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Effect of home-based childcare on childhood mortality in rural Maharashtra, India: a cluster randomised controlled trial

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ABSTRACT

Background Melghat, an impoverished rural area in Maharashtra state, India; has scarce hospital services and low health-seeking behaviour. At baseline (2004) the under-five mortality rate (U5MR) (number of deaths in children aged 0–5 years/1000 live births) was 147.21 and infant mortality rate (IMR) (number of deaths of infants aged under 1 year/1000 live births) was 106.6 per 1000 live births. We aimed at reducing mortality rates through home-based child care (HBCC) using village health workers (VHWs).

Methods A cluster-randomised control trial was conducted in 34 randomly assigned clusters/villages of Melghat, Maharashtra state, between 2004 and 2009. Participants included all under-five children and their parents. Interventions delivered through VHWs were patient–public involvement, newborn care, disease management and behaviour change communications. Primary outcome indicators were U5MR and IMR. Secondary outcome indicators were neonatal mortality rate (NMR) (number of neonatal deaths aged 0–28 days/1000 live births) and perinatal mortality rate (PMR) (number of stillbirths and early neonatal deaths/1000 total births). Analysis was by intention-to-treat at the individual level. This trial was extended to a service phase (2010–2015) in both arms and a government replication phase (2016–2019) only for the intervention clusters/areas (IA).

Findings There were 18 control areas/clusters (CA) allocated and analysed with 4426 individuals, and 16 of 18 allocated IA, analysed with 3230 individuals. The IMR and U5MR in IA were reduced from 106.60 and 147.21 to 32.75 and 50.38 (reduction by 69.28% and 65.78%, respectively) compared with increases in CA from 67.67 and 105.3 to 86.83 and 122.8, respectively, from baseline to end of intervention. NMR and PMR in IA showed reductions from 50.76 to 22.67 (by 55.34%) and from 75.06 to 24.94 (by 66.77%) respectively. These gains extended to villages in the service and replication phases.

Interpretation This socio-culturally contextualised model for HBCC through VHWs backed up with institutional support is effective for significant reduction of U5MR, IMR and NMR in impoverished rural areas. This reduction was maintained in the study area during the service phase, indicating feasibility of implementation in large-scale public health programmes. Replicability of the model was demonstrated by a linear decline in all the mortality rates in 20 new villages during the government phase.

Trial registration number NCT02473796.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A Cochrane review of integrated community case management programmes revealed scarcity of effective, replicable, scientifically sound, community health worker driven, intervention model in the rural tribal community of India and developing countries for reducing very high under-five mortality rate (U5MR) and infant mortality rate (IMR).

WHAT THIS STUDY ADDS

⇒ This cluster randomised controlled trial with robust study design, sound scientific base, using an integrated approach of home-based newborn care, post-neonatal infectious disease management, antenatal care and behaviour change communication in the intervention arm had a significant impact on U5MR, IMR, neonatal mortality rate and perinatal mortality rate in an impoverished area that was sustained for 10 years following the trial, compared with the standard of care clusters.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Government policies can be framed for wider, long-term and sustainable replication of this community-based childcare model via community health workers for reducing U5MR and IMR in rural, difficult to access, impoverished areas of world with scarcity of health services and low health-seeking behaviour.

INTRODUCTION

Globally it has been estimated that there were 5.2 million under-5 years childhood deaths in 2019[1] of which 20% occurred in India.[2] In India in 2004, the mortality rates/1000 live births were U5MR (number of deaths

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in children aged 0–5 years/1000 live births): 76,[1] IMR (number of deaths of infants aged under 1 year/1000 live births): 58[1] and NMR (number of neonatal deaths aged 0–28 days/1000 live births): 38.8[2] and NMR in 2001 was 37.9.[3] In contrast the IMR for industrialised countries was 5.0 in 2005.[4] Infant mortality remains an important measure of social well-being. While diarrhoea, pneumonia, malaria and under nutrition are common preventable causes of post-neonatal deaths in rural India, the major reason for these high rates are persistent difficulties in access to treatment and in navigation of the referral pathways.[1 5] Even after accessing health facilities, the quality of care in most rural areas in low-income and middle-income countries (LMICs) is poor.[6] Despite the development of the WHO guidelines for care at first level facilities and hospitals,[7] most countries in LMICs, do not have well-functioning health systems that reach rural areas where mortality is highest.[8] The cost of even outpatient care can push marginalised families into poverty, since 'free care' is rarely available.[9] Health facilities alone are ineffective at averting a large proportion of childhood deaths in rural areas.[10] Quality neonatal care is not available to most neonates in LMICs because hospitals are inaccessible and costly.[11] A combination of community outreach and health system strengthening would be necessary to reduce child deaths in rural India.[12]

Though the Indian U5MR and NMR have declined between 2000 and 2015 (U5MR=46.6, NMR=27),[13] there are remarkable disparities between rural and urban areas, between poorer and richer districts.[14] We found that IMR in India reduced from around 80 to 34 per 1000 live births at the national level from 1990 to 2016.[15] In 2004, just prior to start of the study, the rural population in India constituted 71.1% of Indian population and the U5MR varied between 8 and 131.5, while NMR varied between 3.8 and 84, in New Delhi and Odisha (tribal dominated state), respectively.[16] HBNC interventions have been shown to prevent 30%–60% of newborn deaths in high-mortality settings,[17] and the WHO recommends community-based preventive and curative care for high risk and poor populations by CHWs supported by the health system with focused training.[18 19]

We present results of a 15 years HBCC study in a rural area of India that started as a cluster randomised control trial (cRCT) (2004–2010), had a service phase (2011–2015) and a replication phase (2016–2019).

METHODS

Study design and participants

We conducted a community based, cRCT of HBCC, in rural Melghat, Maharashtra, India. Since interventions were administered by VHWs at the village level, a village was defined as a cluster unit to minimise treatment contamination between intervention and control groups.[20]

The study area, Melghat is spread over 4000 km^2, in 320 villages, with a population of 280 000. A baseline survey revealed widespread faulty child-rearing practices, large family sizes, treatment by traditional faith healers and low health-seeking behaviour.[21] The government healthcare system consists of: (a) subcentre staffed with one paramedical worker per 4–5 villages, (b) a primary health centre (PHC) for 30 villages manned by a physician. (The physician to population ratio was >1:10 000). The average distance of PHCs from villages was 19 km. Every village participated in the Integrated Child Development Scheme (ICDS) providing food supplementation, immunisation, deworming and oral rehydration solution (ORS) to all under-fives.[22]

Hypothesis

Cluster-level objectives were to reduce the U5MR and IMR from 147.21 to 106.60/1000 live births, respectively, by at least 35% in the usual resident population of 14 120 in 16 villages of Melghat over 5 years.

Patient and public involvement

Aim of patient and public involvement in the study

Our survey-based analysis (year 2002–2003) of very high U5MR in Melghat revealed that the existing policies, healthcare system and government interventions were malaligned to the community's needs and socio-cultural practices, resulting in low healthcare seeking behaviour. A survey was done to understand the underlying causes of the very high U5MR in Melghat. Hence, we included community participation and patient and public involvement (PPI) as a critical part of the intervention to reduce U5MR and IMR.

Description of the methods used for PPI

The public was first involved through gramsabha/community meetings with >60% of adults in the villages in attendance. We obtained informed written consent from the community members present at these meetings, that were designed to explain the aims and methods to be used in the research study. The principal investigator and the study team conducted these meetings to understand the community's needs, their demand for health services, as well as acceptable and approachable methods for service delivery. Our team conducted door-to-door surveys to understand the health problems, priorities, along with the most important and common causes of deaths. After this, we discovered that the community wanted easily accessible, free, culturally acceptable services from a person who knew the local language and traditions and who respected the community and understood its problems. They identified HBCC as the most urgent need. Thus the experience, preferences and health needs of community members were used to design the methodology of the study. We worked in close association with the traditional health system (ie, birth attendants, community leaders and traditional faith healers).

We conducted all our interventions in the community in accordance with their requests, respecting their culture, traditional practices, language and socioeconomic conditions. The women showed reluctance for hospital-based delivery and newborn care. They preferred delivery by

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traditional birth attendants (TBAs). Hence, the HBCC programme was implemented by trained tribal, socially sensitive, female VHWs who provided culturally acceptable good quality care and BCC in the local dialect. Our trained TBAs provided safe and hygienic home deliveries.

Subsequently informed written consent was obtained from parents of all study children who participated in the trial, prior to any study related interventions.

Recruitment in the study

Local tribal VHWs recruited study participants from the community in which they lived.

Outcome selection by PPI

After intensive community meetings and surveys, we realised that the high under-five mortality was a health priority of the community. Hence, we kept U5MR and IMR as the primary outcome measures.

The extent to which PPI influenced the study overall

With the help of PPI, we could plan culturally acceptable, easily accessible and affordable interventions following community needs. Community participation played a crucial role in understanding the problems and appropriate solutions to solve them. PPI also helped to sustain our study for 17 years. The government assisted in replication of our PPI model in the 20 new villages.

PPI involvement in dissemination of the study results to participants and linked communities

The community selected VHWs, TBAs and key persons in the villages to implement our interventions and share results during gramsabhas once every 4 months and to mobilise the community for our programme.

Inclusion and exclusion criteria

The participants were under-five children, their parents and pregnant women who were permanent residents of 34 study villages in Melghat. Children migrating with parents and leaving the study area for more than 6 months were considered as having migrated permanently, and were excluded from the analyses.

Randomisation and masking

Dharni block of Melghat, consisting of 160 villages, was divided into five zones. The sample size required 36 villages (clusters). Eight villages from each zone were randomly selected and two more villages from neighbouring Chikhaldara block were randomly added using a lottery method by a member of the study community in order to generalise the results beyond our block and to understand the impact on different blocks, with a different administrative structure. Out of these 42 clusters, 36 clusters were selected based on their willingness to participate. The clusters were block stratified according to their distances from the base hospital (<5 km, 5–25 km and >25 km). A random allocation sequence assigned clusters to the intervention arm (IA) and control arm (CA) by an external person. The allocation was masked, concealed and based on clusters and not on individuals. Participants were blinded after assignment to interventions. Infants and children in both the CA and IA received standard care following Government of India guidelines at its village, PHC and hospitals. In addition, IA received supervised HBCC assigned by investigators.

The de-facto method[23] was used for calculation of mortality rates. All births and deaths actually occurring in the clusters or hospitals from IA and CA were included. A complete enumeration methodology was used to include all under-fives and pregnant women in clusters. The VHWs collected the vital events in the two arms by prospective door-to-door surveys of the households within 24 hours of the event. They filled the death and birth forms, confirmed by the parents or near relatives in the absence of parents, who signed the forms. Each vital event was confirmed by a data collection supervisor (within 15 days) and a retrospective surveyor (within 6 months) by door-to-door visits to the household. All vital events were further confirmed by a sarpanch (elected village head) and a police patil (government appointed village key person) within 15 days of the event. We also collected vital data from government health and the ICDS records, to supplement any missing vital data. Verbal autopsies were conducted to by data collection supervisors and VHWs. Deaths were verified by the, sarpanch and police patil. While implementation could not be masked due to the visible nature of the intervention, boundaries to limit communication between the two arms were closely monitored. Patients living in the CA were not treated in the IA during the research phase.

After obtaining community consent to do the trial, approval from the MAHAN independent ethical committee was obtained. Informed written consent was obtained from the parents of all infants and children who participated in the study. The study was registered with ClinicalTrials.gov.

Study phases

Baseline phase: January 2004–December 2004

Microplanning

Participatory community meetings were held at the start of the study (online supplemental annexure-1) that provided an introduction of the study to the community, invited their collaboration, identified resources for child health and finally resulted in obtaining written community consent from village elders at both IA and CA. Interventions were based on inputs from qualitative focus group discussions and surveys regarding high-risk behaviours for child mortality, potential barriers to implementation and taking into consideration factors affecting behaviour change. The study team activities in CA were: (a) consent of villagers, (b) census, (c) village mapping at the beginning of the research phase, (d) collection of vital statistics, for example, death, birth, verbal autopsies to define the causes of deaths during the entire research and service phases and (e) anthropometry at the baseline and at the end of the research phase (online

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supplemental annexure-1). Consent was needed in the control area as we were collecting (a) census data, (b) personal vital data of birth, deaths and cause of deaths and (c) anthropometry of children.

Selection and trainings of field workers

VHWs, data collection supervisors, medical supervisor, BCC supervisors, programme manager, retrospective surveyors and TBAs as external stakeholders (online supplemental annexure-2) formed the field team in IA. External stakeholders were from the clusters but were not paid workers of MAHAN trust. They assisted our HBCC programme to achieve its objectives. VHWs, data collection supervisors, programme manager and retrospective surveyors formed the field team in CA. The VHWs were local, tribal, married, semiliterate, socially sensitive women selected through community meetings. VHW's received monthly trainings, details of which are provided in online supplemental annexure-2.

Data collection

VHWs conducted a census and baseline survey regarding births, under-five deaths, maternal and child healthcare practices and demographic information in January 2004. They were supervised by data collection supervisors. Similar information was verified from government agencies, parents, cluster heads and independent retrospective surveyors to detect any missed events. Verbal autopsies of all under-five deaths were conducted by supervisors and VHWs, and reviewed by two physicians using standard methods.[24] A third physician adjudicated discrepancies.

Baseline data verification was done by the Rajmata Jijau Mother and Child Health and Nutrition Mission (RJMCHNM) of the state government and UNICEF.[25] Data monitoring and safety was performed by the State Tribal Department. Finally, a third-party evaluation was conducted by the Government Medical College, Aurangabad, India.

In the implementation arm of the study, the population size was 13 150 during the implementation/research phase, 10 932 during the service phase and 29 335 during the replication phase. The number of VHWs in the implementation arm were 24 during the research phase, 20 during the service phase and 42 during the replication phase.

Intervention phase: January 2005–December 2009

Interventions were delivered by VHWs, implemented in a sequential phase-wise manner and continued subsequently. All VHWs were trained monthly in the first year with refresher trainings 2 monthly until the end of the study (online supplemental annexure-2).

Subphase 1: January 2005–December 2009

Community-based management of acute respiratory infections, diarrhoeal illness and malaria, in post-neonatal under-fives was done using co-trimoxazole (for pneumonia), ORS (for diarrhoea) and Furoxone/norfloxacin (for unresponsive diarrhoea), metronidazole (for dysentery) and chloroquine syrup (for malaria) respectively, as per guidelines (online supplemental annexure-3).

Subphase 2: November 2006–December 2009

Implementation of antenatal, natal and newborn care was added to the above post-neonatal management (online supplemental annexure-4). Briefly, VHW's conducted three home visits and examined each pregnant mother, encouraged her to avail facility care and provided iron and calcium supplements. Tetanus immunisation was given by the auxiliary nurse midwife. Pregnancy-induced hypertension and pedal oedema were monitored and paid special attention. Clean and safe home deliveries[26 27] were conducted by trained TBAs assisted by trained VHWs. High-risk pregnant women were referred to hospitals.[28–30] At birth the VHWs recorded neonatal observations and the birth weight, kept the baby warm, applied Gentian violet (1%) to the umbilical cord, administered 1 mg vitamin K_1 intramuscularly and initiated early breast feeding. Subsequently VHW's did 7 or 13 household visits to normal or high-risk newborn, respectively, within 28 days of birth and weekly thereafter. At subsequent household visits, breast feeding was observed, advise was given to mothers to keep babies warm and babies were observed for danger signs of illness and received care as outlined below. VHWs provided high-risk newborn care for low-birth weight and premature babies and for hypo–hyperthermia and breast-feeding problems. They maintained asepsis and provided referral if required. VHWs identified babies with prematurity defined as a gestational age at birth of <37 weeks.[31–35] Expected date of delivery (EDD) was calculated from last menstrual period. VHWs maintained an EDD calendar. Low birth weight was defined as a birth weight of ≤2500 g.[36] The weight was measured by VHWs and confirmed by medical supervisors using a salter or electronic weighing scale.

Subphase 3: May 2007–December 2009 online supplemental annexure-4

Birth asphyxia was managed by mouth–nose suction using an oral mucus sucker, tactile stimulation, Ambu bag and mask ventilation.[37]

Neonatal sepsis was diagnosed clinically[38 39] by the simultaneous presence of two of seven signs (poor sucking; weak cry; limp extremities; vomiting or abdominal distension; convulsions, altered consciousness; severe chest indrawing; umbilical infection) and babies were referred immediately to the hospital. When hospital referral was not accepted, syrup cotrimoxazole and intramuscular gentamicin were administered by the VHW following WHO guidelines.[40 41]

BCC was conducted for health, hygiene, infant and young child feeding, malnutrition, antenatal and newborn care, breast feeding, diarrhoea, malaria, pneumonia and growth.

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We extended the intervention to only the intervention areas during the service phase and the replication phase.

Service phase: January 2010–December 2015

The healthcare delivery by VHWs was continued in the IA with supervision by supervisors. We continued data collection in CA and IA.

Replication phase: September 2016–August 2019 (Only for the IA)

The Government of Maharashtra (India) validated the replicability of interventions for reducing NMR, IMR and U5MR by randomly adding 20 new villages (population: 19 437) from Dharni block. The government adopted the same methods used in the service phase for these villages with our collaboration. An integrated accelerated approach of simultaneous implementation of all interventions was adopted following a 2-month training for VHW's and supervisors in the government villages. Due to a successful outcome of the trial, it was stopped after 31 August 2019. It was evaluated by measuring reduction in IMR, U5MR, NMR and perinatal mortality rate (PMR) (total number of stillbirths and early neonatal deaths per 1000 total births) from baseline to the end (figure 5). The tribal development department of government of Maharashtra appointed a committee from one of the medical schools for its evaluation.

Outcomes

The primary outcome measures are comparisons between IA and CA, at both individual and cluster levels, for IMR and U5MR at baseline (2004) and subsequent years. The secondary outcome measures are NMR and PMR.

Statistical analysis

Sample size was estimated to detect a reduction of at least 50% in U5MR in the IA. Preliminary data from Melghat in 2004 estimated the U5MR at 140/1000 live births. The intracluster correlation coefficient (ICC) for U5MR was assumed to be 0.01, and the average live births per cluster per year was 20, which resulted in a variance inflation factor or design effect of 1.19. Hence, to detect a desired mortality reduction of 50% in IA with 95% confidence and 80% power, a sample size of 359 live births was needed per arm, with 18 clusters per arm.

Participants fulfilling the inclusion criteria were recruited and observed in each year of the study periods. The data on cluster characteristics from control and intervention areas, defined on a nominal scale, were summarised in frequencies and percentages and compared using the Pearson's χ^2 test. Since the number of characteristics at the cluster level was large, an approach based on wealth quintiles was used to classify clusters into homogeneous subsets. The characteristics were dichotomised into 0 and 1 indicating absence or presence of the attribute, while distances (continuous) were retained in the same format. This mixed data set was subjected to principal component analysis (PCA) using the PCA mix function in the R-programming tool. A weighted index was obtained for each cluster referred to as the cluster-status index. On similar lines, the analysis was performed at the household level, based on household level characteristics, to generate a wealth index. Each index array was categorised into five quintiles forming five homogeneous subsets, with level (I) indicating a weaker cluster or household, while (V) indicated better placement. 'Weaker cluster' indicates a village with poor infrastructure. Similarly, a weaker household indicates a lack of essential facilities at the domestic level. 'Better placement' suggests villages with required infrastructure, and households with necessary amenities. Table 1 and online supplemental table 1S provide the cluster and household level factors determining their status.

To assess the change in the mortality rates in different age categories, the crude incidence rate ratios (cIRR) were obtained for primary and secondary outcomes, for each intervention year (2005–2009) with reference to the base year (2004), independently for each of the two arms. In this year-wise comparison, the distribution of cluster-status index was altered due to the varying number of live births and the household level wealth index within clusters across years. Therefore, in the individual-level analysis the incidence rate ratios for each outcome were adjusted for each year with respect to the base year using a log-binomial regression (the adjusted incidence rate ratio (aIRR)). The analysis was performed independently for the two arms. The convergence issue of log-binomial regression was not met for any of the outcomes.

The difference between crude and adjusted incidence rate-ratios between the two arms was obtained for each year along with 95% CIs.[42] The effect on mortality rates during the intervention and service and replication phases were assessed through the magnitude of these differences and the associated statistical significance.

To determine whether the effect of the intervention was uniform across clusters, a cluster level analysis was performed and ICCs were obtained for the primary outcomes.

All analyses were performed using R-3.4.3 (R-Core Team 2017), and statistical significance was tested at the 5% level. The statistician was masked to treatment groups while analysing the data. Interim analyses were not done.

Role of the funding source

Funding source: Stichting Geron, Caring Friends (MAHN 1) and Bajaj Holdings and Investment Limited (2242/BHIL).

The funding sources had no role in study design, data collection, analysis, interpretation, report writing and in the decision to submit the paper for publication.

We have included an author reflexivity statement as online supplemental material/appendix S1.

RESULTS

Out of 36 equally randomised clusters in two study arms, two clusters from the IA did not participate due

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Table 1 Cluster characteristics in control and intervention areas

Characteristics	Control (N=18)	Intervention (N=16)	P value
Subcentres (no. (%))	14 (77.8)	5 (31.3)	**0.006**
Primary health centre (no. (%))	0	0	–
Distance from primary health centre (km) (mean (SD))	11.5 (9.9)	17.1 (12.7)	0.166
Distance from base hospital (km) (mean (SD))	31.1 (14.9)	30.7 (20.0)	0.958
Distance from subdistrict hospital (km) (mean (SD))	29.1 (14.1)	33.7 (16.1)	0.393
Village council (no. (%))	8 (44.4)	3 (18.8)	0.109
Emergency health facilities (no. (%))	8 (44.4)	3 (18.8)	0.109
ANM workers (no. (%))	9 (50.0)	5 (31.3)	0.268
ASHA workers (no. (%))	2 (11.1)	0	0.169
Anganwadi workers (no. (%))	17 (94.4)	15 (93.8)	0.999
Major source of water in the village (no. (%))			
Well	5 (27.8)	5 (33.3)	0.693
Hand pump	7 (38.9)	7 (46.7)	
Others*	6 (33.3)	3 (20.0)	
Road facility (no. (%))			
Tar	8 (44.4)	4 (25.0)	0.106
Dirt	7 (38.9)	12 (75.0)	
Government transport facility present (no. (%))	11 (61.1)	4 (25.0)	**0.034**
Private transport facility present (no. (%))	15 (83.3)	10 (62.5)	0.169
Mobile/telephone connectivity present (no. (%))	10 (55.6)	8 (50.0)	0.746
Anganwadi present (no. (%))	15 (83.3)	15 (93.8)	0.347

Bold p values indicate statistical significance.
*Tap, pond and river.
anganwadi worker, grassroot worker of the integrated child development scheme covering food supplementation to under-five children and preschool education; ANM, auxiliary nurse midwife trained for two academic sessions to conduct deliveries and minor ailments like oral rehydration solution for diarrhoea, deworming and routine immunisation; ASHA, Accredited Social Health Worker placed in every village who assist ANM's for management of deliveries and referral of high-risk mothers and children.

to non-cooperation of health workers. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram modified for cRCT is presented in figure 1. Out of 4426 total infants and children included in the CA, 2316 were live births and there were 378 deaths (163.21 deaths per 1000 live births), while in the IA, there were 3230 infants and children with 2299 live births and 267 deaths (116.13 deaths per 1000 live births). The male: female ratios were 1.018 and 1.058 in CA and IA, respectively. The cluster-level characteristics were compared between the two study groups (table 1). The number of subcentres (p=0.0064) and the presence of government transport facility (state government transport bus services) (p=0.0343) were significantly better in the CA.

The 34 clusters were classified into five levels (quintiles) based on the cluster-status index. The distribution of clusters in these levels was almost uniform (ie, seven in each level, except level 3 with six clusters). The household variables of under-five children, (online supplemental table 1S), were used to obtain a Wealth Index and thus classify subjects into quintiles, mirroring their economic status. The year-wise distribution of live births into five quintiles based on their cluster-status and wealth index and their comparison with the base year are given in table 2 for both the arms. The cluster-status index quintile distribution for the years 2008 and 2009 were significantly different from the base year ($p<0.05$) in the IA, while the Wealth Index distribution differed significantly from the base year for the years 2008 and 2009 in the CA and for 2009 in the IA. In the IA, the cluster status index distribution for 2008 and 2009 were significantly different compared with the baseline year, 2004. During 2008 and During, 2009, there were increased cases of cluster status I and status IV and V compared with the baseline year. Due to higher proportions in the extreme cluster levels, the difference was significant.

There was significantly higher proportion of subjects in wealth index level I in 2008 and 2009 compared with year 2004. In the IA, in 2009, the proportions increased in level I and decreased in levels II and III, resulting in significant differences.

Table 3 shows the IRR computed for different infant and under-five children categories across years in the two arms, and the per cent reduction between the two arms.

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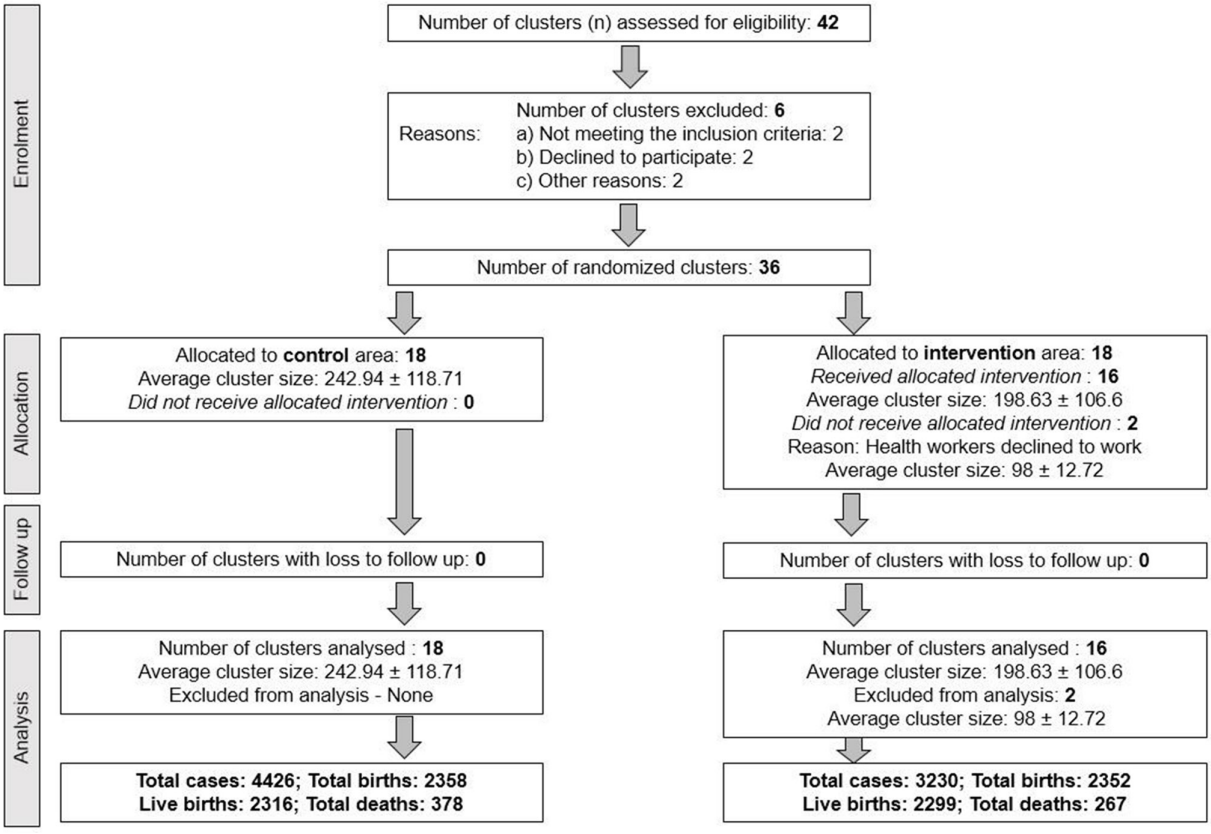

Figure 1 Cluster randomised control trial flow diagram.

In the CA, the IMR and U5MR for the period 2005–2009 were significantly higher than the baseline year, as indicated by cIRR >1. The differences in the distribution of cluster level and household level status in these years compared with the baseline year (table 2), were adjusted for and presented as aIRR (table 3). The effect of covariates on the crude rate ratios were marginal until the year 2007, but thereafter the reduction in the aIRR was noticeable (>10%) compared with their respective cIRR although the effects were statistically insignificant. The wealth index differentials primarily contributed to the difference in aIRRs for the years 2008–2009 (table 2).

In the IA clusters, for the IMR and U5MR, both IRRs were reduced for the each of the years 2005–2009 compared with the reference. The effects of covariates were noticeable as indicated by the change in IRRs (>10%) for the above years for the IMR. However, this covariate effect was not observed for the U5MR.

The IMR and U5MR in IA were reduced from 106.60 and 147.21 to 32.75 and 50.38 (reduction by 69.28% and 65.78%, respectively) compared with increases in CA from 67.67 and 105.26 to 86.83 and 122.75, respectively, from baseline to end of intervention. The >50% relative reduction in both IMR and U5MR in the IA were significantly different when comparing the crude rate ratios for CA and IA, for each of the years 2005–2009, culminating in a >70% reduction in both in 2009. The relative reduction in adjusted IRRs while not significant in the first year after introduction of the intervention for the IMR, were significantly reduced in each of the subsequent years for both IMR and U5MR with at least a sustained >50% relative reduction after 2007.

NMR in IA showed reductions from 50.76 to 22.67 (by 55.34%) and PMR from 75.06 to 24.94 (by 66.77%) respectively. The secondary outcomes on NMR and PMR are presented in online supplemental table 2. Consistently in the CA, except for the PMR in 2006, both rates were consistently higher in years subsequent to the baseline year (increased with an average of 28.5% during the research phase). In contrast, for the IA for most years there was a reduction in both parameters. This resulted in significant relative reductions in both the cIRR and aIRR in the IA compared with the CA that were consistently above 50% after 2007.

A cluster-level analysis was performed in the two arms independently, using ICCs. Table 4 shows IMR and U5MR along with ICCs at baseline year (2004) and at the end of study year (2009) for the two arms. In both the arms, ICCs for IMR and U5MR were higher at baseline compared with end of study period. This indicates that the between-cluster variability was higher at baseline, which declined at the end of the intervention period in both the arms. For infant mortality, in the IA, the per cent ICC change was 82.95% (95% CI 77.76% to 88.13%), which was significantly higher than that of CA (45.83%) (95% CI 24.52% to 67.13%). For the U5MR, in IA the reduction of ICC was 46.15% (95% CI 26.83% to 65.47%), which was better than CA 31.85% (95% CI 5.99% to 57.70%).

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Table 2 Year wise categorisation of live born infant families based on cluster level infrastructure (cluster-status index) and economic status of household (wealth index) in two study areas

Year	Live births	Control area											
		Cluster-status index—quintiles (n (%))						Wealth index—quintiles (n (%))					
		I	II	III	IV	V	P value*	I	II	III	IV	V	P value*
2004	399	18 (4.5)	116 (29.1)	63 (15.8)	76 (19.1)	126 (31.6)	Base year	54 (13.5)	87 (21.8)	87 (21.8)	91 (22.8)	80 (20.1)	Base year
2005	398	11 (2.8)	100 (25.1)	78 (19.6)	84 (21.1)	125 (31.4)	0.301	56 (14.1)	86 (21.6)	84 (21.1)	87 (21.9)	85 (21.4)	0.987
2006	376	19 (5.1)	103 (27.4)	43 (11.4)	79 (21.0)	132 (35.1)	0.394	49 (13.0)	80 (21.3)	87 (23.1)	95 (25.3)	65 (17.3)	0.828
2007	335	18 (5.4)	84 (25.1)	49 (14.6)	60 (17.9)	124 (37.0)	0.523	52 (15.5)	80 (23.9)	65 (19.4)	77 (22.9)	61 (18.2)	0.795
2008	474	16 (3.4)	138 (29.1)	96 (20.3)	82 (17.3)	142 (29.9)	0.457	139 (29.3)	76 (16.0)	100 (21.1)	87 (18.4)	72 (15.2)	<0.001
2009	334	10 (2.9)	99 (29.6)	52 (15.6)	59 (17.7)	114 (34.1)	0.796	97 (29.0)	48 (14.4)	47 (14.1)	76 (22.8)	66 (19.8)	<0.001
Year	Live births	Intervention area											
		Cluster-status index—quintiles (n (%))						Wealth index—quintiles (n (%))					
		I	II	III	IV	V	P value**	I	II	III	IV	V	P value**
2004	394	95 (24.1)	51 (12.9)	57 (14.5)	107 (27.2)	84 (21.3)	Base year	86 (21.8)	93 (23.6)	75 (19.0)	57 (14.5)	83 (21.1)	Base year
2005	363	81 (22.3)	32 (8.8)	40 (11.0)	109 (30.0)	101 (27.8)	0.067	107 (29.5)	63 (17.4)	64 (17.6)	59 (16.3)	70 (19.3)	0.066
2006	406	109 (26.9)	42 (10.3)	37 (9.1)	115 (28.3)	103 (25.4)	0.087	96 (23.6)	80 (19.7)	76 (18.7)	67 (16.5)	87 (21.4)	0.689
2007	333	80 (24.0)	33 (9.9)	33 (9.9)	99 (29.7)	88 (26.4)	0.143	81 (24.3)	68 (20.4)	48 (14.4)	63 (18.9)	73 (21.9)	0.213
2008	406	110 (27.1)	36 (8.9)	38 (9.4)	125 (30.8)	97 (23.9)	0.047	109 (26.9)	79 (19.5)	65 (16.0)	66 (16.3)	87 (21.4)	0.273
2009	397	129 (32.5)	30 (7.6)	31 (7.8)	99 (24.9)	108 (27.2)	0.0002	109 (27.5)	62 (15.6)	62 (15.6)	60 (15.1)	104 (26.2)	0.013

Bold p values indicate statistical significance. Cluster-status index was derived based on characteristics listed in table 1, while wealth index was derived based on household level characteristics listed in online supplemental table 1S. The quintiles I–V indicate gradient towards improved cluster status or household economic status.
*Obtained using Pearson's χ^2 test between base year and subsequent years

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Table 3 Comparison of mortality rates in control and intervention groups from 2004 to 2009 (primary outcomes)

		Control				Intervention				Absolute reduction in IRR between intervention and control arms	
				Incidence rate ratio (95% CI), p value				Incidence rate ratio (95% CI), p value		(95% CI), p value	
	Year	Deaths/ live births	Incidence rate/1000 live births	Crude (cIRR)	Adjusted (aIRR)*	Deaths/ live births	Incidence rate/1000 live births	Crude (cIRR)	Adjusted (aIRR)*	Crude	Adjusted
Infant mortality	2004	27/399	67.7	Ref.	Ref.	42/394	106.6	Ref.	Ref.	Ref.	Ref.
	2005	43/398	108.0	1.60 (0.99 to 2.58), 0.054	1.24 (0.80 to 1.94), 0.332	22/363	60.6	0.57 (0.34 to 0.95), 0.029	0.75 (0.48 to 1.17), 0.214	0.36 (0.18 to 0.72), 0.002	0.60 (0.32 to 1.13), 0.056
	2006	43/376	114.4	1.69 (1.04 to 2.74), 0.031	1.55 (1.03 to 2.38), 0.044	35/406	86.2	0.81 (0.52 to 1.27), 0.352	0.83 (0.54 to 1.26), 0.367	0.48 (0.24 to 0.93), 0.028	0.54 (0.29 to 0.97), 0.018
	2007	47/335	140.3	2.07 (1.29 to 3.33), 0.002	1.75 (1.16 to 2.68), 0.011	18/333	54.1	0.51 (0.29 to 0.88), 0.014	0.48 (0.27 to 0.82), 0.010	0.24 (0.12 to 0.51),<0.001	0.27 (0.14 to 0.55), <0.001
	2008	49/474	103.4	1.53 (0.96 to 2.44), 0.075	0.99 (0.64 to 1.56), 0.972	21/406	51.7	0.49 (0.29 to 0.82), 0.006	0.43 (0.25 to 0.72),<0.001	0.32 (0.16 to 0.64),<0.001	0.43 (0.22 to 0.87), 0.011
	2009	29/334	86.8	1.28 (0.75 to 2.18), 0.350	0.80 (0.49 to 1.31), 0.367	13/397	32.8	0.31 (0.16 to 0.57),<0.001	0.26 (0.13 to 0.48),<0.001	0.24 (0.10 to 0.55),<0.001	0.32 (0.14 to 0.74), <0.001
Under-five mortality	2004	42/399	105.3	Ref.	Ref.	58/394	147.2	Ref.	Ref.	Ref.	Ref.
	2005	55/398	138.2	1.31 (0.88 to 1.96), 0.183	1.26 (0.87 to 1.83), 0.218	31/363	85.4	0.58 (0.38 to 0.90), 0.013	0.58 (0.38 to 0.86), 0.011	0.44 (0.25 to 0.79), 0.006	0.46 (0.26 to 0.79), <0.001
	2006	65/376	172.9	1.64 (1.11 to 2.42), 0.011	1.57 (1.11 to 2.24), 0.010	44/406	108.4	0.74 (0.50 to 1.09), 0.124	0.76 (0.52 to 1.08), 0.136	0.45 (0.26 to 0.78),<0.001	0.48 (0.29 to 0.80), <0.001
	2007	60/335	179.1	1.70 (1.15 to 2.53), 0.007	1.64 (1.16 to 2.36), 0.012	29/333	87.1	0.59 (0.38 to 0.92), 0.019	0.59 (0.38 to 0.89), 0.013	0.35 (0.19 to 0.63),<0.001	0.36 (0.21 to 0.63), <0.001
	2008	62/474	130.8	1.24 (0.84 to 1.84), 0.276	1.06 (0.73 to 1.55), 0.759	30/406	73.9	0.50 (0.32 to 0.78), 0.002	0.51 (0.33 to 0.76),<0.001	0.40 (0.22 to 0.73),<0.001	0.48 (0.27 to 0.84), <0.001
	2009	41/334	122.8	1.17 (0.76 to 1.79), 0.483	0.92 (0.62 to 1.37), 0.668	20/397	50.4	0.34 (0.21 to 0.57),<0.001	0.36 (0.21 to 0.57),<0.001	0.29 (0.15 to 0.56),<0.001	0.39 (0.21 to 0.74), <0.001

*Adjusted for sex, wealth index of individual and village/cluster status using log-binomial regression.
aIRR, adjusted IRR; cIRR, crude IRR; IRR, incidence rate ratio.

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Table 4 Intracluster correlation coefficient for primary outcomes at baseline (2004) and end of intervention period (2009) in the two study groups

	Control				Intervention			
Parameters	IMR—2004	IMR—2009	U5MR—2004	U5MR—2009	IMR—2004	IMR—2009	U5MR—2004	U5MR—2009
Live births	399	334	399	334	394	397	394	397
Deaths	27	29	42	41	42	13	58	20
Mortality rate/1000 live births	67.7	86.8	105.3	122.8	106.6	32.8	147.2	50.4
ICC* (95% CI)	0.16 (0.05 to 0.28)	0.09 (0.01 to 0.18)	0.11 (0.02 to 0.21)	0.08 (0.00 to 0.16)	0.13 (0.03 to 0.23)	0.02 (0.00 to 0.06)	0.10 (0.02 to 0.19)	0.06 (0.00 to 0.12)
ICC (% change w.r.t 2004) (95% CI)	45.8% (24.5% to 67.1%)		31.9% (5.9% to 57.7%)		82.9% (77.8% to 88.1%)		46.2% (26.8% to 65.5%)	

*The intracluster correlation coefficient (ICC) for binary data.
IMR, infant mortality rate per 1000 live births; U5MR, under-five mortality rates per 1000 live births.

The reduction in primary outcomes in the IA during the intervention phase was maintained during the service phase for the next 6 years (figure 2). In the CA, there was a reduction in IMR and U5MR from 2014 onwards when the government started an HBNC intervention. The IRRs and relative reductions for primary outcomes for all phases are shown in figure 3. In the service period, the reductions for IMR and U5MR were consistently below

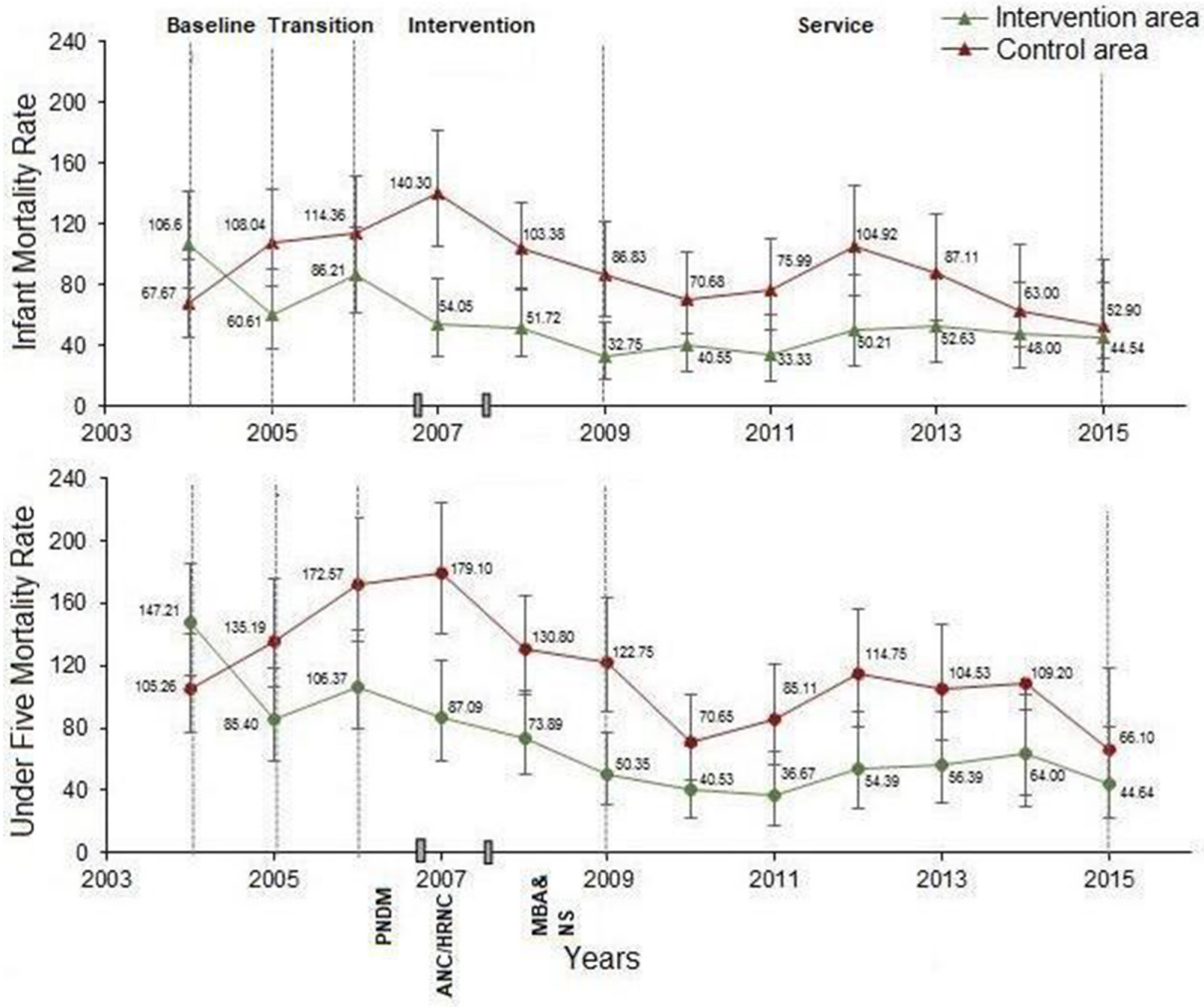

Figure 2 Line plots showing infant and under-five mortality rates in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

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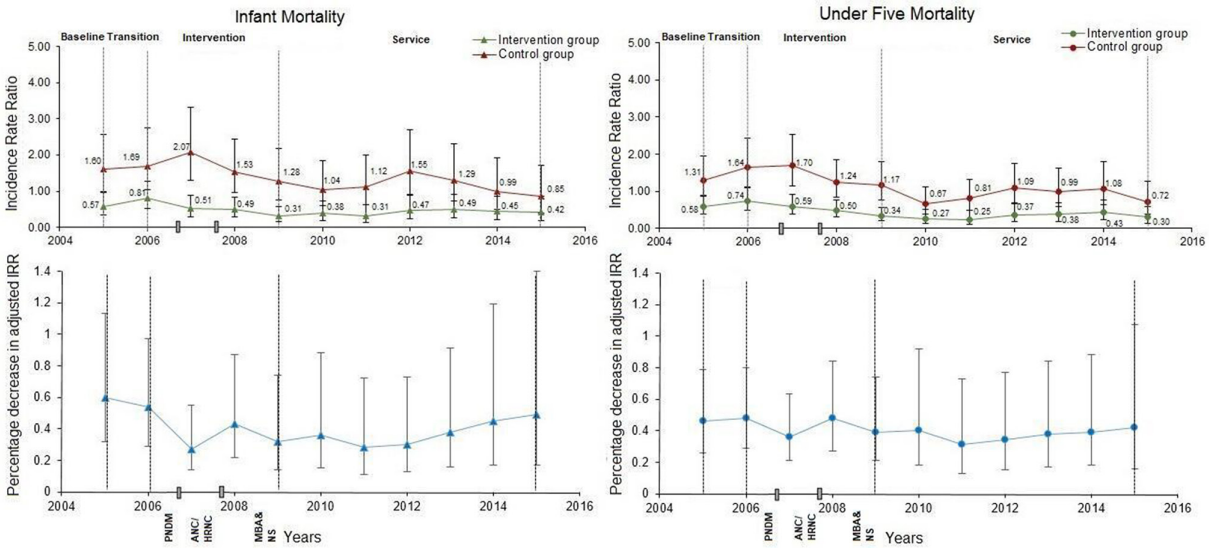

Figure 3 Line plots showing incidence rate ratio (IRR) and percentage decrease in IRR for infant and under-five mortalities in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

50% in the IA. Figure 4 shows the reduction in NMR and PMR in the IA, which was maintained during the service period.

During the replication phase, the baseline IMR and U5MR were reduced from 71.63and 85.96 to 28.50 and 45.13, respectively (figure 5). The NMR and PMR were reduced from 51.58 and 48.02 to 16.63 and 23.47, respectively, in 2 years. The reduction in IMR and NMR were statistically significant (p=0.022 and p=0.019, respectively). The reductions for U5MR and PMR were not significant (p=0.071 and p=0.1763, respectively). There were no harms or unintended effects in either group.

Results of PPI in the study. Focus group discussions with PPI improved community participation.

DISCUSSION

Our study shows a major reduction in primary and secondary outcomes in the IA compared with the CA at the end of the Research Phase. The integrated multipronged approach to HBCC resulted in significant reductions of U5MR and IMR in this high-mortality area. The reduction in intercluster correlation coefficients for both IMR and U5MR in the IA shows that variability of outcomes between clusters declined at the end of the intervention period. The per cent change for IMR in the IA was highest, indicating that the significant reduction in IMR was nearly consistent across all clusters by the end of study. This consistency was much higher than the CA. Similarly, the per cent reduction in ICC for U5MR in the IA was higher than that of CA, indicating uniform effectiveness of the intervention in the IA. The increased mortality rate in the control arm might have occurred due to changing priorities of senior district administrators (as a part of government policy)

After completion of the Research Phase, the reduction in mortality indicators was maintained during the Service Phase of the next 6 years in the IA, mimicking the situation of large-scale public health programmes. This indicates the feasibility of programme implementation at scale. The consistency of reduction in IMR and U5MR prompted the Government of Maharashtra in India to extend the methodology using government resources. The replicability of the model was then proven by the decline in all the mortality rates in the 20 new villages during the Replication Phase. This series of sequential studies has now been instrumental in driving subsequent governmental programmes.

We provide the following example directly related to this study, to empower the many non-governmental organisations and researchers in India and other countries with carefully collected, verified data of their own, to challenge data collected by less vigorous, transparent collection methods and work with local, state and national governments to effect policy changes.

This study has a significant impact on state government policies. (a) In Melghat, the MAHAN study, found an IMR of 96 per 1000 live births whereas the ICDS data recorded IMR at 31. The government and UNICEF verified this discrepancy by actual field visits and approved MAHAN findings. (b) The government could not ignore this more reliable MAHAN survey data as it generated more attention to combating U5MR in the state, especially in the poorer rural districts.[25] This lead to the formation of the 'RJMCHNM',[25] by the state government to work in collaboration with UNICEF for reduction of U5MR in Maharashtra. (c) Subsequently the Indian and Maharashtra State Government funded and replicated HBCC, in 33 villages of Melghat. (d) Before 2013, grassroot front line health workers were not allowed to use antibiotics for the treatment of post-neonatal childhood infections, which policy was changed by a state government committee, based in part on this study by MAHAN and another one by SEARCH.

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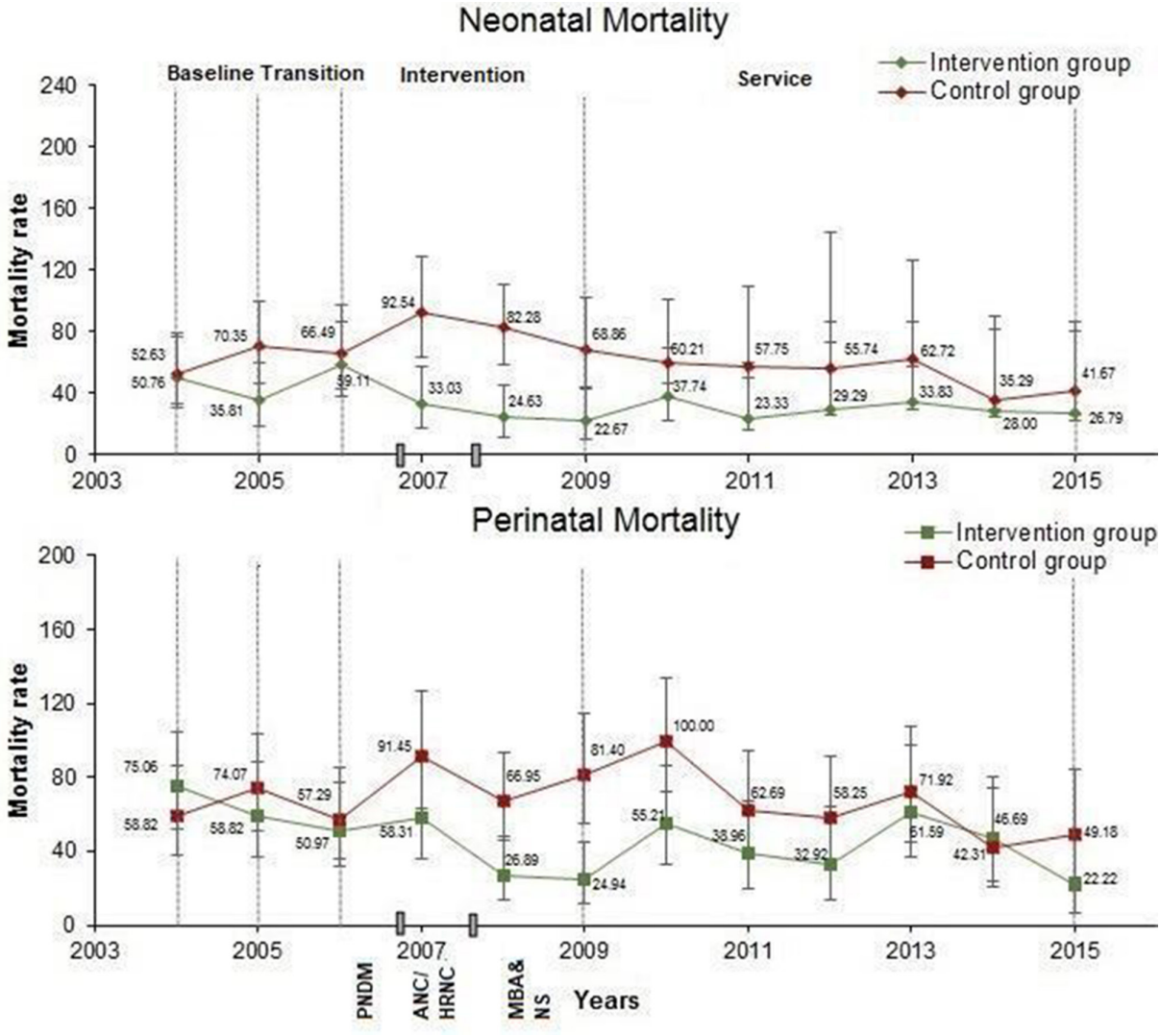

Figure 4 Line plots showing neonatal and perinatal mortality rates in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

The Government of India has empowered Accredited Social Health Worker for HBNC. However, this does not include management of neonatal sepsis or birth asphyxia, which is still a lacuna. Today, 33% of deliveries are home deliveries in rural India. The facilities for treatment of neonatal diseases are available at an average distance of 32 km from villages. Trauma due to transport of sick neonates in suboptimal conditions endanger lives, reflecting high NMR, as also proved by Mori *et al*.[43]

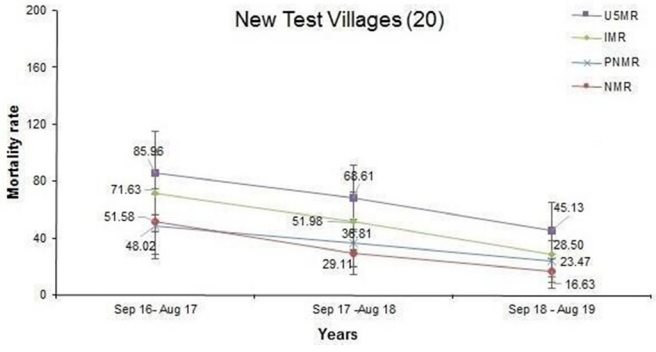

Figure 5 Line plots showing different mortality rates in a new set of test villages (government villages) exposed to intervention during the observation period 2016–2019. IMR, infant mortality rate; NMR, neonatal mortality rate; PNMR, perinatal mortality rate; U5MR, under-five mortality rates.

Our model is cost-effective as the average cost of treatment of each child including the research cost in this project was Indian National Rupees (Rs.) 592 (US$8) per year (unpublished data). In comparison the National Sample Survey Organisation revealed that the average total treatment expenditure per patient in rural and urban areas for outpatient management is Rs.509 (US$6.8) and Rs.639 (US$8.6), and hospitalisation Rs.16 956 (US$229.1) and Rs.26 455 (US$357.5) respectively. We plan to conduct a formal cost-effectiveness analysis.

Our study follows many of the principles of the census-based, impact-oriented approach.[44] These principles included the following:

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1. We developed a cooperative partnership with local communities.
2. We worked together with the local community, identified and decided their heath priorities. We planned and implemented the programme as per need of the community.
3. Our interventions included regular planned home visits.
4. We regularly measured the impact of our interventions on health of the children until the age of 5 years.

Our study highlights the importance of community sensitisation, acceptance and participation. Our active and effective system of community-based VHWs made this programme successful.

Integrated management of childhood illnesses (IMCI)[45] has been implemented in India from 2003 onward for wider community coverage and impact. The original IMCI was primarily first level facility based, did not include care of the sick early newborn (the time when one in three child deaths occurs) and it did not emphasise HBNC. The newborn component was added to the integrated management of neonatal and childhood illnesses (IMNCI) programme in India in 2004.[46] Unfortunately, IMNCI has not been successful in India, despite having sound principles. It was the implementation of the programme that faltered not only in India but in many other countries. The reasons for the failure of the programme were: irregular funding, lack of refresher trainings of fieldworkers, poor supervision/mentorship,[47] irregular availability of key supplies, weak referral hospitals and frequent transfer of staff.[48] _ENREF_34 A 2017 review of community IMCI found only one RCT that showed a reduction of 8% in under-five mortality after 2 years using cIMCI.[49]

Recognising these challenges globally, WHO in conjunction with UNICEF and USAID launched iCCM, iCCM in Africa (2012). A Cochrane review of iCCM programmes found no impact on child mortality due to poor study design of the trials.[50] These faced critical challenges due to lack of integration into national health systems, lack of political commitment and non-coordination with funding agencies. Funding was largely dependent on development partners, and sustainability of funding remained a critical concern for delivery of iCCM services. The problems in supply of commodities, utilisation, scale, quality, financing and monitoring of services were not resolved. A strong referral system for facility-based treatment was not developed simultaneously, and, finally, iCCM policy did not include treatment of neonatal sepsis.[51]

In India at present, complete HBCC has not been implemented by the government. The major obstacles in implementing community-based health programmes in India are: poor trainings and monitoring of grassroot workers, poor referral support for quality treatment, the rigid hierarchical structure of the health system, failure to incorporate community participation into large-scale primary healthcare programmes[52] and opposition from professional bodies such as the Indian Medical Association and the Indian Academy of Pediatrics. Nevertheless, the Government of Maharashtra has taken many steps to implement HBNC in high mortality rural areas. Critically, the HBCC programme did not require strengthening of the primary healthcare facilities or of the referral facilities, which are still a major obstacle in most developing countries. Empowering community workers to provide basic and advanced care for the well and sick child and the provision of basic essential medicines obviates the need for the most part for referral and will decrease the burden on these facilities if widely implemented, making it a much more cost-effective strategy.

VHWs played a critical role to reduce the mortality in the community and provided appropriate grassroots healthcare. Community health workers (CHWs) are essential for achieving the health-related Sustainable Development Goals.[53] A significant increase in continuous funding for CHW programmes is needed. National and state governments should increase political support for prioritising CHW programmes during economic growth and make additional health-related funding available. This paradigm shift will be an essential step in escalating development in achieving current global health goals and in reaching the goal of Health for All.[54]

The limitations of this trial include possible spillover effects as the CA and the IA were in contiguous areas. There were differences in between IA and CA for baseline IMR, U5MR and the household level characteristics, although they were adjusted during analysis by obtaining a wealth index. Finally, this strategy might not be applicable for the urban setting. Malaria rapid diagnostic tests (RDTs) were not used for malaria diagnosis during research and service phase. It was based on a clinical diagnosis after excluding other causes of fever. Our VHWs used malaria RDTs during the government replication phase. This was a relatively small study and it might be difficult to scale up this complex HBCC approach. However, the principles, methods, VHW monitoring, simple treatment modalities and collaboration with government makes this a feasible modality for reductions of IMR and U5MR in the Indian subcontinent and other LMICs.

In conclusion, progressive policies on CHW programmes must be backed up by concrete institutional support to enable CHWs to fulfil their role.[55] While VHWs are not a panacea for weak health systems, they can make a major contribution to health system strengthening if they have focused tasks, adequate remuneration and the active involvement of the communities in which they work.[19] Thus the prerequisites for successful programme delivery are: (a) Selection of a VHW through a transparent community participatory process based on merit, (b) Intensive, focused regular trainings and monitoring of VHWs, (c) Maintenance of the supply chain, (d) The programme must be backed up by concrete institutional support. HBCC is possible with local resources. It is affordable, acceptable, measurable, safe, achievable and effective. It should be replicable in other impoverished

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areas of the world having inadequate medical facilities and a high U5MR.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Name of Ethics Committee: MAHAN Institutional Review Board (IRB), Reference ID 1/2004. IRB meets standard of BMJ. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. Aggregate data that underlie the results reported in this article, after de-identification (text, tables, figures and appendices) will be shared. Study protocol has been added in the supplementary materials. As per guidelines of Government of India (GOI), individual participant data will not be available. Data will be made available: The beginning 9 months and ending 36 months following article publication. Data will be shared with investigators whose proposed use of the data has been approved by an independent review committee, the GOI and ethical review by the ICMR and Government of Maharashtra (India), Tribal Section clearance, identified for this purpose. Proposals may be submitted up to 35 months following article publication. After 36 months the data will be available with investigator support.

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Author note The reflexivity statement for this paper is linked as an online supplemental file1.

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Appendix S1 – Reflexivity Statement.

Consensus statement on measures to promote equitable authorship in the publication of research from international partnerships.[1]

Study conceptualisation

1. **How does this study address local research and policy priorities?**

   This study was conducted in a rural area of Maharashtra, India with high infant and under 5 mortalities, the reduction of which is a high global, national and local priority. Research into sustainable methods for mortality reduction have become top priorities for the local villages and Amravati district, as well as Maharashtra state and India. It is a global priority for achieving the SDG's .

2. **How were local researchers involved in study design?**

   The local researchers Dr. Ashish Satav, Dr. Kavita Satav, Dr. Abhijit Bharadwaj, Mrs. Jayashri Pendharkar designed the study from the beginning. Dr. Ashish and Dr. Kavita realised the need of reducing very high malnutrition and mortality in this area and were involved in developing solutions for high mortality rates in this area, three years before starting the study. They realised that the low and delayed health seeking behaviour and scarcity of doctors were major causes of the high U5MR and IMR in this region. Hence the local researchers designed the home-based child care program to address health care needs of the community and to reduce U5MR and IMR.

Research management

3. **How has funding been used to support the local research team?**

   This project was funded by national and international funding agencies to support the recurring expenditure and salary expenses of the local research staff working in this project. Entire funds were utilized on activities by the local research team. The international researcher's contribution was voluntary and he was paid nothing for his involvement in this study.

Data acquisition and analysis

4. **How are research staff who conducted data collection acknowledged?**

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All investigators have been included as co-authors, and given priority as first author and the subsequent authors. Contribution made by the data collection team has been recognized in the acknowledgment section.

5. Do all members of the research partnership have access to study data? How have members of the research partnership been provided with access to study data?

All members of the research partnership have access to the study data. All data are housed on databases at the local site. The statisticians work with these databases to run analysis. All authors requested analyses that satisfied their individual probing of the data for consistency of data and completeness of data.

6. How was data used to develop analytical skills within the partnership?

The senior investigators arranged multiple meetings with the junior staff for the data analysis. The junior staff were trained by the statistician for data analysis throughout the entire study period. The data staff were given responsibilities to analyse the data locally as much as they can. Quality of data was assessed by the LMIC statistician and investigators. Local team members were actively involved in data analysis, and all data analysis was only done locally. Data was never sent out of the country.

Data interpretation

7. How have research partners collaborated in interpreting study data?

Five inclusive online and offline workshops were held during the process of data interpretation. The first two sessions served to define the issue of research and agreement that we should focus on the development of equitable partnership. At the conclusion of these two sessions, researchers formed working groups to conduct literature reviews. These reviews were reported back at a subsequent workshop where all partners collaborated to agree on recommendations and contents of the results and discussion sections. During final meetings, all the investigators interpreted the final study data with the help of data team. Local team members were involved in conception, design, data acquisition and data analysis. [(2)]

Drafting and revising for intellectual content

8. How were research partners supported to develop writing skills?

The research team for drafting and revising the intellectual content is predominantly composed of senior Indian investigators. The junior authors were supported by senior academics who worked in small groups to

develop and refine their writing skills. The senior author guided the Indian writing team for publication in international medical journals.

9. How will research products be shared to address local needs?

The study results will be disseminated with the local community members, key public representatives, local government health and integrated child development scheme staff (village to district level) and other local voluntary organisations and academicians. Advocacy meetings will be conducted with above external stakeholders who influences local policy changes and if needed public interest litigation will be filed for its implementation in all 300 villages of the two rural blocks of Amaravati district. For its wide dissemination in local community, we will use methods like community meetings, davandi (announcement in local language by a key person), pamphlets, street plays, one to one counselling, group counselling and audio-visual shows.

This study will be published in an open access platform. A post-publication dissemination plan has been devised to discuss the study findings and recommendations across a wide constituency of scientific fora and conferences. This will include interactions with research leaders engaged in setting national and international health priorities and other fields involved in national collaborations, and also with the media including press and journalists, based in Maharashtra state and other states of India. We propose to conduct advocacy meetings with government officers and other stakeholders who are especially dealing with the implementations of various health schemes and integrated child development schemes in the community and other voluntary organisations (NGOs, CBOs) and academicians for replication of the study in other parts of the country.

Authorship

10. **How is the leadership, contribution and ownership of this work by LMIC researchers recognised within the authorship?**

Authors Ashish Satav, Vibhawari Dani and Dhananjay Raje worked as part of the senior authorship team in developing this manuscript, and their contribution has been recognised as joint first and main co- authors respectively. We have specifically included researchers based in the USA (Eric Simoes) within the senior authorship team as last author. We acknowledge, that the authorship team is predominantly based in LMIC.

LMIC team members were given ample opportunity to sign off on the final manuscript version. [(2)] All LMIC authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. [(2)]

11. **How have early career researchers across the partnership been included within the authorship team?**

We have included early career researchers (Kavita Satav, Abhijit Bharadwaj, Jayashri Pendharkar) within the authorship team. They attended all the workshops, contributed to the literature review and evidence synthesis and for development of the consensus recommendations. They are based in India.

12. **How has gender balance been addressed within the authorship?**

Five authors are male (Ashish Satav, Abhijit Bharadwaj, Dhananjay Raje, Suresh Ughade, Eric Simoes) and three authors are female (Kavita Satav, Jayashri Pendharkar and Vibhawari Dani).

Training

13. **How has the project contributed to training of LMIC researchers?**

All the senior authors based in LMIC have contributed to the training of the early career research staff. The senior author from USA assisted with the planning of the analysis as well as assisted with writing, and as such contributed to training of all LMIC authors as well.

Infrastructure

14. **How has the project contributed to improvements in local infrastructure?**

This project has directly contributed to improvements in local infrastructure. This project has strengthened the research capacity of the local investigators, developed a resource pool of grass root manpower which can now do other research studies also. We could procure some logistics like vehicles and other valuable items, which can be used, for other projects even after the end of this research study.

Governance

15. **What safeguarding procedures were used to protect local study participants and researchers?**

We have conducted gram sabhas (community meetings) in all the villages before start of the study. Informed written consents were obtained from the senior key persons and 60% of the villagers for execution of the study. The pros and cons of the study were discussed with the villagers in detail. Participants were actively involved in the study from the beginning to the end of the implementation phase. The field level staff was selected by the community. Free services were provided to all the villagers during the study. Due to the extensive community involvement, the community actively supported the local study participants. For reporting adverse events, a fast-track (bottom to top) system was developed from village level up to investigator level. There was a provision of free treatment in the study hospital for any adverse events. All legal formalities specified as per the government norms were fulfilled. Government was an active partner for a substantial period of six years in this research study. Databases are in password protected databases behind firewalls, so study participant personal information is secure.

Local researchers were protected, as all research activities were governed by an Ethics committee and an IRB; the study had to pass scrutiny of the local gram sabhas (community meetings), needed 60% agreement of the villagers where the study was going to be done, and needed tribal department, Government of Maharashtra clearance. Thus, they were protected both from the ethical and law perspectives. Of course, as all data was kept at the local site all research data was under the complete control of the local researchers, and there was no question of the foreign entity using any data for non-sanctioned use. The local researcher's access to, control of and use of the data is absolute.

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EFFECT OF HOME-BASED CHILD CARE ON CHILDHOOD MORTALITY IN RURAL MAHARASHTRA, INDIA: A CLUSTER RANDOMIZED CONTROLLED TRIAL

Annexure-1:

Community meetings.

Community meetings were regularly arranged (Baseline, weekly, quarterly) for community involvement including awareness, consent and acceptance.

Local panchayats (Village Councils), women's micro-credit groups (small saving groups) and gramsabhas are some structures, which were used for ensuring community participation.

Community participation was sought at the following stages:

a. Key person visits.
b. Village meetings (Gram sabha).
c. The villagers were invited to recommend potential candidates for the work of village health workers (VHWs)
d. Launch meetings.
e. Periodic interactions with the villagers to give feedback and encourage suggestions.
f. Small saving groups.
g. Village health committee.
h. Local panchayats (Village Councils).

Participatory community meetings provided introduction, collaboration, identified resources for child health and written community consent. Interventions were based on inputs of qualitative research like focus group discussions and surveys regarding high-risk behaviours for child mortality, individuals with key roles, potential barriers, factors affecting behaviour change.

Important condition for community meeting was that at least 50% of the adults should be present in the meeting. The community meetings were started from beginning to the end of the research and continued in replication phase also.

The study area was divided randomly by lottery method into two clusters: intervention area (IA) and control area (CA). Community meetings were conducted in both clusters (IA and CA) to obtain consent of the villagers to conduct the study and collect the vital events.

Interventions in control areas:

The interventions in the control clusters were census, village mapping, collection of vital events (deaths and births) by VHWs and were confirmed by retrospective surveyors, data collection supervisors, TBAs and from government health and ICDS systems, sarpanch (elected village head) and police patil (government appointed). Verbal autopsies were conducted in control area to know the causes of deaths by data collection supervisors and VHWs.

Annexure-2: Selection, trainings and supervision of field workers:

VHWs, data collection supervisors, medical supervisor, behaviour change communication (BCC) supervisors, program manager, retrospective surveyors and traditional birth attendants as external stakeholders formed a field team.

The VHWs were local, married, semi-literate, socially sensitive, tribal women selected through community meetings.

Village health workers' (VHW) Selection

Eligibility criteria:

- Female
- Semiliterate: Education at least 5th standard.
- Should belong to same village and community and should be able to communicate in local language.
- Married so that she can continue for a longer period. It is preferable to have a child so that she can understand the problems and importance of pregnancy and labour.
- Should be sensitive to the problems of society.
- Have good communication skills.
- Should be enthusiastic towards her duties.
- Must be acceptable to the community so that it will empower community participation.

Selection Process

• Project director, project manager and social worker organized pre planned village/community meetings (gramsabha). Village head, police patil and at least 60% of all the adults (both male and female) of the village were present in the village meeting. Information about the project was given and the need and eligibility criteria for selection of VHW for the project was explained in the gram sabha. Consent of gram-sabha and community participation was vital for the project.

• Three women were selected by the gram-sabha (community meetings). Then those three women from every village were called to MAHAN base hospital for four-day residential selection camp.

• Detailed information about the project was given e.g. role of the VHW, expectation of the work from VHW, incentive for work, award-punishment process.

• Each of the women were given a poster and asked to speak about it. They had to clear written examination and oral interview.

• To check the attitude & self-interest of person, we organized shramdan (labour donation) and allotted them responsibilities e.g., food committee, care committee, cleanliness committee and a committee to observe the participation of every woman. They were sent to few villages for field testing to know how they interact with the community.

• Communication skills were closely monitored.

At the end of camp, one VHW was selected from each village.

Other staff:

Program manager and supervisors were selected through theory examination, oral interview and field visit observations.

Supervisors were of three types: Medical supervisors, BCC supervisors and data collection supervisors.

External stake holders: External stakeholders are from the clusters but were not paid workers of MAHAN trust. They assisted our HBCC program to achieve the objectives.

1) Traditional Birth Attendant (TBA):

TBAs from intervention clusters were called to our base hospital and their knowledge, attitude and practices about delivery and interest in community social work was tested. All those TBAs who fulfilled the selection criteria were selected. Two to three TBAs from each village were selected as different TBAs were called by the community for conducting deliveries. TBAs were trained for clean and safe delivery. They were also advised to call VHWs for newborn care during the delivery. TBAs were paid by villagers for the delivery work. The payment of TBAs by MAHAN was based on fair market value, and was job based rather than a fixed salary.

2) Traditional faith healers (TFHs):

TFHs have good influence on community. They were paid by villagers. We counselled TFHs for referral of patients to VHWs and hospitals.

GANTT Chart.

Sr. No	**Activity**	**Full implementation Phase 36 months**
1	Appointment of project manager & trainer-supervisor.	•
2	Orientation of project manager.	•
3	Training of supervisors	• • • • • • •
4	Selection of VHW.	•
5	Training of VHW and supervisor	• • • • • • • • • • • • •
6	Revision training	• • • • • • •
7	TBA training.	• • •

Training

We are detailing the training and supervision, but please note that since this is a trial. Hence, trial-based trainings and job-based trainings were done simultaneously.

Training is required for three categories of workers:

1. Training of trainer cum supervisor of VHW.
2. Training of VHWs
3. Training of TBAs.

1) The training of trainer cum supervisor

HBCC is a new concept for the trainer cum supervisors themselves.

Monthly initial trainings were conducted. The total duration of training was of 60 days, which was imparted in number of training workshops spaced by suitable time interval (of about one months). The actual number, which has been found most effective, is total 12 workshops of 5 days each over a period of 12 months.

2) Training of the VHWs.

Trainings of the VHWs for post neonatal disease management were carried out using the training material developed by the MAHAN trust. The training for home based neonatal care was conducted using the training material developed by SEARCH & trainers approved by SEARCH, Gadchiroli. Monthly initial residential trainings of 5 days each were conducted for one year and 4 months. Then refresher trainings were conducted 3 days every month for one year. Afterwards, 3 days trainings were conducted every alternate month till the end of the project. The total duration of the initial training of VHWs was for 80 days.

3) Training of TBAs

The TBAs were trained in three workshops each of two-day duration. Experience sharing and providing helpful inputs to foster close collaboration between the VHWs and the TBAs was an essential feature of the TBA training.

4) Orientation of the project manager

Since the project manager is the person who is responsible for implementation of the HBCC, it is most essential that he understands fully, each aspect of the implementation of HBCC and hence an orientation workshop for the project manager was considered very important.

Topics of training for VHWs :

Village mapping, census data collection, vital statistics data collection, home based child care for the following diseases: diarrhea, malaria, pneumonia, nutrition, antenatal care, home based neonatal care, normal new-born and high-risk new-born care, hypothermia, vitamin K injection, birth asphyxia, neonatal sepsis, and behaviour change communication, hygiene.

Method of trainings: Class room training and field training,

Lecture, group discussion, demonstration, participatory learning, peer group learning, pictorial flipchart, audio-visual show, role play, etc.

Trainers:

Dr. Ashish Satav (M.D. Chief trainer), SEARCH team, Dr. Dani (Pediatrician), Dr. Shinde (Pediatrician), community physicians, medical supervisors and BCC supervisors.

The trainer cum supervisor of the VHWs: The supervisors of the VHWs were responsible for training of the VHWs, providing support and guidance to them in the field. The responsibilities as trainer included training of the VHWs in classrooms and ongoing training in the field during supervisory visits.

The medical supervisor was responsible for VHW training on post neonatal disease management, antenatal care, normal new-born care, high risk new-born care and management of neonatal sepsis and birth asphyxia.

The BCC supervisor was responsible for VHW training on hygiene, behaviour change communication, disease prevention, etc. He/ She gave advice & guidance to VHWs on preparation of teaching aids.

The program manager was given the task of organizing training of supervisors, VHWs and TBAs.

Supervision/Monitoring.

It was three tier system.

Supervision of village workers activities:

a) In field:

The treatment of patients by 5 to 6 VHWs were monitored once a week by one medical supervisor and BCC of parents by 5 to 6 VHWs were supervised weekly by one BCC supervisor. Vital statistics data collection of 10 VHWs were monitored fortnightly by each data collection supervisor. The project manager monitored the activities of each VHW once a month.

b) From the record. The VHW activities were monitored regularly by checking their various forms and registers by supervisors (once a week) and project manager (once a month).

Monitoring of the supervisor activities:

The daily activities of all supervisors were monitored through daily report by the project manager & through weekly/ monthly meetings and reports by the pediatrician and project director. The project manager monitored the supervisor activities during field visit once a month.

Monitoring of the project manager activities:

The project director and Pediatrician monitored the activities of project manager via daily report, during weekly meeting & monthly report. Project director and pediatrician visited the villages to monitor activities of all subordinate staff intermittently and whenever needed.

Monitoring indicators:

1. Infant mortality rate = $\frac{\text{Total no. of infant deaths in one year}}{\text{Total No. of live births in that population in the same year (TLB)}} \times 1000$

2. U5MR = $\frac{\text{Total no. of children deaths (0-5 years) in one year}}{\text{Total No. of live births in that population in the same year (TLB)}} \times 1000$

3. Neonatal mortality rate = $\frac{\text{Total no. of new-born deaths in one year}}{\text{Total No. of live births in that population in the same year (TLB)}} \times 1000$

4. Perinatal mortality rate = $\frac{\text{Total no. of still birth + early new-born deaths in one year}}{\text{Total No. of births (live plus still births) in that population in the same year}} \times 1000$

Annexure-3: Community based management of ARI, diarrhea and malaria, in post-neonatal U5 children.

Sub-Phase 1: January 2005 –December 2009: Community based management of ARI, Diarrhea and Malaria, in post-neonatal U5 Children was done with co-trimoxazole, ORS and furoxone (if no response), metronidazole (if dysentery) and chloroquine syrup, respectively as per the standard guidelines. It was delivered by VHWs and regularly monitored by medical supervisors. The period of January 2005 to April 2005 was used for intensive field training, demonstration and supervised pilot treatment activities to understand challenges in actual work. From May 2005, we start actual interventions.

It was continued till the end of research and replication phase.

Provide treatment to post neonatal children under the age of 5 years for:

a. Pneumonia

- Repeat three home visits to children receiving ARI treatment.

  Complete pneumonia form.

b. Diarrhea and dysentery.

- Repeat one home visit to children receiving treatment for diarrhea.

  Complete diarrhea form.

c. Malaria.

- Repeat two home visits to children receiving treatment for malaria.

  Complete malaria form.

Before starting treatment, parents were advised to take the children to hospital for treatment. If parents refused to go to hospital, then informed written consents were obtained before starting treatment.

A) Pneumonia treatment:

1) Cotrimoxazole syrup: was given to children for 5-7 days in the morning and evening. (Trimethoprim: 8 to 10 mg/kg body weight per day in two divided doses).

Age of the patient	Cotrimoxazole pediatric tab. (BD doses)	Cotrimoxazole syrup (BD doses)
	(T 20 + S100)	**T 40 mg + S200 mg (Per 5ml)**
New born baby		1.25 ml to 1.5 ml as per body weight
1 month to 2 months	1 tablet	2.5 ml
2months to 12 months	2 tablets	5 ml
12 months to 5 years	3 tablets	7.5 ml

The patients were examined on the first, second, fourth and seventh day by VHW and once by medical supervisor.

2) Paracetamol in the case of fever (temperature more than 100° F), headache or limb pain of the patient, after drinking milk or after eating food.

Age	**Paracetamol syrup (5 ml = 125 milligram)** (Thrice a day as per body weight: 10-15 mg kg per dose)
New-born baby to 1month	1 to 1.5 ml
1month to 1 year	2 to 5 ml
1 year to 5 years	5 to 8 ml (¼th tablet of 500mg)

3) Asthaline syrup was given if patient has wheeze, breathless/tachypnea even after 2 days treatment of cotrimoxazole. Salbutamol (Asthaline) syrup 0.1 mg/kg body weight 8 hourly to patients above the age of 2 years.

Note: If the patient become serious or no response, send the patient to hospital immediately.

B) Malaria treatment:

Check-up	**1st day**	**2nd day**	**3rd day**
1) Temperature	°F	°F	°F
2) Breath rate (in 1min.)			
3)Are lower ribs pulled inside?	Yes/No	Yes/No	Yes/No
4)Is the child unconscious?	Yes/No	Yes/No	Yes/No
5)Is there any boil?	Yes/No		
6) Is there history of burning micturition?	Yes/No	Yes/No	
7) Is there any pus discharge from ear?	Yes/No	Yes/No	

Diagnosis: If the child had fever (temperature >100 ^{0}F) especially intermittent type with chills, did not have any evidence of other infective source of fever, then it was diagnosed as clinical malaria and the child was empirically treated for malaria.

Treatment of Malaria

Medicine	Doses		
1) Syrup- chloroquine-(after eating food or drinking milk) (1 ml=10mg) (First dose, 10mg per kg body weight, second dose 5 mg per kg body weight, third dose 5 mg per kg body weight, fourth dose 5 mg per kg body weight.)	1 month to 1 year		1 year to 5 year
	4 to 9 ml (40 to 90 mg)	first dose	9 to 18 ml (90 to 180mg)
	After 6 hours		
	2 to 4.5 ml		4.5 to 9 ml
	2 to 4.5 ml	after 12 hours	4.5 to 9 ml
	2 to 4.5 ml	after 12 hours	4.5 to 9 ml

2) Paracetamol in the case of fever (temperature more than 100° F), headache or limb pain of the patient, after drinking milk or after eating food.

Age	**Paracetamol syrup (5 ml = 125 milligram)** (Two to Three times a day as per body weight: 10-15 mg kg per dose)
New-born baby to 1month	1 to 1.5 ml
1month to 1 year	2 to 5 ml
1 year to 5 years	5 to 8 ml (¼th tablet of 500mg)

If the patient's condition has not recovered/ worsens/ becomes unconscious/has reduced or absent urine output, then refer the patient immediately to the hospital.

C) Treatment of diarrheal diseases:

1. MAHAN ORS or WHO ORS or homemade ORS as per dehydration of patient and status of dehydration. (100ml per kg per day)

2. Drugs:

Name of the disease	Treatment	1 month to 1 year	1 year to 5 years
A) Diarrhea (Only if there is no relief after 24 hours of ORS therapy or severe dehydration or fever/ dysentery)	1) Tab. norfloxacin 100mg Or Syrup norfloxacin 5ml=100mg (5.2-17.9 mg/kg/day for 3 to 5 days.)	1 to 2.5 ml BD for 5 days (as per body weight)	Half to 1 BD for 5 days 2.5 ml to 5 ml BD for 5 days (As per body weight)
	Or 2) Syrup. furoxone 5ml=50mg (7mg/kg/day)	0.5 to 1.5 ml four times a day for 3 days (as per body weight)	1.5 to 3ml four times a day for 3 days (as per body weight)

B) Dysentery (In addition to above treatment)	Syrup metronidazole (5ml=200mg) (20-30 mg/kg/day) plus Norfloxacin/Furoxone as above.	1 to 2 ml thrice a day for 5 to 7 days (as per body weight)	2 to 3 ml thrice a day for 5 to 7 days (as per body weight)
Vomiting	Domperidone 5mg (0.3 mg/kg given T.D.S. before meals as per need)	¼ to half Tab. Thrice a day	Half to 1 Tab. Thrice a day
Worm infestation.	Albendazole 400mg	Only above the age of two years: 1 tab. on first day Second tab. after 15 days	

Annexure-4: Home based neonatal care (HBNC)

Sub-Phase 2*:*

November 2006 -December 2009: Implementation of antenatal, natal and newborn care i.e., HBNC was added to post-neonatal disease management. It was continued till the end of research project and in replication phase.

A) Antenatal care: (ANC)

1) The village health worker (VHW)

The VHW is the direct provider of components of the HBNC. Preparation of list of women in the reproductive age group who can become pregnant and preparation of list of pregnant women; provision of maternal health care, neonatal health care and the child health care as specified in the HBNC package are the main responsibilities of the VHW. Record keeping is also an essential component of her responsibility. These records include: record of history of the pregnant woman, condition of the pregnant woman. She works in smooth collaboration with traditional birth attendants (TBA)

Other job responsibilities of VHWs are as follows:

- She periodically visits every house in her village and collect information on all married women of child bearing age-every 2 months
- Make a list of women eligible to become pregnant, every 6 months
- Identify pregnant women and register them (Pregnant Mothers Form)- every month. And collect information on their previous deliveries and present condition.
- Refer pregnant women to auxiliary nurse midwife (ANM) for iron and folic acid & for tetanus toxoid injection.
- Organize and assist supervisors in conducting group health education for pregnant women every 4 months in the village and evaluate effect of health education.
- Make two antenatal visits to pregnant women in the village as follows:

a) <u>At 7th month of pregnancy</u>

i) Conduct health screening (pregnant mothers form)

ii) Provide health education (using counseling cards appropriately) on

Nutrition during pregnancy.

Danger signs in pregnancy and appropriate action

Provide health information sheet to expectant mothers

iii) Advise on taking iron and folic acid and tetanus toxoid from ANM

b) <u>At 9th month of pregnancy</u>

i. VHWs made home visits in the third trimester.
ii. Conduct health screening (pregnant mothers form).
iii. Provide health education (using counseling cards appropriately) on danger signs in pregnancy and labor & action to be taken.
iv. Planning for delivery.
v. Breast feeding especially within one hour of delivery.

The traditional birth attendant (TBA)

a) Reinforce the health education messages given by VHWs to pregnant mothers and her relatives such as mother and mother-in-law.

b) Encourage mother to access antenatal care (ANC) from the regular government health services or VHW.

c) Insist that family calls VHW (if VHW not present) to assist and guide her during delivery e.g., cleaning of blades with spirit, application of G.V. paint to umbilical cord, guidance on hygiene within few hours after delivery.

d) Work in collaboration with VHW.

Medical supervisor

Check list of pregnant women, supervision and guidance of work of VHW, conduct group health education of pregnant women during the village visit (once in 15 days). Organize training of VHWs for HBNC.

B) Natal care:

The traditional birth attendant (TBA)

a) Conduct hygienic and safe delivery.
b) Recognize danger signals in mother (delivery, post-partum) and refer.
c) Clean and cover the baby properly (in absence of HBNC VHW).
d) Initiate early and exclusive breast-feeding.
e) Work in collaboration with VHW.

The TBA is also an independent source for collection of information on births and deaths.

VHWs: VHWs made home visits, attended delivery and observed labour. Her job responsibilities were as follows.

a) Record information on delivery and birth. (Delivery Form)
b) Give emotional support to mother and family.
c) Encourage/assist cleanliness, hand washing, use of new blade, etc.
d) Assist TBA in safe delivery and referral when necessary.
e) Recognize danger signals in newborn and refer when necessary.
f) Clean and cover the baby properly.
g) Encourage mothers to start breast-feeding in the first hour after birth and continue exclusive breastfeeding on demand.
h) Work in collaboration with TBA.
i) Watch of birth asphyxia, if birth asphyxia present, then start birth asphyxia management.

To prevent umbilical cord infection, VHW and TBAs were trained and encouraged for hand washing with soap three times, cord cutting with a clean sterile blade and tying with clean thread, and applying gentian violet to the umbilical stump.

C) Newborn care:

VHWs made home visits, observed neonates at birth, visited the home on days 2, 3, 5, 7, 14, 21, 28 (total 7 visits for normal neonates) and on any other day if the family called, to take history, examine mother and child. VHW weighed the child each week, and managed minor illnesses and pneumonia in the neonates and recorded the data. They followed up the neonates for 28 days after birth, until the mother left the village, or until the neonate died, whichever was earlier.

During the normal and high-risk neonatal care phase of the study, traditional birth attendants and VHWs placed chloramphenicol ointment or gentamicin eye drops in the eyes of all babies, encouraged skin hygiene, applied 1% gentian violet to umbilical cord and pyoderma or intertrigo. VHWs gave an injection of vitamin K 1 mg to each baby using dispensable insulin syringe.

Temperature maintenance was ensured (baby was kept warm) by keeping the room warm in winter, by drying the baby immediately after birth and covering in multilayered cloth, by use of head cover and baby clothes, and by wrapping the baby in a blanket in winter. Neonates' axillary temperature was measured by VHWs using digital thermometer (Sakura, Japan). Birth weight was assessed within 6 h of birth by hand-held spring weighing-balance (Salter, UK). Neonates with gestation of less than 37 completed weeks (calculated from the last date of menstruation), or those with birth weight below 2500 g were considered as high-risk babies. For high-risk babies, 13 home visits were conducted by VHWs. These babies were managed by maintaining temperature, frequent breast feeding, Kangaroo mother care, preventing recurrent handling by different people and 13 home visits. High-risk babies or babies with hypothermia (temperature <95°F or 35°C) were kept in sleeping bags or blankets after initial warming with heated cloth. Fever (>99°F or 37.2°C) was treated with oral acetaminophen. Health workers and birth attendants encouraged mothers to start breast-feeding in the first hour after birth and continue exclusive breastfeeding. If the baby was unable to breast feed, expressed breast milk was fed by paladi spoon. Health workers managed inverted nipples or painful breasts and breast pump was used if needed. Breast milk, if inadequate, was supplemented with sheep's milk or cow's milk and fed by spoon.

The next phase included management of neonatal sepsis and asphyxia and has been described under the case management section.

Sub-Phase3: May 2007 - December 2009.

It was continued till the end of replication phase.

A) Case management:

1) Birth Asphyxia: The case management of neonates was done as described in details by Bang et al. Briefly, the VHWs were issued with a care kit (the contents of the kit are as described in the annexure 6) and trained to diagnose and manage neonatal disorders. Birth asphyxia was diagnosed at 30 second or 1 min after birth, and managed by clearing mucus from mouth- nose, with an oral infant mucus sucker with mucus trap (Romsons, India) and tactile stimulation. If necessary, artificial respiration was provided by ambu bag and mask (Phoenix Medical Systems, Chennai, India).

2) Neonatal sepsis: We used the term neonatal sepsis collectively for septicemia, meningitis, or severe pneumonia, diagnosed clinically.

Neonatal sepsis was diagnosed clinically,[(1)] by simultaneous presence of any 2 of 7 signs: i) baby's cry became weak or abnormal or stopped; ii)baby stopped sucking or mother felt that sucking definitely became weak or reduced; iii)limp extremities or baby became drowsy or unconscious/ presence of convulsions; iv) skin temperature more than 99°F (37.2°C) or less than 95°F (35.0°C); v)purulent discharge from umbilicus; vi)diarrhea or persistent vomiting or distension of abdomen; vii)grunting or severe chest indrawing; respiratory rate 60 or more per min in a quiet baby even after two counts.[(2)], [(3)]

From May 2007, the VHW were trained for recognition and management of neonatal sepsis.

After training, the VHWs were assessed, and on reaching a satisfactory competence (evaluated by experts from SEARCH) they started treating sepsis at home from May 2007. When the hospital referral was not accepted, treatment was given by VHW.

(i) Gentamicin once a day was given by intramuscular injection with disposable insulin syringes (40 units/mL) over antero-lateral aspect of the thigh.

Weight of baby in grams	**Dose: Premature babies**	**Dose: Full term babies**
Less than 1500	5mg	8mg
1500-2000	5mg	10mg
2000-2500	7mg	12mg
2500-3000	9mg	15mg
Above 3000		18mg
Frequency-duration	Once a day for 10 days	Once a day for 7 days

(ii) Syrup co-trimoxazole (sulphamethoxazole 200 mg, trimethoprim 40 mg/5 mL) 1.25 mL was also given twice a day for 7 days for fully mature babies and for 10 days for premature babies.[(4)]

(iii) Oral acetaminophen10mg/kg/dose for fever.

The trial did not provide for any referral care to neonates apart from that already available at government hospitals. The family was free to seek care from other sources as well. The rate of hospital admission was recorded.

B) **The intensive health and nutrition education part** of this phase included providing health, hygiene and nutrition-malnutrition education with the help of flip charts and an audiovisual CD to women in the villages. The education addressed care and nutrition during pregnancy, initiating early and exclusive breast feeding, complementary feeding, infant and young children feeding practices (locally available, homemade, safe food), prevention of infection, temperature maintenance, importance of weight gain, growth chart, recognizing danger signs or symptoms in neonates, and seeking immediate help from a health worker.

Job description of VHW under Home- Based newborn Care (HBNC)

1) The village health worker (VHW)

The VHW is the direct provider of components of the HBNC. Provision of neonatal health care and the child health care as specified in the HBNC package are the main responsibilities of the VHW. Record keeping is also

an essential component of her responsibility. These records include: record of delivery, first examination of the neonate, condition of the mother and the neonate during home visits, diagnosis and the treatment provided.

VHWs have to observe the newborn after delivery

a) Observe the newborn baby at 30 seconds after birth for cry, respiration, umbilical cord pulsations and movement of limbs.
b) Determine whether the baby is normal or asphyxiated or is a still birth: and if the baby is not normal initiate asphyxia management
c) Dry and wrap the baby
d) Observe the newborn baby at 5 minutes (severe asphyxia) or 20 minutes (still birth) after birth for cry, respiration, umbilical cord pulsations and movement of limbs
e) Initiate breast-feeding: assist as necessary for flat or inverted nipples.
f) Initiate management of birth asphyxia if needed
    i. By using mucous sucker, ambu-bag and mask (tube& mask) as per requirement
    ii. Determine at 20 minutes after birth if new born is a stillbirth.

Perform first examination of the baby 1 hour after birth and complete the first examination part of the newborn form. Determine whether the newborn is a high-risk baby or not.

Provide care for the normal newborn

a) Provide 'Danger signs in newborn' information sheet to the family of the newborn and explain.
b) Provide care for the high-risk newborn.
c) Provide 'High risk baby' information sheet to the family of the newborn and explain.
d) Give Vitamin K injection.
e) Conduct 7 regular home visits for mother and the normal newborn baby on day 2,3,5,7,15,21 and 28 and additional if baby is sick on any other day, conduct examination and record findings and fill
    i. Home visit form.
    ii. Part I of the newborn health care evaluation form on 2nd day and Part II by completion of the 28th day.

iii. Breast feeding problem diagnosis form on each day of visit

iv. Sepsis diagnosis form on each day of visit

f) Conduct 13 regular home visits for mother and the high-risk newborn baby on day 2,3, 4,5,6,7,9,12,15,18,21,24,28 and additional if needed, and fill

i. Home visit form.

ii. Part I of the newborn health care evaluation form on 2nd day and Part II by completion of the 28th day.

iii. Breast feeding problem diagnosis form on each day of the visit.

iv. Sepsis problem diagnosis form on each day of the visit.

Identify and manage following problems in newborn baby after proper consent, if the parents are not willing to take the baby to hospital.

1) Asphyxia.
2) Premature birth.
3) Low birth weight< 2500 gms.
4) Hypothermia.
5) Breast feeding problem.
6) Inadequate weight gain.
7) Neonatal sepsis.
8) Pneumonia.

Decide after 24 hours of initiating treatment (for some of above conditions) whether there is improvement. If yes, continue treatment, if no, refer to hospital.

Health education of mother after delivery.

Continue home visits in second month (1 visit every week), if at 28 days after birth the weight of the baby is less than 2.5 kg.

a) Complete 2nd month Home Visit Form.

b) Initiate treatment for problems described above.

- Self-evaluate the care, identify success, deficiencies, etc.
- Maintain all registers and records.

- Maintain VHW kit and seek timely replacement/repair.
- Maintain medicine stock and seek timely replenishment.
- Work with the supervisor on the day of her visit.
- Cooperation with government health care system or other health providers.

Medical supervisor:

Medical supervisors were a physician trained in homeopathic medicine and a pharmacist/ANM (both trained for supervision of VHS by SEARCH), visited each village once every 2 weeks. The medical supervisors verified the data recorded by the VHWs, corrected and educated them. Both medical supervisors verified the drug stock record, conducted supervision and training of VHWs. They did not provide any treatment.

If a neonate was found seriously ill, hospital admission was recommended, but the final decision was left to the family. Records of the neonates in the intervention area who were attended by the female VHWs but who died, were reviewed by an independent physician and pediatrician, who assigned cause of death by use of criteria similar to those used by the expert group of the National Neonatology Forum of India. The primary cause of death included prematurity,[5] low birth weight babies,[6] birth asphyxia, neonatal sepsis, breast feeding problems, ARI, Malaria, diarrhea, malnutrition, other (e.g., malformations, hypothermia, tetanus), and cause not known.

Recording of births and child deaths was done during 2004–09 by independent set of workers i.e., data collection supervisors and retrospective surveyors in the intervention and the control areas. Besides prospective reporting by VHWs and data collection supervisors, retrospective surveyors undertook a house-to-house survey in both areas, once every 6 months, to detect any missed events. Births and neonatal deaths were counted in the village where the events actually occurred. If a hospital-born neonate was brought to a village, it was included. Similarly, if an ill neonate from the area was admitted to hospital and died there, the death was included. Costs (training, equipments, wages and incentives, medicines and supplies, records, supervision and transport) were recorded.

Additional responsibilities of medical supervisor

1) Visit each newborn twice. Conduct detail examination.
2) Supervise all activities conducted by VHWs.
3) Training of VHWs for newborn care.

Annexure 5:

The Service phase (1st January 2010 to 31st December 2015):

The health care delivery by VHW continued but cross checking and monitoring of each and every process by program manager and principal investigator was not maintained; however, supervision by supervisors continued. It was like in large public health system where regular daily monitoring by higher medical staff is lacking. The objective is to see whether our methodology will work in large public health system or not. If it works, then MAHAN will approach to policy makers to make it government policy to replicate similar interventions in all tribal blocks of India.

The Replication phase (1st September 2016 – 31st August 2019):

Dr. Ashish Satav was always asked by government staff that: is really the home-based child care model is replicable or not in new area without Dr. Satav. Hence to give practical reply to this question, we randomly selected 20 new villages for replication of our intervention. The Government of Maharashtra validated the replicability of interventions for reducing neonatal, infant and under-five mortality rates by randomly adding those 20 new villages from Dharni block. The Government of India provided financial support via tribal development department. Government and MAHAN in collaboration adopted the same methods used in the service phase for these villages. An integrated accelerated stepwise approach of simultaneous implementation of all interventions was adopted following a one-month training for VHW's and supervisors in the Government-MAHAN adopted villages. There were no control villages during this phase.

The government vision was that if we can successfully reduce the mortality rates in new 20 villages, then government may plan to replicate it in all tribal villages of Melghat.

Annexure 6:

List of items in the VHW kit and medicine stock

Sr. No	**Item**	**Make**	**Quantity per VHW**
1	Wrist watch		1
2	Digital thermometer	Becton & Dickinson B-D soft Flexible digital thermometer	1
3	Weighing Scale with sling	1.Salter weighing Scale. Model-Super Samson. Capacity: 5kg 2. Salter weighing Scale Capacity: 25kg. 3. Adult weighing scale	1 1 1.
4	Photo album of 13 photograph	MAHAN and SEARCH,	1 album
5	Ambu bag	Phoenix, Chennai	1
6	Warm bag (to keep a pre-term or cold baby)	Made to order as per scientific specifications.	2-3
7	Blankets (1 meter *1 meter)	Can be purchased/ ordered locally	500 per year.
8	Kangaroo mother care blouse	Made to order as per scientific specifications locally.	2
9	Disposable plastic Mucus extractor	Can be purchased/ordered locally	2
10	Health education booklet/flipchart	Made by MAHAN and SEARCH	2
11	Palady (special spoon) for feeding neonates	Can be purchased/ordered locally	2

Sr. No	**Item**	**Make**	**Quantity per VHW**
12	Torch with cells	Can be purchased/ ordered locally	1
13	Spoon	Can be purchased/ ordered locally	1
14	Trunk for storage of kit, records etc, size 22" x 12" x 10"	Can be purchased/ ordered locally	2
15	Bag for carrying kit/ material during home visits.	Can be purchased/ordered locally	1
16	Tab paracetamol 500 mg	Can be purchased/ ordered locally	225 per month.
17	Tab acetylsalicylic acid 300 mg (aspirin) (for adults)	Can be purchased/ ordered locally	200 per month
18	Gentian violet paint 400 ml bottle	Can be purchased/ ordered locally	1 bottle per month
19	Injection gentamicin vial 80 mg x 2 ml vial (40 mg per ml)	Can be purchased/ ordered locally.	1-2Vials per month
20	Surgical cotton	Can be purchased/ ordered locally	1 bundle per month
21	Tab. co- trimoxazole (trimethoprim 20 mg+ sulphamethoxazole 100 mg)	Can be purchased/ ordered locally	200 per month
22	Syrup co- trimoxazole (trimethoprim 40 mg + sulphamethoxazole 200 mg)	Can be purchased/ ordered locally	10 per month

Sr. No	**Item**	**Make**	**Quantity per VHW**
23	Spirit	Can be purchased/ ordered locally	100 ml per month
24	Insulin syringe (for injecting gentamicin)	Can be purchased/ordered locally	10 per month
25	Tab. salbutamol- 2mg	Can be purchased/ ordered locally	20 per month
26	Injection vitamin K 10 mg ampoule.	Can be purchased/ ordered locally.	One per newborn*
27	Eye ointment chloromycetin eye applicap.	Can be purchased/ ordered locally	Two per newborn(1000 for 19 villages)
28	Oral rehydration packets.	Can be purchased/ ordered locally.	15 packets per month.
29	Tab. albendazole	Can be purchased/ ordered locally.	20 per month
31	Syrup chloroquine	Can be purchased/ ordered locally	10 bottles (60 ml. each)
32	Tab. furoxone	Can be purchased/ ordered locally	150 tab. Per month
33	Tab. norfloxacin 100mg	Can be purchased/ ordered locally	150 tab. Per month
34	Amoxycillin 125mg dispersible tablets	Can be purchased/ ordered locally	100 per month

Sr. No	**Item**	**Make**	**Quantity per VHW**
35	Syrup metronidazole	Can be purchased/ ordered locally	5 bottles
36	Syrup furoxone	Can be purchased/ ordered locally	10 bottles.
37	Syrup albendazole 10 ml.	Can be purchased/ ordered locally	3 bottles.
38	Syrup paracetamol	Can be purchased/ ordered locally	15-bottles/month
39	Tab. domperidone 5 mg.	Can be purchased/ ordered locally	15 per month.
40	Tab. Chlorpheniramine maleate (CPM)	Can be purchased/ ordered locally	10 tab./ month.
41	Antiseptic powder (10gram)	Can be purchased/ ordered locally	2-3 packs/month
42	Adhesive plaster	Can be purchased/ ordered locally	1 pack per month

Supplementary tables:

Table 1S: Household level characteristics of U5 children in Control and Intervention area

Variable	**Category**	**Control**	**Intervention**
		n=4426	**n=3230**
Main occupation [No. (%)]	Farmer	2382 (53·8)	1421 (43·9)
	Labour	96 (2·2)	31 (0·9)
	Government job	12 (0·3)	27 (0·8)
	Private job	1360 (30·7)	1190 (36·8)
	Unemployed*1	576 (13·0)	561 (17·4)
Agriculture [No. (%)]	Yes	2160 (48·8)	1305 (40·4)
Wall Type*2 [No. (%)]	Kaccha	3348 (75·6)	2306 (71.4)
Roof Type*3 [No. (%)]	Kaccha	3320 (75·0)	2222 (68·8)
Electricity [No. (%)]	Yes	334 (7·5)	328 (10·2)
House ownership [No. (%)]	Yes	3680 (83·1)	2513 (77·8)
Use of toilet [No. (%)]	Yes	240 (5·4)	258 (7·9)
Cooking facility*4 [No. (%)]	Wood	3380 (76·4)	2594 (80·3)
Separate kitchen [No. (%)]	Yes	1046 (23·6)	378 (11·7)
Drinking water source	Well	836 (15·5)	609 (18·9)
[No. (%)]	Hand pump	1649 (37·3)	972 (30·1)
	Tap	645 (14·6)	681 (21·1)
	Well & hand pump	301 (6·8)	248 (7·7)
	Well & Tap	305 (6·9)	96 (2·9)
	Others*5	690 (15·6)	624 (19·3)
Vehicle [No. (%)]	None	3113 (70·3)	2184 (67·6)
	Bullock cart / Cycle or both	1203 (27·2)	938 (29·0)
	Others*6	110 (2·5)	108 (3·3)
Media [No. (%)]	None	4083 (92·3)	2856 (88·4)
	Radio / newspaper / both	343 (7·8)	374 (11·6)

Variable	**Category**	**Control**	**Intervention**
		n=4426	**n=3230**
Animals [No. (%)]	None	2797 (63·2)	2068 (64·0)
	Cattle	1629 (36·8)	1162 (35·9)
Community type [No. (%)]	Tribal	3792 (85·7)	2695 (83·4)
	Others[*7]	634 (14·3)	535 (16·6)
Caste [No. (%)]	Korku	3488 (78·8)	2411 (74·6)
	Other castes[*8]	938 (21·2)	819 (25·4)
Mother literacy [No. (%)]	Literate	1663 (37·6)	1306 (40·4)
Father literacy [No. (%)]	Literate	2720 (61·5)	2125 (65·8)

[*1]No work / household work; [*2]*Kaccha wall*: Made up of soil; [*3]*Kaccha roof*: Made up of tin/ thatch / mixed material; [*4]Others used Kerosene / Gas / Sigri; [*5]Pond / River / Hand pump & River / Well & River or not fixed; [*6]Bullock cart with two-wheeler or four-wheeler; [*7]Non-tribals and others; [*8]Gond, Bhilala, Mongia, Gavlan, Balai

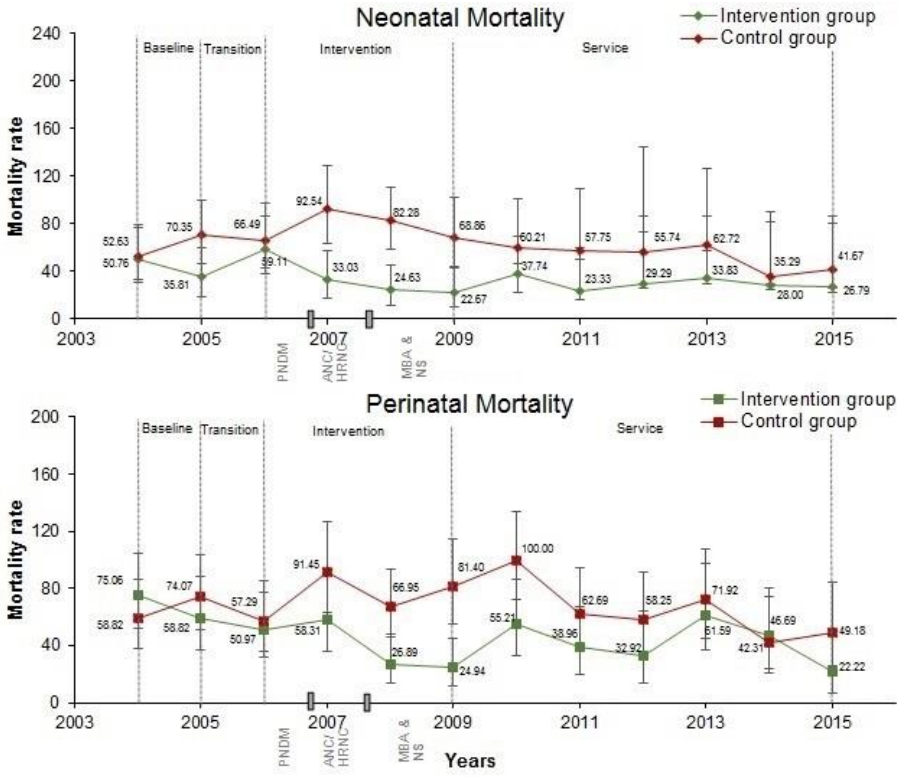
Table 2S: Comparison of mortality rates in Control and Intervention groups from 2004-2009 [Secondary outcomes]

	Year	CONTROL				INTERVENTION				Absolute reduction in IRR between intervention and control arms	
		Deaths /Live Births	Incidence Rate/1000 Live Births	Rate Ratio (95% CI), P-value		Deaths /Live Births	Incidence Rate/1000 Live Births	Rate Ratio (95% CI), P-value		(95% CI), P-value	
				Crude (cIRR)	Adjusted (aIRR)*			Crude(cIRR)	Adjusted (aIRR)*	Crude	Adjusted*
Neonatal Mortality	2004	21/399	52·6	Ref.	Ref.	20/394	50·8	Ref.	Ref.	Ref.	Ref.
	2005	28/398	70·4	1·34 (0·76 to 2·35), 0·313	1·23 (0·71 to 2·16), 0·462	13/363	35·8	0·71 (0·35 to1·42), 0·325	0·83 (0·43 to 1·58), 0·572	0·53 (0·22 to1·30); 0·166	0·67 (0·29 to 1·59); 0·183
	2006	25/376	66·5	1·26 (0·71 to 2·26), 0·428	1·18 (0·68 to 2·08), 0·557	24/406	59·1	1·16 (0·64 to 2·11), 0·615	1·16 (0·65 to 2·10), 0·588	0·92 (0·40 to 2·11); 0·845	0·98 (0·44 to 2·21); 0·482
	2007	31/335	92·5	1·75 (1·01 to 3·09), 0·043	1·75 (1·05 to 2·99), 0·029	11/333	33·0	0·65 (0·30 to 1·35), 0·248	0·63 (0·29 to 1·28), 0·211	0·37 (0·14 to 0·95); 0·038	0·36 (0·14 to 0·89); 0·018
	2008	39/474	82·3	1·56 (0·92 to 2·27), 0·096	1·47 (0·88 to 2·51), 0·141	10/406	24·6	0·49 (0·23 to 1·04), 0·056	0·48 (0·22 to 0·98), 0·047	0·31 (0·13 to 0·76); 0·009	0.33 (0·13 to 0·81); <0·001
	2009	23/334	68·9	1·31 (0·72 to 2·38), 0·371	1·01 (0·57 to 1·79), 0·977	9/397	22·7	0·45 (0·20 to 0·98), 0·039	0·44 (0·19 to 0·93), 0·038	0·34 (0·13 to 0·93); 0·035	0·44 (0·16 to 1·16); 0·041

Perinatal Mortality	2004	24/408	58·8	Ref.	Ref.	31/413	75·1	Ref.	Ref.	Ref.	Ref.
	2005	30/405	74·1	1·26 (0·74 to 2·15), 0·398	1·14 (0·67 to 1·94), 0·624	22/374	58·8	0·78 (0·45 to 1·35), 0·381	0·85 (0·51 to 1·42), 0·543	0·62 (0·29 to 1·33); 0·219	0·74 (0·36 to 1·56); 0·222
	2006	22/384	57·3	0·97 (0·55 to 1·74), 0·928	0·95 (0·54 to 1·66), 0·858	21/412	50·9	0·68 (0·39 to 1·18), 0·168	0·68 (0·39 to 1·15), 0·145	0·70 (0·32 to 1·56); 0·383	0·72 (0·33 to 1·56); 0·208
	2007	31/339	91·5	1·55 (0·91 to 2·65), 0·101	1·47 (0·89 to 2·45), 0·132	20/343	58·3	0·78 (0·44 to 1·36), 0·377	0·77 (0·44 to 1·32), 0·355	0·50 (0·23 to 1·09); 0·083	0·52 (0·25 to 1·10); 0·038
	2008	32/478	66·9	1·14 (0·67 to 1·93), 0·632	1·05 (0·63 to 1·78), 0·849	11/409	26·9	0·36 (0·18 to 0·71), 0·002	0·36 (0·17 to 0·68), <0·001	0·32 (0·13 to 0·75); 0·009	0·34 (0·14 to 0·82); 0·008
	2009	28/344	81·4	1·38 (0·80 to 2·39), 0·241	1·09 (0·64 to 1·86), 0·752	10/401	24·9	0·33 (0·16 to 0·68), 0·001	0·33 (0·15 to 0·64), <0·001	0·24 (0·09 to 0·59); <0·001	0·30 (0·12 to 0·74); <0·001

*Adjusted for sex, wealth index of individual and village/cluster status using log-binomial regression

Figure 1S: Line plots showing neonatal and perinatal mortality rates in intervention and control areas in different phases across time.



PNDM: Post-Natal Disease Management; ANC: Antenatal Care; HRNC: High Risk New-born Care; MBA: Management of Birth Asphyxia; NS: Neonatal Sepsis.

Annexure 7

Payment or honorarium of village health workers.

The village health workers were paid by MAHAN trust. The payment of VHWs was based on fair market value, and was job based rather than a fixed salary. Given the length of time that the project has been running, the salaries were adjusted for inflation. For this reason, it is not possible to give exact numbers.

MAHAN Trust, Melghat: Template of VHWs reimbursement for HBCC project. Date

Sr. No.	Particular	Rate (Rs)	Month	
			Unit	Amount
1	New born baby visit form (A form)	10		
2	Presence during delivery	150		
3	Pregnancy registration before 12 weeks	20		
4	ANC after 12 weeks	10		
5	ANC health education	20		
6	Diarrhea treatment	10		
7	Malaria treatment	15		
8	Pneumonia treatment	20		
9	Treatment of other diseases of 0-5 years age group patient	5		
10	Health education for 0-5 years age group	20		
11	New born birth asphyxia management.	60		
12	New born sepsis management.	60		

Sr. No.	Particular		Rate (Rs)	Month	
				Unit	Amount
13	New born hypothermia treatment.		10		
14	Weight record of child 0- 5 yrs.		2		
15	Height/length record of child 0- 5 yrs.		2		
16	Head circumference record of child 0- 5 yrs.		2		
17	MUAC record of child 0- 5 yrs.		2		
18	Birth slip preparation and submission to office.		10		
19	Death slip preparation and submission to office.		20		
20	Visit of project manager or guest to the VHW. (Time duration.)	Up to half hour	25		
		Half to 2 hours.	50		
		2 to 4 hours.	75		
		Above 4 hours.	150		
21	HBCC coordinator visit		100		
22	Medical supervisor visit		150		
23	Statistical/data collection supervisor visit		140		
24	Pregnant woman weight record		1		
25	BCC supervisor visit		140		

Received by: Name and sign

Confirmed by:

Medical supervisor: Name & Sign:			
BCC supervisor: Name & Sign:			
Data collection supervisor: Name & Sign:			
Coordinator: Name & Sign:			
Project manager: Name & Sign:			
Finance manager: Name & Sign:			

Accountant: Chief Functionary

Annexure 8

"Vital Event Capture Methodology"

The village health workers collected the vital events in the two arms by door-to-door surveys of the households immediately after the event occurred, within 24 hours. They filled out the death and birth forms, confirmed it by the parents or near relatives (in the absence of parents) who signed the forms. Each vital event was confirmed by a data collection supervisor (within 15 days) and a retrospective surveyor (within 6 months) by door-to-door visits of the households. The vital events were further confirmed by the sarpanch (elected village head) and the police patil (government appointed village key person) within 15 days. We also collected vital data from government Health and Integrated Child Development Scheme departments, to collect any missing vital data. Verbal autopsy was conducted by data collection supervisors and VHWs. It was confirmed by parents, the sarpanch and the police patil.

The verbal autopsies revealed the causes of death. It helped us to plan our interventions to reduce the deaths. The findings are given in the table below.

Underlying Causes of death	**Number**	**%**
Prematurity / LBW	388	30.19
RDS / Pneumonia	180	14.01
CNS Infection	172	13.39
Diarrhoeal diseases	133	10.35
Fever including malaria	87	6.77
Birth injury / asphyxia	74	5.76
Hypothermia	59	4.59
Malnutrition	51	3.97
Sepsis	48	3.74
Others	93	7.24
Total	**1285**	**100.00**
Most probable causes of deaths.		**%**
Prematurity / LBW	388	26.23

Breast feeding problem	194	13.12
RDS / Pneumonia	180	12.17
CNS Infection	172	11.63
Diarrheal diseases	133	8.99
Fever including malaria	87	5.88
Birth injury / asphyxia	74	5.00
Hypothermia	59	3.99
Malnutrition	51	3.45
Sepsis	48	3.25
Others	93	6.29
Total	**1479**	**100.00**

Appendix S1 – Reflexivity Statement.

Consensus statement on measures to promote equitable authorship in the publication of research from international partnerships.[7]

Study conceptualisation

1. **How does this study address local research and policy priorities?**

   This study was conducted in a rural area of Maharashtra, India with high infant and under 5 mortalities, the reduction of which is a high global, national and local priority. Research into sustainable methods for mortality reduction have become top priorities for the local villages and Amravati district, as well as Maharashtra state and India. It is a global priority for achieving the SDG's.

2. **How were local researchers involved in study design?**

   The local researchers Dr. Ashish Satav, Dr. Kavita Satav, Dr. Abhijit Bharadwaj, Mrs. Jayashri Pendharkar designed the study from the beginning. Dr. Ashish and Dr. Kavita realised the need of reducing very high malnutrition and mortality in this area and were involved in developing solutions for high mortality rates in this area, three years before starting the study. They realised that the low and delayed health seeking behaviour and scarcity of doctors were major causes of the high U5MR and IMR in this region. Hence the local researchers designed the home-based child care program to address health care needs of the community and to reduce U5MR and IMR.

Research management

3. **How has funding been used to support the local research team?**

   This project was funded by national and international funding agencies to support the recurring expenditure and salary expenses of the local research staff working in this project. Entire funds were utilized on activities by the local research team. The international researcher's contribution was voluntary and he was paid nothing for his involvement in this study.

Data acquisition and analysis

4. How are research staff who conducted data collection acknowledged?

All investigators have been included as co-authors, and given priority as first author and the subsequent authors. Contribution made by the data collection team has been recognized in the acknowledgment section.

5. Do all members of the research partnership have access to study data? How have members of the research partnership been provided with access to study data?

All members of the research partnership have access to the study data. All data are housed on databases at the local site. The statisticians work with these databases to run analysis. All authors requested analyses that satisfied their individual probing of the data for consistency of data and completeness of data.

6. How was data used to develop analytical skills within the partnership?

The senior investigators arranged multiple meetings with the junior staff for the data analysis. The junior staff were trained by the statistician for data analysis throughout the entire study period. The data staff were given responsibilities to analyse the data locally as much as they can. Quality of data was assessed by the LMIC statistician and investigators. Local team members were actively involved in data analysis, and all data analysis was only done locally. Data was never sent out of the country.

Data interpretation

7. How have research partners collaborated in interpreting study data?

Five inclusive online and offline workshops were held during the process of data interpretation. The first two sessions served to define the issue of research and agreement that we should focus on the development of equitable partnership. At the conclusion of these two sessions, researchers formed working groups to conduct literature reviews. These reviews were reported back at a subsequent workshop where all partners collaborated to agree on recommendations and contents of the results and discussion sections. During final meetings, all the investigators interpreted the final study data with the help of data team. Local team members were involved in conception, design, data acquisition and data analysis. [(8)]

Drafting and revising for intellectual content

8. How were research partners supported to develop writing skills?

The research team for drafting and revising the intellectual content is predominantly composed of senior Indian investigators. The junior authors were supported by senior academics who worked in small groups to develop and refine their writing skills. The senior author guided the Indian writing team for publication in international medical journals.

9. How will research products be shared to address local needs?

The study results will be disseminated with the local community members, key public representatives, local government health and integrated child development scheme staff (village to district level) and other local voluntary organisations and academicians. Advocacy meetings will be conducted with above external stakeholders who influences local policy changes and if needed public interest litigation will be filed for its implementation in all 300 villages of the two rural blocks of Amaravati district. For its wide dissemination in local community, we will use methods like community meetings, davandi (announcement in local language by a key person), pamphlets, street plays, one to one counselling, group counselling and audio-visual shows.

This study will be published in an open access platform. A post-publication dissemination plan has been devised to discuss the study findings and recommendations across a wide constituency of scientific fora and conferences. This will include interactions with research leaders engaged in setting national and international health priorities and other fields involved in national collaborations, and also with the media including press and journalists, based in Maharashtra state and other states of India. We propose to conduct advocacy meetings with government officers and other stakeholders who are especially dealing with the implementations of various health schemes and integrated child development schemes in the community and other voluntary organisations (NGOs, CBOs) and academicians for replication of the study in other parts of the country.

Authorship

10. **How is the leadership, contribution and ownership of this work by LMIC researchers recognised within the authorship?**

Authors Ashish Satav, Vibhawari Dani and Dhananjay Raje worked as part of the senior authorship team in developing this manuscript, and their contribution has been recognised as joint first and main co- authors respectively. We have specifically included researchers based in the USA (Eric Simoes) within the senior authorship team as last author. We acknowledge, that the authorship team is predominantly based in LMIC. LMIC team members were given ample opportunity to sign off on the final manuscript version.[(8)] All LMIC authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.[(8)]

11. **How have early career researchers across the partnership been included within the authorship team?**

We have included early career researchers (Kavita Satav, Abhijit Bharadwaj, Jayashri Pendharkar) within the authorship team. They attended all the workshops, contributed to the literature review and evidence synthesis and for development of the consensus recommendations. They are based in India.

12. **How has gender balance been addressed within the authorship?**

Five authors are male (Ashish Satav, Abhijit Bharadwaj, Dhananjay Raje, Suresh Ughade, Eric Simoes) and three authors are female (Kavita Satav, Jayashri Pendharkar and Vibhawari Dani).

Training

13. **How has the project contributed to training of LMIC researchers?**

All the senior authors based in LMIC have contributed to the training of the early career research staff. The senior author from USA assisted with the planning of the analysis as well as assisted with writing, and as such contributed to training of all LMIC authors as well.

Infrastructure

14. How has the project contributed to improvements in local infrastructure?

This project has directly contributed to improvements in local infrastructure. This project has strengthened the research capacity of the local investigators, developed a resource pool of grass root manpower which can now do other research studies also. We could procure some logistics like vehicles and other valuable items, which can be used, for other projects even after the end of this research study.

Governance

15. What safeguarding procedures were used to protect local study participants and researchers?

We have conducted gram sabhas (community meetings) in all the villages before start of the study. Informed written consents were obtained from the senior key persons and 60% of the villagers for execution of the study. The pros and cons of the study were discussed with the villagers in detail. Participants were actively involved in the study from the beginning to the end of the implementation phase. The field level staff was selected by the community. Free services were provided to all the villagers during the study. Due to the extensive community involvement, the community actively supported the local study participants. For reporting adverse events, a fast-track (bottom to top) system was developed from village level up to investigator level. There was a provision of free treatment in the study hospital for any adverse events. All legal formalities specified as per the government norms were fulfilled. Government was an active partner for a substantial period of six years in this research study. Databases are in password protected databases behind firewalls, so study participant personal information is secure.

Local researchers were protected, as all research activities were governed by an Ethics committee and an IRB; the study had to pass scrutiny of the local gram sabhas (community meetings), needed 60% agreement of the villagers where the study was going to be done, and needed tribal department, Government of Maharashtra clearance. Thus, they were protected both from the ethical and law perspectives. Of course, as all data was kept at the local site all research data was under the complete control of the local researchers, and there was no question of the foreign entity

using any data for non-sanctioned use. The local researcher's access to, control of and use of the data is absolute.

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EFFECT OF HOME-BASED CHILD CARE ON CHILDHOOD MORTALITY IN RURAL MAHARASHTRA, INDIA: A CLUSTER RANDOMIZED CONTROLLED TRIAL.

Supplementary tables:

Table 1S: Household level characteristics of U5 children in Control and Intervention area

Variable	Category	Control	Intervention
		N=4426	N=3230
Main occupation [n (%)]	Farmer	2382 (53·8)	1421 (43·9)
	Labour	96 (2·2)	31 (0·9)
	Government job	12 (0·3)	27 (0·8)
	Private job	1360 (30·7)	1190 (36·8)
	Unemployed[*1]	576 (13·0)	561 (17·4)
Agriculture [n (%)]	Yes	2160 (48·8)	1305 (40·4)
Wall Type*[2] [n (%)]	Kaccha	3348 (75·6)	2306 (71.4)
Roof Type*[3] [n (%)]	Kaccha	3320 (75·0)	2222 (68·8)
Electricity [n (%)]	Yes	334 (7·5)	328 (10·2)
House ownership [n (%)]	Yes	3680 (83·1)	2513 (77·8)
Use of toilet [n (%)]	Yes	240 (5·4)	258 (7·9)
Cooking facility[*4] [n (%)]	Wood	3380 (76·4)	2594 (80·3)
Separate kitchen [n (%)]	Yes	1046 (23·6)	378 (11·7)
Drinking water source [n (%)]	Well	836 (15·5)	609 (18·9)
	Hand pump	1649 (37·3)	972 (30·1)
	Tap	645 (14·6)	681 (21·1)
	Well & hand pump	301 (6·8)	248 (7·7)
	Well & Tap	305 (6·9)	96 (2·9)
	Others[*5]	690 (15·6)	624 (19·3)
Vehicle [n (%)]	None	3113 (70·3)	2184 (67·6)
	Bullock cart / Cycle or both	1203 (27·2)	938 (29·0)
	Others[*6]	110 (2·5)	108 (3·3)
Media [n (%)]	None	4083 (92·3)	2856 (88·4)
	Radio / newspaper / both	343 (7·8)	374 (11·6)
Animals [n (%)]	None	2797 (63·2)	2068 (64·0)
	Cattle	1629 (36·8)	1162 (35·9)
Community type [n (%)]	Tribal	3792 (85·7)	2695 (83·4)
	Others[*7]	634 (14·3)	535 (16·6)
Caste [n (%)]	Korku	3488 (78·8)	2411 (74·6)
	Other castes[*8]	938 (21·2)	819 (25·4)
Mother literacy [n (%)]	Literate	1663 (37·6)	1306 (40·4)
Father literacy [n (%)]	Literate	2720 (61·5)	2125 (65·8)

[*1]No work / household work; [*2]*Kaccha wall*: Made up of soil; [*3]*Kaccha roof*: Made up of tin/ thatch / mixed material; [*4]Others used Kerosene / Gas / Sigri; [*5]Pond / River / Hand pump & River / Well & River or not fixed; [*6]Bullock cart with two-wheeler or four-wheeler; [*7]Non-tribals and others; [*8]Gond, Bhilala, Mongia, Gavlan, Balai

Table 2S: Comparison of mortality rates in Control and Intervention groups from 2004-2009 [Secondary outcomes]

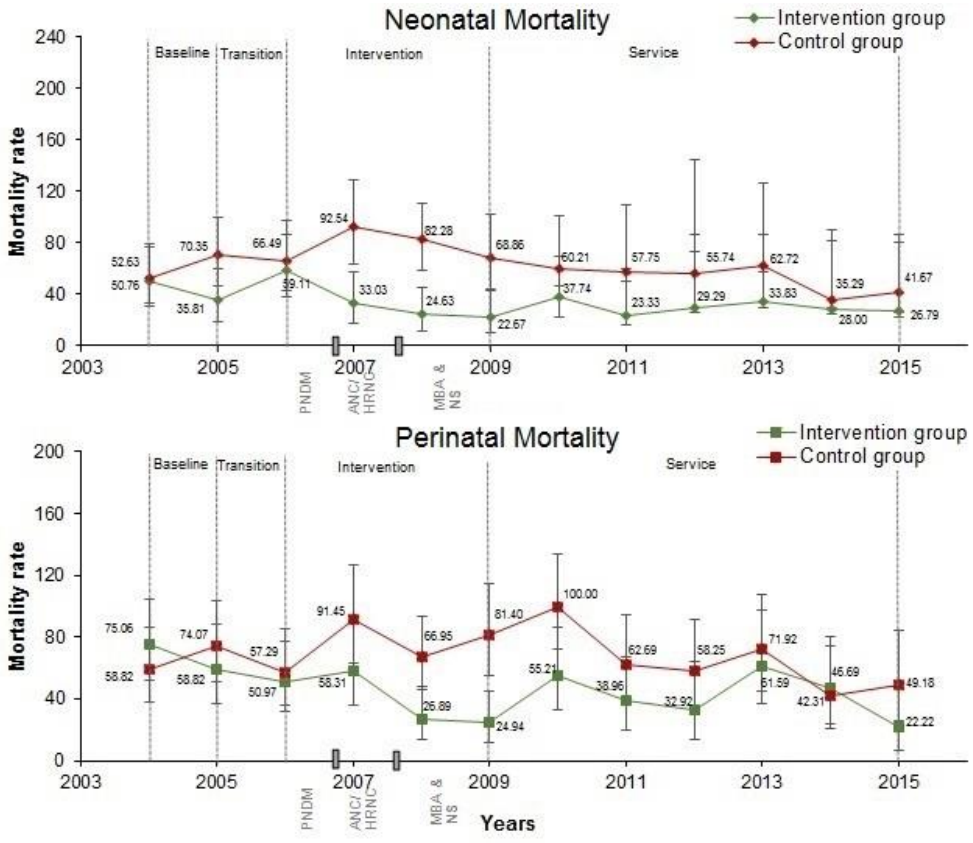
	Year	CONTROL					INTERVENTION						
		Live Births	Deaths	Rate	Incidence Rate Ratio (95% CI), P-value		Live Births	Deaths	Rate	Incidence Rate Ratio (95% CI), P-value		Absolute change in IRR between intervention and control arm (95% CI), P-value	
					Crude IRR	Adjusted* IRR				Crude IRR	Adjusted* IRR	Crude	Adjusted*
Neonatal Mortality	2004	399	21	52·63	REF	REF	394	20	50·76	REF	REF		
	2005	398	28	70·35	1·34 (0·76 - 2·35), 0·31	1·23 (0·71 -2·16), 0·46	363	13	35·81	0·71 (0·35 -1·42), 0·33	0·83 (0·43 - 1·58), 0·57	0·53 (0·22 -1·30); 0·17	0·67 (0·29 - 1·59); 0·18
	2006	376	25	66·49	1·26 (0·71 - 2·26), 0·43	1·18 (0·68 -2·08), 0·55	406	24	59·11	1·16 (0·64 - 2·11), 0·61	1·16 (0·65 - 2·10), 0·59	0·92 (0·40 - 2·11); 0·84	0·98 (0·44 - 2·21); 0·48
	2007	335	31	92·54	1·75 (1·01 - 3·09), 0·04	1·75 (1·05 -2·99), 0·03	333	11	33·03	0·65 (0·30 - 1·35), 0·25	0·63 (0·29 - 1·28), 0·21	0·37 (0·14 - 0·95); 0·04	0·36 (0·14 - 0·89); 0·02
	2008	474	39	82·28	1·56 (0·92 - 2·27), 0·09	1·47 (0·88 -2·51), 0·14	406	10	24·63	0·49 (0·23 - 1·04), 0·06	0·48 (0·22 - 0·98), 0·05	0·31 (0·13 - 0·76); 0·01	0.33 (0·13 - 0·81); 0·00
	2009	334	23	68·86	1·31 (0·72 - 2·38), 0·38	1·01 (0·57 -1·79), 0·98	397	9	22·67	0·45 (0·20 - 0·98), 0·04	0·44 (0·19 - 0·93), 0·04	0·34 (0·13 - 0·93); 0·03	0·44 (0·16 - 1·16); 0·04

Table 2S: Comparison of mortality rates in Control and Intervention groups from 2004-2009 [Secondary outcomes]

	Year	CONTROL					INTERVENTION						
		Live Births	Deaths	Rate	Incidence Rate Ratio (95% CI), P-value		Live Births	Deaths	Rate	Incidence Rate Ratio (95% CI), P-value		Absolute change in IRR between intervention and control arm (95% CI), P-value	
					Crude IRR	Adjusted* IRR				Crude IRR	Adjusted* IRR	Crude	Adjusted*
Perinatal Mortality	2004	408	24	58·82	REF	REF	413	31	75·06	REF	REF		
	2005	405	30	74·07	1·26 (0·74 - 2·15), 0·40	1·14 (0·67 - 1·94), 0·63	374	22	58·82	0·78 (0·45 - 1·35), 0·39	0·85 (0·51 - 1·42), 0·54	0·62 (0·29 - 1·33); 0·22	0·74 (0·36 - 1·56); 0·22
	2006	384	22	57·29	0·97 (0·55 - 1·74), 0·93	0·95 (0·54 - 1·66), 0·86	412	21	50·97	0·68 (0·39 - 1·18), 0·17	0·68 (0·39 - 1·15), 0·15	0·70 (0·32 - 1·56); 0·38	0·72 (0·33 - 1·56); 0·20
	2007	339	31	91·45	1·55 (0·91 - 2·65), 0·11	1·47 (0·89 - 2·45), 0·13	343	20	58·31	0·78 (0·44 - 1·36), 0·38	0·77 (0·44 - 1·32), 0·36	0·50 (0·23 - 1·09); 0·08	0·52 (0·25 - 1·10); 0·04
	2008	478	32	66·95	1·14 (0·67 - 1·93), 0·63	1·05 (0·63 - 1·78), 0·85	409	11	26·89	0·36 (0·18 - 0·71), 0·00	0·36 (0·17 - 0·68), 0·00	0·32 (0·13 - 0·75); 0·01	0·34 (0·14 - 0·82); 0·01
	2009	344	28	81·4	1·38 (0·80 - 2·39), 0·24	1·09 (0·64 - 1·86), 0·75	401	10	24·94	0·33 (0·16 - 0·68), 0·00	0·33 (0·15 - 0·64), 0·00	0·24 (0·09 - 0·59); 0·00	0·30 (0·12 - 0·74); 0·00

*Adjusted for sex, wealth index of individual and village/cluster status using log-binomial regression; P-values equal to 0·00 should be read as < 0·01

Figure 1S: Line plots showing neonatal and perinatal mortality rates in intervention and control areas in different phases across time.



PNDM: Post-Natal Disease Management; ANC: Antenatal Care; HRNC: High Risk New-born Care; MBA: Management of Birth Asphyxia; NS: Neonatal Sepsis.