Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial

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Summary

Background **Neonatal deaths in developing countries make the largest contribution to global mortality in children younger than 5 years. 90% of deliveries in the poorest quintile of households happen at home. We postulated that a community-based participatory intervention could significantly reduce neonatal mortality rates.**

Methods **We pair-matched 42 geopolitical clusters in Makwanpur district, Nepal, selected 12 pairs randomly, and randomly assigned one of each pair to intervention or control. In each intervention cluster (average population 7000), a female facilitator convened nine women's group meetings every month. The facilitator supported groups through an action-learning cycle in which they identified local perinatal problems and formulated strategies to address them. We monitored birth outcomes in a cohort of 28 931 women, of whom 8% joined the groups. The primary outcome was neonatal mortality rate. Other outcomes included stillbirths and maternal deaths, uptake of antenatal and delivery services, home care practices, infant morbidity, and health-care seeking. Analysis was by intention to treat. The study is registered as an International Standard Randomised Controlled Trial, number ISRCTN31137309.**

Findings **From 2001 to 2003, the neonatal mortality rate was 26·2 per 1000 (76 deaths per 2899 livebirths) in intervention clusters compared with 36·9 per 1000 (119 deaths per 3226 livebirths) in controls (adjusted odds ratio 0·70 [95% CI 0·53–0·94]). Stillbirth rates were similar in both groups. The maternal mortality ratio was 69 per 100 000 (two deaths per 2899 livebirths) in intervention clusters compared with 341 per 100 000 (11 deaths per 3226 livebirths) in control clusters (0·22 [0·05–0·90]). Women in intervention clusters were more likely to have antenatal care, institutional delivery, trained birth attendance, and hygienic care than were controls.**

Interpretation **Birth outcomes in a poor rural population improved greatly through a low cost, potentially sustainable and scalable, participatory intervention with women's groups.**

Introduction

Of the world's 4 million annual neonatal deaths, 98% occur in developing countries.[1] Infant and child mortality rates have declined, notably through better control of diarrhoea, pneumonia, and vaccine-preventable disease, and the importance of the newborn period has increased. In India, neonatal mortality now accounts for up to 70% of infant mortality.[2] Most perinatal and neonatal deaths happen at home, and many could be avoided with changes in antenatal, delivery, and newborn care practices.[3] However, primary and secondary health-care systems have difficulties in reaching poor rural residents, and a potentially effective perinatal health strategy must recognise this reality. In Makwanpur district, Nepal, for example, 90% of women give birth at home, and trained attendance at delivery is uncommon.[4]

We are unaware of any randomised controlled trial of community-based strategies to reduce neonatal mortality, a shortfall that indicates the absence of information on demand-side interventions.[5] Two studies have made important contributions in this area. Bolivia's Warmi project—an uncontrolled before-and-after study—was implemented in a poor rural population of 15 000 people with little health-system infrastructure. The project worked with women's groups to encourage participatory planning for mother and infant care,[6–8] and showed a fall in perinatal mortality rate from 117 to 44 per 1000 births over 3 years. In India, the SEARCH group reported a non-randomised controlled study from a rural population of 80 000 in Gadchiroli, Maharashtra.[9] The intervention entailed training of traditional birth attendants, health education, and a new cadre of supervised village health workers who visited newborn infants at home, identified warning signs, and managed sepsis with antibiotics. After 3 years the neonatal mortality rate had fallen by 62%. Replication and scaling up of this exciting community-based model presents policy makers with some challenges, particularly because of the need for a new cadre of community health worker to deliver injectable antibiotics at home.

Community participation has long been advocated to build links between primary services and their users,[10–12] and to improve service quality.[13–15] However, the evidence base for the effectiveness of participatory models is scarce.[5,16] Previously, we showed no effect of direct education by health workers on infant care practices and care-seeking behaviour after delivery.[17] In view of the Bolivian model, we thought that a participatory approach might have more effect on perinatal care practices and might increase consultation for difficulties in pregnancy and the newborn period. Although external facilitators of user groups have proven valuable in agriculture and forestry,[18,19] to our knowledge no study has rigorously assessed such a potentially scalable approach to improving reproductive health outcomes.

We postulated that a community-based participatory intervention could reduce the neonatal mortality rate from 60 to 40 per 1000 livebirths. The MIRA Makwanpur trial was a cluster-randomised controlled trial of such an intervention in a rural mountainous area of Nepal. The trial tested a large-scale intervention, using facilitators to work with women's groups in a population of 170 000 covering 1600 km^2. A cluster design was chosen because the intervention was structured around communities rather than individuals.

Methods

Study location and population

With a population of more than 23 million and a gross national income of US$240 per person,[20] Nepal is a poor country whose development challenges are exacerbated by its geography and unstable political situation. Life expectancy is 61 years. The total fertility rate is 4·4 children per woman in rural areas,[21] and the estimated maternal mortality ratio is 539 per 100 000 livebirths.[22] 57% of women cannot read.[23] The estimated infant mortality rate is 64 per 1000 livebirths, the neonatal mortality rate 39 per 1000 livebirths, and the perinatal mortality rate 47 per 1000 births.[21] In rural areas, 94% of babies are born at home,[22] and only 13% of births are attended by trained health workers.[21]

Makwanpur district lies in Nepal's central region where the middle hills join the plains. The population of about 400 000 subsists mainly on agriculture and the largest ethnic groups are Tamang and Brahmin-Chhetri. The district hospital in the municipality of Hetauda has facilities for antenatal care and delivery, although operative delivery was not available during the study period. There are 7852 people per hospital bed.[24] The district health system makes perinatal care available through a network of primary health centres, health posts, subhealth posts, and outreach clinics. Traditional birth attendants are available throughout the district, but their attendance at births is less common than in some other parts of south Asia.[4]

Nepal is administratively divided—in descending order of size—into development regions, zones, districts, village development committees, and wards. We chose the village development committee as the cluster unit of randomisation for the following reasons: it is a standard

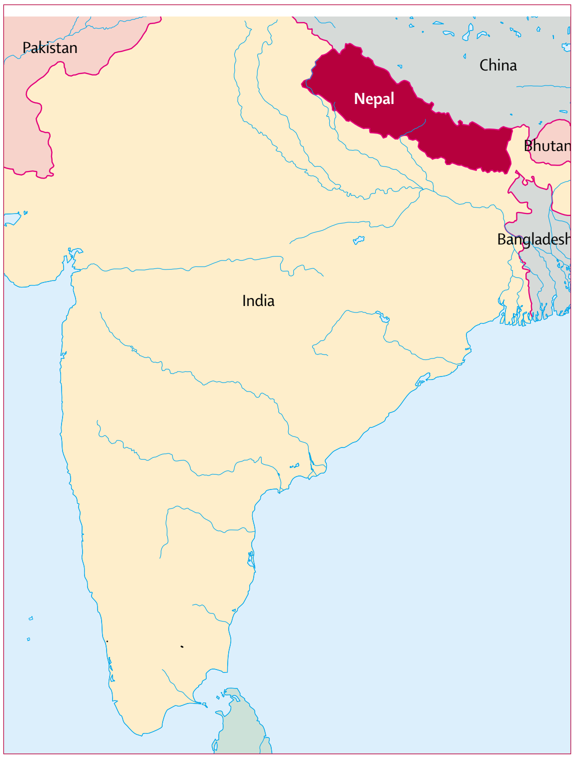

Figure 1: **Makwanpur District, Nepal, and distribution of study village development committees**

geopolitical unit, committee representatives were key points of liaison, and discussions with local people suggested that randomisation of smaller units would increase the risk of contamination. All 43 village development committees in Makwanpur district were eligible for randomisation, of which one was excluded at baseline for security reasons.

We enrolled a closed cohort of married women of reproductive age. Inclusion criteria were: consent given for involvement; age 15–49 years inclusive on June 15, 2000; married; and potential to become pregnant. Exclusion criteria included long-term separation from spouse and widowhood. Women who chose to participate in the study gave verbal consent and were free to decline to be interviewed at any time.

Procedures

We matched 42 village development committees into 21 pairs. Because we did not have disaggregated neonatal mortality figures, pairing was based on a process of topographic stratification, grouping of village development committees with similar ethnic group distributions, and matching of pairs with similar population densities. We used a list of random numbers to select 12 pairs. These 24 village development committees formed the study clusters. We randomly allocated one cluster in each pair to either intervention or control on the basis of a coin toss (figure 1). Because of the

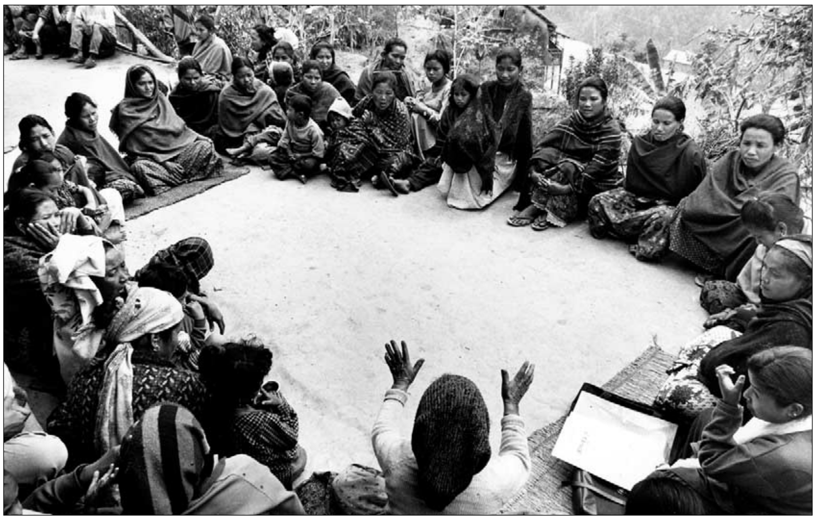

Figure 2: **Typical women's group meeting**
Picture courtesy of Thomas Kelly and Save the Children, USA.

nature of the intervention the trial allocation was not masked, but analysis of primary and secondary outcomes was not done until just before the data monitoring committee meeting at 30 months. We generated the cluster allocation sequence in Kathmandu before enrolment of participants.

Enrolment activities were done from September, 1999, to November, 2000. A team of local enumerators mapped the 24 village development committees on foot, identified and allocated a unique identification number to every household (defined as a group of individuals sharing one kitchen), did a baseline census of demographic and socioeconomic indicators, and generated a list of female household members according to predefined written protocols. This document was scrutinised by a data auditor, a surveillance manager, and a group of local supervisors and converted into a list of women meeting the inclusion criteria for the cohort. From March, 2001, to July, 2001, a team of 44 field interviewers visited every potential member of the cohort, reassessed her for inclusion, explained the study, asked for her consent, allocated her a unique identification number, and completed an individual questionnaire, which included questions on demography, education, maternity history, details of any preceding pregnancy, home-care practices, and use of health services for perinatal illness.[4]

Surveillance began in February, 2001, and involved 28 931 participants in 28 376 households. The strategy we used was adapted from one used by the Nepal Nutrition Intervention Project, Sarlahi,[25] and has been described in detail elsewhere.[26] It entailed 255 ward enumerators, 25 field interviewers, and nine field coordinators. The local female enumerator visited all cohort members in the ward she was responsible for every month over the study period to record menstrual status. She recorded data on individualised printed forms. The nine ward enumerators of every cluster met with a cluster interviewer once a week. In the absence of other explanatory circumstances, pregnancy was registered when a cohort member ceased menstruation for 3 months. The cluster interviewer did two interviews for every pregnancy: the first at 7 months of gestation, as near as possible to the transition between our definitions of miscarriage and stillbirth; and the second at 1 month postpartum, as near as possible to the transition between neonatal and infancy periods. In the event of an unfortunate outcome (miscarriage, maternal death, stillbirth, or neonatal death), the interview was done by a senior field coordinator. The interview was developed in Nepali and piloted and repiloted by the local team. It was modular to deal with different outcomes, covering antenatal, delivery and postpartum care, home care practices, maternal morbidity, neonatal morbidity, health service usage, and cause of death in the event of mortality.

In the event of neonatal death, we used an approach refined and locally adapted from existing questionnaires to establish cause of death. An open question about the cause of death was followed by a modular series of closed questions. The answers to these questions were designed to produce a classification of 14 causes of neonatal death based on those used by SEARCH in India,[9] and were classified by a paediatrician (DO) on

Phase	Meeting	Aim
Introduction		
	1	To introduce the study to the group
	2	To discuss why mothers and newborn infants die and how the intervention will work in the community
Problem identification		
	3	To ascertain how women understand maternal and neonatal problems
	4	To find out about maternal and neonatal problems in the community
	5	To understand the frequency of maternal and neonatal problems and to identify strategies to obtain information in the community
Problem prioritisation		
	6	To share information from other women in the community and to prioritise three important maternal and neonatal health problems
Planning together		
	7	To discuss possible strategies for addressing the priority problems
	8	To discuss involvement of other community members in developing strategies
	9	To discuss preparation for a meeting of community members
	10	To hold a meeting involving other community members to discuss the activities of the women's groups, the priority problems identified by the groups, and possible strategies, and reach consensus

Table 1: **First ten women's group meetings**

the basis of open text responses, modular closed questions, and a computer algorithm.

The average population per cluster was about 7000, spread over an area of 60 km^2. For every intervention cluster we recruited one local female facilitator. Shortlists for this role were derived from nomination by community leaders, advertisement, and word of mouth, after which all potential candidates were interviewed. A cluster consisted of nine wards. The facilitator—a literate locally resident woman—convened one women's group meeting a month in every ward (figure 2). Some groups set up by local female community health volunteers already existed but their activity was sporadic. The role of the facilitator was to activate and strengthen groups and support them through an action research cycle.

The intervention needed a facilitator rather than a teacher, with abilities and training in participatory communication techniques. She needed to have a grasp of perinatal health issues and some knowledge of potential interventions so she could act as a broker of information and a catalyst for change. Although it was important that none of the facilitators had a health background, we gave them brief training in perinatal health issues. Supervision, and a manual based on the Warmi project methodology,[8] was integral to facilitator training and support. One supervisor provided support for every three facilitators by attending group meetings and making regular community visits.

The first step of the intervention was to discuss issues around childbirth and care behaviours in the community, which allowed facilitators to develop participatory learning skills and generated information on pregnancy and childbirth, covering beliefs and practices in both uncomplicated and complicated pregnancies.[27,28] The facilitators then supported the women's groups through monthly meetings (table 1). This phase of ten meetings lasted almost a year. In the next steps of the intervention, the women's groups implemented and assessed their strategies. One result of the process was that women sought more information about perinatal health. This information was provided through the iterative design and playing of a picture card game that addressed prevention, treatment, and consultation for typical problems in mothers and babies.

The form and content of discussions within women's groups varied, as did levels of involvement and potential strategies. Some typical strategies were community-generated funds for maternal or infant care, stretcher schemes, production and distribution of clean delivery kits, home visits by group members to newly pregnant mothers, and awareness raising with a locally made film to create a forum for discussion. Throughout the process the groups were involved in other health-related activities in their communities.

A baseline service audit identified weaknesses in the provision of antenatal, delivery, and newborn care in Makwanpur district. Because we aimed to test solely the effects of the women's group intervention, health-service strengthening activities were undertaken in both intervention and control areas. We decided to do this process on ethical grounds because we hoped that it would benefit control areas[29] and on theoretical grounds because we thought that a degree of improvement in services would be necessary for the success of the trial intervention. We therefore ensured that primary health centres in the study area were equipped with locally made resuscitaires (open incubators that allow access to newborn babies while keeping them warm), phototherapy units, warm cots, and neonatal resuscitation equipment. We remedied some shortfalls in essential neonatal drugs once only and discussed strategies for resupply with local health-service managers. In partnership with the District Public Health Office, we organised training in essential newborn care for all cadres of government health staff and for female community health volunteers and traditional birth attendants. Community-based workers received a basic newborn care kit containing a rubber bulb for suction, tube-and-mask for assisted respiration, iodine, gauze, a baby wrapping cloth, and a pictorial manual.

We postulated that the women's group activities might lead to reductions in neonatal mortality rates in intervention clusters compared with control clusters. At the outset, we did not think perinatal mortality rates would be affected much, since we did not envisage that changes in home-care practices would lead to reductions in stillbirth rates.

The primary outcome was neonatal mortality rate (deaths in the first 28 days per 1000 livebirths). Prospective interviews undertaken through the surveillance system provided information on several other outcomes, including stillbirths and maternal deaths, uptake of antenatal and delivery services, home-care practices at delivery and postpartum, infant morbidity, and health-care seeking. We obtained background demographic and socioeconomic information to investigate cluster comparability.

Surveillance coordinators observed 10% of interviews and reviewed all questionnaires at nodal points in the field before transmitting them for review by data auditors. After audit and correction, sometimes needing transfer back to the site of collection, data were double-entered into a relational database management system in Microsoft SQL Server 7.0 (Microsoft Corporation, Redmond, WA, USA). The system further addressed data quality through predefined acceptability constraints.

We defined miscarriage as cessation of a presumptive pregnancy before 28 weeks of gestation and stillbirth as fetal death after 28 weeks of gestation but before delivery of the baby's head, which was a modification of the 22-week definition to meet local practicalities. We classified neonatal death as death of a liveborn infant within 28 completed days of birth. Early neonatal deaths refer to deaths within 7 completed

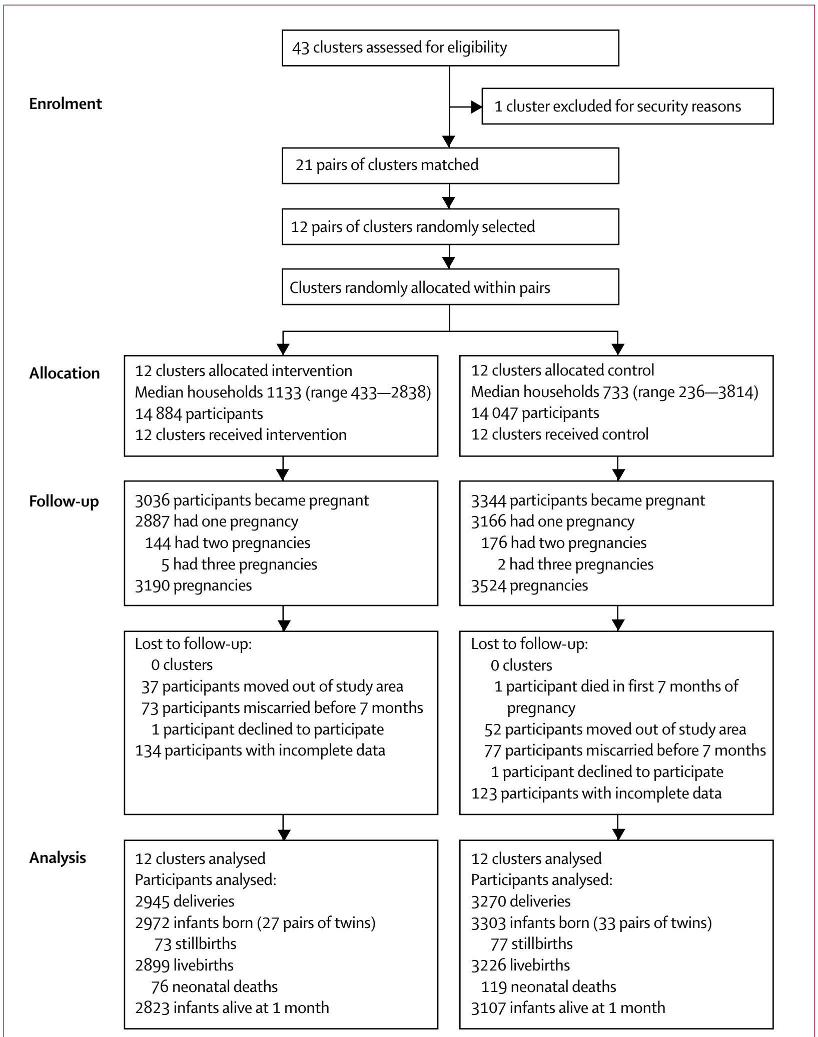

***Figure 3:* Trial profile**

days and late neonatal deaths from 7 to 28 completed days of birth. Perinatal death describes either a stillbirth or an early neonatal death.

The study was approved by the Nepal Health Research Council and the ethics committee of the Institute of Child Health and Great Ormond Street Hospital for Children, and was done in collaboration with His Majesty's Government Ministry of Health, Nepal. We discussed the aims and design of the trial at a national meeting in 1998. After this time, we held a series of meetings with members of the Makwanpur District Development Committee, the Chief District Officer, and local stakeholders. In early 2000, the chairpersons of the 24 village development committees involved in the study gave signed consent on behalf of their communities.

Benefits to the control clusters were improvements in equipment and training provided at all levels of the health-care system. All community-based members of the study team were recruited locally and undertook their activities in their home areas. When the study surveillance team noted minor illness in mothers or infants, they encouraged attendance at an appropriate health facility. In the event of severe illness, team members had an ethical responsibility to assist with rapid and appropriate transport and treatment, irrespective of allocation. All information provided by participants remained confidential. Access to information was restricted to interviewers, supervisors, data auditors, and officers, and research staff at the analytical level. No analyses or outputs included the names of participants.

Statistical analysis

To determine the number of cluster pairs to be enrolled, we had to estimate the coefficient of variation in outcome between clusters within matched pairs (k_m) and the expected number of births per cluster over the timescale of the study. Based on national and district estimates, we assumed a neonatal mortality rate of 60 per 1000 livebirths, an average of 480 births per cluster, and a k_m value in the range 0·15–0·3. We estimated that inclusion of 12 pairs of clusters would allow us to detect a reduction in neonatal mortality of between 27% and 38% (37–44 per 1000 livebirths) with 80% power at a 5% significance level.[30] The corresponding estimates of intraclass correlation are between 0·0055 and 0·0061. Because we did not envisage any adverse effects of the intervention at either cluster or participant level we did not use any stopping rules. After the first year of surveillance, we saw that birth rates were lower than expected on the basis of estimates. The trial steering group decided not to assess neonatal mortality rates until we had obtained data for 2 complete years of births from introduction of the intervention. We therefore undertook a preliminary analysis in November, 2003, and presented the findings to an independent data monitoring committee. The committee considered issues of quality, confidentiality, and analysis and recommended definitive analysis and publication of the 2-year findings.

The analysis was undertaken as intention to treat at both cluster and participant levels. Participants who had begun the trial as residents of a given cluster were retained as residents even if they had moved to another cluster during the trial period.

Within the prospective cohort, we compared neonatal mortality rates, stillbirth rates, and maternal mortality ratios between control and intervention groups, taking account of clustering and the paired nature of the data, with hierarchical logistic models (Mlwin version 1.1). We estimated intraclass correlation coefficients from retrospective neonatal mortality and stillbirth data by analysis of variance within Stata version 8. Secondary outcomes and process indicators were compared with adjustment for clustering. All estimates are presented with 95% CIs. This study is registered as an

International Standard Randomised Controlled Trial, number ISRCTN31137309.

Role of the funding source

Representatives of the UK Department for International Development (DFID) suggested that no health-care activities should be carried out in parallel with existing government services and that—for sustainability reasons—no funding should be available for women's group activities. Apart from these issues, the sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 3 shows the trial profile. All 24 clusters selected for inclusion received their allocated intervention. Between Nov 1, 2001, and Oct 31, 2003, 3190 pregnancies happened in intervention clusters and 3524 in controls. Presumptive miscarriage rates were 2·3% (73/3190) in intervention clusters and 2·2% (77/3524) in control clusters. Loss to pregnancy follow-up as a result of migration, withdrawal of consent, or incompleteness of surveillance data was 5·4% (172/3190) in intervention clusters and 5·0% (176/3524) in control clusters. 2972 births (including 54 twins) were available for analysis in intervention clusters and 3303 (including 66 twins) in control clusters.

Table 2 presents baseline characteristics of intervention and control clusters. Although the median number of households per cluster was lower in control clusters, the total numbers of households and participants who became pregnant were similar. Some evidence exists of less poverty in intervention than control clusters: household asset scores and participant schooling—but not recalled annual food sufficiency—seem to slightly favour the pooled intervention clusters. The age breakdown does not suggest differences between intervention and control clusters, either for population structure or for participants who became pregnant.

For estimated baseline mortality rates, participants in intervention clusters recalled 11 415 livebirths and 290 neonatal deaths in the 5 years preceding our census (neonatal mortality rate 25·4 per 1000 livebirths). Participants in control clusters recalled 12 132 livebirths and 304 neonatal deaths (neonatal mortality rate 25·1 per 1000 livebirths). Cluster-specific breakdown of these pooled data showed that neonatal mortality rates were higher in intervention than control clusters in four pairs, similar in four pairs, and higher in control than intervention clusters in four pairs. Although valid for cluster comparison, the prospective findings in the same population suggest that maternity histories substantially underestimated actual neonatal mortality rates.

	Intervention clusters	Control clusters	Pregnancies in intervention clusters	Pregnancies in control clusters
Number of households	14879	13497	2923	3189
Median per cluster (range)	1133 (433–2838)	733 (236–3814)	207 (158–451)	248 (59–796)
Number of participants	14884	14047	3036	3344
Median per cluster (range)	1110 (487–2824)	777 (219–4069)	214 (164–463)	264 (61–835)
Household asset score	13532	12170	3036	3344
None of the assets on the list	6122 (45%)	6233 (51%)	1545 (51%)	1866 (56%)
Clock, radio, iron, or bicycle	4094 (30%)	4476 (37%)	954 (31%)	1171 (35%)
More costly appliances	3316 (25%)	1461 (12%)	537 (18%)	307 (9%)
Household food sufficiency	13532	12170	3036	3344
Less than 8 months annually	4090 (30%)	3372 (28%)	972 (32%)	1002 (30%)
Participant age	13532	12170	3036	3344
Younger than 20 years	1130 (8%)	973 (8%)	719 (24%)	731 (22%)
20–29 years	5192 (38%)	4758 (39%)	1696 (56%)	1804 (54%)
30–39 years	4265 (32%)	3782 (31%)	556 (18%)	704 (21%)
40 years or older	2945 (22%)	2657 (22%)	65 (2%)	105 (3%)
Participant schooling	13532	12170	2893	3141
None	11031 (82%)	10741 (88%)	2122 (73%)	2681 (85%)
Primary	1562 (12%)	957 (8%)	503 (17%)	307 (10%)
Secondary or higher	939 (7%)	472 (4%)	268 (9%)	153 (5%)
Participant could not read	8981 (66%)	9664 (79%)	1734 (60%)	2418 (77%)

Table 2: **Baseline characteristics of intervention and control clusters and pregnancies in intervention and control areas**

Figure 4 shows within-cluster neonatal mortality rates for each of the 12 cluster pairs. The line of equality has been superimposed on this graph. In 11 cluster pairs, neonatal mortality rates were lower in the intervention group. The pooled rate in the intervention group was nearly 30% lower than in the control group (table 3). Hierarchical modelling—taking clustering into account—yielded an odds ratio of 0·70 (95% CI 0·53–0·94) for neonatal mortality in the intervention clusters compared with the control clusters. The intraclass correlation coefficient estimated from retrospective data was 0·00644 (95% CI 0·00004–0·0128).

Stillbirth rates did not differ between intervention and control clusters (table 3). The intraclass correlation coefficient estimated from the retrospective data was

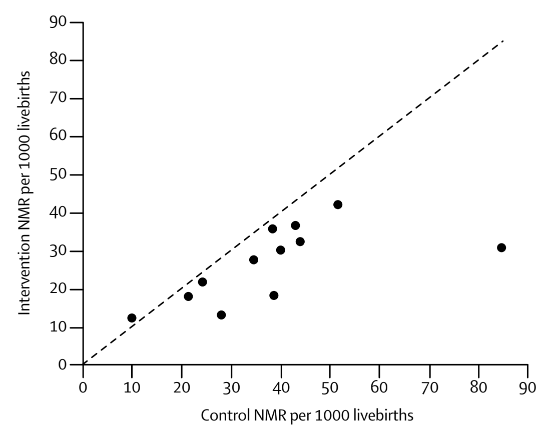

Figure 4: **Neonatal mortality rates in intervention and control areas**
NMR=neonatal mortality rate.

	Intervention clusters	Control clusters	Adjusted odds ratio (95% CI)
Documented births	2972	3303	
Livebirths	2899	3226	
Stillbirths	73	77	
Neonatal deaths	76	119	
Early (0–6 days)	50	70	
Late (7–28 days)	26	49	
Maternal deaths	2	11	
Stillbirth rate per 1000 births	24·6	23·3	1·06 (0·76–1·47)
Neonatal mortality rate per 1000 livebirths	26·2	36·9	0·70 (0·53–0·94)
Maternal mortality ratio per 100 000 livebirths	69	341	0·22 (0·05–0·90)

Table 3: Mortality rate comparisons between intervention and control clusters

0·00438 (95% CI 0–0·00948) for the stillbirth rate. With limited sample size, maternal mortality was not a predefined outcome of the study. The maternal mortality ratio was about 80% lower with intervention than with control clusters (adjusted odds ratio 0·22 [95% CI 0·05–0·90]).

Table 4 presents process indicator outcomes. In general, they suggest so-called healthier behaviours in intervention clusters: women in these clusters were more likely than those in the control clusters to have had antenatal care, to have taken haematinic supplements, to have given birth in a health facility, with a trained attendant or a government health worker, to have used a clean home delivery kit or a boiled blade to cut the umbilical cord, and for the birth attendant to have washed her hands. No differences were noted in delayed wrapping of newborn infants, early bathing, or breastfeeding. Rates of maternal morbidity were similar, but women in intervention clusters were more likely than those in control clusters to have visited a health facility in the event of illness. Likewise, infant illness was more likely to have led to a visit to a health facility.

	Intervention clusters	Control clusters	Adjusted odds ratio (95% CI)
Pregnancies	3190	3524	
Any antenatal care	1747 (55%)	1051 (30%)	2·82 (1·41–5·62)
Any iron and folic acid supplements	1574 (49%)	1152 (27%)	1·99 (1·14–3·46)
Any perceived maternal illness from 7 months gestation to 1 month postpartum	668 (21%)	926 (26%)	0·74 (0·43–1·28)
Visited health facility in event of illness	333 (50%)	207 (22%)	3·37 (1·78–6·37)
Deliveries	2945	3270	
Institutional deliveries	201 (7%)	66 (2%)	3·55 (1·56–8·05)
Birth attended by government health provider	272 (9%)	102 (3%)	3·12 (1·62–6·03)
Specifically, doctor, nurse, or midwife	207 (7%)	69 (2%)	3·53 (1·54–8·10)
Birth attended by traditional birth attendant	199 (7%)	129 (4%)	1·70 (0·93–3·11)
Used a clean home delivery kit	550 (19%)	154 (5%)	4·59 (2·83–7·45)
Used a boiled blade to cut the cord	1580 (54%)	827 (26%)	3·47 (1·39–8·69)
Attendant washed her hands	1988 (68%)	1064 (33%)	5·5 (2·40–12·6)
Livebirths	2899	3226	
Cord undressed or dressed with antiseptic	2356 (81%)	2349 (73%)	1·62 (0·58–4·55)
Baby wrapped within 30 min	1975 (68%)	2257 (70%)	0·92 (0·37–2·31)
Baby bathed within 1 h	2880 (99%)	3207 (99%)	1·11 (0·46–2·71)
Infants alive at 1 month	2823	3107	
Any of three infant illnesses (cough, fever, diarrhoea)	919 (33%)	1320 (42%)	0·65 (0·36–1·20)
Taken to health facility in event of illness	219 (24%)	131 (10%)	2·84 (1·65–4·88)
Breastfed infants	2864	3181	
Initiated within 1 h	1780 (62%)	1718 (54%)	1·40 (0·52–3·79)
Discarded colostrum	820 (29%)	1344 (42%)	0·55 (0·27–1·10)

Table 4: Process indicator outcomes

The most usual causes of neonatal death were complications of preterm birth, presumptive birth asphyxia, and infection. The pattern of causes did not differ between groups, but we noted that infection-related deaths were less frequent in intervention clusters.

Discussion

We have shown that an intervention in rural Nepal, entailing women's groups convened by a local woman facilitator, reduced neonatal mortality by 30%. Maternal mortality, although not a primary outcome of the trial, was also significantly lower in intervention areas. The intervention seemed to bring about changes in home-care practices and health-care seeking for both neonatal and maternal morbidity. The activities of one facilitator in a population of 7000 rapidly reached a high proportion of pregnant women, even in poor and remote communities. Only 8% of married women of reproductive age ever attended a group, but the groups attracted 37% of newly pregnant women, and members raised awareness of perinatal issues outside the groups themselves.

Cluster-randomised trials are susceptible to bias. The intervention and control areas had similar retrospective neonatal mortality rates, but some differences were noted in literacy and poverty indicators. We do not think these factors could account for the noted differences in mortality rates, but they do merit further investigation. Surveillance methods could have affected outcomes, although this activity would have taken place in both intervention and control areas.

Two potential effect modifiers were the convening of women's groups in collaboration with government-trained female community health volunteers and health-system strengthening activities across intervention and control areas. Would work with women's groups have the same degree of effect in areas where no community health volunteer was present or no training of health workers in essential newborn care took place?

Security problems in the district escalated during the third year of the study. Supervisory activities were intermittently compromised in four clusters (two intervention and two control), and although no women's group was disbanded, four groups had to postpone their meetings several times.

The intervention seemed to be acceptable: 95% of groups remained active at the end of the trial despite no financial incentives and the opportunity costs incurred by women spending time away from other tasks. With appropriate investment and political commitment, we think the intervention could be scaled up rapidly. Scaling-up could be achieved through both government and non-government organisations and would not necessarily need to be managed by health-sector personnel, although coordination would be essential. Local rather than central government might be preferable to lead the process for reasons of participation, accountability, and sustainability.

A cost-effectiveness analysis was done alongside the study. The cost per newborn life saved was US$3442 ($4397 including health-service strengthening costs) and per life year saved $111 ($142 including health-service strengthening costs). This value compares favourably with the World Bank's recommendations that interventions less than US$127 per disability-adjusted life year saved are some of the most cost effective.[31] Our estimates probably underestimate the programme's cost-effectiveness. They do not include benefits to infants born outside the closed cohort surveillance; they ignore longer-term benefits of the intervention to subsequent pregnancies; they exclude benefits to infants of reduced morbidity and to mothers from reduced morbidity and mortality; and they omit potential savings in set-up and supervision costs if the activities were replicated elsewhere.

Two key elements distinguished our approach from conventional health education. First, women's groups looked at demand-side and supply-side issues. Second, the approach emphasised participatory learning rather than instruction. The women's group strategies—the picture card game, health funds, stretcher schemes, production and distribution of clean delivery kits, and home visits—also entailed interaction outside the groups, which increased awareness of perinatal issues.

The renewed interest in community participation in health care[32] is attributable partly to the scarcity of resources committed to primary care and partly to the perceived failure of conventional health education and primary health care to deliver substantial health benefits.[17,33,34] A major challenge has been to engage users and enable them to adopt positive health care behaviours. In many countries, local-health committees have had little accountability to their communities, and the level of representation of beneficiaries such as women is low.[35,36] Beneficiaries themselves can be passive in the face of service bureaucracies[37–39] because of an absence of local ownership, different perceptions of priorities, and capture of resources by powerful groups.

If participation is a key element of primary health care then few controlled studies have been done of its effect on health outcomes. Participation is typically seen as an adjunct to implementation rather than as a primary intervention, and the distinction between a didactic approach to health education at community level and a participatory approach to developing strategies is blurred. For example, community-based health promoters have increased exclusive breastfeeding rates in Mexico[40] and India,[41] where diarrhoeal morbidity was also diminished. In Ethiopia, a randomised controlled trial of mother coordinators trained to teach other local mothers to recognise symptoms of malaria in their children and to promptly give chloroquine achieved a 40% reduction in under-five mortality.[42]

The procedure used to establish cause of death suggested that infection accounted for fewer deaths in intervention than control clusters. This finding lends support to the noted rises in antenatal care, trained birth attendance, clean delivery kit use, hand washing by birth attendants, and care seeking in the event of neonatal morbidity. These data complement the work of SEARCH,[9] whose intervention consisted of a package of activities. Scaling up the use of injectable antibiotics by community health workers presents difficulties for policy makers, and our less intensive intervention achieved half the SEARCH mortality reduction.

The effect of the intervention on maternal mortality was surprising in view of the size and power of the study and obviously needs replication. If validated, the finding would be noteworthy for the potential of this approach to achieve Millennium Development Goals.[43] The participatory strategy could benefit other health outcomes such as stillbirths, infant and childhood mortality, and malaria and HIV infection in pregnancy. The absence of effect on stillbirth rates shown in this trial does not rule out future success if issues such as nutrition received greater emphasis in women's groups.[44]

The trial findings raise several issues that we intend to address in subsequent work: differential changes in care practices between group members and non-members, the process of diffusion of behaviour changes within the population, an examination of potential confounding within the cluster-randomised design, further analysis and refinement of the verbal autopsies, and a detailed discussion of cost-effectiveness.

Progress towards the Millennium Development Goals for maternal and child mortality reduction has faltered. Our findings suggest that a demand-side intervention can achieve great reductions in neonatal and maternal mortality in poor and remote communities. The approach—a local woman facilitating women's groups—is potentially acceptable, scalable, sustainable, and cost effective as a public-health intervention. Assessment of demand-side interventions needs greater attention in primary care.[5] Studies are needed to assess how we can replicate the approach in different settings, as are large trials to examine effects on maternal morbidity and mortality.

Contributors

All authors contributed to the design of the study and criticised drafts of the paper. D S Manandhar and A M de L Costello were responsible for the conception and overall supervision of the trial. B P Shrestha managed the project under initial guidance from J R Shrestha. K M Tumbahangphe, S Tamang, S Thapa, D Shrestha, and B Thapa managed data collection, field intervention, health service activities, data entry and administration, respectively. N Mesko and J Morrison were technical advisors on intervention and qualitative aspects of the study, and D Osrin on quantitative aspects. J Borghi conducted the economic analysis with help from B Thapa. M Manandhar and H Standing advised on the facilitation process. D Osrin and A Wade carried out the

quantitative analysis. A M de L Costello and D Osrin wrote the first draft of the paper and were responsible for subsequent collation of inputs and redrafting.

Conflict of interest statement

We declare that we have no conflict of interest.

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