Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial

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Summary

Background In rural India, most births take place in the home, where high-risk care practices are common. We developed an intervention of behaviour change management, with a focus on prevention of hypothermia, aimed at modifying practices and reducing neonatal mortality.

Methods We did a cluster-randomised controlled efficacy trial in Shivgarh, a rural area in Uttar Pradesh. 39 village administrative units (population 104 123) were allocated to one of three groups: a control group, which received the usual services of governmental and non-governmental organisations in the area; an intervention group, which received a preventive package of interventions for essential newborn care (birth preparedness, clean delivery and cord care, thermal care [including skin-to-skin care], breastfeeding promotion, and danger sign recognition); or another intervention group, which received the package of essential newborn care plus use of a liquid crystal hypothermia indicator (ThermoSpot). In the intervention clusters, community health workers delivered the packages via collective meetings and two antenatal and two postnatal household visitations. Outcome measures included changes in newborn-care practices and neonatal mortality rate compared with the control group. Analysis was by intention to treat. This study is registered as International Standard Randomised Control Trial, number NCT00198653.

Findings Improvements in birth preparedness, hygienic delivery, thermal care (including skin-to-skin care), umbilical cord care, skin care, and breastfeeding were seen in intervention arms. There was little change in care-seeking. Compared with controls, neonatal mortality rate was reduced by 54% in the essential newborn-care intervention (rate ratio 0·46 [95% CI 0·35–0·60], p<0·0001) and by 52% in the essential newborn care plus ThermoSpot arm (0·48 [95% CI 0·35–0·66], p<0·0001).

Interpretation A socioculturally contextualised, community-based intervention, targeted at high-risk newborn-care practices, can lead to substantial behavioural modification and reduction in neonatal mortality. This approach can be applied to behaviour change along the continuum of care, harmonise vertical interventions, and build community capacity for sustained development.

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Introduction

Most neonatal deaths occur at home in low resource settings against a backdrop of poverty, unskilled home deliveries, suboptimum care-seeking, and weak health systems.[1–3] Emerging evidence suggests that a substantial reduction in neonatal mortality can be achieved with simple, low-cost interventions within family and community settings.[1–11]

In a study in Maharashtra, India, Bang and colleagues[2,6] reported a 62–70% reduction in the neonatal mortality rate, and attributed 93% of the reduction to active management of sick newborn babies and 7% to primary prevention. Baqui and colleagues[4] reported that an adaptation of this approach in Bangladesh in an effectiveness trial had half the effect (34% reduction) on neonatal mortality. Manandhar and co-workers[3] tested a different approach in Nepal with a community-based participatory action-cycle with no prespecified intervention package, in which women's groups identified priorities and implemented local solutions, and reported improvements in care practices, care-seeking, and a 30% reduction in neonatal mortality rate.

Most neonatal deaths in high-mortality regions are attributable to preventable and behaviourally modifiable causes.[1–11] However, the extent to which a preventive package of evidence-based interventions at the community level could reduce neonatal mortality is unknown. Estimates based on modelling of limited empirical data suggest that 18–32% of neonatal mortality could be averted through high (90%) coverage of simple, affordable, methods for preventive family and community newborn care.[1]

Identification of an effective approach to preventive care that builds on existing capacities and accelerates programme effectiveness is important. The limited

success of large-scale studies of behaviour change interventions has been attributed to poor consideration of the social context that shapes behaviours while treating individual health behaviours as stand-alone entities.[12–18]

We postulated that an intervention based on a socioculturally contextualised approach of behaviour change management systematically applied to modifiable, high-risk newborn-care practices, with an emphasis on hypothermia, within a community with a high neonatal mortality rate could lead to improved care practices and reduced mortality.

Methods

Study area and population

The state of Uttar Pradesh, India, accounts for a quarter of India's neonatal deaths and for 8% of those worldwide, and shares similar sociocultural, demographic, and health system characteristics with other high-mortality Indian states and south Asian countries.[3–5,19–21] The study was done in Shivgarh, a rural block in Uttar Pradesh, with a population of 104 123 divided into 39 village administrative units. Socioeconomic indicators are among the lowest in the state.

The formal health-care system in Shivgarh consists of a community health centre and two primary health centres operated by trained physicians and paramedical staff supported by 18 auxiliary nurse midwives, who are outreach workers catering to a population of 6000–7000 each, and trained to deliver babies, and provide vaccinations and antenatal check-ups. Care-seeking from them, however, is low.[22]

Study design

This study was designed as a three-arm cluster-randomised controlled trial. A control group received the usual services of governmental and non-governmental organisations in the area. One intervention group received a package of preventive essential newborn care, including skin-to-skin care between the infant and a family member, promoted through behaviour change management, layered on existing services available to the control group. The other intervention group received essential newborn care plus the use of a liquid crystal sticker that indicates hypothermia by changing colour (ThermoSpot, Camborne Consultants, Dorset, UK).

See Online for webtable 1

The cluster unit, called a *gram sabha*, is the basic geopolitical and administrative unit for village-level health planning and implementation; use of smaller units would have posed a higher risk of contamination of intervention activites in control clusters. One community-based worker catered to one cluster unit. Stratified cluster randomisation was done at Johns Hopkins University using Stata 7.0 (StataCorp, College Station, TX, USA) to allocate the 39 cluster units randomly to the three study groups, yielding three allocation sequences of 13 clusters each. Baseline covariates used for stratification were standard of living index, an indicator associated with mortality, and religion, which was assumed to be associated with differences in care practices.[23]

The study had two distinct and administratively independent components: the intervention (development phase and implementation phase), and evaluation. Because of the visible nature of the intervention, allocation was not masked; however, boundaries to limit communication between the two teams were closely monitored.

The study was registered at clinicaltrials.gov, number NCT00198653. The Committee on Human Research at the Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA, and the Ethical Review Committee at King George Medical University, Lucknow, India, approved the study protocol. A data safety and monitoring board consisting of American and Indian investigators monitored the study.

Intervention

Design of the community-based intervention for behaviour change management took place from May–September, 2003, and required strategic inputs on: high-risk behaviours for neonatal mortality; individuals with key roles in the practice and continuation of these behaviours; and potential barriers, opportunities, and factors affecting behaviour change. Participatory social mapping of all villages in the study area provided an introduction to the community, initiated the process of collaborative engagement, served to identify community resources for newborn health, and facilitated the planning of home visitations and group interventions. Qualitative research activities provided the evidence base for investigators and community members to co-develop the intervention strategy, which underwent further refinement based on findings of trials of improved practices.

Domiciliary care practices were mapped against the existing evidence base of risk factors for neonatal mortality and morbidity. Practices that were assessed to be potentially harmful, preventable, within community control, and amenable to change were selected for behavioural modification (webtable 1). The corresponding set of ideal practices formed the intervention package of essential newborn care, broadly categorised into birth preparedness, hygienic delivery, and immediate newborn care including clean umbilical cord and skin care, thermal care including skin-to-skin care, breastfeeding, and care-seeking from trained providers (webtable 1).

We focused on hypothermia during the initial formative research phase, and findings led the team to expand to a broader package of essential newborn care. Moreover, when we learned during the formative phase of the success of the Makwanpur study, Nepal, on neonatal mortality reduction through a community

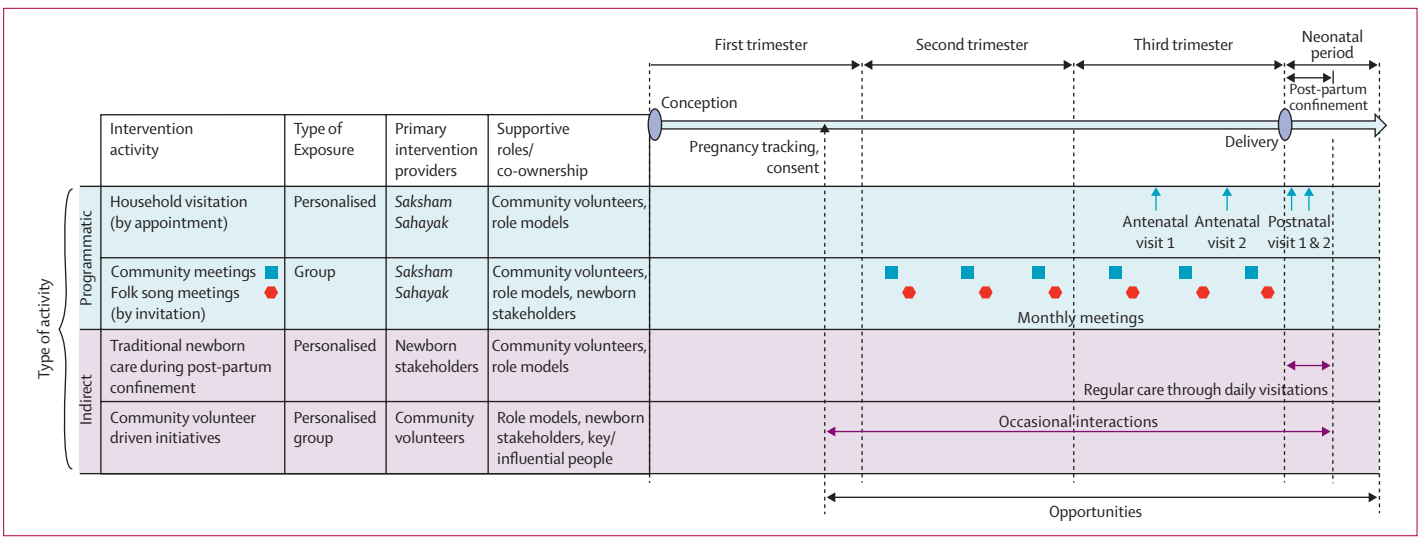

Figure 1: **Exposure of pregnant women, households, and the Shivgarh community to the intervention package**
Saksham Sahayak=community health worker.

action cycle approach, we added mortality reduction as an outcome in addition to care practices.[3] Almost all targeted, high-risk practices were associated with disruption in the warm chain (a cycle of procedures taken at birth to prevent heat loss) and susceptibility to infection such as sepsis (webtable 1). Prevention, recognition, and management of hypothermia were perceived by the community to be within behavioural control, by contrast with other risks that were commonly attributed to supernatural factors, such as "evil spirits". Thus, we used attention to hypothermia to facilitate the uptake of the broader essential newborn-care package by the community.

Individual behaviours were influenced by collective behaviours and social norms, and sustained by a complex, multilevel network of relationships within the community. We therefore developed a multilevel strategy targeting: community stakeholders, newborn stakeholders, and households with immediate support groups (webpanel). At each level, the target group consisted of individuals who were identified to have key roles as influencers, decision makers, supporters, and practitioners of newborn care and normative behaviour within the community. The support of community stakeholders such as village heads, community leaders, respected members, priests, and teachers was crucial in building trust with the community and ensuring acceptance of the programme. The newborn stakeholder target group included traditional newborn-care providers and birth attendants, unqualified medical practitioners, and, to a lesser extent, health system workers, some of whom had strategic access to the newborn and mother during post-partum confinement, were perceived by the community as domain experts, and played an active part in sustaining targeted practices. Health system workers such as auxillary nurse midwives were engaged only at the community level as part of newborn stakeholder group meetings in order to keep contamination of the intervention into control clusters to a minimum. The household target group included the pregnant woman or mother, who was the primary care provider, but usually not empowered to make decisions; the mother-in-law, who was usually the key decision maker on newborn-care practices; other female members who played supportive roles; and male members, including the father-in-law and husband, who controlled access to the household, made financial and logistical arrangements, and influenced care-seeking decisions. The family's immediate support group included neighbours and relatives who influenced family behaviours and helped with deliveries.

Formative research revealed that the high-risk practices were perceived by the community to be favourable for newborn health, and that multiple barriers to behaviour change existed in the form of knowledge, skills, and sociocultural, economic, and spiritual factors. The behaviour change management approach was based on trust, and developed as a participatory process of respectful engagement with the community to lead individuals and families from current towards improved behaviours through a path of least social, cultural, economic, and spiritual resistance to change. We sought to understand existing practices, design relevant behaviour change messages, create a shift in reasoning in favour of improved practices, negotiate barriers to change by optimising available resources and providing viable alternatives, equip households with necessary skills, build self-confidence, and create a supportive environment.

To minimise resistance to change, messages were designed to promote improved newborn-care practices to align with existing cultural values and traditions, so that they were not perceived as externally imposed

See Online for webpanel

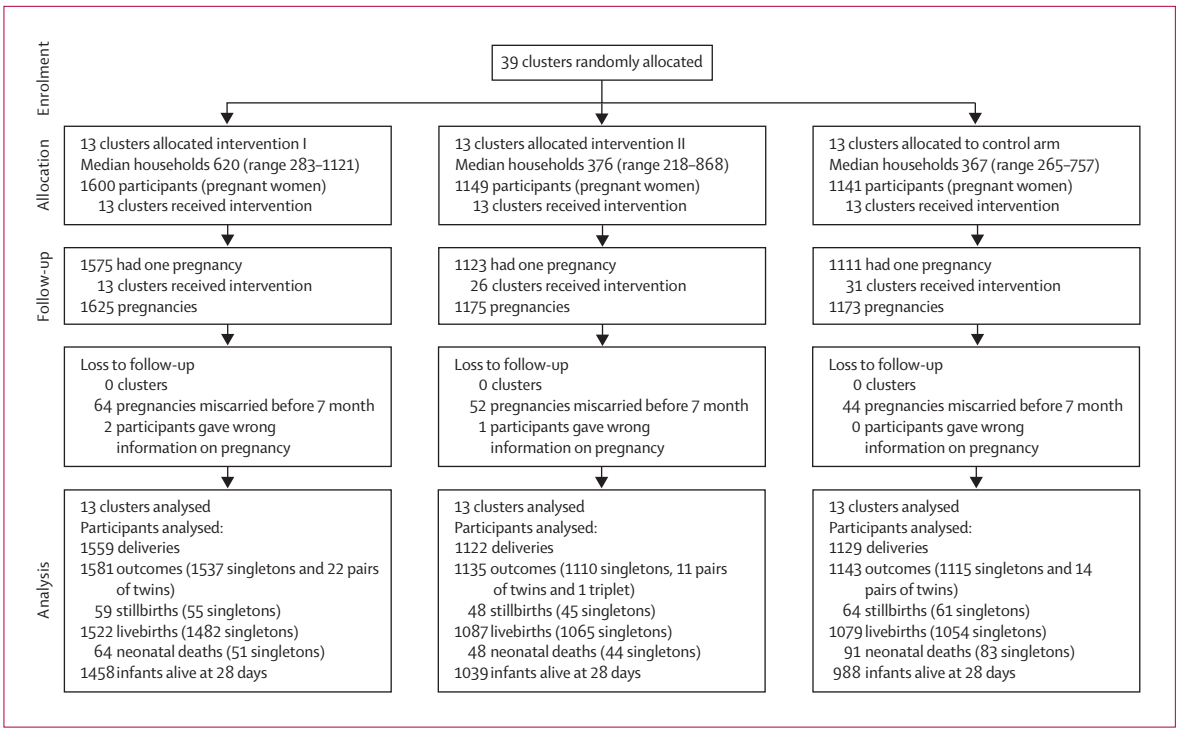

Figure 2: **Trial profile**

interventions. Behaviour change messages drew analogies between the improved newborn-care practices and other commonly observed and favourably perceived behaviours and practices, while exposing inconsistencies between the corresponding high-risk practices and healthful practices in other domains (webtable 1). This approach created a condition of cognitive dissonance, and thus motivation for change in behaviour, thereby reducing the challenge of behaviour change to one of behavioural alignment with already existing beliefs and practices in other areas of daily life.[24]

The primary enablers of behaviour change were paid (US$35–40 per month) community-based health workers, the *Saksham Sahayak* (n=26), who were recruited from the local community based on 12 years or more of education, proficient communication and reasoning skills, commitment towards community work, and references of community stakeholders.[25] They received a combination of classroom-based and apprenticeship-based field training over 7 days on knowledge, attitudes, and practices related to essential newborn care within the community, behaviour change management, and trust-building. After training, suitable candidates were closely mentored and supervised by a regional programme supervisor (n=4) responsible for 6–7 *Saksham Sahayaks*, for an additional week before final selection was made.

See Online for webtable 2

Newborn-care stakeholders within the community, considered specialists and domain experts, had strategic access to newborn babies during the confinement period for the first 4–9 days after delivery, and were simultaneously targets of the intervention as well as natural partners of the *Saksham Sahayak* for working with families to ensure adherence with the intervention (figure 1, webpanel). Volunteers from within the community, called *Saksham Karta*, played a key part in programme advocacy, trust-building, and social legitimisation of changes in behaviour. Their participation, therefore, was aimed to promote the continuation of behaviour change beyond the study period, and they were able to support families with knowledge, skills, and resources. Additionally, mothers who were beneficiaries of the intervention and displayed exemplary practices were promoted as role models to inspire other pregnant women in their community.

The intervention was delivered from January, 2004, to May, 2005. *Saksham Sahayaks* first engaged with community stakeholders in community meetings to seek their approval, sensitise them towards the importance of their role in newborn survival, encourage shared learning, and create a supportive environment (figure 1, webtable 2). Folk song group meetings, where messages to promote behaviour change were incorporated into folk songs, were held by *Saksham Sahayaks* on a monthly basis with participants from diverse target groups. They also held separate monthly meetings with newborn-care stakeholders and with community volunteers to discuss experiences, challenges, and strategies.

Early identification of pregnant women by *Saksham Sahayaks* was a prerequisite for seeking consent,

enrolling them into the programme, and providing timely intervention. This process was accomplished through 3-monthly cycles of door-to-door household visits by *Saksham Sahayaks*, self-reporting by pregnant women, and information provided by community volunteers. An antenatal visit was planned for 60 days before the expected date of delivery and another for 30 days before the expected date of delivery to provide ample time for effective behaviour change negotiation, ensure birth preparedness, and build trust with the family to negotiate subsequent entry into the room of confinement after delivery for postnatal visits (webtable 3). Post-partum confinement was a universal practice, and coincided with the initiation of almost all the targeted practices and occurrence of most newborn deaths.[26,27] As some of the new practices were skill-based, the first postnatal visit was planned within 24 h of the delivery and the second postnatal visit was planned on day 3 (webtable 3). In case of sick neonates, no treatment was provided, but families were advised to seek care at the nearest health facility.

Regional programme supervisors had daily meetings with their team to discuss the work plan, progress, challenges, and lessons learned. Monthly programme meetings took place, in which all four regional teams came together to discuss experiences. Performance assessment of *Saksham Sahayaks* included feedback from community members, spot checks by their supervisors during home visits and community meetings to assess their level of community engagement, and monitoring by the supervisors of whether targets for home visits and community meetings were being met.

Coverage of household visits by *Saksham Sahayaks* was calculated as the ratio of total visitations recorded during the study period to the total number of women eligible for the visitations. For coverage on antenatal visits, all pregnancies were considered eligible and for coverage on postnatal visits, all women with at least one liveborn baby were considered eligible for the visits. Household visits by newborn-care stakeholders and community volunteers in the absence of *Saksham Sahayaks* were not recorded. The monthly coverage of group meetings was based on monitoring reports by *Saksham Sahayaks*.

Evaluation

The evaluation system was independent of programme implementation, and standard procedures were established to guide evaluation team recruitment, training, and supervision and to preserve segregation from the programme.[25] Training varied from 7 to 15 days, depending on task, the supervisor to data collector ratio was 1:6 and 15% or more of all household data was randomly subjected to back checks, spot checks, and truncated re-interviews.

Each resident (n=104 123) was given a unique identifier and information on demographic and socioeconomic indicators was collected for each household (n=18 989). Neonatal deaths and stillbirths were assessed for the year before the intervention through retrospective recall based on a truncated pregnancy history of all women in reproductive age. For the same time period, information on knowledge, attitudes, practices, and constraints regarding maternal care and essential newborn care was

	Essential newborn care	Essential newborn care plus ThermoSpot	Control
Household and resident characteristics			
Total households, N	7937	5243	5809
Households per cluster (median [range])	620 (283–1121)	376 (218–868)	367 (265–757)
Residents per household (cluster mean [SD])	5·4 (0·2)	5·6 (0·4)	5·6 (0·3)
Religion			
Hindu	94·3 (4·7)	93·6 (6·3)	93·6 (5·9)
Muslim	5·7 (4·7)	6·4 (6·3)	6·4 (5·9)
Caste distribution of Hindu households			
Scheduled caste/scheduled tribe	56·5 (16·1)	49·9 (20·9)	42·1 (16·4)
Backward caste	30·2 (12·9)	33·0 (17·7)	37·3 (17·0)
Upper caste	13·3 (6·2)	17·1 (14·7)	20·6 (8·0)
Standard of living index*			
Low	33·2 (1·2)	33·5 (1·8)	34·4 (1·8)
Medium	57·4 (1·8)	56·5 (2·0)	56·1 (2·1)
High	9·4 (1·2)	10·0 (1·3)	9·5 (1·3)
Literate women of reproductive age (15–49 years)	39·4 (8·6)	38·0 (9·7)	38·5 (11·4)
Marital status of women of reproductive age			
Unmarried	13·7 (2·4)	13·3 (2·2)	12·7 (4·4)
Married	82·2 (2·2)	83·3 (2·4)	83·3 (4·3)
Widow	4·2 (1·0)	3·3 (1·2)	4·0 (0·5)
Selected practices			
Place of delivery			
Home	91·1 (9·3)	95·4 (3·4)	93·0 (6·8)
Health facility	7·9 (8·3)	3·1 (3·3)	4·8 (4·5)
On the way	1·0 (1·4)	1·4 (1·9)	2·2 (3·7)
Routine antenatal care check-up (≥1)†	3·4 (3·9)	2·6 (3·6)	4·5 (4·8)
Tetanus toxoid vaccination (≥2)	93·9 (3·6)	93·0 (5·5)	90·3 (8·2)
Skilled birth attendant‡	16·6 (4·6)	12·0 (5·0)	13·0 (5·0)
Delivery in hands	6·0 (4·1)	4·4 (5·3)	8·3 (6·2)
Wiping of whole body	12·0 (5·8)	14·6 (6·4)	12·5 (6·0)
Bathing within 24 h	99·3 (1·7)	96·7 (7·6)	98·2 (4·7)
Skin-to-skin care	0·9 (1·5)	0·7 (1·7)	0·7 (1·2)
Cord cut with clean blade	24·2 (8·1)	26·2 (11·9)	25·3 (8·5)
Breastfeeding within 1 h of birth	2·3 (3·8)	1·7 (2·8)	2·6 (3·3)
Mortality rates			
Stillbirths per 1000 births	24·4 (17·1)	30·5 (27·2)	27·2 (19·2)
Neonatal deaths per 1000 livebirths	64·1 (21·8)	58·9 (31·0)	54·2 (25·1)
Perinatal deaths per 1000 births	68·4 (30·6)	65·5 (31·6)	60·0 (28·6)

Data are cluster mean, % (SD) unless otherwise stated. *Calculated using National Family Health Survey method (International Institute for Population Sciences [IIPS] and ORC Macro 2000). †Antenatal care was considered only if the pregnant women visited a governmental or private healthcare facility and included measurements of blood pressure, weighing, and an abdominal examination. This definition was changed in the endline survey to include only two of these three procedures, to align with the definition commonly adopted in health surveys like National Family Health Survey.[23] ‡Includes auxillary nurse midwives, nurses, and qualified doctors.

Table 1: **Baseline characteristics**

See Online for webtable 3

	Essential newborn care	Essential newborn care plus ThermoSpot
Number of pregnancies	1632	1179
Antenatal visit 1 (60 days before expected date of delivery)	989 (60·6%)	740 (62·8%)
Antenatal visit 2 (30 days before expected date of delivery)	884 (54·2%)	711 (60·3%)
Number of mothers eligible on day 0*	1474	1055
Postnatal visit 1 (day 0)	1001 (67·9%)	711 (67·4%)
Postnatal visit 2 (day 3)	998 (67·7%)	704 (66·7%)

*Number of mothers who had at least one baby alive on day 0.

Table 2: **Direct household visits by community health workers (overall coverage by intervention arm)**

	Number of participants per activity	Number of activities per month	Monthly coverage
Newborn-care stakeholder meetings	5–6	4	20–24
Community meetings*	18–20	3	54–60
Folk song meetings*	8–10	3	24–30
Community volunteer meetings†	30–35 for entire region (4–6 from each Intervention cluster unit)	1	4–6

*In each of the three or four hamlet groups in the intervention clusters. †Facilitated by regional programme supervisor for his entire region, consisting of 6–7 intervention clusters.

Table 3: **Group interventions (approximate monthly coverage per intervention cluster)**

collected from a randomly selected sample (50%) of all women (n=2757) who had delivered.

Systems were put in place to ascertain pregnancy and birth outcomes in the study population by the independent evaluation team recruited and trained for this purpose. Tracking of all outcomes at 28 days after birth, namely miscarriages, stillbirths, livebirths, and neonatal deaths, in the entire study area, was done by the independent evaluation team. Miscarriage was defined as termination of a self-reported pregnancy before 190 days from the date of the last menstrual period. Stillbirth was defined as a baby born beyond 190 days from the date of the last menstrual period but did not move, breathe, or cry at birth. Neonatal death was defined as death of a liveborn infant within 28 completed days of birth. Perinatal deaths included stillbirths and neonatal deaths within 7 completed days of birth.

As part of the baseline survey, all pregnant women in the study area were identified. Subsequently, a systematic approach was used by the evaluation team to obtain information on pregnancies and outcomes to ensure the accuracy and completeness of the data: pregnancies identified through 3-monthly door-to-door visits (by the *Saksham Sahayaks* in the intervention arms and by the evaluation team in the control arm) were followed-up for an outcome based on expected date of delivery; an active delivery notification system was established with community informants, who notified the evaluation team about deliveries in their village on a daily basis; two door-to-door inquiries on pregnancy outcomes were done, once during and once after the study period, to enumerate and ascertain all outcomes, irrespective of the place of delivery; and any discrepancies were resolved through a follow-up home visit by a supervisor. All livebirths were followed-up through the infant period, and all deaths were recorded.

In a separate survey, all families with stillbirths and neonatal deaths were administered a brief questionnaire by two independent data collectors to differentiate neonatal deaths from stillbirths. In the event of a disagreement, the final decision was made by a supervisor who also administered the questionnaire in the home and reached an independent assessment of whether the death was a stillbirth or neonatal death.

Information on knowledge, attitudes, practices, and constraints regarding maternal care and essential newborn care was collected from July to October, 2006, from 88% of all mothers (n=3400) who had delivered in all study clusters during the implementation phase through a semi-structured format designed to minimise respondent bias.

All data forms underwent scrutiny for logical inconsistencies, skip patterns and missing values. The data were coded and double-entered into a relational database on Microsoft Access 2000. The data entry interface was designed to check for referential integrity, missing values and acceptability constraints. Errors identified at any level were referred back to the field for correction.

Statistical analysis

Based on national rural estimates, we assumed an average of 122 births would occur per cluster during the planned intervention period (crude birth rate 26·2 per 1000 population×3500 population per cluster×1·33 years) and a neonatal mortality rate of 60 per 1000 livebirths with an intercluster coefficient of variation (k) of 0·083.[23] The corresponding estimate of intraclass correlation was 0·0012. Assuming a loss to follow-up of 10%, for detecting a 40% reduction in neonatal mortality rate in each intervention arm compared with the control arm over 16 months with 80% power at 5% significance level, we estimated a sample size requirement of 13 clusters per study arm.[28] Since the ThermoSpot device was not postulated to reduce neonatal mortality, but rather was thought to result in a 20% improvement in identification of hypothermia by care providers (results to be reported separately) and to possibly influence care-seeking, no comparison of neonatal mortality rate between the two intervention arms was planned.

Preliminary masked analysis on neonatal mortality rates was done in March, 2005, at the first meeting of the data and safety monitoring board. On internal unmasking

of the cluster assignment to the three intervention arms by the monitoring board, and subsequent analysis at the individual level, the board recommended completion of the planned study duration, final measurement, and analysis. The intervention was continued until May 15, 2005, to complete 16 months of the trial, as planned from the outset, and to include all women who had already been given antenatal visits.

Primary analysis was undertaken as intention to treat at cluster level. All usual residents of a household who had resided in the study area for 15 days or more in succession during the 6 months before delivery, and delivered during the study period were considered eligible for analysis, irrespective of the place of delivery. Analysis was done at cluster level using SPSS 15.0.

There was no prespecified plan for statistical analysis; however, we have used conservative analytical methods. The baseline covariates used for adjustment were identified before the adjusted analysis was done. To account for clustering, point estimates for stillbirth rates, neonatal mortality rates, and perinatal mortality rates for each study arm were calculated as the mean of cluster event rates, giving an equal weight to each cluster.[29] The intervention was not considered to affect miscarriage rates, thus no comparison of miscarriage rates across study arms was undertaken. Neonatal and perinatal

	Cluster mean (%)			Rate ratio (95% CI)	
	Essential newborn care	Essential newborn care plus ThermoSpot	Control	Essential newborn care *vs* control	Essential newborn care plus ThermoSpot *vs* control
Care during pregnancy					
Routine antenatal care check-up (≥1)* (A·1)	26·4	21·9	14·4	1·84 (1·08–3·14) p=0·03	1·52 (0·91–2·53) p=0·09
Tetanus toxoid vaccination (≥2) (A·2)	94·4	94·7	91·8	1·03 (1·00–1·06) p=0·09	1·03 (1·00–1·07) p=0·10
Maternal care-seeking (A·3)					
Auxillary nurse midwife/nurse	37·6	38·5	26·5	1·42 (1·09–1·85) p=0·02	1·45 (1·13–1·87) p=0·007
Primary health centre doctor	35·8	34·4	36·9	0·97 (0·78–1·21) p=0·78	0·93 (0·73–1·20) p=0·58
Unqualified medical practitioner	40·9	38·6	47·9	0·85 (0·70–1·05) p=0·15	0·81 (0·64–1·02) p=0·09
Traditional healer	0·4	0·5	0·9	0·45 (0·11–1·78) p=0·29	0·52 (0·11–2·59) p=0·42
Others†	1·8	2·7	5·7	0·33 (0·13–0·83) p=0·05	0·47 (0·23–0·96) p=0·11
Newborn care					
Birth preparedness					
Preparation of room of confinement (1·1)	18·3	25·8	11·9	1·54 (1·13–2·09) p=0·02	2·18 (1·66–2·84) p=0·0001
Identification of health facility (1·2)	13·9	12·1	4·1	3·43 (2·12–5·54) p<0·0001	2·99 (1·93–4·63) p<0·0001
Previous identification of birth attendant (1·3)	51·9	53·5	44·6	1·16 (0·99–1·37) p=0·06	1·20 (1·02–1·41) p=0·03
Identification of delivery supervisor (1·4)	25·1	21·3	4·3	5·79 (4·16–8·06) p<0·0001	4·93 (3·45–7·03) p<0·0001
Identification of newborn attendant (1·5)	21·7	16·5	4·4	4·94 (3·19–7·63) p<0·0001	3·75 (2·39–5·87) p<0·0001
Previous arrangement of money (1·6)	23·7	24·1	15·3	1·55 (1·15–2·09) p=0·009	1·58 (1·17–2·12) p=0·007
Arrangement of mattress for newborn babies (1·7)	47·1	49·0	31·1	1·51 (1·19–1·93) p=0·001	1·58 (1·24–2·01) p=0·0004
Arrangement of clothing for thermal care of newborn babies (1·8)	74·2	77·5	59·6	1·25 (1·10–1·41) p=0·001	1·30 (1·15–1·46) p=0·0001
Hygienic delivery and immediate newborn care					
Place of delivery (2·1)					
Home	78·8	80·3	84·3	0·93 (0·86–1·02) p=0·14	0·95 (0·87–1·05) p= 0·32
Health facility	19·7	18·0	14·0	1·41 (0·93–2·13) p=0·08	1·29 (0·83–2·02) p=0·25
Others (on the way)	1·5	1·7	1·7	0·87 (0·33–2·33) p=0·79	0·96 (0·35–2·60) p=0·93
Delivery attendant (2·2)					
Family member(s)/village person(s)	60·2	57·9	62·6	0·96 (0·85–1·09) p=0·56	0·92 (0·78–1·09) p=0·37
Traditional birth attendant	6·5	7·7	10·3	0·63 (0·39–1·01) p=0·11	0·76 (0·44–1·29) p=0·33
Unqualified medical practitioner	0·1	0·6	0·7	0·13 (0·02–1·09) p=0·08	0·80 (0·22–2·88) p=0·74
Qualified doctor/auxillary nurse midwife/nurse	26·7	27·1	19·7	1·36 (0·92–1·99) p=0·11	1·38 (0·91–2·08) p=0·13
Unattended deliveries	6·6	6·7	6·8	0·96 (0·72–1·29) p=0·80	0·99 (0·65–1·50) p=0·96
Delivery in hands (2·3)	47·2	41·2	16·2	2·91 (2·39–3·53) p<0·0001	2·54 (2·08–3·10) p<0·0001
Wiping of whole body (2·4)	92·7	92·4	18·4	5·05 (4·20–6·06) p<0·0001	5·03 (4·18–6·03) p<0·0001
Covering/wrapping newborn (2·5)	22·9	21·4	15·8	1·45 (1·17–1·81) p=0·002	1·36 (1·05–1·75) p=0·03

(Continues on next page)

	Cluster mean (%)			Rate ratio (95% CI)	
	Essential newborn care	Essential newborn care plus ThermoSpot	Control	Essential newborn care *vs* control arm	Essential newborn care plus ThermoSpot *vs* control arm
(Continued from previous page)					
Thermal care including skin-to-skin care					
Bathing within 24 h (3·1)	18·3	20·6	68·1	0·27 (0·23–0·31) p<0·0001	0·30 (0·27–0·34) p<0·0001
Skin-to-skin care within 24 h (3·2)	84·9	85·5	10·0	8·49(6·58–10·93) p<0·0001	8·55 (6·64–10·98) p<0·0001
Baby covered/clothed during massage (3·3)	5·6	5·9	2·4	2·27 (1·13–4·57) p=0·02	2·42 (1·16–5·06) p=0·03
Umbilical cord care and skin care					
Tying cord within ½ h of birth (4·1)	85·5	82·8	78·6	1·09 (1·00–1·18) p=0·06	1·05 (0·96–1·16) p=0·31
Cutting of cord within ½ h of birth (4·2)	36·1	40·8	31·7	1·14 (0·88–1·47) p=0·31	1·29 (0·97–1·71) p=0·08
Cord cut with clean blade (4·3)	69·1	67·3	58·7	1·18 (1·06–1·31) p=0·006	1·15 (1·02–1·29) p=0·03
Re-tying cord (4·4)	46·7	45·5	78·1	0·60 (0·47–0·76) p=0·0001	0·58 (0·49–0·70) p<0·0001
Application of ash/clay on cord (4·5)	38·9	36·1	60·9	0·64 (0·52–0·79) p=0·0003	0·59 (0·51–0·70) p<0·0001
Application of clay on body (4·6)	19·2	16·6	35·2	0·55 (0·37–0·80) p=0·005	0·47 (0·30–0·74) p=0·002
Breastfeeding					
Pre-lacteal feed (5·1)	38·4	33·5	79·9	0·49 (0·42–0·57) p<0·0001	0·43 (0·39–0·47) p<0·0001
Breastfeeding in <1 h of birth (5·2)	70·6	67·6	15·5	4·57 (3·38–6·15) p<0·0001	4·37 (3·23–5·90) p<0·0001
Danger sign recognition and care–seeking					
Reported any illness during the newborn period (6·1)	21·9	21·8	30·0	0·73 (0·60–0·88) p=0·004	0·73 (0·58–0·91) p=0·01
Care-seeking providers used (6·2)					
Auxillary nurse midwife/nurse	2·4	4·6	3·2	0·76 (0·24–2·39) p=0·09	1·45 (0·53–3·94) p=0·08
Doctor	22·1	28·7	13·5	1·63 (0·94–2·85) p=0·07	2·13 (1·16–3·89) p=0·01
Unqualified medical practitioner	33·1	29·2	46·7	0·71 (0·56–0·89) p=0·03	0·62 (0·41–0·95) p=0·02
Traditional healer	14·4	17·7	16·2	0·89 (0·58–1·37) p=0·09	1·10 (0·66–1·80) p=0·10
Others†	8·6	9·6	6·4	1·33 (0·66–2·69) p=0·11	1·49 (0·74–2·97) p=0·12

Measurement indicator number shown in parentheses after indicator. *Definition of antenatal care differed in endline and baseline surveys. Routine antenatal care was considered if the pregnant woman visited a governmental or private health-care facility for antenatal care and it included any two of blood pressure measurement, weighing, and abdominal examination. †Family members, relatives, or village person.

Table 4: **Comparison of practice indicators by study arm**

mortality rates were adjusted for standard of living index,[23] religion, and caste at the cluster level using Poisson regression.[30,31] The intervention effect was estimated using the rate ratio (RR), and 95% CI for the RRs were calculated on a logarithmic scale using a Taylor series approximation.[29,30] An unpaired *t* test on the cluster event rates at 5% significance level was used to test the intervention effect.[31]

For the analysis of practice indicators, all live singleton births (ie, not multiple births) were included from the endline survey on knowledge, attitudes, practices, and constraints. The estimation of rates (unadjusted for baseline covariates), RR, CI, and test of significance for practice indicators was done using the approach outlined above for the mortality analysis.

Role of the funding source

The funding sources 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

The trial profile is shown in figure 2. Pregnancies identified (28·6 per 1000 population) and crude birth rate (26·6 per 1000 population) did not differ statistically across the three arms.

Key baseline characteristics for the three study arms were similar (table 1). The study population was predominantly Hindu with around half from scheduled castes and tribes (ie, the lowest caste designation), roughly a third had low standard of living index, and literacy in the female reproductive age group was below 40%. Routine antenatal care (ie, seeking antenatal care at a health facility where all three of blood pressure, fundal height, and weight gain were recorded) was low (<10%), more than 90% of deliveries occurred at home and less than 15% were attended by a skilled birth attendant. The 1-year retrospective neonatal mortality rates across the three groups were similar.

Among all eligible women, coverage of antenatal visits was around 60% and postnatal visits around 65% in both intervention arms (table 2). Estimates of monthly coverage of community meetings, folk song meetings, and meetings with newborn-care stakeholders and

	All births					Singleton births				
	Essential newborn care	Essential newborn care plus ThermoSpot	Control	Rate ratio (95% CI)		Essential newborn care	Essential newborn care plus ThermoSpot	Control	Rate ratio (95% CI)	
				Essential newborn care *vs* control	Essential newborn care plus ThermoSpot *vs* control				Essential newborn care *vs* control	Essential newborn care plus ThermoSpot *vs* control
Documented births, N	1581	1135	1143	..		1537	1110	1115	..	..
Livebirths	1522	1087	1079	..		1482	1065	1054	..	..
Stillbirths	59	48	64	..		55	45	61	..	..
Neonatal deaths in singletons, n	64	48	91	..		51	44	83	..	..
Early (0–6 days)	53	36	67	..		42	32	62	..	..
Late (7–28 days)	11	12	24	..		9	12	21	..	..
Mortality rates (mean of cluster event rates)										
Stillbirths per 1000 births	39·1	46·1	54·1	0·72 (0·52–1·00) p=0·06	0·85 (0·56–1·29) p=0·44	38·0	43·9	53·1	0·72 (0·51–1·01) p=0·06	0·83 (0·54–1·26) p=0·37
Neonatal deaths per 1000 livebirths	41·0	43·2	84·2	0·49 (0·36–0·82) p=0·0001	0·51 (0·36–0·73) p=0·001	33·1	41·1	79·1	0·42 (0·30–0·58) p=0·0001	0·52 (0·36–0·75) p=0·002
Adjusted neonatal deaths per 1000 livebirths	..	..	..	0·46 (0·35–0·60) p=0·0001	0·48 (0·35–0·66) p=0·0001	..	..	..	0·44 (0·33–0·59) p<0·0001	0·50 (0·36–0·69) p=0·0003
Perinatal deaths per 1000 births	72·2	77·9	113·2	0·64 (0·49–0·82) p=0·002	0·69 (0·51–0·93) p=0·02	64·1	73·7	109·9	0·58 (0·44–0·77) p=0·001	0·67 (0·49–0·93) p=0·02
Adjusted perinatal deaths per 1000 livebirths	..	..	..	0·59 (0·47–0·74) p<0·0001	0·62 (0·47–0·81) p=0·0001	..	..	..	0·54 (0·38–0·76) p=0·0002	0·53 (0·38–0·73) p=0·0001

Table 5: **Comparison of mortality rates by study arms**

community volunteers are shown in table 3.

Although not directly targeted, an improvement was observed in antenatal care coverage through formal health sector providers in the essential newborn care arm versus the control arm (table 4). Large improvements were seen in multiple aspects of birth preparedness. There was no significant increase in institutional deliveries and deliveries by a skilled birth attendant in the intervention arms.

Significant improvements were seen with targeted newborn-care practices, including wiping the whole body of the infant immediately after delivery, deferment of bathing until after the first 24 h, initiation of skin-to-skin care within 24 h, and covering the baby after birth and during massage. Significant improvement was seen in cutting of the umbilical cord with a clean blade and avoidance of application of potentially harmful substances to the umbilical cord such as ash or clay, and use of clay to rub the skin to remove vernix. We noted a reduction in pre-lacteal feeding; conversely, initiation of breastfeeding within 1 h of birth was significantly increased in the intervention arms compared with the control arm. Maternal report of neonatal illness and care-seeking from unqualified medical practitioners was reduced in the intervention arms; roughly a third of mothers of sick newborn babies who sought care went to qualified providers such as doctors, nurses, or auxillary nurse midwives.

Both unadjusted and adjusted neonatal and perinatal mortality rates showed significant reductions in both intervention arms (table 5). Adjusted neonatal mortality rate was 54% lower in the essential newborn care arm than the control arm (RR 0·46, 95% CI 0·35–0·60, p=0·0001) and 52% lower in the essential newborn care plus ThermoSpot arm than the control arm (RR 0·48, 95% CI 0·35–0·66, p=0·0001).

Discussion

A behaviour change management appraoch that promoted interventions to prevent high-risk newborn-care practices, targeted at multiple stakeholders within communities, led to substantial behavioural modification and reduced neonatal mortality. The intervention was developed and implemented based on findings

from formative research, with active participation of community members throughout the research cycle, thus addressing the fundamental need for people to be involved in decisions affecting their lives, and also building community capacity for sustained action. The study highlights the importance of understanding the existing sociocultural context for translating scientific evidence into effective and sustainable delivery strategies at the community level.

The intervention that included the use of the ThermoSpot did not seem to have an advantage over the package of essential newborn care. However, in other settings, and for a lower intensity intervention with fewer visits by trained community workers, the ThermoSpot might still offer an advantage for timely recognition, prevention, and management of hypothermia.

Although a cluster-randomised controlled trial is considered the most valid design for studies of this nature, it is not without methodological limitations and biases.[32–34] Firstly, as a random effect, the clusters allocated to the essential newborn care arm contained a greater number of households, and therefore, more birth outcomes. However, we used the *t* test, which is robust to departures from underlying assumptions of both homogeneity of variance and normality.[35] Secondly, there were more low-caste households in the essential newborn care arm than in the control arm. Since there is evidence that caste could be associated with neonatal mortality,[10] we did an adjusted analysis which produced results similar to the unadjusted analysis. Thirdly, pregnancy identification was done by the *Saksham Sahayaks* in intervention clusters as a routine part of programme implementation, and by the independent evaluation team in control clusters to ensure programmatic relevance and scalability. This activity helped the *Saksham Sahayaks* to build trust and rapport with community members, facilitated access to the room of confinement during the critical early newborn period and negotiation during scheduled home visits, and probably enhanced programme effectiveness. The potential for bias was kept to a minimum by collating and triangulating information from two other independent and complementary sources in addition to uniform outcome tracking by the evaluation team. The fact that the crude pregnancy rates and crude birth rates recorded in the three arms were similar, and very close to figures reported from other surveys,[23] is indicative of the robustness and completeness of data collection. Fourthly, although there was no prespecified mortality analysis plan at the outset of the study, we have used conservative analytical methods recommended for analysis of cluster randomised controlled trials. Fifthly, in the sample size calculation, the estimated intraclass correlation value was small. However, other assumptions were conservative. The p values obtained and the narrow confidence intervals with upper bounds well below 1, support the study findings.

The programme management system and organisational culture, though seldom described with any level of detail, are important processes that have a bearing on the effect of the study.[25] The primary implementers of the programme, the *Saksham Sahayaks*, were literate, village-based men and women whose compensation was similar to existing community-based workers in India. They were carefully selected, trained, and supervised, and systematically evaluated and rewarded.[25] Home visits, although few, were strategically timed, and together with group meetings, led to stepwise capacity building of families through multiple exposures to the intervention package. Intervention in the room of confinement on day 0 was critical and presented a substantial barrier, particularly for male *Saksham Sahayaks*, which was successfully breached through community engagement and acceptance, ensuring early change of practices.[26] Community volunteers and existing newborn-care stakeholders supported and supplemented the activities of the *Saksham Sahayak*, ensuring greater reach and rapid social legitimisation, and favouring sustainability. Thus, the coverage figures for household visits by the *Saksham Sahayak* underestimate the extent to which families were exposed to the intervention. The trial was designed to be an efficacy study of a model approach to promotion of preventive essential newborn care, and, therefore, the programme execution standards were probably better than those within the existing public health system. The effect of this approach at scale and in regions with low neonatal mortality rates is not known, but effectiveness might be expected to be diminished.

A marked improvement was seen in both intervention arms for most practices that were identified as high risk for neonatal mortality (webtable 1 and table 4). Because the intervention package was designed to minimise the risks of hypothermia and sepsis (webtable 1), mitigation of a combination of risk factors for these causes of death seemed to have contributed to the reduction in neonatal mortality rate. The study design involving implementation of a package of essential newborn care, however, limits us from quantifying the mortality reduction attributable to specific practices. Care-seeking seemed to have a small role, however, since only routine antenatal care increased and only in one of the intervention arms. Nor could we segregate the effect of the behaviour change approach, which, besides leading to changes in practices, also led to increased social capital, gender equity, and community empowerment, which will be examined separately.[36]

The intervention design sought to combine an evidence-driven intervention with community participation and ownership.[37] The findings indicate that barriers to behaviour change need to be negotiated through a path of least resistance to change, and that individuals can be led through a process of reasoning

based on their own cultures,[38] which can lead to a better understanding, retention, and acceptance of the intervention package. An intervention of this nature could possibly act through a more complex sociobiological pathway than more readily understood linear principles of causation based on biomedical risk factors and corresponding interventions.

Our findings validate those of *The Lancet* Neonatal Survival series and indicate that an initial focus on preventive family and community interventions can bring about early success in reducing neonatal mortality while working to strengthen health systems.[1] The proposed strategy has a short operational gestation period and is compatible with an evolving public health system aimed at increasing access and care at health facilities. These results also corroborate those of other studies of community-based newborn care,[2–6,8] and of behavioural research,[39–42] which have also shown that social networks are an important field of influence, and that targeting multiple levels of community stakeholders to shape community norms along with household practices is crucial. The inclusion of men in educational interventions also has a greater effect on targeted behaviours associated with maternal health than educating women alone.[43]

Regions with high neonatal mortality rate and high prevalence of preventable high-risk practices are potentially poised to benefit from application of the principles of this study. The National Rural Health Mission in India offers a unique opportunity for scaling-up newborn survival in India. We are studying the effect of the approach used in the current trial when implemented by the Shivgarh community, with little input from the project staff. Meanwhile, the current strategy has been adopted for scale-up as a flexible framework for intervention development. The approach has been integrated into the child survival programme of Uttar Pradesh, and currently is being scaled-up to a population of over 30 million through the public health system, using trained Accredited Social Health Activists to promote the package of preventive essential newborn care.

Contributors

Initial draft of the paper was written by VK, AK, and GLD. All other authors provided feedback on drafts of the paper. GLD and VK were responsible for the conception of the study and primarily responsible for the overall supervision and implementation of the trial. VS and PS were responsible for programme implementation and SM coordinated programme evaluation activities. RPM, S Ah, and AK conducted the quantitative analyses. MB, MS, REB, S Aw, AHB, GKM, JVS, and RCA provided technical inputs to programme development and implementation.

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Conflict of interest statement

We declare that we have no conflict of interest.

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