

Community-based intervention package for preventing maternal morbidity and mortality and improving neonatal outcomes

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1. Background

The Millennium Development Goal for maternal health (MDG-5) calls for a reduction in maternal mortality by two-thirds by the year 2015 ([Sachs 2005](#)). According to year 2000 estimates, around 529,000 maternal deaths occur each year. The maternal mortality ratio for sub-Saharan Africa was estimated to be nearly 1000 per 100,000 live births: almost twice that of south Asia, four times as high as in Latin America and the Caribbean, and nearly 50 times higher than in industrialised countries ([AbouZahr 2003](#)). Most of these maternal deaths seem to occur between the third trimester and the first week after the end of pregnancy ([Ronsmans 2006](#)). Mortality has also been found to be extremely high on the first and second days after birth ([Hurt 2002](#)).

Almost 80 per cent of the maternal deaths are due to direct obstetric causes including severe bleeding (haemorrhage), infection, complications of unsafe abortion, eclampsia, and obstructed labor; with other causes being related to the unfavourable conditions created by lack of access to health care, illiteracy and factors related to poverty ([Hoj 2003](#)). The estimated 529,000 maternal deaths are the tip of the iceberg, and many more women are estimated to suffer pregnancy-related illnesses (9.5 million), near-miss events which are the life-threatening complications that women survive (1.4 million), and other potentially devastating consequences after birth ([Ashford 2002](#); [Say 2004](#); [WHO 2000](#)). The consequences of near-miss events on women themselves and their families can be substantial, and recovery can be slow, with lasting sequelae. An estimated 10 to 20 million women develop physical or mental disabilities every year as a result of complications or poor management ([Ashford 2002](#); [Murray 1998](#)). The long-term consequences are not only physical, but are also psychological, social, and economic ([Filippi 2006](#)).

Pregnancy-related illnesses and complications during pregnancy and delivery are associated with a significant impact on the fetus, resulting in poor pregnancy outcomes ([Walsh 1994](#)). In developing countries, almost two-thirds of births occur at home and only half are attended by a trained birth attendant ([WHO 1996](#)). Of the 136 million babies born every year, approximately 3.2 million are stillbirths and four million are neonatal deaths, 98 per cent of which are in developing countries. The first week of life is a particularly vulnerable period, with 60 to 70 per cent of neonatal deaths occurring within the first seven days after birth ([Stanton 2006](#); [Zupan 2005](#)). In the 1970s the World Health Organization promoted training of traditional birth attendants (TBAs) as a major public health strategy to reduce the burden of mortality and morbidities related to pregnancy and childbirth. However, the evidence of the impact of this strategy on maternal and neonatal outcomes is still limited ([Sibley 2007](#)). In developing countries, most of the maternal and perinatal deaths and morbidities occur at home. The reasons are multi-factorial, including poverty; poor health status of women; illiteracy; lack of information regarding the availability of health services/providers; lack of control on household resources and decision making authority; poor antenatal and obstetric care, both within the community and health facilities; absence of a trained attendant at delivery; inadequate referral system for emergency obstetric care; inadequate or lack of transportation facilities; and absence of/poor linkages of health centres with the communities ([Ensor 2004](#); [Kawuwa 2007](#)). The greater part of maternal and neonatal deaths can be prevented with early recognition and proper implementation of required skills and knowledge ([Ray 2004](#)). Soon after the Alma-Ata Declaration, arguments for selective rather than comprehensive primary health care dominated and it was then recognized that community participation was important in supporting the provision of local health services and in delivering interventions at community level ([Rosato 2008](#)). Recent analysis indicates that 41 to 72 per cent of newborn deaths can be prevented by available interventions like tetanus toxoid immunization to mothers, clean and skilled care at delivery newborn resuscitation, prevention of hypothermia, exclusive breastfeeding, clean umbilical cord care, management of pneumonia and sepsis, if provided at high coverage, and around half of this reduction is possible with community

based Interventions ([Darmstadt 2005](#)). Therefore, a significant proportion of these mortalities and morbidities can be addressed by developing a community-based package of improved maternal care during pregnancy, delivery and postpartum, as well as care of the newborn. These should be supplemented by developing and strengthening linkages with the local health systems.

The objective of the proposed review is to assess the effectiveness of such community-based intervention packages in preventing maternal and perinatal mortality and morbidities; and improving health outcomes. A previously published review has analyzed the impact of community-based individual interventions and few package intervention during the antenatal, intrapartum and postnatal periods on perinatal and neonatal health status and identified number of interventions that can be implemented in the community-based neonatal care programs including: tetanus toxoid immunization, prevention of maternal infections, breastfeeding counseling and birth preparedness at antenatal stage; clean and skilled care at delivery in intrapartum stage; newborn resuscitation, prevention of hypothermia, hypoglycemia and prophylactic eye care in immediate newborn care stage; and exclusive breastfeeding, clean umbilical cord care, management of pneumonia and sepsis, post natal visits and birth spacing in post natal stage ([Bhutta 2005](#)). However this review will not only evaluate the effectiveness of community-based interventions package on perinatal and neonatal mortality and morbidities but will also identify its impact on reducing maternal mortality and morbidities and improvement in other health outcomes. This review will not evaluate the impact of training of only TBAs in maternal and newborn care ([Sibley 2007](#)), or effectiveness of a health education strategy designed for mothers and other family members on newborn survival ([Thaver 2009](#)), as these are being evaluated in other reviews.

2. Objectives

To assess the effectiveness of community-based intervention packages in preventing maternal and perinatal mortality and morbidities; and improving health outcomes.

3. Methods

3.1 Criteria for considering studies for this review

Types of studies

We will include community-based, randomised or quasi-randomised controlled trials, irrespective of language or publication status in this review. We will include both individual and cluster randomised designs.

Types of participants

Pregnant women at any period of gestation.

Types of interventions

Intervention package would include additional training of outreach workers namely, lady health workers/visitors and community midwives; and community/village health workers or facilitators in maternal care during pregnancy, delivery and in the post partum period; and routine newborn care.

Additional training is defined as training other than the usual that health workers have received from their governmental or non-governmental organisation and would include a combination of training in providing basic antenatal, natal and postnatal care; preventive essential newborn care, breastfeeding counseling, management and referral of sick newborns, skills development in behaviour change communication and community mobilisation strategies to promote birth and newborn care preparedness. The training sessions may be lectures, supervised hands-on training in a health care facility and/or within the community.

The control group would receive their usual training in maternal care during pregnancy, delivery and in the post partum period; and newborn care.

Types of outcome measures

Primary outcomes

Maternal mortality defined as number of maternal deaths per live births. Maternal death will be defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management.

Secondary outcomes

1. Neonatal mortality defined as the number of neonatal deaths from any cause among total live births:
 - Early neonatal mortality: neonatal deaths in the first week of life;
 - Late neonatal mortality: neonatal deaths from 7 to 28 days of life.
2. Perinatal mortality defined as stillbirths and early neonatal deaths; that is, neonatal deaths in the first week of life among all stillbirths and live births.
3. Stillbirths defined as fetal death after 28 weeks of gestation but before delivery of the baby's head per all births.
3. Low birth weight defined as birth weight less than 2500 g.
4. Complications of pregnancy, including prolonged or obstructed labor, eclampsia, post partum haemorrhage, post partum depression (as defined by the authors).
5. Referral to a health facility for any complication during pregnancy, delivery, or the post partum period.
6. Institutional delivery/delivery at a health facility.
7. Birth attended by a health provider (doctor, nurse, midwife or a trained health worker).
8. Initiation of breastfeeding within one hour of birth
9. Exclusive breastfeeding at 6 months of age
10. Health care seeking for maternal and/or neonatal morbidities
11. Infant's weight for age and height for age Z scores at 6 months of age

3.2 Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (January 31, 2009).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We will also search the World Bank's JOLIS search engine, British Library for Development Studies at IDS as well as IDEAS database of unpublished working papers, google and google scholar. The following search strategy will be modified for the various databases and search engines.

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["community-based nutrition program" OR "community-based primary health care" OR "community-based program" OR "community-based perinatal care" OR "community-based neonatal care" OR "community health" OR "health worker" OR "community involvement" OR "community participation" OR "community program" OR package OR "behaviour change"] AND [pregnancy OR women OR infant OR neonate OR perinatal OR newborn]
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We will restrict the search terms to titles, abstracts and keywords. We will not apply any language restrictions.

3.3 Data collection and analysis

Selection of studies

Two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion and, if required, we consulted the third review author, Zulfiqar Bhutta (ZAB). Studies already identified for inclusion are Baqui (2008), Bhutta (2008), Darmstadt (2005) and Manandhar (2004).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion and, if required, we consulted the third reviewer. Data were entered into Review Manager software ([RevMan 2008](#)) and checked for accuracy.

Assessment of methodological quality of included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2008](#)). Any disagreement was resolved by discussion.

(1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- adequate (any truly random process, e.g. random number table; computer random number generator);
- inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Studies were judged at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results.

We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. We assessed methods as:

- adequate;
- inadequate;
- unclear.

(5) Selective reporting bias

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- adequate (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Other sources of bias

We described for each included study any important concerns we have about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses.

Measures of treatment effect

We will carry out statistical analysis using the Review Manager software (RevMan 2008). For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals (CI). For continuous data, we used the mean difference when outcomes were measured in the same way between trials.

Unit of analysis issues

We included cluster-randomised trials in the analyses along with individually randomised trials. The data of cluster-randomised trials will be incorporated using generic inverse variance method in which logarithms of RR estimates are used along with the standard error of the logarithms of RR estimates.

Data synthesis

We will analyse the data using Review Manager (RevMan 2008) and generate RR with 95% CI for the dichotomous outcomes. We use fixed-effect meta-analysis for combining data where trials are examining the same intervention, and the trials' populations and methods were judged sufficiently similar. Where we suspect clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, we use random-effects meta-analysis. If substantial heterogeneity is identified in a fixed-effect meta-analysis this will be noted and the analysis repeated using a random-effects method.

Subgroup analysis and investigation of heterogeneity

Heterogeneity among the trials was measured by visually inspecting the forest plots and calculating the I^2 statistic. Values of I^2 statistic greater than 50% were considered to be substantial. We pre-specified the following subgroup analysis to investigate heterogeneity:

1. Content of intervention
2. Duration of training
3. Continued education after initial training
4. Baseline mortality (maternal, perinatal and neonatal)
5. Presence/absence of community mobilisers, advocacy or support groups
6. Involvement of other family members through community mobilisation (husband, mother-in-law)
7. Linkages to healthcare systems .

We use the following outcomes in subgroup analysis: maternal, neonatal and perinatal mortality.

Sensitivity analyses

We carried out sensitivity analyses to explore the effect of high risk of bias on the summary estimates.

4. Review team

The review team comprises Dr Zulfiqar A Bhutta (Lead Reviewer), Dr Batool Azra Haider and Zohra Lassi. Drs Zulfiqar A Bhutta and Batool A Haider have co-authored several systematic reviews on evaluations of health care interventions. Dr Zulfiqar A Bhutta provides the content expertise. Dr Batool A Haider provides the methodological expertise (systematic review methods). Dr Batool A Haider and Zohra Lassi provide expertise in statistical analysis. Drs Batool A Haider and Zohra Lassi will be involved in retrieving studies but will also seek help of a search coordinator for this review

5. Timeline

January-March 2009: Identification of articles.

March-April 2009: Data extraction using extraction tables and write-up.

May-September 2009: Internal and external review and dissemination.

6. Acknowledgements

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As part of the pre-publication editorial process, this protocol has been commented on by four peers (an editor and three referees who are external to the editorial team) and the Group's Statistical Adviser.

Contributions of authors

The protocol was written by Dr Batool Azra Haider (BAH) under the guidance of Dr Zulfiqar A Bhutta (ZAB).

Declarations of interest

Dr Zulfiqar A Bhutta is the principal investigator of a trial evaluating community care perinatal care package in Hala, Pakistan.

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