Appendix III

Characteristics of included studies and risk of bias assessments

Bang 1999

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: India. DISTRICT/REGION: Gadchiroli District of Maharashtra State.
Methods	DESIGN: Controlled before-and-after study. UNIT OF ALLOCATION: Pre-existing intervention area separating two control areas. Village-level intervention was distributed to all villages in the intervention area, except for 14 villages where the population was less than 300 or because a suitable woman (to be CHW) could not be found there. AIM: To test a package of home-based neonatal care, including the management of sepsis, with the hypothesis that the intervention will reduce the neonatal mortality rate by at least 25% in 3 years compared with the control area. BASELINE PERIOD: 2 years (April 1993-1995) in both arms. TREATMENT PERIOD: 3 years (April 1995-1998).
Participants	INTERVENTION RECIPIENTS: Pregnant women and their newborns up to 3 years. INTERVENTION SAMPLE SIZE: 38,998 dyads; CHWs unspecified. CONTROL SAMPLE SIZE: 42,149 dyads; CHWs unspecified.
Interventions	CONDITION: Neonatal sepsis. CHW TERM: Village health worker (VHW). CHW PROFILE: Females with 5-10 years of education, willing to work, recruited locally, and trained for 6 months initially. CHW SUPPORT: Performance-linked remuneration. A physician visited each village once every 2 weeks to verify the data recorded by the VHWs, corrected and educated them. INTERVENTION ACTIVITIES: From April 1995, VHWs listed pregnant women in the village, collected data by home visits in the third trimester, observed labour and neonates at birth, visited the home on days 1, 2, 3, 5, 7, 14, 21, 28, and on any other day if the family called, to take history and examine mother and child, weighed the child each week, and managed minor illnesses and pneumonia in the neonates. They followed-up the neonates for 28 days after birth, until the mother left the village, or until the neonate died, whichever was earlier. From April 1996, VHWs provided in home-based management of neonatal illnesses, and from September 1996, home-based management of neonatal sepsis, in addition to earlier tasks. The health workers supported temperature maintenance and breastfeeding, treated superficial infections, and undertook follow-up for 7-10 days twice a day. From April 1997, Health education of mothers and grandmothers about care of pregnant women and neonates was added. IMPLEMENTATION: Proportion of neonates covered by intervention was 75.1% in year 1, 85.3% in year 2, 93.3% in year 3. COST TO PATIENT: Care from VHWs in the intervention area was free of cost. CO-INTERVENTIONS: Male village health workers and TBAs were trained and supported to give case management of pneumonia in children in the action area. Also, TBAs distribute iron and calcium

	tablets to pregnant women, treat common reproductive-tract infections in women, and undertake hygienic delivery. CONTROL: There were other health programmes in both areas, such as reproductive health education for adolescents, management by village health workers of minor health problems such as malaria, scabies, diarrhoea, or wounds, and consultation and prenatal care at the referral clinic outside the field research area.	
Outcomes	MORTALITY: neonatal mortality rate (primary outcome), early and late neonatal mortality rates, infant mortality, perinatal mortality rates. FOLLOW-UP PERIOD: Besides prospective reporting, outcome assessors undertook a house to house survey in both areas once every 6 months to record births and deaths over the three-year intervention period.	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	"In our study, the intervention and the control villages were not randomly selected for reasons of feasibility" (p1959).
Baseline outcome measurements similar	Low	Baseline neonatal mortality rates in the intervention and the control areas were 62 and 58 per 1000 live births, respectively.
Baseline characteristics similar	Low	"Population characteristics at baseline in the intervention and control area were similar (table 1)" (p1959).
Incomplete outcome data (attrition bias)	Low	"Recording of births and child deaths was done during 1993–98 by an independent set of workers in the intervention and the control areas. Besides prospective reporting, they undertook a house to house survey in both areas, once every 6 months, to detect any missed events" (p1958).
Selective outcome reporting (reporting bias)	Low	No protocol identified, but a range of mortality outcomes reported.
Blinding of outcome assessment (detection bias)	Low	No mention of whether outcome assessors were blinded, but mortality is an objective measure so unlikely to be a source of bias.
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	"Our field trial was done in the field research area (100 villages) of SEARCH, comprising an action area of 53 villages, and an adjacent control area of 47 villages" (p1956). Intervention and control villages were grouped into geographic areas. Although adjacent, this protects against contamination.
Other source of bias	Low	Outcomes are verbally reported but mortality is objective.

Bhandari 2012

Setting	GEOGRAPHICAL SETTING: Not specified. COUNTRY: India. DISTRICT/REGION: District Faridabad, Haryana.
Methods	DESIGN: Cluster RCT (parallel group). UNIT OF ALLOCATION: PHC catchment areas; 9 intervention and 9 control.

	AIM: To evaluate the Indian IMNCI programme, which integrates improved treatment of illness for children with home visits for newborn care, to inform its scale-up. BASELINE PERIOD: Baseline survey conducted in all 18 PHC clusters from June to October 2006 (5 months). TREATMENT PERIOD: January to December 2007—trainings and health system strengthening activities (supervision of CHWs, task-based incentives, ensuring supply of drugs to CHWs). January 2008 to March 2010—intervention CHWs implemented IMNCI activities.	
Participants	INTERVENTION RECIPIENTS: Mother-baby dyads. INTERVENTION SAMPLE SIZE: 29,782 dyads; 601 CHWs. CONTROL SAMPLE SIZE: 30,920 dyads; CHWs unspecified.	
Interventions	CONDITION: Newborn illness (danger signs and infections) and infant illness (diarrhea, pneumonia, and malnutrition). CHW TERM: Anganwadi workers. CHW PROFILE: Existing Anganwadi workers trained to improve their skills for the case management of sick children under five with the government's eight day IMNCI Basic Health Worker Course. CHW SUPPORT: Vacant supervisor positions (21 ASHAs) were filled through temporary hiring and trained in supervision skills. Task based incentives for CHWs were expanded to include IMNCI activities. Drug depots were established in villages to ensure regular supply of IMNCI drugs to CHWs. INTERVENTION ACTIVITIES: Anganwadi workers made postnatal home visits on days 1, 3, and 7 to promote early and exclusive breast feeding, delaying bathing, keeping the baby warm, cord care, and care seeking for illness. They assessed newborns for signs of illness at each visit and treated or referred them. They additionally visited low birthweight infants on days 14, 21, and 28. ASHAs, nurses, and physicians treated sick newborns and older children according to IMNCI guidelines. INTERVENTION IMPLEMENTATION: Ninety percent of caregivers in the intervention clusters reported being visited by a CHW at least once in the first 10 days after the infant's birth, and 43% had the recommended three visits. COST TO PATIENT: Not reported. CO-INTERVENTIONS: All health care providers in the intervention clusters, including ASHAs, auxiliary nurse midwives, PHC physicians, private providers, and TBAs, were trained in IMNCI skills. ASHAs ran women's group meetings in every village every three months to raise awareness about newborn care practices. CONTROL: CHWs, nurses, and physicians continued to provide their routine services in both intervention and control areas.	
Outcomes	MORTALITY: Infant (1-365 days) and neonatal (1-28 days; 2-28 days) mortality rates (primary outcomes); perinatal (stillbirths + 1-7 days), and post-natal (29-365 days) mortality rates (AHR). FOLLOW-UP PERIOD: For outcome ascertainment, the surveillance team visited infants at 1, 3, 6, 9 and 12 months of age for vital status confirmation. Births between 1 January 2008 and 31 March 2010 were included; as the follow-up visits were stopped six weeks after 31 March 2010, enrolled infants had a variable follow-up ranging from one to 12 months.	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**

Random sequence generation (selection bias)	Low	"An independent epidemiologist generated 10 stratified randomisation schemes to allocate the clusters to intervention or control groups. We excluded three of these schemes, which had large differences in neonatal mortality rate, proportion of home births, proportion of mothers who had never been to school, and population size. We selected one of the remaining seven allocation schemes by a computer generated random number" (p2).
Baseline outcome measurements similar	Low	Randomisation was stratified by baseline neonatal mortality rates (high, mid, and low).
Baseline characteristics similar	Low	"We adjusted the resulting hazard ratios for important cluster level and individual level differences by including these as covariates in the model" (p3).
Incomplete outcome data (attrition bias)	Low	Trial profile figure provided. "As the attrition rates were much lower than anticipated (about 2%), the Data Safety Monitoring Board considered that the required sample size had been completed in March 2010 after recruitment of 60 702 live births" (p3).
Selective outcome reporting (reporting bias)	Low	Methods clearly define primary / secondary outcomes. Transparent explanation provided for why an additional primary outcome was added after one year of the study: "We added neonatal mortality after 1 day (day 2 to 28 day mortality) as a primary outcome because we found that more than 40% of deaths were occurring in the first 24 hours of life (higher than expected), on which the intervention was unlikely to have an effect" (p3).
Blinding of outcome assessment (detection bias)	Low	"We allocated all households in the intervention and control areas to one of the 110 study field workers who were not involved with IMNCI implementation. The workers visited the allocated households every month to identify new pregnancies and inquire about the outcome of previously identified pregnancies. All households with live births were visited on day 29 and at ages 3, 6, 9, and 12 months to document the vital status of the infant. The surveillance team comprised workers who resided in or near to the areas allocated to them. The surveillance team was not told the intervention status of the community they were visiting. The follow-up procedures were identical in all the clusters" (p3).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	"Although contiguous, the 18 clusters are large and the way healthcare and worker responsibilities are organised within a primary health centre area makes the risk of contamination low" (p2).
Other source of bias	Low	Outcomes are verbally reported but mortality is objective.

Chen 1980

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: Bangladesh. DISTRICT/REGION: Matlab Thana.	
Methods	DESIGN: cluster NRCT. UNIT OF ALLOCATION: Population was divided into two areas, one intervention and one control, each comprised of multiple villages. AIM: To assess effort to distribute locally-produced sucrose-electrolyte packets by resident village workers in rural Bangladesh. BASELINE PERIOD: Longitudinal census programme in place for total population (intervention and control areas) since 1966. Outcome measurement comparisons made to May-Aug 1977 (four months). TREATMENT PERIOD: May 1 to August 1 1978 (four months).	
Participants	INTERVENTION RECIPIENTS: Entire population. INTERVENTION SAMPLE SIZE: 157,281 population; 160 CHWs. CONTROL SAMPLE SIZE: 134,249 population; 130 CHWs.	
Interventions	CONDITION: Diarrhoea. CHW TERM: Village health workers (VHWs). CHW PROFILE: Female village workers who normally conduct vital registration and other work were trained two half-days on indications, use, and possible hazards of domiciliary oral hydration. CHW SUPPORT: None reported. INTERVENTION ACTIVITIES: During routine daily household visits, village workers carried oral therapy packets, enquired about diarrhea, and offered treatment. Fluid measurement and mixing were demonstrated by the workers, and patients were encouraged to take oral fluid if diarrhea was present. During nonwork hours, the resident workers were available at home to villagers should they request assistance. Patients with moderate, severe diarrhea, or other complications were referred to Matlab treatment area. INTERVENTION IMPLEMENTATION: A total of 33,000 packets were distributed over the four month evaluation period. Each CHW distributed over 70 packets/1000 population/month. On average, 1.26 packets were distributed per childhood episode of diarrhoea; 13% children received two packets per episode. COST TO PATIENT: No cost for oral therapy packets from CHWs. CO-INTERVENTIONS: Diarrhoeal treatment facility at Matlab Centre backed by speedboat and jeep ambulances for diarrhoea patients. CONTROL: Female village health workers conducting surveillance and health work, but not distributing packets. Diarrhoeal treatment facility and ambulatory services available to patients in both arms.	
Outcomes	MORBIDITY: Diarrhoeal hospitalisation rates (% DID). FOLLOW-UP PERIOD: Up to 4 months.	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	Estimated study population divided non-randomly into two arms.
Baseline outcome measurements similar	High	"In 1977, the area receiving oral therapy also had a lower rate of hospital visits than the comparison area, although the differential was less marked" (p288). No

		statistical comparison made of baseline hospitalisation rates between the two arms.
Baseline characteristics similar	High	"The distribution villages were more distant from the Matlab facility than the comparison villages, although the availability of free, rapid patient transport reduced the apparent geographic dissimilarity" (p286). The fact that the treatment villages were more distant to the facility could bias hospitalisation rates. No statistical comparisons made of baseline characteristics.
Incomplete outcome data (attrition bias)	Low	Procedures in place to audit data: "Field workers maintained log books on the number of packets received and distributed by date, and age, sex, name and census number of patients. From a list of field workers, every 20th book was selected for review and patients treated were matched with records of hospital admissions. A third source of data was the Matlab hospital, where all patients from the study population were identified and matched with their census numbers. In August 1978, unannounced visits by field assistants were made to a systematic sample of 32 villages (20%) to review the village workers' records" (p287).
Selective outcome reporting (reporting bias)	Low	No study protocol identified, but justification provided for why some relevant outcomes (e.g. mortality) were not reported: "Since effective hospital treatment for acute diarrhea was available to both study populations, and since death due to acute watery diarrhea has been virtually eliminated in the Matlab area, the mortality-reducing or dehydration-reducing effects of domiciliary oral hydration was not examined in this study" (p290).
Blinding of outcome assessment (detection bias)	Low	No mention of blinding of outcome assessors, but hospital admissions is an objective outcome; therefore, unlikely to be subject to detection bias.
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	Map provided; two distinct geographical areas.
Other source of bias	Low	Hospital records used to measure outcome.

Johnson 2013

Setting	GEOGRAPHICAL SETTING: Periurban. COUNTRY: Mali. DISTRICT/REGION: Yirimadio, Bamako.
Methods	DESIGN: Repeated cross-sectional study. UNIT OF ALLOCATION: One PHC catchment area. AIM: To test a health system strengthening intervention in periurban Mali designed to improve child survival by improving rapid access to prevention and treatment. BASELINE PERIOD: A baseline cross-section survey was administered in June 2008, 3 months before intervention roll-out. TREATMENT PERIOD: September 2008 until June 2011.
Participants	INTERVENTION RECIPIENTS: Entire population.

	INTERVENTION SAMPLE SIZE: The baseline population size was 56,000 (11,000 households) but the area experienced rapid population growth due to high birth rates and in-migration; 20 CHWs. CONTROL SAMPLE SIZE: No separate control group.
Interventions	CONDITION: Danger signs for childhood malaria, diarrhoea, pneumonia, malnutrition. CHW TERM: Community Health Worker (CHW). CHW PROFILE: Predominantly female CHWs, aged 18 to 45 years, recruited locally, who could read and write in the local language. CHWs received 36 days of foundational training, approximately half preservice and the rest in modular fashion as in-service training. Training was provided jointly by a nongovernmental organisation and the Ministry of Health in diagnosis and treatment algorithms based on WHO IMCI guidelines. CHW SUPPORT: Group supervision visits occurred weekly, held by a supervising programme manager from the nongovernmental organization. The manager was aided by a senior Captain CHW who provided to community-based support to her fellow CHWs. CHWs were compensated for their work with a monthly stipend. INTERVENTION ACTIVITIES: CHW conducted daily active door-to-door case finding, identifying 16 danger signs and symptoms of childhood illness for children 0–59 months, diagnosing malaria in the home using HRP-2 rapid antigen diagnostic testing, treating malaria in the home with artemisinin-based combination therapy (ACT), referring or accompanying patients with other illnesses to PHC, conducting follow-up visits for treated patients at 24 and 48 hours, and connecting pregnant women with prenatal care and birthing services. INTERVENTION IMPLEMENTATION: During the period of the intervention, CHWs performed on average 7,109 screening home visits per month actively searching for cases of sick children. CHWs identified sick children at an average of 356 sick child assessments per month, 12,120 sick child home visits between 2008 and 2011. They performed malaria RDTs at 6,943 of those visits, an average of 204 malaria RDTs per month. CHWs identified one or more danger signs of severe childhood illness requiring immediate accompaniment to PHC during 4,925 of those home visits. Of the sick children they cared for, they reached 35% within 24 hours of symptom onset, 52% within 48 hours of symptom onset, and 78% within 72 hours of symptom onset. In the 2011 survey, 54% of respondents reported they had been visited by a CHW in the prior 3 years. Of those who had been visited by a CHW, 60% reported a visit within the past month, 78% reported a visit within the past three months. COST TO PATIENT: No fees for CHW care and fees for PHC care were removed for all patients who could not afford to pay, as determined by patient self-reporting to their CHW. CO-INTERVENTIONS: (i) Removal of user fees; (ii) constructing and renovating clinical infrastructure at the PHC; and (iii) training of health care providers at PHC; (iv) the creation of a rapid referral network to identify sick children and refer them to a CHW for early for assessment, which included 13 local religious leaders, 14 education centers, and 238 community organizers; (v) a microenterprise program provided training, savings structures, and low-interest and no-interest loans to women to start or expand revenue generating activities, and a non-formal education curriculum delivered modules on human rights, health and hygiene during 8 hours per week during 3 years.

	CONTROL: At baseline, routine care consisted of PHC primary care, and "relays", local volunteers, who had been trained by the Ministry of Health to share key messages with other community members about maternal and child health.	
Outcomes	MORTALITY: under-five mortality rate (per 1000 live births, HR) MORBIDITY: prevalence of febrile illness among children under five CARE-SEEKING: Early (within 24 hours), effective antimalarial treatment among febrile children under five (%, PR). FOLLOW-UP PERIOD: Independent randomly selected cross-sectional surveys conducted at 0, 12, 24 and 36 months.	
Notes	Limitations of study design mean no causal inference can be made, and we cannot isolate effect of proactive case detection.	
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	Uncontrolled before-and-after design. Although no control group, investigators perform a random sampling of eligible women every year to obtain the representative cross-section: "We utilized a two-stage cluster sampling methodology with probability of selection proportionate to size to achieve a self-weighting sample of households. In the first-stage of sampling, we generated [...] random non-overlapping latitude-longitude coordinates with 100 m radial buffers within the intervention area. Using less than six month old satellite imagery, we counted the number of structures within each cluster as a measure of population density. In the second stage of sampling, interviewers selected households by arriving at the center of the cluster, spinning a pen to identify a random direction, and visiting every second household and choosing a pre-determined number of households proportional to the population density in that cluster. Within each household, one respondent, a female aged 16 or over, was randomly selected from all eligible respondents based on a KISH table" (p4).
Baseline outcome measurements similar	High	Outcome measurements were taken at baseline, but since there was only one baseline measure, the shape of the pre-intervention phase was not established (and no control area for comparison).
Baseline characteristics similar	Low	Due to study design there is no comparison with a control area; authors compare some socio-demographic characteristics of respondents every year to baseline: "Demographic characteristics of the female respondents showed that there was little change in the average age, marital status, or household size of respondents over the four years of surveys. Fewer respondents attended school in 2009 and 2010 compared to 2008 ($p<0.05$), and among school attendees, respondents completed fewer grades in the surveys after 2008 ($p<0.05$)" (p6).
Incomplete outcome data (attrition bias)	High	There is missing data for the primary outcome (i.e. date of birth/death), and they perform multiple imputation. Extent of missingness seems reasonably large and no discussion of this limitation.
Selective outcome reporting (reporting bias)	Low	No suggestion of selective outcome reporting; outcomes pre-specified in the methods are reported in the results

		section. Authors discuss their inability to report the relative contributions of different components of the intervention due to limitations in data collection.
Blinding of outcome assessment (detection bias)	High	Efforts made to minimize bias, but outcome assessors were not blinded. Primary outcome is objective (under-five mortality), secondary objectives less so (fever in the prior two weeks and effective treatment): "Interviewers were hired for the sole purpose of survey administration, and were not members of the communities they surveyed" (p5).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	They compare mortality trends seen in the intervention area to those reported nationally and regionally by a number of different available sources, which suggest that the intervention was independent of other changes: "Without a control arm, we were unable to determine if the differences observed over the course of the study were due to the intervention, or to demographic shifts in the study population, general national trends in health, or other factors [...] Ideally we would compare outcomes in the intervention area with similar areas that did not have the intervention. We planned to use repeated cross sectional surveys to compare the impact of the intervention against similar figures for Mali nationally and in all other urban areas" (p8).
Other source of bias	Low	Outcomes are verbally reported but mortality is objective and morbidity/care-seeking recall is two weeks

Johnson 2018

Setting	GEOGRAPHICAL SETTING: Periurban. COUNTRY: Mali. DISTRICT/REGION: Yirimadio, Bamako.
Methods	DESIGN: Interrupted time series study UNIT OF ALLOCATION: One PHC catchment area. AIM: To assess whether the changes in access to care and child mortality seen in ProCCM communities have been sustained over time. BASELINE PERIOD: A baseline cross-section survey was administered in June 2008, 3 months before intervention roll-out. TREATMENT PERIOD: September 2008 until July 2015.
Participants	INTERVENTION RECIPIENTS: Entire population. INTERVENTION SAMPLE SIZE: The baseline population size was 56,000 (11,000 households) but the area experienced rapid population growth due to high birth rates and in-migration. In the context of rapid population growth, the number of CHWs increased to target a CHW:population ratio of 1:1000, from 20 CHWs in 2008 to 75 in 2013 and then to 150 in 2015. CONTROL SAMPLE SIZE: No separate control group.
Interventions	CONDITION: Childhood malaria, diarrhoea, pneumonia, malnutrition and newborn danger signs. CHW TERM: Community Health Worker (CHW). CHW PROFILE: Female (95%) CHWs, aged 18 to 45 years, recruited locally, who could read and write in the local language. CHWs received 36 days of foundational training. The first CHWs deployed in 2008 received approximately half of this training preservice and the

	rest in modular fashion as in-service training. For CHWs subsequently recruited, most of this training was shifted to be preservice. CHW SUPPORT: Group supervision visits occurred weekly, held by a supervising programme manager from 2008 to 2013 and then by a dedicated cadre of CHW supervisors from 2013 to 2015. Individual monthly field supervision visits from a dedicated cadre of CHW supervisors began in July 2013. CHWs were compensated for their work with a monthly payment of approx. US$75. INTERVENTION ACTIVITIES: CHWs conducted proactive case detection, searching for patients door-to-door for at least 2 hours per day, 6 days per week, and were instructed to be available on call at all times to patients who sought their services. In addition to proactive case detection for patients of all ages, CHWs provided a package of services consistent with iCCM clinical protocols, including: (1) counselling; (2) diagnosis of malaria (all ages), pneumonia, diarrhoeal disease and malnutrition for children under five; (3) treatment of uncomplicated cases of malaria, pneumonia, diarrhoeal disease and moderate acute malnutrition for children under five; (4) referral and accompaniment of patients with danger signs or conditions outside the CHW's scope of practice to the primary health centre, including newborn, pregnancy, or postpartum danger signs; and (5) follow-up visits to support adherence and monitor response to therapy at 24, 48 and 72 hours for all sick patients after the initial evaluation, with an additional visit after 5 days for patients with diarrhoeal disease. INTERVENTION IMPLEMENTATION: In the years after the roll-out of the intervention, documented patient visits in the home or the clinic increased 10-fold. During the period of the intervention, CHWs conducted 618877 proactive case finding home visits, and 29561 home visits for sick children 0–59 months old. In the 2015 survey, 77% of participants reported that they had received a home visit from a CHW within the past 3 years. Of those who reported receiving CHW home visits in that survey, 59% had been visited within the past month, and 77% had been visited within the past 3 months. The percentage of CHW patients aged 0–59 months reached within 24 hours of symptom onset was 25% in year 1 and 62% in year 7. COST TO PATIENT: No fees for CHW care and fees for PHC care were removed for all patients who could not afford to pay, as determined by patient self-reporting to their CHW. CO-INTERVENTIONS: (i) Removal of user fees; (ii) constructing and renovating clinical infrastructure at the PHC; and (iii) training of health care providers at PHC; (iv) the creation of a rapid referral network to identify sick children and refer them to a CHW for early for assessment, which included 13 local religious leaders, 14 education centers, and 238 community organizers; (v) a microenterprise program provided training, savings structures, and low-interest and no-interest loans to women to start or expand revenue generating activities, and a non-formal education curriculum delivered modules on human rights, health and hygiene during 8 hours per week during 3 years. CONTROL: At baseline, routine care consisted of PHC primary care, and "relays", local volunteers, who had been trained by the Ministry of Health to share key messages with other community members about maternal and child health.
Outcomes	MORTALITY: Under-five mortality rate (per 1000 live births, HR). MORBIDITY: Prevalence of febrile illness among children under five.

	CARE-SEEKING: Early (within 24 hours), effective antimalarial treatment among febrile children under five (%, PR). FOLLOW-UP PERIOD: Independent randomly selected cross-sectional surveys conducted at 0, 12, 24, 36, 48, 60, 72 and 84 months.	
Notes	Limitations of study design mean no causal inference can be made, and we cannot isolate effect of proactive case detection.	
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	Uncontrolled before-and-after design. Although no control group, investigators perform a random sampling of eligible women every year to obtain the representative cross-section.
Baseline outcome measurements similar	High	Outcome measurements were taken at baseline, but since there was only one baseline measure, the shape of the pre-intervention phase was not established (and no control area for comparison): "The study only conducted one preintervention survey, leaving open the possibility that the baseline rate recorded was an abnormal year. However, that baseline rate is consistent with national and urban rates at the time" (p7).
Baseline characteristics similar	Low	Due to study design there is no comparison with a control area; authors compare some socio-demographic characteristics of respondents every year to baseline: "Demographic characteristics of respondents were similar across study years" (p4).
Incomplete outcome data (attrition bias)	Low	They explicitly discuss missingness and present the missing patterns of the dataset. 85% observations had complete date of birth and death data: "In online supplementary table 2, we present the missing patterns of the dataset with the percentage of complete or incomplete information for each variable to be imputed. The minimum relative efficiency of the imputed dataset was 0.999985, meaning that 99.9985% of the true parameter values were estimated for the variables. Also, the maximum value of the fraction missing info (FMI) for the variables was 0.000763, meaning only 0.076% of sampling variance is attributable to missing data" (p6).
Selective outcome reporting (reporting bias)	Low	No suggestion of selective outcome reporting; outcomes pre-specified in the methods are reported in the results.
Blinding of outcome assessment (detection bias)	High	Efforts made to minimize bias, but outcome assessors were not blinded. Primary outcome is objective (under-five mortality), secondary objectives less so (fever in the prior two weeks and effective treatment).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	They compare mortality trends seen in the intervention area to those reported nationally and regionally by a number of different available sources, which suggest that the intervention was independent of other changes. Authors test for bed net confounding, as there was a concurrent net distribution during the study period.
Other source of bias	Low	Outcomes are verbally reported but mortality is objective and morbidity/care-seeking recall is two weeks

Khan 1990

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: Pakistan. DISTRICT/REGION: Abbottabad District.
Methods	DESIGN: Controlled before-and-after study, but because of the way data was analysed in this study, it is treated as a cluster non-randomised trial in this review. UNIT OF ALLOCATION: Three distinct clusters that included all the villages in the catchment area of an existing basic health unit; 31 intervention villages and 7 control villages. AIM: To assess the impact on child mortality of ARI case management by CHWs in rural, northern Pakistan. BASELINE PERIOD: One year (1984) in the intervention arm, with mortality rates calculated retrospectively; two years in the control arm (1985-86), with mortality rates calculated prospectively. TREATMENT PERIOD: March 1985-December 1987. The intervention was extended to control villages from January to December 1987; the control area therefore became a "phase II intervention area" during the third year of the study.
Participants	INTERVENTION RECIPIENTS: Children under five. INTERVENTION SAMPLE SIZE: 4665 children; 17 CHWs. CONTROL SAMPLE SIZE: 1194 children; CHWs unspecified.
Interventions	CONDITION: Acute lower respiratory infection. CHW TERM: Community Health Worker (CHW). CHW PROFILE: Recruited locally, with at least 10 years' schooling, trained in the autumn of 1984 in management of symptomatic ARI. CHW SUPPORT: Four qualified nurses monitored and supervised CHW activities in the villages. INTERVENTION ACTIVITIES: CHWs systematically visited approximately 200 households every 10-14 days in active ARI case finding, and available to care for cases brought to their attention. If access to PHC was not possible, CHWs administered treatment for suspected pneumonia. INTERVENTION IMPLEMENTATION: Not reported. COST TO PATIENT: Not reported. CO-INTERVENTIONS: Antibacterial and ARI treatment protocols at facility level were standardized for children from the intervention but not from the control villages. A maternal health education component of the intervention included instruction on signs of severe illness, preparation and use of ORS, etc. An intensive immunization campaign in both intervention and control areas increased children immunized appropriately for their age from 5% to 77% by end of year one and to 87% by end of year 3. CONTROL: Control villages received only improved immunisation coverage in addition to standard of care at the PHC until January 1987, and became a phase II intervention area in year 3. Children from control villages were treated at the health units, dispensaries, or by private practitioners on an individual, non-standardized basis, and did not receive antibacterial treatment provided by the study.
Outcomes	MORTALITY: Child and infant mortality rates (% differences). FOLLOW-UP PERIOD: Up to 33 months.
Notes	
Risk of bias	

Bias	Judgement	Justification
Random sequence generation (selection bias)	High	"Control villages were selected non-randomly" (p578)
Baseline outcome measurements similar	High	"The baseline child mortality rate, both in the intervention area (determined retrospectively for 1984) and in the control area (determined prospectively in 1985-86) was 39 deaths per 1000 children per year; the child mortality rate was not assessed for 1984 in the control area." (p580)
Baseline characteristics similar	Unclear	Baseline characteristics reported only qualitatively in the text: "Control villages were selected non-randomly to be representative of other villages in the area, and were similar to the intervention villages with respect to the following characteristics: height above sea level, house construction materials (mud and brick), time to walk to the health unit or dispensary (mean, 30 minutes), age distribution and number of residents per village, maternal education level, proportion of mothers who breast-fed (90%), mean household income (approximately US$ 90 per month), and occupation of the male head of house- hold (farming, 45%; government service, 40%; business, 15%). Five (71%) control villages, compared with two (6%) intervention villages, were inaccessible by road" (p578).
Incomplete outcome data (attrition bias)	High	Data source and methods for measuring outcomes were different for intervention and control clusters: "In the intervention villages, the CHWs maintained active surveillance and recorded all known births, deaths, and migrations. The control villages were surveyed quarterly to ascertain the number of child deaths in the previous 3 months" (p579).
Selective outcome reporting (reporting bias)	Low	No protocol identified but all relevant outcomes in the methods section reported in the results.
Blinding of outcome assessment (detection bias)	Low	Assessors of all-cause mortality not blinded, but this is an objective measure. Cause of death assessors were blinded: "Each case was also reviewed by a doctor at Ayub Medical College, Abbottabad, to confirm the most probable cause(s) of death identified by the nurses; the doctor was aware of the study hypothesis, but did not know the identity of the child's village" (p580).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	Location of control villages relative to intervention villages is not clear. No mention of boundary or separation area, and no discussion of minimizing contamination.
Other source of bias	Low	Outcomes are verbally reported but mortality is objective.

Linn 2015

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: Senegal. DISTRICT/REGION: Saraya Health District, region of Kedougou.
Methods	DESIGN: Controlled before-and-after study. UNIT OF ALLOCATION: Within the catchment area of 4 of the district's 11 health facilities, 15 villages were selected to receive the intervention. From the district's other catchment areas, 15 comparison villages with similar populations and rainfall patterns were selected. AIM: To evaluate the feasibility and effectiveness of the proactive community treatment model (ProACT) in reducing the prevalence of symptomatic malaria. BASELINE PERIOD: Baseline data collected from July 8-11 2013. TREATMENT PERIOD: July 8 through November 28, 2013.
Participants	INTERVENTION RECIPIENTS: Entire population. INTERVENTION SAMPLE SIZE: 4217 people; CHWs unspecified. CONTROL SAMPLE SIZE: 4747 people; CHWs unspecified.
Interventions	CONDITION: Malaria. CHW TERM: Home Care Providers (HCPs) CHW PROFILE: Pre-existing HCPs trained by the health district on community case management of malaria. Intervention HCPs received a separate, day-long training on the proactive component of the model. CHW SUPPORT: Supervision was carried out by community supervisors, health post nurses and the executive team from the health district. Peace Corps Volunteers supported this supervision structure at each level, providing additional supervision for HCPs with lower literacy levels. Intervention HCPs were paid for this additional activity. INTERVENTION ACTIVITIES: HCP performed weekly sweeps, going door to door to every household in the village, verbally inquiring if there was anyone in the household who was febrile or showed other symptoms of malaria. During the sweeps, HCPs checked for individuals of all ages with symptoms of malaria, tested them with RDTs and treated positive, uncomplicated cases with ACTs, in addition to the routine passive CCM services from the HCP. A woman from each household who had received training prior to the programme often acted as the first-level screener and facilitated the identification of symptomatic individuals who were then tested and treated in accordance with the national standard of care. INTERVENTION IMPLEMENTATION: Intervention HCPs completed 89% of the total sweeps for the 21-week study period. Major reasons for non-completion of sweeps were gold mining, illness and, in one village, ACT stock-out. The HCPs performed 1036 RDTs through proactive case detection, 647 of which were positive. HCPs correctly followed national policy for testing and treatment; of all negative RDTs, only two patients were incorrectly given ACTs. In addition to referrals for negative RDTs, 23 severe cases were referred. COST TO PATIENT: ACT free of charge. CO-INTERVENTIONS: After their additional training on the proactive component, HCPs subsequently held community trainings to train one woman from each compound about the symptoms of malaria and to raise awareness about the forth-coming weekly sweeps. The health district also implemented two other malaria control interventions during the study period in all villages in the district: universal coverage distribution of long-lasting insecticidal nets (LLINs) (July 15–25, 100% coverage) and one round of seasonal malaria chemoprevention (SMC) (November 1–4, 90.3% coverage).

	CONTROL: Routine care which included passive case detection and management of malaria by HCPs not trained in the proactive component of the ProACT model, as well as at facility.	
Outcomes	MORBIDITY: Prevalence of symptomatic malaria (AOR DiD) CARE-SEEKING: Care-seeking rates (%) from HCPs via passive case detection, and odds of care-seeking from health facility. FOLLOW-UP PERIOD: 0-21 weeks in the intervention arm; 0, 12, 21 weeks in the control arm (proactive sweeps conducted in comparison villages during the weeks of July 8, September 23 and November 25 to obtain baseline, midline, endline measurements of prevalence).	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	"The intervention villages were selected as a convenience sample on the basis of their proximity to Peace Corps Volunteer sites. As the sites were not randomised, causal impact of the project on malaria incidence and prevalence cannot be proven" (p1444).
Baseline outcome measurements similar	Low	"During baseline sweeps, the mean prevalence was 1.9% in the intervention villages and 1.6% in the comparison villages (p = 0.79)" (p1441).
Baseline characteristics similar	High	The only baseline comparison made is net coverage; no baseline characteristics table is presented. Differences in mining activities and proximity to Peace Corps sites were not controlled for in the analysis: "The aforementioned gold rush could be a potential con-founder due to varying levels of HCP mining activity and transience of village residents. Gold mining was not controlled for as a confounding factor in the analysis because data on gold mining were not systematically collected for the purposes of this study" (p1444).
Incomplete outcome data (attrition bias)	Low	Data excluded from one intervention village (approximately 455 villagers; ~11% total population in intervention arm) due to poor data quality. Intervention and control arms still contained relatively large samples.
Selective outcome reporting (reporting bias)	Unclear	(i) Study protocol unavailable; (ii) authors do not present arm-specific estimates for DiD calculations, just ORs; (iii) unclear if the baseline, midline, and endline sweeps in control villages were compared to only the results of sweeps that same week in intervention villages.
Blinding of outcome assessment (detection bias)	High	Outcome assessors were the HCPs conducting the sweeps; not possible to blind them due to nature of intervention. The outcome of positive RDT is somewhat subjective (depends on screening for symptoms and interpretation of RDT).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	(i) No mention of boundary zone, although intervention and control villages are in separate health catchment areas; (ii) no mention if intervention and control HCPs were trained together or apart, and whether they had ways of interacting with each other; (iii) baseline, midline, endline prevalence sweeps in the control arm

		could serve as proactive case detection every two months, which could bias the results towards the null.
Other source of bias	Unclear	Mining affected delivery of the control intervention at endline, but unable to adjust for it in the analysis.

Mazumder 2014

Setting	GEOGRAPHICAL SETTING: Not specified. COUNTRY: India. DISTRICT/REGION: District Faridabad, Haryana.
Methods	DESIGN: Cluster RCT (parallel group). UNIT OF ALLOCATION: PHC catchment areas; 9 intervention and 9 control. AIM: To determine the effect of implementation of IMNCI strategy on treatment seeking practices and on neonatal and infant morbidity. BASELINE PERIOD: Baseline survey conducted in 2006 (five months), for the purposes of identifying differences in baseline characteristics and stratifying randomisation. TREATMENT PERIOD: January 2007 to April 2010 (40 months).
Participants	INTERVENTION RECIPIENTS: Mother-baby dyads. INTERVENTION SAMPLE SIZE: 29,667 dyads; 601 CHWs. CONTROL SAMPLE SIZE: 30,813 dyads; CHWs unspecified.
Interventions	CONDITION: Newborn illness (danger signs and infections) and infant illness (diarrhea, pneumonia, and malnutrition). CHW TERM: Anganwadi workers. CHW PROFILE: Existing Anganwadi workers trained to improve their skills for the case management of sick children under five with the government's eight day IMNCI Basic Health Worker Course. CHW SUPPORT: Vacant supervisor positions (21 ASHAs) were filled through temporary hiring and trained in supervision skills. Task based incentives for CHWs were expanded to include IMNCI activities. Drug depots were established in villages to ensure regular supply of IMNCI drugs to CHWs. INTERVENTION ACTIVITIES: Anganwadi workers made postnatal home visits on days 1, 3, and 7 to promote early and exclusive breast feeding, delaying bathing, keeping the baby warm, cord care, and care seeking for illness. They assessed newborns for signs of illness at each visit and treated or referred them. They additionally visited low birthweight infants on days 14, 21, and 28. ASHAs, nurses, and physicians treated sick newborns and older children according to IMNCI guidelines. INTERVENTION IMPLEMENTATION: Ninety percent of caregivers in the intervention clusters reported being visited by a CHW at least once in the first 10 days after the infant's birth, and 43% had the recommended three visits. COST TO PATIENT: Not reported. CO-INTERVENTIONS: All health care providers in the intervention clusters, including ASHAs, auxiliary nurse midwives, PHC physicians, private providers, and TBAs, were trained in IMNCI skills. ASHAs ran women's group meetings in every village every three months to raise awareness about newborn care practices. CONTROL: CHWs, nurses, and physicians continued to provide their routine services in both intervention and control areas.

Outcomes	MORBIDITY: Prevalence (%, ARR) of neonatal danger signs and infection; infant diarrhoea, pneumonia, stunting and wasting; hospital admissions for neonatal and infant illnesses. CARE-SEEKING: Treatment (%, ARR) from any provider, from appropriate provider, and within 24 hours of symptom onset for neonatal and infant conditions. FOLLOW-UP PERIOD: Interviews of the randomly selected subsample were conducted at infant age 29 days (or within next 14 days), 6 months (day 150 to 170) and 12 months to ascertain newborn care practices.	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	Low	"An independent epidemiologist generated 10 stratified randomisation schemes to allocate the clusters to intervention or control groups. We excluded three of these schemes, which had large differences in neonatal mortality rate, proportion of home births, proportion of mothers who had never been to school, and population size. We selected one of the remaining seven allocation schemes by a computer generated random number" (p2).
Baseline outcome measurements similar	Low	Randomisation was stratified by baseline neonatal mortality rates (high, mid, and low).
Baseline characteristics similar	Low	"Some important baseline differences between the intervention and control clusters remained despite the randomisation; the intervention clusters were less accessible, had a lower proportion of births in health facilities, and had families with lower economic status but higher literacy. We have adjusted for these differences in the analysis" (p5).
Incomplete outcome data (attrition bias)	Low	"During its periodic review, the Data Safety Monitoring Board recommended cessation of enrolment when approximately 60 000 infants had been included in the main trial. At this point, 12 367/13 200 (93.7%) caregivers had been interviewed at infant age 29 days, 6121/6600 (92.7%) at 6 months, and 4062/6600 (61.5%) at 12 months. As attrition rates were lower than anticipated, the number of interviews that needed to be conducted was lower than estimated. However, the numbers available were sufficient to detect the assumed differences in outcomes between intervention and control groups at approximately 80% power" (p3).
Selective outcome reporting (reporting bias)	Low	Authors are forthcoming with regards to which outcomes were pre-specified and which were not: "The pre-specified outcome reported here is the effect of the intervention on treatment seeking practices. As a post hoc exploratory analysis, we also report some morbidity, hospital admission, post-neonatal infant care, and nutritional status outcomes" (p2).
Blinding of outcome assessment (detection bias)	Low	"Caregivers were interviewed by an independent team of research assistants, who were unaware of the intervention status of communities" (p3).

Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	A higher level of randomisation was chosen to minimise contamination: "Choosing a smaller unit of randomisation, such as a sub-centre that covers a fifth of the population of a primary health centre, would have given us a larger number of clusters and improved randomisation and statistical efficiency. However, this would have resulted in a higher risk of contamination because health workers within a primary health centre share mechanisms for supervision, monitoring, and supply of drugs" (p5).
Other source of bias	Low	Outcomes are verbally reported but information on treatment seeking practices (the pre-specified outcome) and illnesses is based on two-week recall. Hospitalisation outcomes based on 3-month recall but this is a post-hoc exploratory analysis. Nutritional outcomes assessed using anthropometric measurement.

Navarro 2013

Setting	GEOGRAPHICAL SETTING: Urban. COUNTRY: Dominican Republic. DISTRICT/REGION: Not reported.
Methods	DESIGN: Cluster controlled trial (pair-matched). UNIT OF ALLOCATION: Geographic areas named 'branches' of communities assisted by a catholic parish; 8 intervention and 8 control. AIM: To test the hypothesis that children participating in the Mother-Child Pastoral from pregnancy would have better nutritional indicators in respect both to stunting and overweight, in the second year of age, compared to children in communities of similar socioeconomic conditions where the program does not exist. BASELINE PERIOD: From Sep 2005 to Mar 2006, baseline data were collected in the last quarter of pregnancy and/or in the four months immediately after childbirth, in both intervention and control groups. TREATMENT PERIOD: Starting in April 2005 with pregnant women (before the third quarter of pregnancy) living in intervention branches.
Participants	INTERVENTION RECIPIENTS: Pregnant women and their infants under 2 years of age. INTERVENTION SAMPLE SIZE: 266 mother-child dyads; number of CHWs unspecified. CONTROL SAMPLE SIZE: 337 mother-child dyads; 0 CHWs.
Interventions	CONDITION: Malnutrition and risk of overweight. CHW TERM: Community counselors. CHW PROFILE: Community volunteers (most of whom are women with the same formal education profile as the mothers benefited), who participate in a 60-hour basic training facilitated by health professionals previously trained in key practices of IMCI. CHW SUPPORT: None reported. INTERVENTION ACTIVITIES: Monthly home visits to pregnant women to support health and nutrition during pregnancy. Then, fortnightly home visits during the first month and a half after child

	birth to support breastfeeding and newborn care. Thereafter, semi-structured home visits were carried out once every month to deal with feeding, vaccination, newborn care, danger signs, prevention and treatment of infectious diseases, and physical growth monitoring to check the progress on the child's weight-for-age curve. Based on this evaluation, the counselors followed a nutritional advice protocol. When the deflection from the expected trend continued for more than two consecutive evaluations, the counselor referred the mother for evaluation by a health professional, and then resumed monitoring. INTERVENTION IMPLEMENTATION: Not reported. COST TO PATIENT: Not reported. CO-INTERVENTIONS: Groups of pregnant women met every fifteen days according to protocols defined in ten educational meetings on health and nutrition during pregnancy. Following the first month and a half after childbirth, group meetings of mothers were held, covering the same components as the home visits, including growth monitoring. CONTROL: Usual local health facilities. In both groups there were no other community health and nutrition intervention for pregnant women and children under 2 years of age.	
Outcomes	MOBIDITY: Prevalence of stunting, at risk of overweight, infant diarrhoea, emergency during infant diarrhoea (AOR); mean length-for-age z-score, mean BMI-for-age z-score (mean diff). CARE-SEEKING: ORS treatment for infant diarrhoea (AOR). FOLLOW-UP PERIOD: 0-24 months; data on health and nutrition indicators were collected in both groups when the children were aged between 13 and 24 months (Apr to Sep 2007).	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	"Sampling was not random, since intervention areas had been decided before this study" (p3).
Baseline outcome measurements similar	Unclear	Outcome measurements (i.e. nutritional status) not compared at baseline.
Baseline characteristics similar	Low	Groups paired according to socioeconomic index. Additionally, baseline characteristics were compared between groups, presented in a results table, and differences adjusted for in analysis: "From the 21 studied variables three had a $p<0.05$ (child's age, maternal work status and waste disposal) and two $p\cong0.1$ (household income and maternal age). These variables were included in the multivariate regression analysis to adjust for a possible confounding effect" (p6).
Incomplete outcome data (attrition bias)	High	"After about a year and a half of follow-up the intervention group lost 26% of its subjects and the control group lost 22%. The main cause for this was changing the place residence" (p6). "Given the high mobility of the studied population it was not possible to measure the outcome variables in those subjects that were lost during the study. To assess whether these individuals differed from those who were followed up to the end, statistical analyses were carried out comparing baseline data" (p6). Some statistical differences were found between baseline characteristics that could be

		related to nutritional status, such as mother's age, child's birth order, and household wealth.
Selective outcome reporting (reporting bias)	Low	All pre-specified outcomes from methods section were reported in results.
Blinding of outcome assessment (detection bias)	High	"Another limitation of the study consists that the assessors could not be blind in regards to the allocation of the participants, since it was practically impossible not to recognize when a participant of the study was also a participant of the intervention group. To reduce bias, interviewers had not taken part in the intervention and were trained using proper instruction manual for their questionnaires. Anthropometry assessment followed standardized procedures" (p10).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	Not explicitly discussed. Branches made up of multiple communities assisted by a Catholic parish; appears as if study investigators defined 'branch' for study purposes. No map included in paper; not clear whether intervention and control areas on contiguous or not.
Other source of bias	Low	Primary outcomes assessed using anthropometric measurement; diarrhoeal outcomes subject to reporting bias as they are based on mother's 12-month recall, but these are secondary outcomes.

Pandey 1991

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: Nepal. DISTRICT/REGION: Jumla district.
Methods	DESIGN: Non-randomised stepped-wedge trial, but because of the way data was analysed this study is treated as an uncontrolled before-and-after study in this review. UNIT OF ALLOCATION: Progressive phase-in, subdistrict by subdistrict, over the first 12 months. 8 subdistricts in early treatment group, 10 in late treatment group; total of 18 of Jumla's 30 subdistricts. AIM: To see whether community members could manage childhood pneumonia in an area of Nepal lacking in basic health services, and whether this intervention in isolation could reduce childhood mortality. BASELINE PERIOD: A household census of children aged under five in the 18 subdistricts was done at the start of the study. TREATMENT PERIOD: Programme implemented in early treatment group in Aug-Dec, 1986 (1586 children in Aug 1986, and an additional 1721 in Nov-Dec 1986) until the end of the study in 1989. Programme implemented in late treatment group in June-Aug 1987 until 1989.
Participants	INTERVENTION RECIPIENTS: Children under five. INTERVENTION SAMPLE SIZE: 3307 children under five; 1 CHW per 1000 population. CONTROL SAMPLE SIZE: 3377 children under five; no CHWs.
Interventions	CONDITION: Childhood pneumonia. CHW TERM: Community Health Workers. CHW PROFILE: Village members selected on the basis of reputation with the community, ability to travel from village to village, and functional literacy skills. They were trained in groups of 12 over 9 days

	with a curriculum based on the WHO strategy for community-based pneumonia control and stressed case detection, treatment, education of mothers about warning signs, and basic record-keeping. They were not trained to carry out other health interventions. CHW SUPPORT: Management efforts to assuring quality of services included supervisory visits every two weeks and a rigorous system of control over antimicrobial stocks. Senior project staff, who were local trained workers, visited fieldworkers twice a month to assess and supervise their performance. Adherence to protocol was also monitored by periodic external evaluation of workers. These (part-time) CHWs were paid salaries commensurate with those in the public sector. INTERVENTION ACTIVITIES: Every day each health worker visited 10-15 households with children under five, most within a half-hour walk of his home, with the goal of completing a round of the target households (about 160) under his responsibility every two weeks. During house visits workers actively sought out, treated, and followed-up cases of pneumonia in children under five. When a presumed case of pneumonia was identified (using a battery-operated beeping timer to assess respiratory rates), the worker gave the parents cotrimoxazole paediatric suspension. The worker revisited each child under treatment on the third and sixth days after diagnosis to assess compliance and the child's status. A child who did not improve after four doses of cotrimoxazole, or who relapsed within three days of the initial treatment course, was treated with second-line antibiotics by programme supervisors. Because referral for in-patient care of was not practicable in this setting, all pneumonias, irrespective of severity, were treated with oral antibiotics at home. INTERVENTION IMPLEMENTATION: More than 80% of all households in treatment areas were visited every two weeks; fewer than 5% were visited less frequently than every month. On average, each worker had 1-2 children under treatment at any time. The workers adhered to the protocol; only 4% had to be replaced because of poor performance. Less than 5% of all antimicrobial use was for conditions other than childhood pneumonia. During the three years of the study, 15 167 courses of antibiotic treatment for pneumonia were given, an average of 0.85 treatments per child under five per year. COST TO PATIENT: Cotrimoxazole was given free of charge. CO-INTERVENTIONS: No other health services were provided, and referral of children to hospital was not practicable. During the study the programme was effectively the only source of pneumonia care outside the district headquarters, and no more than 1% of children from study subdistricts with pneumonia are estimated to have been treated from sources outside this programme. CONTROL: Standard of care, largely lacking in basic health services.	
Outcomes	MORTALITY: risk of death for children under five, aged 0-6 days, aged 7 days to 5 months, aged 6-11 months, aged 12-59 months; risk of pneumonia- and diarrhoea-related death. FOLLOW-UP PERIOD: 0-36 months; all births and childhood deaths were registered throughout the study period by a set of village-based enumerators, who received a fee for each reported event.	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**

Random sequence generation (selection bias)	High	"Deliberate allocation of subdistricts to early versus later intervention was done so that they were geographically intermingled" (p994).
Baseline outcome measurements similar	Unclear	Investigators do not compare baseline risk of death between early and late intervention groups, but rather assess the overall effect of programme maturity: "Data were grouped according to the length of time that the treatment programme had been in effect in each individual subdistrict, and data from the as yet untreated subdistricts served as the reference standard against which effect was assessed" (p995).
Baseline characteristics similar	Low	Under-five gender, age, immunization and nutritional status (individual-level characteristics) were compared between early and late groups; no significant differences. No cluster-level characteristics compared, although subdistricts were selected to be similar in socioeconomic, ethnic and health characteristics.
Incomplete outcome data (attrition bias)	Unclear	Each child was followed from initial census or birth to the fifth birthday, death, or end of study (children born during the study were added), but no comment about children loss to follow-up after initial census.
Selective outcome reporting (reporting bias)	Unclear	Test for trend (assessment of programme maturity) is only performed for under-five mortality and not the other age groups. However, if the primary outcome was mortality among children under five (which is unclear from the report), it is okay and even best not to do unplanned subgroup analyses.
Blinding of outcome assessment (detection bias)	Low	System designed to minimise detection bias even if not blinded: "To avoid bias due to programme staff assessing the effect of their own treatment, enumerators and interviewers were completely separate from intervention programme staff […]. Enumerators collected birth and death information, with equal intensity and with identical methods in all areas monitored, irrespective of whether intervention was in progress. About 10% of interviews were repeated to assure accuracy of reporting. Periodic sub-censuses found less than 1 % under-enumeration" (p994).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	"Subdistricts were chosen as the units of intervention and analysis because, in view of their geographic layout, the likelihood of children from other areas contaminating the results was low" (p994). "Contamination of treatment across subdistricts was continuously monitored and found to be negligible; fewer than 1% of treatments were given to children outside the workers' catchment areas" (p995).
Other source of bias	Low	Outcomes are verbally reported but mortality is objective.

Tomlinson 2014

Setting	GEOGRAPHICAL SETTING: Periurban.

	COUNTRY: South Africa. DISTRICT/REGION: Umlazi, KwaZulu-Natal.	
Methods	DESIGN: Cluster RCT (parallel group). UNIT OF ALLOCATION: Unspecified clusters; 15 per arm. AIM: To assess the effect of CHW home visits to pregnant and post-natal women on 12-week post-natal outcomes, including infant HIV-free survival and exclusive and appropriate infant feeding. BASELINE PERIOD: NA. TREATMENT PERIOD: June 2008 to December 2010.	
Participants	INTEVRENTION RECIPIENTS: Pregnant women and their newborns up to week eight. INTERVENTION SAMPLE SIZE: 1821 dyads; CHWs unspecified. CONTROL SAMPLE SIZE: 2136 dyads; CHWs unspecified.	
Interventions	CONDITION: Neonatal illness (including reducing mother-to-child HIV transmission for HIV-free infant survival). CHW TERM: Community Health Worker. CHW PROFILE: Women residing in the neighbourhoods, who were literate and conversant in English and first language is Zulu. Trained for 10 days in PMTCT, IMCI, and newborn care guidelines. CHW SUPPORT: Paid a salary in line with existing South African Government stipends for CHWs. Local hospital notified CHWs when intervention participants gave birth. INTERVENTION ACTIVITIES: A structured home visiting programme with specific content covered at each visit; postnatal visits included assessment of newborn (breathing, thermal care, colour, bleeding, eye care, danger signs) and assessment of mother (bleeding, signs of infection, mastitis). Mother-child dyads in the intervention arm were scheduled to receive seven home-based visits: two during pregnancy and one within 48 h of delivery, during days 3-4 and 10-14, during weeks 3-4 and 7-8. Low birth weight neonates received two extra visits within the first week. IMPLEMENTATION: Just over 40% of mother-child dyads received all seven visits. Coverage was 73.9% for visit one, 67.5% for visit two, 58.7% for visit three, 62.7% for visit four, 70.3% for visit five, 73.5% for visit six, 87.2% for visit seven. COST TO PATIENT: Not reported. CO-INTERVENTIONS: None reported. CONTROL: CHWs in control clusters conducted three home visits (one during pregnancy and two during weeks 4-6 and 10-12 post-delivery) to assist with securing identity documents during pregnancy, infants' birth certificate, and child or other social grants.	
Outcomes	MORTALITY: HIV-free survival at 12 weeks (primary), neonatal mortality. MORBIDITY: Mother-to-child HIV transmission, prevalence of diarrhoea, hospitalisation for diarrhoea, mean weight-for-age score (malnutrition), mean weight-for-length score (wasting), mean length-for-age score (stunting). CARE-SEEKING: Antenatal HIV testing, preparations for delivery, clinic visit within first week of life, infant HIV testing at 6 weeks. FOLLOW-UP PERIOD: 12 weeks post-natal	
Notes		
Risk of bias		
Bias	**Judgement**	**Justification**

Random sequence generation (selection bias)	Low	"We used simple computer-generated randomisation, with clusters assigned in a 1:1 allocation ratio" (p257).
Baseline outcome measurements similar	Unclear	Randomised trial with no baseline measurement of outcomes.
Baseline characteristics similar	Low	"At baseline, similarity between the intervention and control arm's characteristics was achieved through the random allocation used" (p261). Among women assessed at 12 months, their baseline age, education, and marital status were compared, as well as household level socioeconomic characteristics, such as electricity and water source. Baseline characteristics found to be similar. No significant differences were noted.
Incomplete outcome data (attrition bias)	Low	Authors present a detailed trial profile, with loss to follow-up data. Attrition account for with specific reasons for exclusion; similar between groups.
Selective outcome reporting (reporting bias)	Low	All primary and secondary outcomes reported in published protocol.
Blinding of outcome assessment (detection bias)	Low	"Data collectors blinded to arm visited participants in their home to obtain informed consent. At 12 weeks post-natally, data collectors conducted interviews at [the] hospital" (p258-59)
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	Intervention and control clusters (both with CHWs) are contiguous, not clearly defined: "sub-places" (p257).
Other source of bias	Unclear	Outcomes verbally reported; recall period not specified.

Uwimana 2012

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: South Africa. DISTRICT/REGION: Sisonke district of KwaZulu Natal province.
Methods	DESIGN: Cluster RCT. UNIT OF ALLOCATION: Villages; 3 intervention and 3 control. AIM: To explore training and integrating different types of CCWs involved in TB and HIV programmes into one cadre of CCW; to develop and implement an integrated model for provision of TB⁄HIV/PMTCT care by CCWs; and to assess the performance of up-skilled CCWs in providing integrated TB⁄HIV⁄PMTCT services. BASELINE PERIOD: Cross-sectional baseline survey conducted in 2008, prior to randomization. TREATMENT PERIOD: A phased implementation approach was used to train CCWs in all villages from Oct 2009 to Feb 2011, first in intervention clusters, then in non-selected sites, and lastly in control clusters. There was an interval of ten months between training of intervention and control clusters. Routine monthly data were collected and outcomes assessed from Mar to Dec 2010.
Participants	INTERVENTION RECIPIENTS: Entire population. INTERVENTION SAMPLE SIZE: Target population unspecified; 4038 beneficiaries (3556 adults and 482 children); 39 CHWs each allocated 50-100 households.

	CONTROL SAMPLE SIZE: Target population unspecified; 6600 beneficiaries (6226 adults and 374 children); 50 CHWs each allocated 50-100 households.	
Interventions	CONDITION: HIV, tuberculosis. CHW TERM: Community Care Workers (CCWs). CHW PROFILE: CCWs were previously home-based carers or CHWs employed and managed by NGOs, with high school certificate or grade 9 with > 3 years' experience. Thirty-nine CCWs from the intervention clusters were trained over a period of 30 days (October 2009) and were then placed in the clinics for practical training on HIV counselling and testing (HCT) and TB and STI case finding for a further month. CHW SUPPORT: CCWs received support and supervision from Community Health Facilitators (CHFs) at the PHC and the nurse in charge of the PHC clinic. CCWs were paid a stipend ($200/month). INTERVENTION ACTIVITIES: CCWs in the intervention arm were 'up-skilled' in the provision of TB⁄HIV⁄PMTCT integrated services: screening of household members for TB symptoms and referring to clinic for further care, providing treatment adherence support to household members diagnosed with TB, screening of household members for STI symptoms and referring STI subjects to clinic for further care, provision of HIV counseling and testing in homes, providing ART adherence support and tracing of ART defaulters, and counseling for HIV+ pregnant women and referring for antenatal care. INTERVENTION IMPLEMENTATION: In the intervention clusters, a total of 5588 households were visited by CCWs, whereby 72% of household members were served by CCWs. The majority (91%) of household members received education on TB⁄HIV⁄PMTCT, 44% were screened for TB and 32% for STIs. Of 482 children served, 180 (37%) were traced as TB contacts and referred to the clinics. A total of 684 clients were offered HCT, 92% accepted to be tested. COST TO PATIENT: Not specified. CO-INTERVENTIONS: Prior to the provision of TB/HIV/PMTCT services, trained CCWs held multi-sectoral community mobilisation events in the villages with traditional leaders, government officials, health workers and other stakeholders to introduce the services to be provided by up-skilled CCWs. During community mobilizations, CCWs distributed condoms, provided HCT, TB and STI screening, TB sputa collection and referral of TB and STI suspects to health facilities. Other services such as issuing of birth certificates, identification documents, and application for grants were also provided. CONTROL: Standard of care, including 'non-up-skilled CCWs' who had not yet been trained on providing home-based HCT, they were only promoting HCT and referring clients to the clinic for HIV testing.	
Outcomes	CARE-SEEKING: Patients screened for TB symptoms, STI symptoms, TB suspects referred to clinic, STI suspects referred to clinic. FOLLOW-UP PERIOD: 0-10 months; routine monthly data were collected and outcomes assessed from Mar to Dec 2010.	
Notes	No data provided separately for children under five, our study population of interest.	
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	Low	"Six of the 11 surveyed villages were randomly selected into three intervention and three control clusters matched on demographic and socio-economic factors and access to health facilities. The remaining five villages were too

		different to match and were identified as 'non-selected sites" (p489).
Baseline outcome measurements similar	Unclear	Several outcome measures assessed with a baseline survey for study area overall (including non-selected sites), but no comparisons possible between study arms.
Baseline characteristics similar	Unclear	Randomisation was matched on demographic, socioeconomic and health system factors but no measures provided of baseline characteristics in intervention versus control clusters.
Incomplete outcome data (attrition bias)	Unclear	Since the outcome data is from routine CCW data, the outcomes are primarily process/implementation indicators. Some of these are difficult to interpret, especially without a baseline intervention versus control comparison e.g. less cases referred could be a result of more cases treated at home or less cases treated at all; cases identified could be an indicator of transmission but could also be a question of CCW performance.
Selective outcome reporting (reporting bias)	Low	No protocol available, but outcomes measured from baseline surveys reported at endline. Authors report patients screened, suspects identified, suspects referred for (a) TB, (b) STIs, (c) HIV. Percentages and p-values provided but no RR or PR reported.
Blinding of outcome assessment (detection bias)	High	CHFs, the supervisors of CCWs, are the outcome assessors collecting routine monthly data on CCW performance (not the CCWs themselves). Outcomes are mostly process indicators (not objective).
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Unclear	Not made entirely clear what activities control CCWs perform and what support they receive. No discussion of contamination or map provided. "There was an interval of 10 months between training of intervention and control clusters" (p490).
Other source of bias	High	Outcomes based on health worker data subject to reporting bias.

Uwimana 2013

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: South Africa. DISTRICT/REGION: Sisonke district of KwaZulu Natal province.
Methods	DESIGN: Cluster RCT. UNIT OF ALLOCATION: Villages; 3 intervention and 3 control. AIM: To conduct an impact assessment of an intervention to enhance the provision of community-based services for TB, HIV and PMTCT. To assess the uptake of TB-HIV/PMTCT services at community level and the performance of trained CCWs in providing integrated care. BASELINE PERIOD: Baseline cross-sectional household survey in September 2009 TREATMENT PERIOD: After training, CCWs in the intervention arm conducted household visits for a period of 10 months. The follow-up household survey was conducted in April 2011 to assess the effectiveness of the intervention.
Participants	INTERVENTION RECIPIENTS: Entire population.

	INTERVENTION SAMPLE SIZE: Sample sizes unspecified; 1417 and 1976 respondents to baseline and follow-up surveys, respectively. CONTROL SAMPLE SIZE: Sample sizes unspecified; 1032 and 1608 respondents to baseline and follow-up surveys, respectively.	
Interventions	CONDITION: HIV, tuberculosis. CHW TERM: Community Care Workers (CCWs). CHW PROFILE: Community health workers and home-based carers were integrated as one cadre to provide the same services; households were re-allocated for each so that each household would be visited by one CCW. Training developed on TB-HIV/PMTCT integrated care, including home-based HIV counselling and testing. CHW SUPPORT: A supervision model was set up whereby each health facility had a community health facilitator allocated to supervise 25 CCWs from the same catchment area and ensure facility-community linkage. CCWs received remuneration. INTERVENTION ACTIVITIES: Services for TB-HIV/PMTCT comprehensive package of care: (1) Health education during household visits and campaigns or community events; (2) Screening of household members for TB symptoms, collection of sputum from suspects and TB suspects referred to the clinic for further care; (3) Treatment adherence support provided to household members diagnosed with TB; (4) Referral of cases requiring further support, including social welfare; (5) Screening of household members for STI symptoms and STI suspect referrals to clinic; (6) Provision of HIV counselling and testing in homes (i.e., pre-HIV test counselling, HIV testing using rapid test and post-test counselling) and ongoing counselling; (7) ART adherence support provided; all HIV-positive pregnant women on ART received support; (8) Provision of adherence to dual therapy, pregnant women educated and counselled on infant feeding options and encouraged to attend antenatal care; (9) Provision of awareness on IMCI, referrals for immunisation and weighing. INTERVENTION IMPLEMENTATION: As part of the intervention, CCWs in the intervention arm were trained to provide home-based HCT. Of 1976 respondents in the intervention arm, 489 (25%) received home-based HCT, resulting in a 14% overall uptake of home-based HCT. The uptake of HIV testing increased significantly in the intervention arm, from 55% to 78% (P< 0.001). COST TO PATIENT: Not specified. CO-INTERVENTIONS: Not specified. CONTROL: Standard of care, including passive case detection from CCWs. Control CCW activities and support unspecified.	
Outcomes	CARE-SEEKING: HIV counselling and testing, TB screening, STI screening, referral for HIV-PCR, sputum collection, ART adherence support, anti-TB DOT support, dual therapy support. FOLLOW-UP PERIOD: 14 months.	
Notes	Same study site and intervention as Uwimana 2012, but this is a pre-post cross-sectional survey design, whereas Uwimana used routine CCW data to assess outcomes. No data provided separately for children under five, our study population of interest.	
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	Low	"Based on the findings of the baseline survey, six clusters were randomly selected into either the intervention or the control arms (three clusters in each arm)" (pS50).

Baseline outcome measurements similar	Low	Authors measure the outcomes before and after the intervention, using cross-sectional surveys. They compare follow-up data between arms without taking into account differences between arms at baseline. Since this is a randomised design, this is acceptable.
Baseline characteristics similar	Unclear	Baseline survey was conducted but only "to obtain information on the clusters in preparation for implementation of the intervention" (pS50). Comparisons made using results from the follow-up survey, which may have changed from baseline; some differences found: "The fact that the control and intervention arms had some differences in socio-economic factors, that the intervention sites had more females interviewed and that more intervention sites lacked schools may have affected the outcomes of this study" (pS53). Since clusters are randomised, scored as unclear risk.
Incomplete outcome data (attrition bias)	Low	No discussion of missing data or why there are more participants in the follow-up survey than in the baseline survey (for both arms). Numbers of respondents are similar across study arms.
Selective outcome reporting (reporting bias)	Low	No protocol available but all outcomes seem to be reported; outcomes measured from baseline surveys reported in follow-up survey. Clear articulation of primary and secondary outcome measures: "The primary outcome measures of the evaluation were 1) TB and HIV case finding, 2) treatment adherence support and 3) access to utilisation of PMTCT services. The secondary outcomes were the integrated management of childhood illnesses, referral to welfare services and treatment outcomes" (pS49).
Blinding of outcome assessment (detection bias)	High	Outcome assessors were separate from CCW delivery staff, "trained field workers" (pS50), but not blinded.
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	High	Contamination discussed as a possibility but unclear how much contamination occurred; no map provided. "In practice, it is difficult to find appropriate control communities and prevent contamination of the outcomes as a result of exposure of individuals in the control communities to the intervention. Various factors outside the control of the researcher led to a certain degree of contamination in the control communities" (pS53). Not clear who control CCWs were or what they did.
Other source of bias	Unclear	Care-seeking outcomes based on verbal reporting and recall period not specified.

Yassin 2013

Setting	GEOGRAPHICAL SETTING: Rural. COUNTRY: Ethiopia. DISTRICT/REGION: Sidama zone.
Methods	DESIGN: Controlled before-after study

	UNIT OF ALLOCATION: Sidama zone, comprised of 19 administrative districts was chosen as the intervention area. Hadiya zone was chosen as a control area. AIM: An implementation study evaluating the introduction of an innovative intervention package in the Southern Region of Ethiopia, to improve TB case detection and treatment outcomes. BASELINE PERIOD: Retrospective surveillance data collected from the TB registers of health facilities providing TB treatment and the quarterly surveillance reports from Sidama zone for the period between June 2009 and September 2010 (16 months) were used as baseline. TREATMENT PERIOD: 14 months from Oct 2010 to Dec 2011.
Participants	INTERVENTION RECIPIENTS: Entire population, particularly women and children. INTERVENTION SAMPLE SIZE: Population over three million; one CHW per kebele (n=524). CONTROL SAMPLE SIZE: Population of 1,355,153; unclear if control zone had HEWs.
Interventions	CONDITION: Tuberculosis. CHW TERM: Health Extension Workers (HEWs) CHW PROFILE: HEWs were salaried females trained for one year by the Health Service Extension Programme (HSEP) and come from and live within the communities they serve. CHW SUPPORT: HEWs were supported by community health promoters (CHPs), who are lay volunteers selected by the community, and 19 HEW supervisors. Support included provision of mobile phone airtime to all HEWs and supervisors and motorbikes for supervisors to transport smeared-slides and return test results and treatment. INTERVENTION ACTIVITIES: HEWs conducted house-to-house visits, identified individuals with a cough for two or more weeks, with or without other symptoms, collected sputum and prepared smears. Supervisors transported smears for microscopy, started treatment, screened contacts and initiated Isoniazid preventive therapy (IPT) for children under five. HEWs provided home-based follow-up of smear positive and negative cases. INTERVENTION IMPLEMENTATION: During the study period, HEWs identified 49,857 individuals with cough for two or more weeks, with or without other symptoms. 8005 household contacts of PTB+ cases were visited by the HEWs and supervisors. Of these, 1,949 (13%) had cough for two or more weeks, with or without other symptoms and 1,290 (66%) provided sputum samples. A total of 2,477 household contacts were children, of which 1,080 (44%) were under 5 years old and asymptomatic and were offered IPT. COST TO PATIENT: Not specified. CO-INTERVENTIONS: In addition to the HEW/supervisor TB activities, the implementation package included (1) familiarisation and awareness creation workshops attended by political, community and religious leaders, teachers, stakeholders, health workers, and ex-TB patients; (2) refresher training of all staff and laboratory technicians involved in TB control activities, and microscope distribution; (3) advocacy activities conveying key messages about TB and availability of services through community meetings, campaigns and local radio. CONTROL: Routine care, including passive case detection from 46 TB diagnostic and treatment centres in the control zone. Unclear whether the control zone included HEWs offering passive case detection and other HSEP preventative and curative services.

Outcomes	CARE-SEEKING: PTB+ case notification rate. FOLLOW-UP PERIOD: 0-14 months.	
Notes	No data provided separately for children under five, our study population of interest.	
Risk of bias		
Bias	**Judgement**	**Justification**
Random sequence generation (selection bias)	High	Intervention zone and comparison zone were not selected randomly leading to possible selection bias: "Hadiya zone, which did not receive the intervention package, was used as a control zone to compare the outcomes" (p2).
Baseline outcome measurements similar	Unclear	A case notification rate 'for 2010' is presented in the methods section for the control zone. In the intervention arm the baseline period is up to September 2010 and intervention period starts in October 2010. It is not clear whether this is an appropriate comparisons nor how this figure was obtained.
Baseline characteristics similar	Unclear	"Hadiya zone has similar characteristics to the intervention zone; it has a population of 1,355,153, 46 TB diagnostic and treatment centres and in 2010, 924 smear-positive TB cases were notified with case notification rate of 68 per 100,000 population and 82% of TB patients were successfully treated" (p2). While it seems as if the zones are similar, authors did not given the specific population for Sidama, nor the number of TB treatment centers, nor number successfully treated.
Incomplete outcome data (attrition bias)	Low	Given data, there would need to be a great deal of missingness in the control arm to change the outcome.
Selective outcome reporting (reporting bias)	Low	All relevant outcomes presented in the results.
Blinding of outcome assessment (detection bias)	High	Outcome assessors are facility staff and/or HEWs; no commentary on blinding, presumably the providers know from which zone the patient comes; identifying cough/symptoms (HEWs), interpreting smears (lab staff), and assessing treatment success (health staff) are subjective.
Blinding of participants and personnel (performance bias)	High	Not possible to blind participants and personnel due to the nature of the intervention.
Protection against contamination	Low	The 1:1 allocation of two distinct zones suggests little contamination.
Other source of bias	High	Outcomes based on health worker data subject to reporting bias.