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

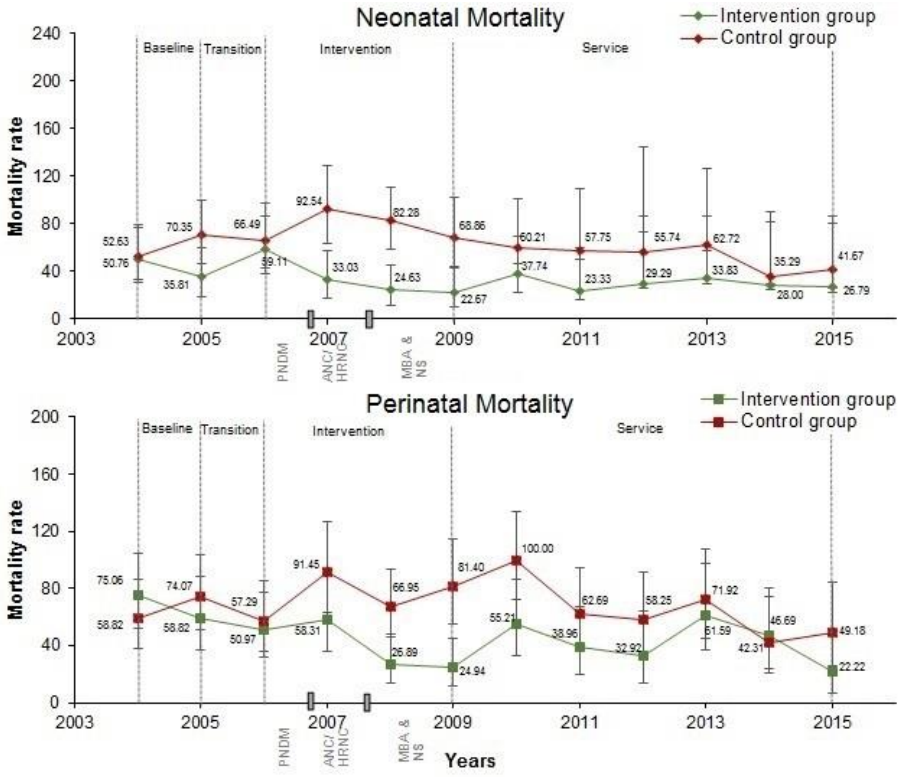
Table 2S: Comparison of mortality rates in Control and Intervention groups from 2004-2009 [Secondary outcomes]

	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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