice. Thus, for behaviours during pregnancy, the denominator was the number of pregnancies (ending in a livebirth or a stillbirth), except for birth preparedness for which the denominator was the number of births ending after February, 2009, when questions about this information were added. Because hygiene behaviours at delivery targeted home births, the number of these was the denominator. For behaviours on the day of birth, the denominator was the number of babies who survived the first day; for exclusive breastfeeding at 28 days (the end of the neonatal period), the denominator was the number of babies for whom information about exclusive breastfeeding in the previous 24 h gathered between days 26 to 32 after birth was available. Newborn bednet use was promoted during the visit on day 7; the indicator for this is therefore the percentage of babies who slept under a bednet during the previous 24 h, with the number of babies who were visited within the first 2 months of life but after day 7 (ie, days 8–56) and who were alive at the visit as the denominator. The denominator for care-seeking is the number of babies visited within 2 months of birth reported as having been severely ill.

Additionally, we also assessed the effect of the Newhints intervention on the coverage gaps for the key

recommended behaviours. The coverage gap[18] is the difference between the percentage of mothers practising the behaviour and the ideal complete coverage of 100%. The mothers in this group were not already practising or planning to practise the recommended behaviours that the Newhints intervention sought to change.

Statistical analysis

The sample size was determined by the main primary outcome NMR. Using baseline data for the NMR (31 per 1000 livebirths) and intraclass correlation coefficient[19] (0·0007256), we calculated that a total sample size of 15 200 livebirths would have 80% power to detect a 25% reduction in NMR at the two-sided 5% significance level, 93% power to detect a 30% reduction, and 60% power to detect a 20% reduction.

Intention-to-treat analyses were done to compare Newhints and control zones with respect to each outcome; intention to treat was defined by zone of residence at pregnancy recruitment. Random-effects logistic regression was used to account for the cluster-randomised design, with relative risks (RR) derived by use of the marginal standardisation technique, and the 95% CIs estimated with the delta method.[20] Analyses were done in Stata (version 11.2).

We also updated the meta-analysis of the effect of home visits on NMR done in 2010 by Gogia and Sachdev[21] to include results from recent trials and the Newhints results presented here. We divided studies into two groups (appendix p 1): the proof-of-principle studies quoted as evidence in the WHO and UNICEF home-visits strategy statement and the four cluster randomised controlled trials, including Newhints, in which the strategy was assessed in a programme setting. We did meta-analyses for each group separately and combined, using fixed-effects models to calculate pooled RRs and 95% CIs, and the generic inverse variance method to estimate between-trial heterogeneity.

This study is registered with ClinicalTrials.gov, number NCT00623337.

Role of the funding source

WHO, Save the Children's Saving Newborn Lives Programme from the Bill & Melinda Gates Foundation, and the UK Department for International Development provided funding. The funders had no role in data gathering, data analysis, or writing of the report. The corresponding author had full access to all the data and had final responsibility for the decision to submit for publication.

Results

Figure 2 shows the trial profile. 98 zones were randomly assigned to Newhints and control. 19 981 women were identified as being pregnant from Nov 1, 2008, the start of the trial, and 1372 of these were still pregnant at the end of the study on Dec 31, 2009. There were 18 609 eligible pregnancies, 9435 in the 49 control zones and 9174 in the 49 Newhints zones. Three groups of pregnancies were not included in the analysis of NMR: 908 (5%) women were lost to follow-up during pregnancy; 1216 (7%) had pregnancies that ended early and did not result in a livebirth or stillbirth; and 156 (<1%) women moved, resulting in a change of treatment groups. The analysis was therefore based on

	Control zones	Newhints zones
Pregnancies	22 436	22 732
Births	22 963	23 221
Facility deliveries	13 295 (58%)	13 197 (57%)
Livebirths	22 211	22 491
Livebirths with status known on day 29	22 008 (99%)	22 276 (99%)
Neonatal deaths (days 1–28)	720	719
Neonatal mortality rate per 1000 livebirths	32·7	32·3
Babies reported as being severely ill in first 2 months	315	280
Care-seeking in hospital or clinic	168 (53%)	147 (53%)
Early initiation of breastfeeding (<1 h of birth)*	9083/21 816 (42%)	9268/22 131 (42%)
Exclusive breastfeeding at age 1 month†	3730/4995 (75%)	3674/5138 (72%)

Data are number, number (%), or n/N (%), unless otherwise indicated. *Restricted to babies who survived the first day. †On the basis of breastfeeding status of babies whose mothers were interviewed between days 26 and 32.

Table 1: **Baseline comparability of key outcomes in the control and Newhints zones during 2005–07**

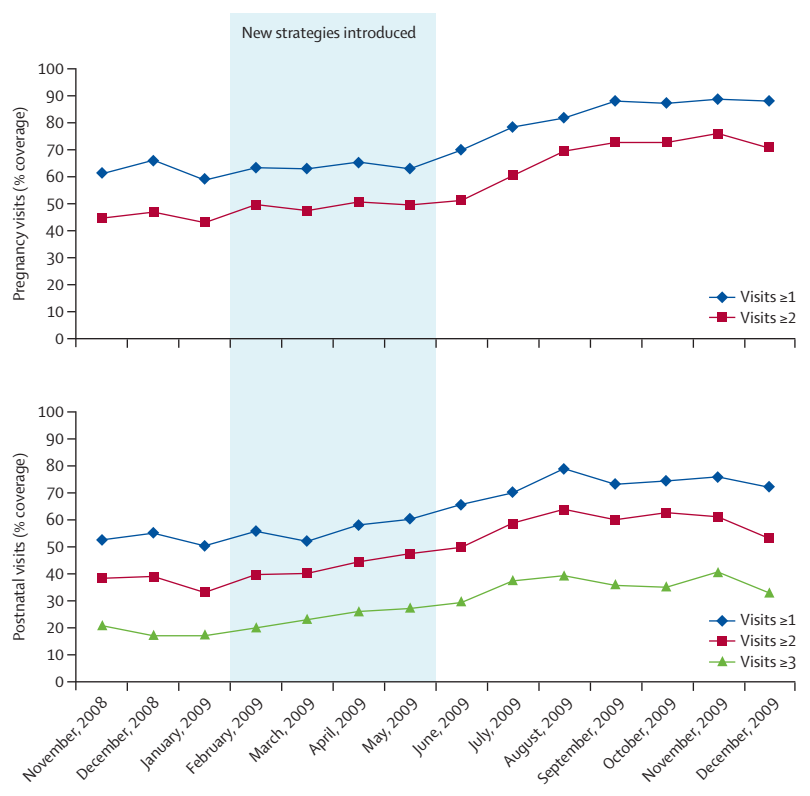

Figure 3: **Coverage of home visits achieved in Newhints zones**
Data for 6029 women who had their post-birth surveillance visit at least 10 days after delivery and whose babies were still alive.

16 329 deliveries that took place between November, 2008, and December, 2009. There were 16 168 livebirths, of which 15 137 were known to be alive at the end of the neonatal period and 482 were known to have died; the status was not known for 549 (3%) babies (293 in control zones and 256 in Newhints zones) whose mothers were lost to follow-up. Figure 2 also shows the number of singleton deliveries (15 990 [98%] of 16 329), livebirths (15 536 [96%] of 16 168), and neonatal deaths (407 [84%] of 482).

The Newhints zones were similar to the control zones at baseline for key outcomes (table 1) and for the sociodemographic characteristics of pregnant women (appendix p 4).

Coverage data for Newhints visits were available for 6029 women who had their post-birth surveillance visit at least 10 days after delivery and whose babies were still alive. Overall 4358 (72%) women in the Newhints zones reported having at least one CBSV visit during pregnancy and 3815 (63%) at least one postnatal visit. Figure 3 shows that this coverage increased substantially after the new strategies were introduced, reaching almost 90% coverage of pregnancy visits by the end of the trial, and about 75% coverage of postnatal visits. More detailed data were available for 3167 women who were in the process evaluation subsample. In this subsample, 1207 (53%) of 2289 first postnatal visits took place on the day of delivery or the day after.

Table 2 shows the effect of the Newhints intervention on promotion of key behaviours. Newhints significantly increased the coverage of all key behaviours except for antenatal care (which was re-enforced rather than targeted) and facility delivery (which increased substantially over the whole area from 58% at baseline [table 1] to 68% [table 2] with the introduction of exemption of registration fees for pregnant women in the National Health Insurance Scheme that provides free delivery and newborn care). The largest increase was for care-seeking, with sick babies in Newhints zones 43% (95% CI 17–76; p=0·001) more likely to be taken to a hospital or clinic than sick babies in control zones (table 2).

Although the coverage of many of the key behaviours was high, the extent to which implementation of Newhints reduced the coverage gap in these was striking. For example, although there was a 10% increase in babies exclusively breastfed at age 1 month in Newhints compared with control zones, this increase represented a 41% reduction (95% CI 20–56) in the coverage gap for exclusive breastfeeding at 1 month (table 2). Similarly, Newhints reduced the coverage gap for handwashing with soap by home birth attendants by

	Denominators		Coverage of key behaviour				Coverage gap in key behaviour			p value*†
	Control zones	Newhints zones	Control zones	Newhints zones	Increase	Relative risk* (95% CI)	Control zones	Newhints zones	Relative risk* (95% CI)	
Four or more antenatal-care visits	8121‡	7859‡	5988 (73·7%)	5975 (76·0%)	2·3%	1·02 (0·96–1·09)	2133 (26·3%)	1884 (24·0%)	0·94 (0·78–1·14)	0·52
Bednet in pregnancy (always or sometimes)	8121‡	7859‡	5135 (63·2%)	5398 (68·7%)	5·5%	1·12 (1·03–1·21)	2986 (36·8%)	2461 (31·3%)	0·77 (0·64–0·92)	0·005
Saved money for delivery or emergency	6941	6681	5525 (79·6%)	5730 (85·8%)	6·2%	1·09 (1·05–1·12)	1416 (20·4%)	951 (14·2%)	0·65 (0·56–0·76)	<0·0001
Arranged transport to facility (in advance)	6941	6681	2061 (29·7%)	2496 (37·4%)	7·7%	1·30 (1·12–1·49)	4880 (70·3%)	4185 (62·6%)	0·88 (0·82–0·95)	0·0004
Baby delivered in a facility	8121‡	7859‡	5539 (68·2%)	5373 (68·4%)	0·2%	0·97 (0·81–1·14)	2582 (31·8%)	2486 (31·6%)	1·08 (0·75–1·57)	0·69
Birth assistant washed hands with soap (home delivery)	2091	1992	1817 (86·9%)	1853 (93·0%)	6·1%	1·05 (1·02–1·09)	274 (13·1%)	139 (7·0%)	0·57 (0·42–0·79)	0·001
Early initiation of breastfeeding (<1 h of birth)	7921	7673	3280 (41·4%)	3743 (48·8%)	7·4%	1·22 (1·07–1·40)	4641 (58·6%)	3930 (51·2%)	0·85 (0·76–0·95)	0·004
Skin to skin contact (any)	7921	7673	1931 (24·4%)	3355 (43·7%)	19·3%	2·30 (1·85–2·87)	5990 (75·6%)	4318 (56·3%)	0·70 (0·63–0·78)	0·0002
Delayed first bath (>6 h)	7921	7673	2269 (28·6%)	3131 (40·8%)	12·2%	1·65 (1·27–2·13)	5652 (71·4%)	4542 (59·2%)	0·80 (0·71–0·90)	<0·0001
Exclusive breastfeeding (26–32 days)	1371	1414	1091 (79·6%)	1217 (86·1%)	6·5%	1·10 (1·04–1·16)	280 (20·4%)	197 (13·9%)	0·59 (0·44–0·80)	0·001
Baby sleeping under bednet (8–56 days)	5846	5756	4291 (73·4%)	4548 (79·0%)	5·6%	1·09 (1·03–1·15)	1555 (26·6%)	1208 (21·0%)	0·71 (0·58–0·88)	0·002
Care-seeking, sick babies taken to hospital or clinic	139	132	77 (55·4%)	102 (77·3%)	21·9%	1·43 (1·17–1·76)	62 (44·6%)	30 (22·7%)	0·45 (0·28–0·73)	0·001

Data are number (%), unless otherwise indicated. *Adjusted for clustering. †Applies to both the coverage and the coverage gap analyses. ‡Excludes 171 pregnant women in control and 174 in Newhints zones who were unable to report their number of antenatal-care visits, and an additional two women in each group with missing information for bednet use.

Table 2: **Effect of the Newhints intervention on coverage of key behaviours and coverage gaps**

	November, 2008, to December, 2009				June to December, 2009			
	Control zones	Newhints zones	Relative risk* (95% CI)	p value	Control zones	Newhints zones	Relative risk* (95% CI)	p value
All babies								
Livebirths	7898	7721	..	..	3521	3423	..	..
Neonatal deaths (days 1–28)	252	230	..	..	113	101	..	..
Neonatal mortality rate per 1000 livebirths	31·9	29·8	0·92 (0·75–1·12)	0·405	32·1	29·5	0·91 (0·67–1·22)	0·528
All babies, post day 1								
Neonatal deaths (days 2–28)	122	103	..	..	62	45	..	..
Neonatal mortality rate per 1000 livebirths	15·4	13·3	0·85 (0·64–1·13)	0·268	17·6	13·1	0·74 (0·47–1·17)	0·204
Singletons								
Livebirths	7607	7396	..	..	3389	3258	..	..
Neonatal deaths (days 1–28)	220	187	..	..	105	80	..	..
Neonatal mortality rate per 1000 livebirths	28·9	25·3	0·86 (0·69–1·08)	0·202	31·0	24·6	0·78 (0·56–1·08)	0·135
Singletons, post day 1								
Neonatal deaths (days 2–28)	109	82	..	..	58	33	..	..
Neonatal mortality rate per 1000 livebirths	14·3	11·1	0·77 (0·57–1·04)	0·085	17·1	10·1	0·59 (0·35–0·98)	0·042

Data are number, unless otherwise indicated. *Adjusted for clustering.

Table 3: **Effect of the Newhints intervention on neonatal mortality rates after the end of training of community-based surveillance volunteers and after introduction of new implementation strategies**

43%, for bednet use by 23% for pregnant women and 29% for babies, and for care-seeking for sick newborn babies by 55% (table 2).

Fewer neonatal deaths occurred in the Newhints zones than in the control zones; the adjusted RR for NMR was 0·92 (0·75–1·12; table 3). The RRs for post day 1 NMRs, particularly targeted by the intervention, were lower, corresponding to larger reductions in the NMR, for all babies and singletons (table 3). The adjusted RR for post day 1 NMR for singletons corresponded to a 23% reduction in mortality rate (table 3).

As expected, the RRs were lower after improved implementation was achieved. The adjusted RR for post day 1 NMR in the last 7 months of the trial corresponded to reductions in mortality rate of 26% in all babies and 41% in singletons (table 3).

Discussion

Newhints achieved an 8% reduction (95% CI –12 to 25; p=0·405) in overall NMR (table 3). Figure 4 and the panel show this finding in context with other evidence. Figure 4 shows that this small reduction is similar to the small reductions in NMR achieved in the other three trials to test the effect of the home visit strategy delivered in a programme setting. The summary estimate represents an overall reduction in NMR of 12% (5 to 18; figure 4). Because there is no suggestion of any heterogeneity between the trials (p=0·850), this summary estimate represents the combined evidence of the reduction in NMR that might be achieved through home visits delivered in a programme setting. Individually the trials were not powered to detect a reduction of this size; Newhints was designed to have 80% power to achieve a 25% reduction. However, together the four trials have sufficient power. Thus, although the 95% CI for the reduction achieved in the Newhints trial included one, as did the 95% CIs for two of the other three trials, the 95% CI for the summary estimate does not.

Figure 4 also shows that much higher reductions were achieved in the proof-of-principle studies; the meta-analysis summary estimate showed a 45% reduction (95% CI 37 to 52) but there was substantial heterogeneity (p=0·020).

We also looked at the effect of the Newhints intervention on post day 1 NMR; Newhints would not be expected to have more than a small effect on day 1 NMR because it does not tackle deaths from birth asphyxia, an important cause of early deaths; and because of the logistical difficulties inherent in CBSVs attending promptly after birth. Although a high coverage of postnatal visits was achieved with Newhints, only 53% of these took place on the day of birth or the day after. The reduction in post day 1 NMR was 15% (95% CI –13 to 36; table 3) and, as expected, this was larger than for overall mortality rate. It is similar to the 14% reduction (5 to 21) achieved for post day 1 NMR in the Haryana trial.[13]

The reduction in NMR in the Newhints zones was accompanied by high compliance by the families with the CBSV referrals of sick babies, 86% of whom were taken to a health facility, and 73% to hospital.[23] It was also accompanied by increased coverage of essential newborn-care practices including a substantial improvement in care-seeking with 77% of families taking babies they perceived as severely ill to a clinic or hospital in Newhints zones compared with 55% in control zones, an increase in relative risk of 43% (95% CI 17–76; table 2). Additionally, for practices where coverage was already

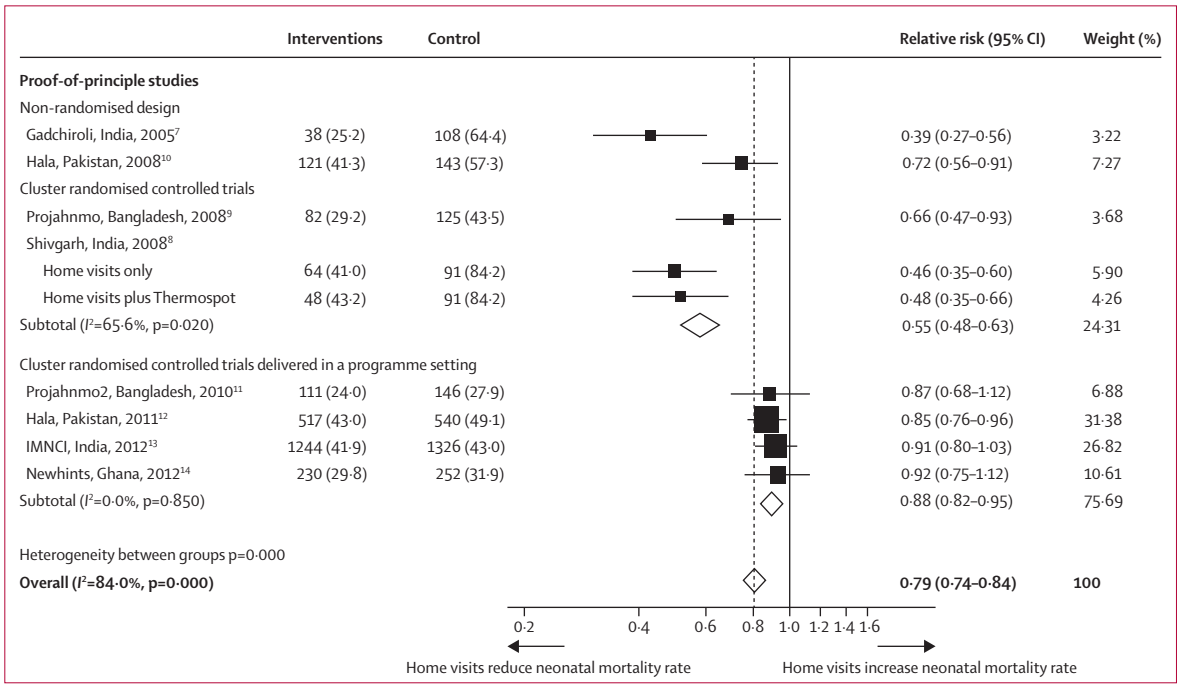

Figure 4: **Meta-analysis of the effect of home visits on neonatal mortality rate**
Data are number (neonatal mortality rate per 1000 livebirths). IMNCI=integrated management of the newborn and childhood illnesses.

Panel: Research in context

Systematic review

We updated the 2010 meta-analysis by Gogia and Sachdev[21] of the effect of home visits on neonatal mortality rate (NMR) to include results from cluster randomised trials and the Newhints' results presented here. We divided studies into two groups: four proof-of-principle studies[7–10] cited as evidence in the WHO and UNICEF home-visits strategy statement (all of which were in the 2010 review[21]) and four new cluster randomised controlled trials,[11–14] including Newhints, in which the strategy has been assessed in a programme setting. These two groups include all trials[8,9,11–14] identified through a search of the PubMed library with the key search terms "newborn", "neonatal", "mortality", "cluster*", and "trial" in the abstract.

Interpretation

The 8% reduction (95% CI –12 to 25; p=0·405) in NMR achieved in Newhints is similar to that achieved in the other trials done in programme settings, all of which were in south Asia; the meta-analysis summary estimate is a reduction of 12% (5 to 18). Because there is no suggestion of any heterogeneity between the trials (p=0·850), this summary estimate appropriately represents the combined evidence of the reduction in NMR that might be achieved through home visits delivered in a programme setting. It is much lower than the meta-analysis summary estimate of a 45% reduction (37 to 52) for the proof-of-principle studies that informed the WHO and UNICEF joint statement.[5] However, as newborn deaths account for 41% of all child deaths, this percentage translates into a 4·9% reduction in child mortality rate, similar to the most effective child survival interventions.[22]

high (such as exclusive breastfeeding and use of bednets), Newhints substantially reduced the coverage gaps.

However, the effect on NMR might have been reduced by several factors. First, the home visits approach does not tackle asphyxia, an important cause of neonatal deaths. Second, the difficulty in getting to families on the day of birth means that many babies are not assessed at the time of highest mortality risk; potentially preventable early deaths are missed and the introduction of special-care behaviours for low birthweight babies is delayed. Third, the potential increase in coverage of key preventive behaviours achievable with the Newhints intervention was reduced because many of these were already practised by a large proportion of women. Fourth, there might be problems with the quality of newborn care in health facilities not able to avoid preventable newborn deaths in facility births on the day of delivery (68% of births took place in a facility) or to provide adequate care for sick newborn babies referred by the CBSVs or taken by their families.[23]

Last, the evaluation took place immediately after the Newhints intervention was fully implemented and over a short timeframe (14 months), whereas for teething problems to be solved and programmes to become embedded takes time. Of note was that the reported effect of 34% reduction included in figure 4 for the Projahnmo trial is based on the last 6 months of the assessment of the trial, much higher than the effect over the full 30 months of assessment, which was 13% (95% CI –8 to 30).[9] Similarly, when the Newhints analyses were restricted to the 7 months after the introduction of new implementation strategies, all effect estimates were higher. The adjusted RR for post day 1 NMR in the last 7 months of the trial corresponded to a 26% reduction in NMR (–17 to 53; table 3); for singletons, the reduction in NMR was 41% (2 to 65; table 3).

The results of the Newhints trial provide the first evidence of the potential for the home visits strategy to reduce NMR in sub-Saharan Africa. The findings of the meta-analysis suggest that the effect achieved is consistent with reductions achieved in trials done in south Asia in programme settings, and with the meta-analysis estimate of 12% (95% CI 5–18; figure 4). Because newborn deaths account for 41% of all child deaths, this percentage translates into a 4·9% reduction in child mortality rate, similar to the most effective preventive interventions identified in the child survival series in *The Lancet*.[22] However, on the one hand, achievement of this level of reduction at scale in routine health services will be challenging. On the other hand, a more substantial effect might be achieved if the Newhints home visit intervention was accompanied by improvements in quality of neonatal care in health facilities, and if innovative, effective strategies could be developed to increase coverage of home visits on the day of birth. The reduction in NMR would also be expected to be higher if Newhints was implemented in settings with large coverage gaps in key preventive behaviours.

Contributors

BRK drafted the report, and all the authors reviewed and approved it. BRK, AM, CT-A, SO-A, and ZH were responsible for the design of the Newhints trial; ZH, AM, AHAtA, CT-A, BW, TG, SS, and BRK for intervention content and data gathering instruments; AHAtA, AM, CT-A, BW, TG, SS, and SO-A for trial conduct; SD, SA-E, SS, BRK, AHAtA for database design and management; and SS for the analyses.

Conflicts of interest

We declare that we have no conflicts of interest.

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