



WHO
recommendations
on health promotion
interventions
for maternal and
newborn health
2015



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Acronyms

ANC	Antenatal care	ITS	Interrupted Times Series	NGO	Nongovernmental organization
ANM	Auxiliary nurse-midwife	LAC	Latin America and Caribbean	NM	Neonatal mortality
BF	Breastfeeding	MAPEDIR	Maternal and Perinatal Death Inquiry and Response Project	OR	Odds ratio
BPCR	Birth Preparedness and Complication Readiness	MASCOT/ MH-SAR	Multilateral Association for Studying Health Inequalities and Enhancing North-South and South-South Cooperation	PM	Perinatal mortality
CI	Confidence interval	WHO/MCA	WHO Department of Maternal, Newborn, Child and Adolescent Health	PN	Postnatal care
C/I	Care-seeking for complications or illness in women and newborns	MCH	Maternal and Child Health	PP	Postpartum care
EmOC	Emergency obstetric care	MDSR	Maternal Death Surveillance and Response	RCT	Randomized controlled trial
FB	Facility birth	MM	Maternal mortality	RR	Relative risk
FCI	Family Care International	MI	Male involvement	SB	Stillbirth
FGM	Female genital mutilation	MN	Maternal and newborn	SBA	Skilled birth attendant
GDG	Guideline Development Group	MNH	Maternal and newborn health	SRH	Sexual and reproductive health
GRADE	Grading of Recommendation, Assessment, Development and Evaluation	MoH	Ministry of Health	TBA	Traditional birth attendant
IFC	WHO Working with individuals, families and communities Framework	MWH	Maternity waiting home	UN	United Nations
				UNICEF	United Nations Children's Fund
				UNFPA	United Nations Population Fund
				USD	United States dollar
				WHO	World Health Organization

RECOMMENDATION 1

Birth preparedness and complication readiness (BPCR)

Question: What interventions used to implement BPCR are effective for increasing use of skilled birth attendants (SBAs) and for improving other maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	One randomized control trial (RCT) of weak methodological quality. Very serious¹	Participants, intervention and outcomes directly address the review question. Single BPCR intervention using facility education sessions with poor women and husbands in a maternity hospital in urban Nepal. No serious indirectness	Reports a non-significant increase in use of SBAs in both intervention groups (husband and wife or wife alone receive health education) compared with control (wife receives no education). Difficult to determine if results are due to educating men or educating men and their wives. Sample is biased towards women who attended antenatal care (ANC) with husbands. Not applicable	Low
	n=13	Quasi-experimental and observational studies: four rated of moderate and nine of weak methodological quality. Very serious²	Some directness in participants, but indirect comparisons for interventions and outcomes. Interventions vary widely in terms of: single BPCR or with other components, number of activities, level of intervention, and people trained to provide BPCR messages. Definitions of SBA vary. Serious³	Variation in results across studies. Three quasi-experimental studies and one pre and post with a control group report significant improvements. One quasi-experimental study reports more improvement in comparison group. Four before and after studies report significant improvements in SBA or facility birth. Two report slight improvements from baseline and one a greater improvement in SBA in the unexposed group. One qualitative study indicates an increase in the number of women giving birth with a midwife. Very serious⁴	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth (continued)	n=6 ^a	Three RCTs: two of moderate and one of weak methodological quality. Serious⁵	Indirectness in participants, interventions and outcomes. Interventions vary in relation to single or multiple, number of BP activities, level of intervention and people trained to deliver BP messages. Outcomes reported differently across studies. Very serious⁶	Some similarity in results. Two cluster RCTs report percentage of women giving birth at a facility was significantly higher in the intervention arms compared to control arm. In the other trial facility births were higher and more women gave birth with a qualified attendant in the intervention arm, but these were not significant differences. Serious⁷	Very low
		One quasi-experimental and one observational study rated weak quality and one quasi experimental rated moderate quality. Very serious⁸	Some indirectness. Participants differed in the two studies; interventions all multiple and implemented at facility and community level but different activities and people trained to deliver BP messages. One reports facility birth, the other two SBAs. Serious⁹	Variation in results. One quasi-experimental study reports significant increases in facility birth in the intervention and the comparison areas baseline to follow-up, but not the control area. The other shows significant improvement in use of SBAs in the intervention area. In the pre and post study there was a reduction in births assisted by a health provider. Very serious¹⁰	Very low
Care with skilled birth attendant or facility in case of complications/ illness in women and newborns	n=4	Three observational studies: two rated moderate and one rated weak methodological quality; one quasi-experimental study rated weak. Very serious¹¹	Indirectness in participants, interventions and outcomes. Interventions vary in relation to single or multiple, number of BP activities, level of intervention and people trained to deliver BP messages. Outcomes reported differently across studies; one reports on care-seeking for newborns. Very serious¹²	The three before and after studies report more women seeking skilled care for complications between baseline and follow-up. The quasi-experimental study reports a significant increase in women with complications seeking treatment at a facility in the intervention group. Serious¹³	Very low

^a These studies were of BPCR interventions specifically aiming to increase access to skilled care in case of complications. These studies took place in contexts with low SBA use and where the majority of births take place at home; consequently the BPCR messages are different and the intervention also contributed to ensure safe birth practices at home. The studies are Ahluwalia et al. (2003); Ahluwalia et al. (2010); Baqui et al. (2008); Darmstadt et al. (2010); Hossain and Ross (2006); Kumar et al. (2012); Midhet and Becker (2010).

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Care with skilled birth attendant or facility in case of complications/ illness in women and newborns (continued)	n=6 ^b	Three RCTs: two of moderate and one of weak methodological quality. Serious¹⁴	Interventions vary in relation to single or multiple, number of BP activities, level of intervention and people trained to deliver BP messages. Outcomes reported differently across studies. Very serious¹⁵	One (weak) RCT reports significant increases in women with complications seeking care in pregnancy and after delivery, but no significant difference between study arms for care seeking for delivery complications. One reports significantly fewer women with complications went to unqualified practitioners and the other care-seeking from a qualified provider for neonates with complications increased significantly more in the intervention arm than comparison. Serious¹⁶	Very low
		One quasi-experimental and a pre and post and a follow-up evaluation of the same intervention; all rated of weak quality. Very serious¹⁷	Some indirectness. Participants differed in the studies. Interventions were multiple and implemented at facility and community level but different activities and people were trained to deliver BP messages. All three report on care-seeking for women with complications. Serious¹⁸	All report benefit of BP intervention on care-seeking for complications. The quasi-experimental study reports significant increases in women seeking care for complications in the intervention and comparison groups but not the control arm. Both evaluations report increases in the number of women with complications seeking hospital care but only the follow-up study estimates what percentage this represents and is based on old surveillance data. There is no comparable data from a control group of women who did not receive the intervention. No serious inconsistency¹⁹	Very low
Maternal mortality	n=1	One RCT of moderate methodological quality. Serious²⁰	Participants, intervention and outcomes directly address the review question. Multiple BPCR interventions, using Community Health Worker (CHW) home visits in rural villages in India. No serious indirectness	Reports a non-significant downward trend in maternal mortality in the intervention arm compared to control but the study is not powered to detect a significant reduction in maternal mortality, a secondary outcome of the study. Not applicable	Low

^b These studies were of BPCR interventions specifically aiming to increase access to skilled care in case of complications. See above.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Maternal mortality (continued)	n=1	One quasi-experimental study of moderate quality. Serious²¹	Participants, interventions and outcomes directly address the review question. Multiple BPCR intervention using community volunteers and facility staff to provide BPCR messages via facility education sessions, visual aids and community mobilization activities in a rural area of Burkina Faso. No serious indirectness	Reports lower mortality risk in the intervention group and a decline over time but this is not significantly different to the non-intervention or control areas. Difficult to attribute change to any one of the service delivery interventions or to the broad based communication and outreach activities. Not applicable	Very low
Neonatal mortality	n=4 ^c	Two RCTs of moderate quality and one of weak methodological quality. Serious²²	Indirectness in participants and interventions. All were multiple interventions including BPCR and other components; however, level of intervention varied as did type of activity and people trained to provide BPCR messages. Outcomes reported consistently as neonatal mortality rate. Serious²³	One trial reports significantly lower neonatal mortality in the BP intervention group. The other two report no significant difference in neonatal mortality by study arm (in one there is a risk of contamination between study arms). Very serious²⁴	Very low
		One quasi-experimental study of moderate quality. Serious²⁵	Participants, intervention and outcomes directly address the review question. The intervention was multiple (i.e., implemented additional interventions as well as birth preparedness), was implemented at the community level, and used home visits by volunteers to provide BPCR education. Reports neonatal mortality rate. No serious indirectness²⁶	The study showed no difference in neonatal mortality rates between the intervention and comparison groups or from baseline and endline. Not applicable²⁷	Low
	n=1	One observational study of moderate quality. Serious²⁸	Participants, intervention and outcomes directly address the review question. A single BP intervention provided BP messages via home visits at community level. Reports number of reported deaths within first 28 days of life. No serious indirectness²⁹	The study showed fewer neonatal deaths over time but there is no comparison group and the change could be due to factors other than the intervention. Not applicable³⁰	Low

^c These studies were of BPCR interventions specifically aiming to increase access to skilled care in case of complications. See above.

Birth with a skilled birth attendant or facility birth

- 1 **Risk of bias:** Lack of information on data collection and blinding, and potential for selection bias (Mullany et al., 2007).
- 2 **Risk of bias:** Four studies were quasi-experimental (FCI Kenya, 2007; FCI Tanzania, 2007; Hounton et al., 2008; Turan, Tesfagiorgis and Polan, 2011) and one was a pre and post study with a control group (Sood et al., 2004 Indonesia). Most did not describe control of confounders (except Turan, Tesfagiorgis and Polan, 2011), nor blinding of assessors/participants. Data collection methods are likely to be valid in those that pre-tested or used validated tools (FCI Kenya, 2007; FCI Tanzania, 2007); others rely on self-reporting or changed fieldwork contractors baseline to endline (Sood et al., 2004 Indonesia; Turan, Tesfagiorgis and Polan, 2011). Seven were one group before and after evaluations (Fonseca-Becker and Schenck-Yglesias, 2004; Hodgins et al., 2010; McPherson et al., 2006; Moran et al., 2006; Mushi, Mpembeni and Jahn, 2010; Sinha, 2008; Sood et al., 2004 Nepal). In Fonseca-Becker and Schenck-Yglesias (2004) and Moran et al. (2006) there may be problems with reliability due to changed fieldwork teams. Participants selected using non-random methods or did not describe selection procedure (Mushi, Mpembeni and Jahn, 2010; Sood et al., 2004 Nepal), did not consider confounders, and relied on self-reporting in unvalidated surveys or changed fieldwork contractors from baseline to endline (McPherson et al., 2006; Sood et al., 2004 Nepal). Validity/reliability of survey tool unknown and it changed baseline to follow-up; selection bias is possible, and no information about possible confounding factors (Sinha, 2008). One qualitative feasibility study rated weak (Skinner and Rathavy, 2009).
- 3 **Indirectness:** Studies were conducted in low-income countries (Cambodia, India, Nepal, Tanzania, Eritrea, Burkina Faso, Kenya and Indonesia) and a middle-income country (Guatemala). All studies included women and most also included men or husbands and other community members as target groups for interventions. Interventions were either single birth preparedness interventions (Hodgins et al., 2010; McPherson et al., 2006; Mullany et al., 2007; Mushi, Mpembeni and Jahn, 2010; Skinner and Rathavy, 2009; Turan, Tesfagiorgis and Polan, 2011) or multiple (included family planning, newborn care practices, improvements in clinical skills and service delivery in the intervention) (FCI Kenya, 2007; FCI Tanzania, 2007; Fonseca-Becker and Schenck-Yglesias, 2004; Hounton et al., 2008; Moran et al., 2006; Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal). The number of activities

or intervention approaches used by projects to address BPCR, the level of intervention (facility or community or both), and the people trained to provide BPCR messages varied across the studies. Eleven studies report on facility birth and 10 on use of skilled birth attendants (four studies provide definitions of SBA: FCI Kenya (2007), FCI Tanzania (2007), Hounton et al. (2008), Sood et al. (2004 Indonesia)).

- 4 **Inconsistency:** Variation in results across studies. Three quasi-experimental studies (FCI Tanzania, 2007; Hounton et al., 2008; Turan, Tesfagiorgis and Polan, 2011) and one pre and post study with a control group (Sood et al., 2004 Indonesia) report significant improvements in the primary outcome in the intervention area; the other quasi-experimental study reports a higher increase in SBA in the control area (FCI Kenya, 2007). Four of the one group before and after studies report significant improvements in SBA or facility birth (Fonseca-Becker and Schenck-Yglesias, 2004; Moran et al., 2006; Mushi, Mpembeni and Jahn, 2010; Sinha, 2008); the other three report slight improvements from baseline (Hodgins et al., 2010; McPherson et al., 2006) and greater improvement in SBA in the unexposed group at endline (Sood et al., 2004 Nepal). The qualitative study (with pre and post facility data) indicates an increase in women giving birth with a midwife, but this is based on data from all villages linked to 10 health centres and not just the villages where the intervention occurred (Skinner and Rathavy, 2009).
- 5 **Risk of bias:** Two cluster RCTs rated moderate (Darmstadt, et al., 2010; Kumar, 2012). Potential for selection bias, allocation concealment unlikely, outcome assessors were likely to have been aware of intervention status of participants, and women unlikely to be blind to cluster allocation (Midhet, 2010).
- 6 **Indirectness:** The study population varied: either recently delivered women (Darmstadt et al., 2010), women who delivered during the study period (Kumar et al., 2012) or women residing in a pre-determined village/cluster (Midhet and Becker, 2010). Interventions were multiple (i.e. included other interventions as well as BPCR). Kumar et al. (2012) and Darmstadt et al. (2010) used home visits to address BPCR whereas Midhet and Becker (2010) used community mobilization activities and visual aids containing BPCR information/messages. In Darmstadt et al. (2010) and Kumar et al. (2012) interventions were implemented at community level and Midhet and Becker (2010) were at facility and community level; the people trained to provide BPCR messages varied across the studies. Darmstadt et al. (2010) and Midhet and Becker (2010) reported on facility births in the district hospital or women giving birth at medical facilities.

Ahluwalia et al. (2003) reported on births assisted by a provider (dispensary or hospital staff) and Kumar et al. (2012) reported both facility births and delivery with a qualified attendant (doctor, ANM, nurse).

- 7 **Inconsistency:** In two cluster RCTs percentage of women giving birth at a facility was significantly higher in the intervention arms compared to control (Midhet, 2010; Darmstadt, 2010). In the Kumar trial, births in a health facility were higher in the intervention group and more women in the intervention arm delivered with a qualified attendant but these were not significant differences.
- 8 **Risk of bias:** Data collection is poorly described; selection bias is unclear; blinding is not described; and there is no information on confounding factors (Hossain and Ross, 2006). No information on validity and some recall bias possible through self-reporting in household surveys and no information on how many agreed to participate (Baqui et al., 2008). Pre and post study (Ahluwalia et al., 2003) used a routine monitoring system set up by CARE but no indication of reliability, and there is no information about the recruitment or selection of participants for baseline/endline assessments.
- 9 **Indirectness:** Studies conducted in (low income) Bangladesh, India, and Tanzania. Participants varied and were either recently delivered women and their families (Ahluwalia et al., 2003; Baqui et al., 2008) or women, husbands, decision-makers, newborn care-takers and community agents (Hossain and Ross, 2006). Interventions were all multiple (i.e. included other interventions as well as BPCR). Ahluwalia et al. (2003) and Baqui et al. (2008) used home visits to address BPCR and Hossain and Ross (2006) used community mobilization activities and visual aids containing BPCR information/messages as well as home visits. Ahluwalia et al. (2003) and Hossain and Ross (2006) implemented interventions at the facility and community levels and Baqui et al. (2008) at community level only; the people trained to provide BPCR messages varied across the studies. Hossain and Ross (2006) reported on percentage of total births in facilities, Baqui et al. (2008) reported births in a health facility or at home with a skilled birth attendant, and Ahluwalia et al. (2003) reported on births assisted by a provider (dispensary or hospital staff).
- 10 **Inconsistency:** One quasi-experimental study reports significant increases in facility birth in the intervention and the comparison areas baseline to follow-up, but not the control area (Hossain and Ross, 2008). The other quasi-experimental (Baqui et al., 2008) reports significant improvement in use of skilled

Birth with a skilled birth attendant or facility birth (continued)

birth attendants in a health facility or at home from baseline to endline in the intervention district. In the pre and post study there was a reduction in births assisted by a health provider (Ahluwalia et al., 2003).

Care with skilled birth attendant or facility in case of complications/illness in women and newborns

- 11 **Risk of bias:** Fonseca-Becker and Schenck-Yglesias (2004) rated moderate. Data collection methods unreliable (different contractors conducted baseline/endline surveys) McPherson et al. (2006) and Hodgins et al. (2010) rated moderate: validated tools and reliable data collection methods, blinding is not relevant in the before and after design, controlled for some confounders at analysis. Potential for selection bias, assessors are aware of intervention status, and there is little information on confounders and if controlled for (FCI Tanzania, 2007).
- 12 **Indirectness:** Studies conducted in Guatemala, Nepal and Tanzania. All included women, and most also targeted men or husbands and other community members. Interventions were either single birth preparedness-related interventions (Hodgins et al., 2010; McPherson et al., 2006) or multiple (included family planning, newborn care practices, improvements in clinical skills and service delivery in the intervention) (FCI Tanzania, 2007; Fonseca-Becker and Schenck-Yglesias, 2004). The number of activities or intervention approaches used by projects to address BPCR, the level of intervention (facility or community or both), and the people trained to provide BPCR messages varied. All studies report on women with complications seeking skilled care; some report this as total number of women seeking care (FCI Tanzania, 2007), others report women with complications seeking skilled care in pregnancy, delivery or after delivery (Fonseca-Becker and Schenck-Yglesias, 2004; McPherson et al., 2006). Hodgins et al. (2010) report on care-seeking on recognising danger signs in newborns, in pregnancy and at delivery.
- 13 **Inconsistency:** Some similarity in results. The before and after studies generally report more women seeking skilled care for complications between baseline and follow-up (Fonseca-Becker and Schenck-Yglesias, 2004; McPherson et al., 2006) and Hodgins et al. (2010) report increases in percentage of respondents seeking care following recognitions of danger signs in newborns, in pregnancy and at delivery. The quasi-

experimental study reports a significant increase in women with complications who sought treatment at a facility in the intervention group (FCI Tanzania, 2007).

- 14 **Risk of bias:** Selection bias is possible (Darmstadt et al., 2010; Kumar et al., 2012). Potential for selection bias, allocation concealment unlikely, outcome assessors were likely to have been aware of intervention status of participants, and women unlikely to be blind to allocation (Midhet and Becker, 2010).
- 15 **Indirectness:** Studies conducted in Bangladesh, Pakistan and India. The study population varied: participants were either recently delivered women (Darmstadt et al., 2010), women who delivered during the study period (Kumar et al., 2012) or women residing in a pre-determined village/cluster (Midhet and Becker, 2010). Kumar et al. (2012) and Darmstadt et al. (2010) both used home visits to address BPCR whereas Midhet and Becker (2010) used community mobilization activities and visual aids containing BPCR information/messages. In Kumar et al. (2012) and Darmstadt et al. (2010) interventions were at community level and Midhet and Becker (2010) were at the facility and community levels; the people trained to provide BPCR messages varied across the studies. Midhet and Becker (2010) reported on care-seeking for women with complications; Darmstadt et al. (2010) reported care-seeking for neonatal complications and Kumar et al. (2012) care-seeking for newborn illness as well as for women during intrapartum and postpartum periods.
- 16 **Inconsistency:** One cluster RCT reports significant increases in number of women with complications seeking care in pregnancy and after delivery, but no significant difference between control and intervention groups for care-seeking for delivery complications (Midhet and Becker, 2010); the other two report significantly fewer women went to unqualified practitioners as first point of care (Kumar et al., 2012) and care-seeking from a qualified provider for neonates with complications increased significantly in the intervention arm (Darmstadt et al., 2010).
- 17 **Risk of bias:** Data collection is poorly described, selection bias is unclear, blinding is not described and no information is provided on confounding factors (Hossain and Ross, 2006). Risk of selection bias in both the pre and post (Ahluwalia et al., 2003) and the post-evaluation (Ahluwalia et al., 2010) studies; although data collection was through CARE-implemented monitoring systems (Ahluwalia et al., 2003) there is no indication of reliability, and in the follow-up study the authors acknowledge that routine surveillance data at facilities varies in quality and completeness (Ahluwalia et al., 2010); no information on potential factors influencing the outcomes over time.

- 18 **Indirectness:** Studies conducted in Bangladesh and Tanzania. Participants were either recently delivered women (Ahluwalia et al., 2003), community members purposefully selected only in villages that had adopted a community-supported emergency transport system at the end of the intervention (Ahluwalia et al., 2010), or women, husbands, decision-makers, newborn care-takers and community agents (Hossain and Ross, 2006). Interventions were multiple (i.e. included other interventions as well as BPCR). Ahluwalia et al. (2003; 2010) used home visits to address BPCR and Hossain and Ross (2006) used community mobilization activities and visual aids containing BPCR information/messages as well as home visits. Both studies implemented interventions at facility and community level; the people trained to provide BPCR messages varied. Both reported on care-seeking for women with complications.
- 19 **Inconsistency:** The quasi-experimental study reports significant increases in women seeking care for complications in the intervention and comparison groups but not control (Hossain and Ross, 2006). The pre and post evaluation reports increase in pregnant women attending the district hospital treated for obstetric complications (but this could be due to increased demand or better reporting), and in 10 villages with functional transport systems at least 36 women with obstetric emergencies had used the transport systems to seek hospital care (Ahluwalia et al., 2003). The follow-up survey reports six villages with functioning transport systems provided transport to 29 pregnant women with obstetric difficulty (an estimated 22 percent of pregnant women potentially in need of EMoC); estimates are based on old surveillance data (Ahluwalia et al., 2010).

Maternal mortality

- 20 **Risk of bias:** Assessors were blind to intervention status for preliminary analysis (but cannot tell for full analysis) (Kumar et al., 2012).
- 21 **Risk of bias:** Comparison district appears similar to intervention district, data on maternal deaths is collected via a validated tool with some potential for recall bias, and two key confounders were controlled for at analysis (Hounton et al., 2008).

Neonatal mortality

- ²² **Risk of bias:** Two cluster RCTs rated moderate (Kumar et al., 2012; Darmstadt et al., 2010). Potential for selection bias, allocation concealment is unlikely, and women unlikely to be blind to cluster allocation (Midhet and Becker, 2010).
- ²³ **Indirectness:** Studies conducted in South Asia (Bangladesh, India, Pakistan). Participants varied: two studies included recently delivered women (Darmstadt et al., 2010), one included women who delivered during the study period (Kumar et al., 2012) and in Midhet and Becker (2010) the participants were women residing in a pre-determined village/cluster. Interventions varied: most were multiple (i.e., programmes that implemented additional interventions as well as birth preparedness), birth preparedness interventions were either implemented at the community level (Darmstadt et al., 2010; Kumar et al., 2012) or both the community and facility levels (Midhet and Becker, 2010) and used a range of interventions including home visits by volunteers to provide BPCR education (Kumar et al., 2012; Darmstadt et al., 2010), community mobilization activities (Midhet and Becker, 2010) and visual aids containing BPCR information (Midhet and Becker, 2010). All three studies report neonatal mortality rate.
- ²⁴ **Inconsistency:** One cluster RCT reports significantly lower neonatal mortality in the BP intervention group (Kumar et al., 2012), in Midhet and Becker (2010) neonatal mortality rate was lower in the women's and couples' intervention arms but not significantly (and there is potential for contamination between study groups and control arm), and the other cluster RCT reports no significant difference in the study arm or over time (Darmstadt et al., 2010).
- ²⁵ **Risk of bias:** Data collection seems reliable but no information on validity and some recall bias is possible through self-reporting in household surveys, major confounders controlled for at analysis, households selected for survey likely to be representative as blocks and sectors randomly selected, but no information on how many agreed to participate (Baqui et al., 2008).
- ²⁶ **Indirectness:** Conducted in India; included women who delivered during the study period. The intervention was multiple (i.e. implemented additional interventions as well as birth preparedness), was implemented at the community level, and used home visits by volunteers to provide BPCR education. The study reports neonatal mortality rate (number of deaths per 1000 live births).
- ²⁷ **Inconsistency:** Showed no difference in neonatal mortality rates between the intervention and comparison groups and no evidence of change baseline to endline.
- ²⁸ **Risk of bias:** The evaluation used validated tools and reliable data collection methods, blinding is not relevant in the before and after design, and controlled for two confounders at analysis (Hodgins et al., 2010).
- ²⁹ **Indirectness:** Conducted in Nepal with recently delivered women. The intervention was a home-based birth preparedness approach only, implemented at the community level, and used home visits by volunteers to provide BPCR education. The study reports number of reported deaths within first 28 days of life (not rate).
- ³⁰ **Inconsistency:** The one group pre and post evaluation showed a change over time towards fewer neonatal deaths, but there is no comparison group and the change could be due to factors other than the intervention (Hodgins et al., 2010).

RECOMMENDATION 2

Male involvement (MI) interventions for MNH

Question: What interventions used to increase male involvement have been effective in increasing care-seeking behaviour during pregnancy, for childbirth and after birth for the woman and newborn and in improving key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	RCT rated of weak methodological quality, therefore high risk of bias. Serious¹	Participants were married women attending ANC with their husbands. Single intervention involving men. Study reported both facility birth and presence of an SBA. No serious indirectness²	RCT reported no difference between the study groups in facility birth or presence of SBA. Not applicable³	Low
	n=2 ^a	Cluster RCT rated of weak methodological quality, therefore high risk of bias. Focus of trial was increasing access to skilled care for complications. Serious⁴	Participants were women residing in a pre-determined cluster. The intervention was part of a larger programme of work, thus making it difficult to assess male involvement component, the MI component of the trial was multifaceted. Study reported both facility birth and presence of an SBA. No serious indirectness⁵	Study showed a statistically significant benefit for facility birth, but not for presence of skilled birth attendant. Not applicable	Moderate
		One quasi-experimental of weak methodological quality. Focus of study was increasing access to skilled care for complications. Serious⁶	The intervention was multiple: male involvement was just one component of a larger intervention package making it difficult to assess male involvement components. Study reported delivery at a facility. No serious indirectness⁷	Delivery at a facility increased statistically in the intervention group. Not applicable⁸	Low

^a These studies (Midhet and Becker, 2010; Hossain and Ross, 2006) were of interventions specifically aiming to increase access to skilled care in case of complications. Consequently the messages are different and the intervention also contributed to ensure safe birth practices at home.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth (continued)	n=6	All studies were observational: five before and after studies and one programme evaluation study; all were of weak methodological quality. Very serious⁹	Indirectness of participants, interventions and outcome. Components of interventions varied greatly; four studies were parts of large programmes with multiple interventions. The remaining two were single community mobilization interventions. Both outcomes were reported in three studies, facility birth only in the remaining three. Very serious¹⁰	All studies reported some benefit for male involvement either for the presence of SBA/ facility birth or both. In one before and after study there was a statistically significant increase in presence of an SBA for the intervention group. Two pre and post intervention design studies reported a statistically significant increase in facility birth for the intervention group, no SBA data were reported. In a repeat cross-sectional study women (and husbands) reported a statistically significant increase of use of SBA and facility birth for the exposed group. In a repeat cross-sectional design, women reported an increase of presence of SBAs and facility birth for the unexposed group; this finding, however, was contradicted by their husbands, where an increase in SBA and facility birth for the exposed group was reported. In a programme evaluation study an increased use of facility birth was found for the intervention group. Serious¹¹	Very low
Care with a birth attendant or facility in case of maternal complications or illness	n=1 ^b	Cluster RCT rated of weak methodological quality, therefore high risk of bias. Serious¹²	Participants were women residing in a pre-determined cluster. The intervention was part of a larger programme of work, making it difficult to assess male involvement component, which was multifaceted. Study reported women visiting hospital for treatment of problems. No serious indirectness¹³	Study shows a statistically significant increase of women accessing hospital for treatment of problems during pregnancy. Not applicable	Moderate

^b This study (Midhet and Becker, 2010) were of interventions specifically aiming to increase access to skilled care in case of complications. See above.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Care with a birth attendant or facility in case of maternal complications or illness (continued)	n=1	Non-equivalent control group study design; rated of weak methodological quality, therefore high risk of bias. Very serious¹⁴	Participants, intervention and comparison (control group) directly address the review question. Although the study comprised multiple male involvement interventions, it specifically assessed the impact of the interventions on family planning in the postpartum period and STI preventive practices among men and women. No serious indirectness¹⁵	Study reports an increase in visiting the dispensary was found in the intervention group, but not for attending hospital during presence of danger signs. Not applicable	Low
Use of ANC (1 or 4 visits)	n=1	RCT rated of weak methodological quality, therefore high risk of bias. Serious¹⁶	Participants were married women attending ANC with their husbands. Single intervention involving men. Outcome defined as women attending three or more A/N visits. No serious indirectness¹⁷	Reported no difference between the study groups in use of more than three ANC visits. Not applicable¹⁸	Low
	n=1 ^c	Cluster RCT rated of weak methodological quality, therefore high risk of bias. Serious¹⁹	Participants were women residing in a pre-determined cluster. The intervention was part of a larger programme of work, making it difficult to assess male involvement component, which was multifaceted. Outcome defined as visit to qualified health care provider solely for the purpose of routine medical check-up during first or second trimester of pregnancy. No serious indirectness²⁰	Study showed significantly more pregnant women in the intervention arms in comparison to the control arm received adequate prenatal care (visits to qualified health care provider solely for the purpose of routine medical check-ups during first or second trimester of pregnancy) but the differences between intervention arms were not significant. Not applicable	Moderate

^c This study (Midhet and Becker, 2010) were of interventions specifically aiming to increase access to skilled care in case of complications. See above.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Use of ANC (1 or 4 visits) (continued)	n=6	All studies were observational and all were rated of weak methodological quality. Very serious²¹	Indirectness of participants, interventions and outcome. Components of male involvement interventions varied greatly; all studies were parts of large programmes with multiple interventions based on the global Safe Motherhood Initiative (maternal mortality, family planning, skilled care at birth, access to EmOC), thus making it difficult to assess male involvement components. Timing of outcomes reported differed (three or four A/N visits). Very serious²²	One pre and post intervention design study and one programme evaluation showed more women in the intervention arm made three or more ANC visits between baseline and follow-up. Another pre and post study showed an increase in four or more visits. One group before and after evaluation found no significant differences in four or more ANC visits. Two pre and post studies with a control group showed women and husbands exposed to the intervention were significantly more likely to report four or more visits. Serious²³	Very low
Breastfeeding 1-6 months	n=1	Cluster RCT of moderate risk of bias. Serious²⁴	Description of participants unclear. Primary aim was to increase the use of appropriate postpartum family planning, STI and HIV/AIDS protective behaviours. Reported breastfeeding at 3-5 and 6 month intervals. No serious indirectness²⁵	Study reports (data for 3-5 months and 6 months) showing the percentage of women commencing mixed feeding was higher in the intervention group than the control group. Not statistically significant. Not applicable	Low
	n=1	Non-equivalent control group study design; rated of weak methodological quality, therefore high risk of bias. Very serious²⁶	Participants, intervention and comparison (control group) directly address the review question. Although the study comprised multiple male involvement interventions, it specifically assessed the impact of the interventions on family planning in the postpartum period and STI preventive practices among men and women. Study reported breastfeeding at 3, 6 and 6-9 month intervals. No serious indirectness²⁷	Significantly more women in the control group continued exclusively breastfeeding for 6 months compared to the intervention group. A similar increase was found at 3 months but was not statistically significant. Not applicable	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Breastfeeding 1-6 months (continued)	n=1	Cohort analytic rated of weak methodological quality. Very serious ²⁸	Participants, intervention and comparison (control group) directly address the review question. Single study intervention of an education programme. Outcome reported at 3 month interviews with men. No serious indirectness ²⁹	Study reports a significant increase in breastfeeding for the intervention group at 3 months. Not applicable	Very low
	n=1	Repeat cross-sectional study rated of weak quality. Very serious ³⁰	Population included women and family members. Multiple interventions with specific MI education activities plus life-saving skills for women/ family/ TBAs and community mobilization. Outcome reported as breastfeeding within one hour. No serious indirectness	Reports significant increase baseline to follow-up in women breastfeeding within one hour after birth. Not applicable	Very low
Postpartum care visit mother	n=1	RCT rated weak of methodological quality, therefore high risk of bias. Serious ³¹	Study population were married women attending ANC with their husbands. Single intervention involving men. Outcome defined as attended postpartum visit at hospital within two weeks of delivery. No serious indirectness ³²	Study showed women assigned to the couples group were significantly more likely to attend the postpartum visit than those assigned to the control group or women-alone group. Not applicable	Low
	n=2	Both studies were observational: cohort analytic and a programme evaluation using a health information system; both were of weak methodological quality. Very serious ³³	Indirectness in participants, interventions and outcome. Components of interventions varied greatly; one study was part of large programme with multiple interventions, the other was a single intervention of an education programme. Outcome defined as postpartum check-up for wife. Very serious ³⁴	In the cohort analytic study there was no significant difference between men in the control and intervention groups reporting whether their wife had a postpartum check-up. The programme evaluation study showed an increase in postnatal care within 72 hours of birth post intervention. Serious ³⁵	Very low

Birth with a skilled birth attendant or facility birth

- 1 **Risk of bias:** Potential for selection bias, allocation concealment unlikely, and outcome assessors were likely to have been aware of intervention status of participants (Mullany et al., 2007).
- 2 **Indirectness:** Study included married women attending ANC with their husbands, excluding those that lived more than 90 minutes away from facility. The study was performed in a low-income urban setting. Single intervention consisting of two 35-minute educational sessions administered in a private room in the hospital with pregnant women and their husbands when applicable. The trial compared male involvement initiatives with either a control group or trial interventions without male involvement.
- 3 **Inconsistency:** The results indicate impact of the intervention on facility birth and skilled birth is unclear.
- 4 **Risk of bias:** Potential for selection bias; allocation concealment unlikely; outcome assessor is likely to have been aware of intervention status of participants and women unlikely to be blind to cluster allocation (Midhet and Becker, 2010).
- 5 **Indirectness:** Provided little detail about study population, other than women residing in a pre-determined village/cluster. The trial was performed in low-income rural setting. The intervention component of the trial was multifaceted: women were provided information on safe motherhood through pictorial booklets and audio cassettes; traditional birth attendants were trained in clean delivery and recognition of obstetric and newborn complications; and emergency transportation systems were set up. In eight of the 16 intervention clusters, husbands also received specially designed education materials on safe motherhood and family planning. The trial compared the intervention to either a control group or trial interventions without male involvement.
- 6 **Risk of bias:** It was unclear how reliable data collection methods were: a population survey evaluating the Safe Motherhood Initiative was performed (no further information provided); lack of information on recruitment and selection of participants; blinding of outcome assessor/participants was either not relevant or unclear in those studies with a control group (Hossain and Ross, 2006).
- 7 **Indirectness:** The study comprised multiple interventions whereby male involvement was just one component of a larger intervention package thus making it difficult to assess male involvement components. Little detail was provided

regarding study population, other than women residing in a pre-determined village/region.

- 8 **Inconsistency:** Delivery at a facility was increased statistically in the intervention group.
- 9 **Risk of bias:** All were considered high risk of bias due to lack of clarity on methods or unreliable data collection methods: Sood et al. (2004 Indonesia & 2004 Nepal) were population-based surveys (both evaluations of behaviour change campaigns) relying on self-reporting in unvalidated surveys; Sinha (2008) is a pre and post programme evaluation and changes observed may not be attributed with certainty to the intervention; in Purdin, Khan and Saucier (2009), data collected via Health Information Systems, although not clearly described. In the two remaining studies (Mushi, Mpembeni and Jahn, 2010; Turan, Tesfagiorgis and Polan, 2011) it was unclear how reliable their data collection methods were; data collected on all deliveries by SMPs, and cross-checked with hospital data and validated with community feedback (Mushi, Mpembeni and Jahn, 2010), and a cross-sectional survey with women by MOH study team using trained female interviewers (Turan, Tesfagiorgis and Polan, 2011). There was lack of information about recruitment and selection of participants in three studies (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Nepal). The remaining studies provided information on selection to varying degrees. Only in one study (Sood et al., 2004 Indonesia) were baseline and endline samples comparable in terms of age, occupation, religion, and ethnicity. For the remaining studies it was not possible to assess confounding variables. Blinding of outcome assessor/participants was either not relevant or unclear in those studies with a control group (Mushi, Mpembeni and Jahn, 2010; Sinha, 2008; Sood et al., 2004 Indonesia; Turan, Tesfagiorgis and Polan, 2011). The remaining study was a programme evaluation with a historical comparator (Purdin, Khan and Saucier, 2009).
- 10 **Indirectness:** Participants varied across the studies; one study included Afghan refugees living in region of Pakistan (Purdin, Khan and Saucier, 2009). Most studies (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal) comprised multiple interventions, where male involvement was just one component of a larger intervention package. Mushi, Mpembeni and Jahn (2010) and Turan, Tesfagiorgis and Polan (2011) comprised single community mobilization/home visit schemes. Studies provided little detail regarding study population, other than women residing in a pre-determined village/region. All studies were performed

in low-income settings, either rural or urban. Components of the male involvement intervention varied greatly; in all studies the intervention was part of a larger programme of work, for example multiple interventions based on the Safe Motherhood Initiative, making it difficult to assess male involvement components. All studies have reported data for either outcome.

- 11 **Inconsistency:** Six observational studies (Mushi, Mpembeni and Jahn, 2010; Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal; Turan, Tesfagiorgis and Polan, 2011) reported some benefit for male involvement either for the presence of an SBA/facility birth or both. In one before and after study (Mushi, Mpembeni and Jahn, 2010), there was a statistically significant increase in presence of SBA for the intervention group. Two pre and post intervention design studies reported a statistically significant increase in facility birth for the intervention group (Sinha 2008; Turan, Tesfagiorgis and Polan, 2011), no SBA data were reported. In a programme evaluation study using health information system (Purdin, Khan and Saucier, 2009) an increase in use of facility birth was found for the intervention group, of note is the baseline included non-refugee women in addition to refugee women. In a repeat cross-sectional study (Sood et al., 2004 Indonesia) women and husbands reported a statistically significant increase of use of SBA and facility birth (hospital) for the exposed group. The final study was a repeat cross-sectional design (Sood et al., 2004 Nepal); women reported an increase of presence of SBA (doctor) and facility birth for the unexposed group; this finding, however, was contradicted by their husbands, where an increase in SBA and facility birth for the exposed group was reported.

Care with a birth attendant or facility in case of maternal complications or illness

- 12 **Risk of bias:** Potential for selection bias; allocation concealment unlikely; and outcome assessor is likely to have been aware of intervention status of participants and women unlikely to be blind to cluster allocation (Midhet and Becker, 2010).
- 13 **Indirectness:** Little detail on study population, other than women residing in a pre-determined village/cluster. Conducted in a low-income rural setting. Multifaceted intervention: women were provided information on safe motherhood through pictorial booklets and audio cassettes; traditional birth attendants were trained in clean delivery and recognition of obstetric and newborn complications; and emergency transportation systems were set up. In eight of the 16 intervention clusters, husbands

Care with a birth attendant or facility in case of maternal complications or illness (*continued*)

also received education materials on safe motherhood and family planning. The trial compared the intervention to either a control group or trial interventions without male involvement.

- ¹⁴ **Risk of bias:** Lack of clarity on methods; unreliable data collection methods; lack of information about recruitment and selection of participants. Blinding of outcome assessor and participants was unclear (Varkey et al., 2004).
- ¹⁵ **Indirectness:** Included women attending ESIC (clinic) ANC services who were pregnant between 10–26 weeks of gestation, in a stable union and both husband and wife expected to be present at same address at six months postpartum. Although the study comprised multiple male involvement interventions it specifically assessed the impact of the interventions on family planning in the postpartum period and STI preventive practices among men and women.

Use of ANC (1 or 4 visits)

- ¹⁶ **Risk of bias:** Potential for selection bias; allocation concealment unlikely; and outcome assessors were likely to have been aware of intervention status of participants (Mullany et al., 2007).
- ¹⁷ **Indirectness:** Included married women attending ANC with their husbands, excluding those that lived more than 90 minutes away from facility. Conducted in low-income urban setting. Single intervention consisting of two 35-minute educational sessions administered in a private room in the hospital with pregnant women and their husbands when applicable. The trial compared male involvement initiatives with either a control group or trial interventions without male involvement. Data reported on women attending three or more ANC visits.
- ¹⁸ **Inconsistency:** The study reported data on ANC visits and reported no difference between the study groups in more than three ANC visits.
- ¹⁹ **Risk of bias:** Potential for selection bias; allocation concealment unlikely; outcome assessor is likely to have been aware of intervention status of participants and women unlikely to be blind to cluster allocation (Midhet and Becker, 2010).
- ²⁰ **Indirectness:** Little detail on study population, other than women residing in a pre-determined village/cluster. Conducted in a low-income rural setting. The intervention was part of a larger programme of work, thus making it difficult to assess the male involvement component. Intervention was

multifaceted: women were provided information on safe motherhood through pictorial booklets and audio cassettes; traditional birth attendants were trained in clean delivery and recognition of obstetric and newborn complications; and emergency transportation systems were set up. In eight of the 16 intervention clusters, husbands also received specially designed education materials on safe motherhood and family planning. The trial compared the intervention to either a control group or trial interventions without male involvement. Outcome defined as visit to qualified health care provider solely for the purpose of routine medical check-up during first or second trimester of pregnancy.

- ²¹ **Risk of bias:** Lack of clarity on methods in all studies (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal; Turan, Tesfagiorgis and Polan, 2010; Mushi, Mpembeni and Jahn, 2010). Unreliable data collection methods in Sood et al. (2004 Indonesia & 2004 Nepal); population-based surveys (both evaluations of behaviour change campaigns), therefore relying on self-reporting in unvalidated surveys. Sinha (2008): a pre and post programme evaluation; findings are illustrative and not conclusive, and changes observed may not be attributed with certainty to the intervention. In Purdin, Khan and Saucier (2009), data collected via Health Information Systems, although not clearly described. Lack of information about recruitment and selection of participants in three studies (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Nepal). For Sood et al. (2004, Indonesia), the selection methodology followed the same criterion used during the baseline, in addition the endline survey was conducted in the same six districts as the baseline research. However, all studies selected participants using non-random methods or did not describe selection procedure. Only in one study (Sood et al., 2004 Indonesia) were the baseline and endline samples comparable in terms of age, occupation, religion and ethnicity. For the remaining studies it was not possible to assess confounding variables. In the quasi-experimental study (Turan, Tesfagiorgis and Polan, 2010) there is possible selection bias, data collection relies of self-reporting in unvalidated survey and in the one group before and after (Mushi, Mpembeni and Jahn, 2010) selection bias is possible, did not consider confounders.
- ²² **Indirectness:** Participants varied across studies; one study included Afghan refugees living in region of Pakistan (Purdin, Khan and Saucier, 2009). The remaining three studies provided little detail about study population (Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal), other

than women residing in a pre-determined village/region. All studies conducted in low-income settings, either rural or urban. Components of the male involvement intervention varied greatly; in all studies the intervention was part of a larger programme of work, for example multiple interventions based on the Safe Motherhood Initiative, making it difficult to assess male involvement components. Three studies compared male involvement programmes with pre-introduction (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Nepal), one study's endline data included a control group (Sood et al., 2004 Indonesia). Three studies reported on women attending three or more ANC visits (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Nepal). The remaining study (Sood et al., 2004 Indonesia) provided no baseline data for a comparison for this outcome.

- ²³ **Inconsistency:** Four observational studies (Purdin, Khan and Saucier, 2009; Sinha, 2008; Sood et al., 2004 Indonesia; Sood et al., 2004 Nepal) reported data on antenatal visits. One pre and post intervention design study (Sinha, 2008) and one programme evaluation using a health information system (Purdin, Khan and Saucier, 2009) showed more women made three or more ANC visits between baseline and follow-up. Another pre and post study (Mushi, Mpembeni and Jahn, 2010) showed a non-significant increase in four or more ANC visits. One group before and after evaluation (Sood et al., 2004 Nepal) found no significant differences between exposed (post-intervention) and unexposed (pre-intervention) groups in four or more ANC visits, and a pre and post intervention study with a control group (Sood et al., 2004 Indonesia) showed women and husbands exposed to the intervention were significantly more likely to report four or more ANC visits than those unexposed, but no baseline data were provided. One quasi-experimental (Turan, Tesfagiorgis and Polan, 2011) reported a statistically significant increase in more than one and more than four visits.

Breastfeeding

- ²⁴ **Risk of bias:** Selection bias seems unlikely, but it is not clear how clusters initially randomized. Data collection methods might not be reliable as although data management was good throughout trial, it is also possible the outcome assessor was aware of intervention status of participants (Kunene et al., 2004).
- ²⁵ **Indirectness:** Little detail about study population, other than women residing in a pre-determined village/cluster. Conducted in a low-income setting. The intervention comprised clinic-based

Breastfeeding (continued)

couples counselling. The trial compared the intervention control clinics without counselling. The primary aim of the study was to evaluate an expanded antenatal and postpartum care program aimed at improving women's and men's reproductive health, particularly by increasing the use of appropriate postpartum family planning and STI and HIV/AIDS protective behaviours.

- ²⁶ **Risk of bias:** Non-equivalent control group study design in which three dispensaries provided the intervention while three others functioned as control sites; lack of clarity on methods; unreliable data collection methods; lack of information about recruitment and selection of participants; blinding of outcome assessor and participants was unclear (Varkey et al., 2004).
- ²⁷ **Indirectness:** Included women attending ESIC (clinic) ANC services who were between 10-26 weeks of gestation, in a stable union and both husband and wife expected to be present at the same address at six months postpartum. Multiple male involvement interventions but it specifically assessed the impact of the interventions on family planning in the postpartum period and STI preventive practices among men and women.
- ²⁸ **Risk of bias:** Lack of clarity on methods; unreliable data collection methods; lack of information about recruitment and selection of participants; blinding of outcome assessor and participants was unclear (Sahip and Turin, 2007).
- ²⁹ **Indirectness:** Included expectant fathers as employees of large workplaces. Single intervention of an education programme; topics covered in the programme included health and nutrition during pregnancy, antenatal care, support of women during childbirth, breast-feeding, postpartum and postnatal check-ups, postpartum contraception, communication techniques and adjustment to fatherhood.
- ³⁰ **Risk of bias:** Cannot tell if individuals selected are representative so possible selection bias; cannot tell if there are important differences between groups; assessors were not blind to intervention exposure status of participants; no information about data collection to assess validity or reliability (Fullerton, Killian and Gass, 2005).

Postpartum visits for women

- ³¹ **Risk of bias:** Potential for selection bias; allocation concealment unlikely; outcome assessors were likely to have been aware of intervention status of participants (Mullany et al., 2007).

- ³² **Indirectness:** Included married women attending ANC with their husbands, excluding those that lived more than 90 minutes away from facility. Conducted in a low-income urban setting. Single intervention consisting of two 35-minute educational sessions administered in a private room in the hospital with pregnant women and their husbands when applicable. The trial compared male involvement initiatives with either a control group or trial interventions without male involvement.
- ³³ **Risk of bias:** Lack of clarity on methods. For Purdin, Khan and Saucier (2009), data were collected via Health Information Systems, although not clearly described. For Sahip and Turin (2007), the intervention was evaluated using face-to-face interviews with participating fathers using an interviewer-administered questionnaire, which does not appear to be validated; questionnaire data were entered into the computer using the Epi Info programme. There is a lack of information about recruitment and selection of participants in both studies: in Sahip and Turin (2007) the expectant fathers who participated in the education programme were the employees of these large workplaces and participation was voluntary. For Sahip and Turin (2007), although the two groups were not randomized and therefore all variables (known/unknown) will not be balanced for in terms of key background variables such as age, marriage duration, birth place, occupation type, wife's characteristics and sources of health care. Although analyses revealed that the three study groups (control, father only, mother and father) differed in terms of the educational level of the wife. For couples in which both husband and wife attended antenatal education programmes, the wife was more likely to have a university education than couples in which only the husband attended, or neither husband nor wife attended. For Purdin, Khan and Saucier (2009) it was not possible to assess confounding variables. Blinding of outcome assessor and participants unclear in both studies.
- ³⁴ **Indirectness:** Participants varied; one study included Afghan refugees living in region of Pakistan (Purdin, Khan and Saucier, 2009). In Sahip and Turin (2007) the intervention was open to expectant fathers who were the employees of particular large workplaces in Istanbul. Both studies conducted in low-income settings. Components of the male involvement intervention varied: for Purdin, Khan and Saucier (2009), the intervention was part of a larger programme of work using multiple interventions based on the Safe Motherhood Initiative making it difficult to assess male involvement components; Sahip and Turin (2007) used a single education programme for expectant

fathers. The topics covered in the programme included health and nutrition during pregnancy, antenatal care, support of women during childbirth, breastfeeding, postpartum and postnatal check-ups, postpartum contraception, communication techniques and adjustment to fatherhood. Purdin, Khan and Saucier (2009) compared male involvement programmes with pre-introduction. For Sahip and Turin (2007) the control group fathers for the three- and nine-month interviews were recruited from seven workplaces in Istanbul similar to those involved in the intervention.

- ³⁵ **Inconsistency:** In the cohort analytic study (Sahip and Turin, 2007), there was no significant difference between men in the control and intervention groups reporting whether their wife had a postpartum check-up. The programme evaluation study (Purdin, Khan and Saucier, 2009) showed an increase in postnatal care within 72 hours of birth post-intervention.

RECOMMENDATION 3

Interventions to promote awareness of human rights/sexual and reproductive rights and the right to access quality skilled care

Question: What interventions to promote awareness of human rights or sexual and reproductive rights or right to access to quality care are effective in increasing birth with a skilled birth attendant and in improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	One cluster RCT of moderate quality. Serious¹	Participants, intervention, comparison and outcome directly address the review question. Single intervention (community scorecard process) that facilitated meetings that informed community about rights to access quality care, developed action plans and agreed on contracts with providers monitored by the community to improve accountability at health facilities. No serious indirectness²	The cluster RCT reports a significant increase in facility births, reported as additional deliveries at the facility on average per month. Not applicable	Moderate
	n=1	One observational study of weak methodological quality. Very serious³	Participants, intervention, comparison and outcome directly address the review question. Multiple interventions addressing safe motherhood at the community, family and individual levels. Youth and local elected representatives raised awareness about rights and supported review meetings to improve services, monthly meetings were held to foster family support and home visits made to support individual pregnant women. No serious indirectness⁴	This before and after study reports significant increases in births at government health centres and hospitals between baseline and endline (but a significant decrease in births at private clinics). No control group; observed changes may not be result of intervention. Not applicable	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Use of ANC	n=2	Two cluster RCTs: both of moderate methodological quality. Serious⁵	Some direct comparisons. Population is similar across studies but intervention differs. Both single interventions: one used community scorecards as a process to convey information on rights and improve accountability; the other used public meetings and printed materials to convey information about entitlement to services. One made references to rights, the other made reference to entitlements. Serious⁶	Some variation in results. One trial reports a non-significant increase in additional ANC visits per month on average, the other reports a significant increase in prenatal examinations at year 1. Serious⁷	Very low
	n=1	One observational study of weak methodological quality. Very serious⁸	Participants, intervention, comparison and outcome directly address the review question. Multiple interventions based on a human rights framework, just one component of larger safe motherhood programme with a youth committee and community review meetings to pressurize services into improving. No serious indirectness⁹	This before and after study reports improved ANC practices with significant differences between baseline and endline in women who made at least one and more than three visits. No control group; observed changes may not be result of intervention. Not applicable	Very low

Birth with a skilled birth attendant or facility birth

- 1 **Risk of bias:** The method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses) (Bjorkman and Svensson, 2009).
- 2 **Indirectness:** Study conducted in Uganda and the target population was households/communities in rural and poor areas. Single intervention (community scorecards) that facilitated meetings that informed community about rights to access quality care, developed action plans and agreed on contracts with providers monitored by the community to improve accountability at health facilities. Report on facility birth – additional deliveries at the facility on average per month.
- 3 **Risk of bias:** A pre and post programme evaluation; data were self-reported in a household survey; validity/reliability of survey tool unknown and it changed baseline to follow-up; selection bias is possible, and no information about possible confounding factors (Sinha, 2008).
- 4 **Indirectness:** Conducted in Andhra Pradesh, India and the target population was households/communities in rural and poor areas. Multiple interventions addressing safe motherhood with youth and local elected representatives raising awareness about rights and supporting review meetings to improve services, monthly meetings held to foster family support and home visits made to support individual pregnant women. Reports number of women delivering at various types of facilities.

Use of ANC (1 or 4 visits)

- 5 **Risk of bias:** The method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses) (Bjorkman and Svensson, 2009). Randomization appropriate, blinding of data collectors and participants evident but unclear whether assessors were blind; no differences between arms at baseline but some confounders controlled for at analysis; population likely to be representative and data collection seems reliable but unclear validity (Pandey et al., 2007).
- 6 **Indirectness:** Studies conducted in Uganda and India and the target population was households/communities in rural and poor areas. The human rights awareness interventions are diverse: both RCTs used single interventions; one used community scorecards as an intervention that facilitated meetings that informed community about rights to access

- quality care, developed action plans and agreed on contracts with providers monitored by the community to improve accountability at health facilities (Bjorkman and Svensson, 2009); the other RCT used public meetings and print materials to convey information about entitlement to services (Pandey et al., 2007). Both report on ANC visits, slightly differently: Bjorkman and Svensson (2009) report number of additional ANC visits at the facility and Pandey et al. (2007) report change in ANC examinations at year 1.
- 7 **Inconsistency:** One cluster RCT reports a non-significant increase in additional ANC visits per month on average (Bjorkman and Svensson, 2009), the other reports a significant increase in prenatal examinations in the intervention are compared to control at year 1 (Pandey et al., 2007).
- 8 **Risk of bias:** A pre and post programme evaluation; validity/reliability of survey tool unknown and it changed baseline to follow-up; selection bias is possible, and no information about possible confounding factors (Sinha, 2008).
- 9 **Indirectness:** Conducted in India and the target population was households/communities in rural and poor areas. Multiple interventions addressing safe motherhood with youth and local elected representatives raising awareness about rights and supporting review meetings to improve services, monthly meetings held to foster family support and home visits made to support individual pregnant women (Sinha, 2008). Reports on number of women having at least one ANC visit, or more than three.

RECOMMENDATION 4

Maternity waiting homes (MWHs)

Question: What strategies for maternity waiting homes are effective in increasing birth with a skilled birth attendant/ institutional birth and improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or birth in a facility	n=4	Two hospital-based before and after studies: one cross-sectional and one hospital-based cohort study, all of which were rated of weak methodological quality. Very serious¹	Indirectness of participants, interventions and outcome. Components of interventions varied greatly in relation to size, location and facilities for two of the studies. One study provided no detail. Outcome data provided for facility birth only. Very serious²	All studies reported some benefit for MWH for facility birth. In two hospital-based before and after studies and one hospital-based cross-sectional survey data showed there was increase in facility birth post-intervention. The remaining hospital-based cohort reported that all childbirths in the study occurred in hospital. No SBA data were reported. Serious³	Very low
Maternal mortality	n=7	All studies were observational and considered of weak methodological quality: six were hospital-based cohort studies and one a hospital-based before and after study. Very serious⁴	Indirectness of participants, interventions. Components of interventions varied greatly in relation to size, location and facilities. Only one study was powered to detect a significant reduction in maternal mortality. Very serious⁵	All studies reported mortality rates were substantially lower in women admitted to hospital via MWH, but only one study was powered to detect a significant reduction in maternal mortality. Serious⁶	Very low
Maternal morbidity (prolonged/ obstructed labour/uterine rupture)	n=6	All studies were hospital-based cohorts of weak methodological quality. Very serious⁷	Indirectness of participants, interventions. Components of interventions varied greatly in relation to size, location and facilities. Reported outcomes included ruptured uterus, hysterectomies, obstructed labour, and caesarean section. Very serious⁸	Five studies reported a decreased rate of maternal morbidity for women attending MWH, the remaining study showed an increase. Very serious⁹	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Stillbirth	n=6	All studies were hospital-based cohorts of weak methodological quality. Very serious¹⁰	Indirectness of participants, interventions. Interventions varied greatly in relation to size, location and facilities, some providing health education sessions. No definition provided for stillbirth. Very serious¹¹	Results from all studies consistently show reduction in stillbirth rate following intervention. Serious¹²	Very low
Perinatal mortality	n=5	All studies were observational and considered of weak methodological quality: four were hospital-based cohorts and one hospital cross-sectional survey. Very serious¹³	Indirectness of participants, interventions. Components of interventions varied greatly in relation to size, location and facilities. Very serious¹⁴	All studies reported perinatal mortality rates were lower when women admitted to hospital via MWH. Serious¹⁵	Very low
Neonatal mortality	n=3	All three studies were hospital-based cohort studies of weak methodological quality Very serious¹⁶	Indirectness of participants, interventions. Components of interventions varied greatly in relation to size, location and facilities. Very serious¹⁷	All studies reported neonatal mortality rates were lower when women admitted to hospital via MWH. Very serious¹⁸	Very low

Birth with a skilled birth attendant or facility birth

- 1 **Risk of bias:** Lack of clarity on methods in all studies. Data collection methods seem reliable for one study (Andemichael, 2008) as hospital records were used and valid in Wild et al. (2012) as data collected directly from birth register and ambiguities clarified with midwife but cannot tell if any differences in groups studied. Van den Heuvel et al. (1999) did house-to-house visits performing a cross-sectional survey by interview based on a questionnaire. The remaining study (Tumwine and Dungare, 1996) did not describe the methods used. Lack of information about recruitment and selection of participants was not fully described in all studies; health centre staff or trained TBAs (Tumwine and Dungare, 1996) or TBAs alone (Andemichael 2008) prompted women to attend MWHs. The remaining study (van den Heuvel et al., 1999) used a two-stage cluster sampling method.
- 2 **Indirectness:** One study (Tumwine and Dungare, 1996) included only high-risk women (previous obstetric/medical complications etc.; although risk was defined differently for each). Two studies had geographical restrictions (Andemichael, 2008; van den Heuvel et al., 1999) and in Wild et al. (2012) any pregnant woman was eligible to stay at MWHs from 36–38 weeks gestation, and for 3–4 days post-childbirth with priority given to women with risk factors or from rural areas. All studies performed in sub-Saharan Africa (except Wild et al. (2012) in Timor Leste), and all stated the setting was remote or rural. Components of the MWH varied (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental deliveries and caesarean sections etc.). One study (van den Heuvel et al., 1999) provided no detail.
- 3 **Inconsistency:** All studies (Andemichael, 2008; Tumwine and Dungare, 1996; van den Heuvel et al., 1999) reported some benefit for MWH for facility birth. In two hospital-based before and after studies (Andemichael, 2008; Wild et al., 2012) and one hospital-based cross-sectional survey (van den Heuvel et al., 1999) data showed there was an increase in facility birth post-intervention. The remaining hospital-based cohort (Tumwine and Dungare, 1996) reported that all childbirths in the study occurred in hospital. No SBA data were reported.

Maternal mortality

- 4 **Risk of bias:** Lack of clarity on methods in all studies. Data collection methods seem reliable for four studies (Andemichael, 2008; Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012; Kelly et al., 2010) (hospital records), although no information is provided on validity. In two studies (Poovan, Kifle and Kwast, 1990; Tumwine and Dungare, 1996) methods were not described. In the remaining study (van Lonkhuijzen et al., 2003) midwives completed a study questionnaire. Lack of information about recruitment and selection of participants was not fully described in all studies; health centre staff or trained TBAs (Tumwine and Dungare, 1996) or TBAs alone (Andemichael, 2008) prompted women to attend MWH. Four studies (Chandramohan, Cutts and Chandra, 1994; Kelly et al., 2010; Poovan, Kifle and Kwast, 1990; van Lonkhuijzen et al., 2003) recruited women who were considered high risk and the remaining study provided no detail (Gaym, Pearson and Soe, 2012). Blinding of outcome assessor and participants unclear in all studies. In Chandramohan, Cutts and Chandra (1994), although the two groups were not randomized and therefore all variables (known/unknown) will not be balanced for an effort was made to control important/relevant confounders at the analysis stage.
- 5 **Indirectness:** Five studies (Chandramohan, Cutts and Chandra, 1994; Tumwine and Dungare, 1996; Kelly et al., 2010; Poovan, Kifle and Kwast, 1990; van Lonkhuijzen et al., 2003) included only high-risk women (previous obstetric/medical complications etc.; although risk was defined differently for each). One study (Gaym, Pearson and Soe, 2012) any woman wishing to attend could. In the remaining study (Andemichael, 2008) women were required to live more than 10 kilometres away from health facility. All studies were performed in sub-Saharan Africa, all in remote settings. Components of the MWH varied greatly (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental deliveries and caesarean sections, etc.). All studies compared MWH with standard care prior to direct facility admission (Andemichael, 2008; Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012; Poovan, Kifle and Kwast, 1990; Tumwine and Dungare, 1996; van Lonkhuijzen et al., 2003; Kelly et al., 2010).
- 6 **Inconsistency:** All studies reported data for this outcome and all showed some benefit for MWH, but only one study (Kelly et al., 2010) was powered to detect a significant reduction in maternal mortality.

Maternal morbidity (prolonged/obstructed labour/uterine rupture)

- 7 **Risk of bias:** Lack of clarity on methods. Data collection methods seem reliable for three studies (Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012; Kelly et al., 2010) (hospital records), although no information provided on validity. In three studies (Poovan, Kifle and Kwast, 1990; Millard, Bailey and Hanson, 1991; Tumwine and Dungare, 1996) methods were not described. In the remaining study (van Lonkhuijzen et al., 2003) midwives completed a study questionnaire. Lack of information about recruitment and selection of participants was not fully described in all studies; health centre staff or trained TBAs (Tumwine and Dungare, 1996) prompted women to attend MWH. Four studies (Chandramohan, Cutts and Chandra, 1994; Kelly et al., 2010; Poovan, Kifle and Kwast, 1990; van Lonkhuijzen et al., 2003) recruited women who were considered high risk and in Millard, Bailey and Hanson (1991) the selection processes were open in that any woman wishing to attend could do so. The remaining study provided no detail (Gaym, Pearson and Soe, 2012). In Chandramohan, Cutts and Chandra (1994), although the two groups were not randomized and therefore all variables (known/unknown) will not be balanced for an effort was made to control important/relevant confounders at the analysis stage.
- 8 **Indirectness:** Four studies (Chandramohan, Cutts and Chandra, 1994; Kelly et al., 2010; Poovan, Kifle and Kwast, 1990; van Lonkhuijzen et al., 2003) included only high-risk women (previous obstetric/medical complications etc.; although risk was defined differently for each). For Gaym, Pearson and Soe (2012) any woman wishing to attend the MWH could do so. In the remaining study (Millard, Bailey and Hanson, 1991) eligibility was open to all women and those considered high risk and living some distance away were actively encouraged to reside in MWH for the last two weeks of pregnancy. All studies were performed in sub-Saharan Africa; all stated the setting was remote. Components of the MWH varied greatly (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental delivery and caesarean sections, etc.). All studies compared MWH with standard care prior to facility admission.
- 9 **Inconsistency:** Five studies (Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012; Kelly et al., 2010; Millard, Bailey and Hanson, 1991) reported a decreased rate of maternal morbidity for women attending MWH; the remaining study (van Lonkhuijzen et al., 2003) showed an increase. There is little consistency between reported outcomes between studies.

Stillbirth

- ¹⁰ **Risk of bias:** Lack of clarity on methods. Data collection methods seem reliable for three studies (Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012; Kelly et al., 2010) (hospital records), although no information is provided on validity. The remaining three studies' methods were not described (Millard, Bailey and Hanson, 1991; Poovan, Kifle and Kwast, 1990; Tumwine and Dungare, 1996). There was general lack of detailed information about recruitment and selection of participants; in three studies women were selected by health carers (Chandramohan, Cutts and Chandra, 1994; Poovan, Kifle and Kwast, 1990; Tumwine and Dungare, 1996), in one study (Kelly et al., 2010) women received a reduction in hospital fees if they attended a MWH. In Millard, Bailey and Hanson (1991), selection processes were open in that any woman wishing to attend could do so. In the remaining study (Gaym, Pearson and Soe, 2012) processes were not described. In Chandramohan, Cutts and Chandra (1994), although the two groups were not randomized and therefore variables (known/unknown) will not be balanced for an effort was made to control important/relevant confounders, but only at the analysis stage.
- ¹¹ **Indirectness:** Three studies (Kelly et al., 2010; Poovan, Kifle and Kwast, 1990; Tumwine and Dungare, 1996) included only high-risk women (previous obstetric / medical complications etc.; although risk was defined differently for each). Two studies (Chandramohan, Cutts and Chandra, 1994; Gaym, Pearson and Soe, 2012) had no specific eligibility criteria. In the remaining study (Millard, Bailey and Hanson, 1991) eligibility was open to all women and those considered high risk and living some distance away were actively encouraged to reside in MWH for last two weeks of pregnancy. All studies were performed in sub-Saharan Africa. All (excluding Gaym, Pearson and Soe, 2012) stated the setting was remote/rural. Components of the MWH varied greatly (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental deliveries and caesarean sections, etc.). All studies compared MWH with standard care prior to facility admission.
- ¹² **Inconsistency:** All studies consistently report a reduction in the stillbirth rate following the intervention.

Perinatal mortality

- ¹³ **Risk of bias:** All studies were observational and all were of weak methodological quality. Four studies were hospital-based cohorts (Chandramohan, Cutts and Chandra, 1994; Millard, Bailey and Hanson, 1991; Tumwine and Dungare, 1996; van Lonkhuijzen et al., 2003) and one a hospital cross-sectional survey (Larsen and Muller, 1978). Risk of bias is high in all studies due to lack of clarity on method. Data collection methods seem reliable for two studies (Chandramohan, Cutts and Chandra, 1994; Larsen and Muller, 1978) (hospital records), although no information is provided on validity. In two studies (Millard, Bailey and Hanson, 1991; Tumwine and Dungare, 1996) methods were not described. In the remaining study (van Lonkhuijzen et al., 2003) midwives completed a study questionnaire. Lack of information about recruitment and selection of participants was not fully described in all studies; health centre staff or trained TBAs (Tumwine and Dungare, 1996) prompted women to attend MWH. Two studies (Chandramohan, Cutts and Chandra, 1994; van Lonkhuijzen et al., 2003) recruited women who were considered high risk; in Millard, Bailey and Hanson, (1991) the selection processes were open in that any woman wishing to attend could do so and the remaining study provided no detail (Larsen and Muller, 1978). In one study (Chandramohan, Cutts and Chandra, 1994), although the two groups were not randomized and therefore all variables (known/unknown) will not be balanced for an effort was made to control important/relevant confounders at the analysis stage.
- ¹⁴ **Indirectness:** There was variation in participants for all studies: Chandramohan, Cutts and Chandra (1994), Larsen and Muller (1978), Tumwine and Dungare (1996) and van Lonkhuijzen et al. (2003) included only high-risk women (previous obstetric/ medical complications etc.; although risk was defined differently for each). In the remaining study (Millard, Bailey and Hanson, 1991) eligibility was open to all women and those considered high risk and living some distance away were actively encouraged to reside in the MWH for last two weeks of pregnancy. All studies were performed in sub-Saharan Africa; all stated the setting was remote. Components of the MWH varied greatly (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental deliveries and caesarean sections, etc.). All studies compared MWH with standard care prior to facility admission.
- ¹⁵ **Inconsistency:** All studies reported lower perinatal mortality rates for MWH women.

Neonatal mortality

- ¹⁶ **Risk of bias:** Lack of clarity on methods. Data collection methods seem reliable for one study (Chandramohan, Cutts and Chandra, 1994) (hospital records), although no information is provided on validity. In two studies (Millard, Bailey and Hanson, 1991; Tumwine and Dungare, 1996) methods were not described. Lack of information about recruitment and selection of participants was not fully described in all studies; health centre staff or trained TBAs (Tumwine and Dungare, 1996) prompted women to attend MWHs and in Chandramohan, Cutts and Chandra (1994) recruited women who were considered high risk; in Millard, Bailey and Hanson (1991) the selection processes were open in that any woman wishing to attend could do so. Blinding of outcome assessor and participants unclear in all studies. In Chandramohan, Cutts and Chandra (1994), although the two groups were not randomized and therefore all variables (known/unknown) will not be balanced for an effort was made to control important/relevant confounders at the analysis stage.
- ¹⁷ **Indirectness:** Two studies (Chandramohan, Cutts and Chandra, 1994; Tumwine and Dungare, 1996) included only high-risk women (previous obstetric/medical complications etc.) although risk was defined differently for each. In the remaining study (Millard, Bailey and Hanson, 1991) eligibility was open to all women and those considered high risk and living some distance away were actively encouraged to reside in MWH for last two weeks of pregnancy. All studies were performed in sub-Saharan Africa; all stated the setting was remote. Components of the MWH varied greatly (even within studies) in size, location, facilities, length of stay prior to delivery, provision of food, and additional services provided (ANC services, health education, reduced fee for instrumental delivery and caesarean section, etc.). All studies compared MWH with standard care prior to facility admission.
- ¹⁸ **Inconsistency:** All studies reported data for this outcome; all reported neonatal mortality rates were lower when women were admitted to hospital via MWH.

RECOMMENDATION 5

Community-organized transport schemes

Question: What community-organized transport schemes are effective in increasing birth with a skilled birth attendant/institutional birth and improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	One cluster randomized trial of moderate quality. Serious¹	Participants, intervention and outcomes directly address the review question. The intervention was multiple and comprised more than community-organized transport; intervention delivered principally through lady healthworkers (LHWs). No serious indirectness	Women exposed to the multifaceted intervention with a small community-organized emergency transport component are more likely, but not significantly, to report delivering in a facility. Cannot ascribe the improvements to any single component of the intervention package, also LHWs played significant role in implementation. Not applicable	Moderate
	n=2	Two case control studies of weak methodological quality. Very serious²	Evidence of indirectness. Country and settings are similar, but participants and interventions differ across the two studies. Very serious³	The findings are reported differently and vary. Benefit of the BPCR campaign on facility birth with an SBA. In the other, there were more births in a facility in the control group and community transport plans associated with a decrease in home births. Very serious⁴	Very low
Care with skilled birth attendant or facility in case of maternal complications/ illness (no newborn data)	n=2	One pre and post and one post-intervention evaluation of the same intervention, both of weak methodological quality. Very serious⁵	Evidence of indirectness. Both studies were conducted in the same rural, poor communities in Tanzania. The intervention was multiple and complex and focused on training traditional birth attendants (TBAs) and mobilizing communities for timely referral of women with complications as well as facility upgrading; transport planning a small component. Serious⁶	Both evaluations report number of women with complications using the transport system to seek hospital care but only the follow-up study estimates what percentage this represents and this is based on old surveillance data. There is no comparable data from a control group of women who did not receive the intervention. Very serious⁷	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Maternal mortality	n=1	One cluster randomized trial of moderate quality. Serious⁸	Participants, intervention and outcomes directly address the review question. The intervention was multiple and comprised more than community-organized transport; intervention delivered principally through LHWs. No serious indirectness	Fewer deaths reported among women exposed to the multifaceted intervention with a small community-organized emergency transport component. Unable to ascribe improvements to any single component of the three elements of the intervention package and LHWs played key part in implementing all three components. Not applicable	Moderate
Stillbirth	n=1	One cluster randomized trial of moderate quality. Serious⁹	Participants, intervention and outcomes directly address the review question. The intervention was multiple and comprised more than community-organized transport; intervention delivered principally through LHWs. No serious indirectness	Number of stillbirths lower and mortality risk ratio showed stillbirths significantly lower among women exposed to the multifaceted intervention with a small community-organized emergency transport component. Unable to ascribe improvements in perinatal and neonatal outcomes to any single component of the three elements of the intervention package and LHWs played key part in implementing all three components. Not applicable	Moderate
Perinatal mortality	n=1	One cluster randomized trial of moderate quality. Serious¹⁰	Participants, intervention and outcomes directly address the review question. The intervention was multiple and comprised more than community-organized transport; intervention delivered principally through LHWs. No serious indirectness	Number of perinatal deaths lower in intervention group and mortality risk ratio showed perinatal deaths significantly lower among women exposed to the multifaceted intervention with a small community-organized emergency transport component. Unable to ascribe improvements in perinatal and neonatal outcomes to any single component of the three elements of the intervention package and LHWs played a key part in implementing all three components. Not applicable	Moderate

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Neonatal mortality	n=1	One cluster randomized trial of moderate quality. Serious¹¹	Participants, intervention and outcomes directly address the review question. The intervention was multiple and comprised more than community-organized transport; intervention delivered principally through LHWs. No serious indirectness	Neonatal mortality was significantly lower in intervention clusters and seemed lower in areas covered by LHWs than in areas not covered. Almost a quarter of target villages remained uncovered by LHWs and this should be interpreted within the context of a busy functional primary care CHW programme charged with implementing a complex package of community advocacy and education. Unable to ascribe improvements in perinatal or neonatal outcomes to any single component of the three elements of the intervention package. LHWs played a key part in implementing all three components. Not applicable	Moderate

Birth with a skilled birth attendant or facility birth

- Risk of bias:** In the cluster trial randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but data for the outcome were self-reported and the assessors were not blind to intervention status (Bhutta et al., 2011).
- Risk of bias:** A pre and post case control (Sood et al., 2004 Indonesia) and a community-based case control study (Lungu et al., 2001); in both studies there is lack of clarity on methods and unreliable data collection, likely selection bias, and lack of information on confounding.
- Indirectness:** Participants were similar and both involved women as well as husbands and other community members, but one was conducted in a low-income country (Malawi) and the other a middle-income country (Indonesia). In Sood et al. (2004 Indonesia) the intervention was a widely publicized campaign targeting husbands, community, midwives and villagers; the other study was a single intervention including community-organized transport via bicycle ambulance or established community transport plan (Lungu et al., 2001). In one study the outcome facility birth was self-reported (Sood et al., 2004 Indonesia) and in the other births were recorded in facility register by a nurse/midwife (Lungu et al., 2001).
- Inconsistency:** Sood et al. (2004 Indonesia) reports in communities exposed to a BPCR campaign where under one component, community members were encouraged to organize transport, women were significantly more likely to report giving birth at a hospital and a greater proportion of women using an SBA at baseline compared with endline, as well as greater use of SBAs reported by women exposed to the intervention than those not exposed. The other case control study reports community transport plans were associated with a significantly greater decrease in home births than bicycle ambulances (Lungu et al., 2001).

Care with skilled birth attendant or facility in case of maternal complications/illness

- Risk of bias:** There is risk of selection bias in both studies; although data collection for this outcome was through CARE-implemented monitoring systems (Ahluwalia et al., 2003) there is no indication of reliability of these systems, and in the follow-up study the authors acknowledge that surveillance data collected routinely at facilities varies in quality and completeness (Ahluwalia et al., 2010); there is no information on potential factors influencing the outcomes over time.
- Indirectness:** Both studies were conducted in the same rural, poor communities in Tanzania, a low-income country. In the pre and post evaluation (Ahluwalia et al., 2003) the population for the endline survey was not stated, and in the post-intervention evaluation (Ahluwalia et al., 2010) participants were community members purposefully selected to represent different perspectives only in villages that had adopted a community-supported emergency transport system at the end of the intervention. The intervention being evaluated was multiple and complex. There is no control group in these evaluations. Both evaluations report on care with an SBA or in a facility in case of maternal complications or illness.
- Inconsistency:** The pre and post evaluation reports an increase in the number of pregnant women attending the district hospital treated for obstetric complications (but this could be due to increased demand or better reporting as well as referrals), and in 10 villages with functional transport systems at least 36 women with obstetric emergencies had used the transport systems to seek hospital care (Ahluwalia et al., 2003). The follow-up survey reports six villages with functioning transport systems provided transport to 29 pregnant women with obstetric difficulties, and estimates that this represents 22 percent of pregnant women potentially in need of EMoC; estimates are based on surveillance data from 1998 (Ahluwalia et al., 2010).

Maternal mortality

- Risk of bias:** Randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but data for the outcome were self-reported and the assessors were not blind to intervention status (Bhutta et al., 2011).

Stillbirth

- Risk of bias:** Randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but the assessors were not blind to intervention status (Bhutta et al., 2011). Data for this outcome were determined from self-reporting in household surveys and it is possible that mothers in the intervention clusters improved reporting of pregnancy outcomes and early fetal losses. It is also possible that the methods used in verbal/social autopsies resulted in crude differentiation of late miscarriage/stillbirth/early neonatal death and misclassification.

Perinatal mortality

- Risk of bias:** Randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but the assessors were not blind to intervention status (Bhutta et al., 2011). Data for this outcome were determined from self-reporting in household surveys and it is possible that mothers in the intervention clusters improved reporting of pregnancy outcomes and early fetal losses. It is also possible that the methods used in verbal/social autopsies resulted in crude differentiation of late miscarriage/stillbirth/early neonatal death and misclassification.

Neonatal mortality

- Risk of bias:** Randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but the assessors were not blind to intervention status (Bhutta et al., 2011). Data for this outcome were determined from self-reporting in household surveys and it is possible that mothers in the intervention clusters improved reporting of pregnancy outcomes and early fetal losses. It is also possible that the methods used in verbal/social autopsies resulted in crude differentiation of late miscarriage/stillbirth/early neonatal death and misclassification.

RECOMMENDATION 6

Partnership with traditional birth attendants (TBAS)

Question: What new roles for TBAs within the formal health system are effective for increasing childbirth with a skilled birth attendant/institutional birth and for improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=6	All observational studies: two of moderate and four of weak methodological quality. Very serious¹	Evidence of indirectness. Studies in low and middle-income countries; two were of refugee/ internally displaced women only. Interventions varied; were multiple and complex. Difficult to distinguish effect of individual component(s) from the overall programmes or programme from existing safe motherhood initiative activities. Because the pre and post studies lacked concurrent control groups of women who did not receive the intervention, they can at best generate hypotheses of what might work (and not firm conclusions that the TBA interventions alone were effective in improving birth with an SBA). Very serious²	Five studies reported on use of SBAs but many did not define this; two reported facility births. The two studies rated moderate show a trend of increased numbers of women reporting SBA over time. Of those at high RoB, two indicate an increase, one significantly, and one implies fewer women exposed to the intervention had SBA. Hospital births also increased over time in one study where Emergency Obstetric Care (EmOC) provision was part of the intervention in a refugee population and in the study of a culturally adapted childbirth model. Serious³	Very low
Use of ANC (1-4 visits)	n=3	Three observational studies: two of moderate and one of weak methodological quality. Very serious⁴	Evidence of indirectness. One study in a low-income, the others middle-income countries; two studies were of refugee/ internally displaced women only. Interventions varied; were multiple and complex. Difficult to distinguish effect of individual component(s) from the overall programmes or programme from existing safe motherhood initiative activities. Different outcome reporting. Very serious⁵	All studies reported on use of ANC: two defined the number of visits, the other described trends in women receiving some ANC over time. All three studies showed use of ANC increased over time, with larger improvements in ANC use following implementation of TBA interventions in settings with refugee women and internally displaced women. Serious⁶	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Postnatal care visits	n=4	<p>Four observational studies: three of weak and one of moderate methodological quality.</p> <p>Very serious⁷</p>	<p>Evidence of indirectness.</p> <p>Two studies in low and two in middle-income countries; two studies were in settings with refugee women/ internally displaced women only.</p> <p>Interventions varied; were multiple and complex. Difficult to distinguish effect of individual component(s) from the overall programmes or programme from existing safe motherhood initiative activities.</p> <p>Different outcome reporting.</p> <p>Very serious⁸</p>	<p>All studies reported on postnatal visits but definitions of timing of visits varied across studies.</p> <p>All four studies showed that postnatal visits increased over time, with larger relative improvements following implementation of TBA interventions in settings with refugee women and internally displaced women.</p> <p>Serious⁹</p>	Very low

Birth with a skilled birth attendant or facility birth

- ¹ **Risk of bias:** Selection bias is unlikely, confounders were adjusted for these at analysis, data collection methods likely to be valid in one (Mullany et al. 2010) but there is no information on validity or reliability in the other (Frankenberg et al., 2009). One study looks like a controlled before and after study (Fauveau et al., 1991) but does not provide any data from the control area for this outcome. Two are described as pre and post intervention evaluations (Gabrysch et al., 2009; Ronsmans et al., 2001) and one is a retrospective pre-post analysis (Purdin, Khan and Saucier, 2009); in all four routine population-based monitoring or hospital-based data were used to compare data on SBA/facility delivery at a time point before the intervention and after it was in place, and while these sources are likely to be valid, there was little information on reliability. None of these studies included control groups so the changes in SBA over time could be due to other external factors rather than the (complex) TBA interventions.
- ² **Indirectness:** Two studies were conducted in low-income countries (Bangladesh and Myanmar) and four in middle-income countries (Indonesia in two studies, Peru and Pakistan); two studies were of refugee women (Purdin, Khan and Saucier, 2009) or internally displaced women (Mullany et al., 2010) only. All interventions were multiple and complex. All included improving partnership or linkage between TBAs and midwives or other formal health workers; in several studies midwives were posted in communities to work alongside TBAs (Fauveau et al., 1991; Frankenberg et al., 2009; Ronsmans et al., 2001) and others involved capacity strengthening/training of TBAs to attend births alongside trained midwives. Only one study had a control group: Fauveau et al. (1991) used a control area that received a limited MCH-FP intervention but did not provide data for the comparator group. Five studies reported on use of skilled birth attendants but many did not define this; two reported facility birth.
- ³ **Inconsistency:** Overall the studies report improvements in use of SBAs following the implementation of TBA interventions, compared with data in the period before interventions were put in place. In two studies rated moderate one shows a trend towards substantial improvement over time (Frankenberg et al., 2009) and the other shows more women reported being assisted by an SBA baseline to follow-up (Mullany et al., 2010). Of those at high RoB, two indicate an increase in SBA over time (Gabrysch et al., 2009; Ronsmans et al., 2001); one significantly (Ronsmans et al., 2001). One exception is Fauveau et al. (1991) where of the 15 percent of registered women who requested a midwife to be present, only 9 percent had a midwife deliver the baby. Hospital births also increased over time in one study where EmOC provision was part of the intervention in a refugee

population (Purdin, Khan and Saucier, 2009) and in the culturally adapted birth model (Gabrysch et al., 2009).

Use of ANC

- ⁴ **Risk of bias:** Data on ANC use is collected via a repeated population-based survey in Frankenberg et al. (2009) and 2-stage cluster sampling surveys before and after the intervention in Mullany et al. (2010); however, in both surveys women self-reported on receipt and timing of ANC and there is no information about reliability of data collection in one (Frankenberg et al., 2009) and in the other there is no oversight of surveyors (Mullany et al., 2010) which could affect the accuracy of data. Both identified some confounders and adjusted for these at analysis. One study collects data with the same women repeatedly over time and so appears to provide its own control (Frankenberg et al., 2009) while the other collects data on outcomes in two independent groups before and after the intervention (Mullany et al., 2010). One other study (Purdin, Khan and Saucier, 2009) uses health information system data on ANC use before and after the TBA interventions were in place; this is rated weak mainly because there is a risk these data sources are unreliable (no information on who compiled the hospital annual reports or how reliably the HIS data was collected). In this study (Purdin, Khan and Saucier, 2009) participants are likely to include non-refugee women (not the target population) for some of the time period. As none of these studies had control groups the changes in ANC over time could be due to other external factors rather than the (complex) TBA interventions.
- ⁵ **Indirectness:** One study is from a low-income country (Myanmar), the others are middle-income countries (Indonesia and Pakistan); two studies were in settings with refugee women (Purdin, Khan and Saucier, 2009) or internally displaced women (Mullany et al., 2010) only. All interventions were multiple and complex, and all involved improving partnership or linkage between TBAs and midwives or other formal health workers; in one study midwives were posted in communities to work alongside TBAs (Frankenberg et al., 2009) and in the others involved capacity strengthening/training of TBAs to attend births alongside trained midwives (Mullany et al., 2010; Purdin, Khan and Saucier, 2009). All three studies reported on ANC use: one described trends in women receiving some ANC over time (Frankenberg et al., 2009), two reported on a defined number of visits (three or more visits in Purdin, Khan and Saucier (2009) and more than one or more than four visits in Mullany et al. (2010)).

- ⁶ **Inconsistency:** All three studies showed use of ANC increased over time, following the implementation of a TBA intervention (Frankenberg et al., 2009; Mullany et al., 2010; Purdin, Khan and Saucier, 2009). There were larger relative improvements in ANC use over time where TBA interventions were implemented in settings with Afghan refugee women (Pakistan (Purdin, Khan and Saucier, 2009)) and internally displaced women (Eastern Myanmar (Mullany et al., 2010)).

Postnatal care visits for women and baby

- ⁷ **Risk of bias:** Data collection methods are not likely to be reliable; two rely on midwife or staff-maintained records/systems to collect data (Fauveau et al., 1991; Purdin, Khan and Saucier, 2009), and in one pregnant and postpartum women report use of health services via a community survey (Ronsmans et al., 2001) and there is potential for selection bias in all. Data from 2-stage cluster-sampled surveys before and after implementation (Mullany et al., 2010), data are self-reported, attempts to control for confounders at analysis.
- ⁸ **Indirectness:** Two studies conducted in low-income countries (Bangladesh, Myanmar) and two in middle-income countries (Pakistan, Indonesia); of these two were in settings with refugee women (Purdin, Khan and Saucier, 2009) and internally displaced women (Mullany et al., 2010) only. All interventions were multiple and complex, and all involved improving partnership or linkage between TBAs and midwives or other formal health workers; in two studies professional midwives were posted in communities to work alongside TBAs in Indonesia (Fauveau et al., 1991; Ronsmans et al., 2001) and in the others involved capacity strengthening/training of TBAs to attend births alongside trained midwives (Mullany et al., 2010; Purdin, Khan and Saucier, 2009). All four studies reported on postnatal visits: the outcome was defined variously as within 48 hours or 2-4 days (Fauveau et al., 1991), within 72 hours (Purdin, Khan and Saucier, 2009), within the 40-day seclusion and 7-12 hours of birth (Ronsmans et al., 2001) and within 7 days (Mullany et al., 2010). Only Mullany et al. (2010) specified that the postnatal visit was to mother and baby; unclear in others.
- ⁹ **Inconsistency:** All four studies showed that postpartum visits for women increased over time, following the implementation of a TBA intervention (Fauveau et al., 1991; Purdin, Khan and Saucier, 2009; Ronsmans et al., 2001; Mullany et al., 2010). There were larger relative improvements in women receiving postpartum visits where TBA interventions were implemented in settings with Afghan refugee women (Purdin, Khan and Saucier, 2009 Pakistan) and internally displaced women (Mullany et al., 2010 Eastern Myanmar).

RECOMMENDATION 7

Providing culturally appropriate skilled maternity care

Question: What strategies to provide culturally appropriate skilled maternity care lead to an increase in use of skilled maternity care before, during and after birth?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=2	Two observational studies of weak methodological quality. Very serious¹	Evidence of indirectness across the studies. One conducted in a high-income country, the other in a middle-income country. Interventions differ: one is culturally appropriate delivery care, the other antenatal care. Both report facility births; one also reports on use of SBAs. Very serious²	Some similarity in results. New delivery care model resulted in increased births with SBAs and births in the health centre over time; no control group means other factors could influence outcome. Shared ANC showed a trend towards more women attending the programme giving birth at the hospital, but there is no data for comparison groups. Serious³	Very low
Care with skilled birth attendant or facility in case of maternal complications/illness	n=2	Two observation studies rated of moderate quality. Serious⁴	Some indirectness. Both conducted in high-income countries, but population and intervention differed in the two studies. Both report antenatal admissions and length of stay but no data on use of skilled birth attendants. Serious⁵	Results differ across the two studies. One shows significant effect of health advocates on length of stay, but in the other study there was no difference. Antenatal admissions remained the same with the health advocates' intervention in the United Kingdom, but there were more antenatal admissions and emergency room visits in the minority prenatal programme in the United States (but very small numbers). Very serious⁶	Very low

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Use of ANC (1 or 4 visits)	n=11	All observational studies: eight of weak and three of moderate methodological quality. Very serious⁷	Some evidence of directness. All studies conducted in high-income countries with ethnic minority women. Interventions were all multiple, culturally appropriate services and components and would be difficult to replicate; difficult to isolate which component responsible for the outcomes. ANC use reported variously. Serious⁸	Eight studies showed a greater number of ANC visits among women receiving an intervention designed to improve culturally appropriate skilled maternity care and three were unclear on the benefit. Three reported more adequate use of ANC in women receiving the intervention. Serious⁹	Very low
Postpartum care visit mother	n=1	A randomized control study of weak methodological quality. Very serious¹⁰	PICO directly addresses the review question. Participants are low-income Latina/Hispanic pregnant women in a high-income country (USA). The intervention is based on cultural brokers who provide educational and support services to women; the intervention is multifaceted and probably difficult to replicate. The study reports on compliance with the 6-8 week postpartum visit. No serious indirectness	Results show a benefit of the cultural broker; attendance at the postpartum visit was 2.5 times more likely in the intervention group and a trend towards women who met with the prenatal partners more often were more likely to attend the postpartum visit. Interpret with caution given flaws in study design. Not applicable	Low

Birth with a skilled birth attendant or facility birth

- Risk of bias:** One ITS study used routine statistics in a monitoring system set up as part of the project for collecting data on facility birth/SBA (Gabrysch et al., 2009) but in the cohort study there were problems with reliability of the hospital database (Panaretto et al., 2005). Selection bias is likely in both studies: in Gabrysch et al. (2009) although “most” women chose the new delivery model there are not data on this; in Panaretto et al. (2005) the women in the intervention and historical control groups were self-selected as they had chosen to receive care at TAIHS and the intervention group included only low-risk women. There was little information about blinding but likely that assessors were aware of exposure status in both studies (Gabrysch et al., 2009; Panaretto et al., 2005). Attempts made to control for confounders by stratification in Panaretto et al. (2005), but in the other study other external factors that could influence the outcomes were not described (Gabrysch et al., 2009).
- Indirectness:** One study was conducted with poor, indigenous Quechua communities in a middle-income country (Peru) (Gabrysch et al., 2009) and the other with an indigenous population in a high-income setting (Australia) (Panaretto et al., 2005). The interventions were dissimilar too: one focused on culturally appropriate delivery services and had multiple components (Gabrysch et al., 2009), the other focused on antenatal care (Panaretto et al., 2005). Both SBA (attended by a health professional at home) and facility delivery were reported in one study (Gabrysch et al., 2009); the other study reports data on facility delivery in the intervention group only (Panaretto et al., 2005).
- Inconsistency:** The study of new delivery services reports increases in percentage of births with SBAs and births in the health centre over time, but with no control group the changes in outcome observed may not be due to the new delivery model intervention alone (Gabrysch et al., 2009). The antenatal intervention with Aboriginal women showed a trend towards more women attending the shared ANC programme giving birth at the hospital, but there is no data for comparison groups (Panaretto et al., 2005).

Care with skilled birth attendant or facility in case of maternal complications/illness

- Risk of bias:** The participants are somewhat likely to represent the target population; Thompson, Curry and Burton (1998) matched the controls on demographics, and Parsons and Day (1992) relied on labour ward delivery books and case notes to select exposed and control groups which may not be complete or accurate and could affect selection and no attempt to match. Both use hospital records to obtain data on antenatal admissions and length of stay; these are considered valid but there are problems with reliability (missing notes/records) in both studies which could bias the results. Parsons and Day (1992) do not describe how confounders were controlled for, but in Thompson, Curry and Burton (1998) the authors used matching to control for demographic characteristics (other variables were not controlled as there were not data available).
- Indirectness:** Both studies conducted in high-income settings but populations differ: one is high-risk low-income Mexican-American women in the USA (Thompson, Curry and Burton, 1998), the other is Turkish and Asian women in the United Kingdom (Parsons and Day, 1992). The interventions were similar in that they both focused on antenatal period, but the emphasis was on health advocates in one study (Parsons and Day, 1992) and in Thompson, Curry and Burton (1998) the emphasis was on nursing case management and home visits. Both reported on antenatal admissions: Thompson, Curry and Burton (1998) distinguished between ER visits and inpatient admissions, whereas Parsons and Day (1992) reported antenatal hospital admissions; both studies reported outcomes data on mean length of stay. Neither study reports on use of SBAs in case of maternal complications.
- Inconsistency:** In Parsons and Day (1992) length of stay was significantly lower in the health advocates intervention group, but there was no difference between the groups in the Thompson, Curry and Burton (1998) study. There were too few antenatal admissions to calculate statistical differences in the Thompson, Curry and Burton study, but more inpatient admissions and ER visits in the intervention group; in the Parsons and Day study (1992) antenatal admissions remained the same with the health advocates’ intervention, and increased in the control group.

Use of ANC (1 or 4 visits)

- Risk of bias:** For the three rated moderate (Bilenko, Hammel and Belmaker, 2007; Parsons and Day, 1992; Thompson, Curry and Burton, 1998), two were retrospective with controls and one was a before and after study with the intervention group acting as its own control; participants were somewhat likely to be representative of the target population but in all three selection of the control and exposed groups was dependent on birth certificates (Thompson, Curry and Burton, 1998), delivery books (Parsons and Day, 1992) or facility registers (Bilenko, Hammel and Belmaker, 2007) and only one study acknowledges poor recording in women’s notes could have affected selection (Parsons and Day, 1992). In two studies confounders were identified and controlled for in the design by using the same group of women as controls (Bilenko, Hammel and Belmaker, 2007) and by matching on demographics (Thompson, Curry and Burton, 1998). Eight studies rated weak (Jan et al., 2004; Jewell and Russell, 2000; Julnes, 1994; Kildea et al., 2012; Nel and Pashen, 2003; Mason, 1990; Panaretto et al., 2005; Panaretto et al., 2007). Four do not specify the study design: two appear to be retrospective cohort studies (Jewell and Russell, 2000; Julnes, 1994), one is a descriptive account of service improvements (Nel and Pashen, 2003) and the other appears to be a case control (Mason, 1990); two are mixed method evaluations (Jan et al., 2004; Kildea et al., 2012) and the other two are a prospective cohort (Panaretto et al., 2005) and a follow-on before and after study of the same intervention (Panaretto et al., 2007). One of the main sources of bias in these weak studies is poor-quality data sources and unreliable data on ANC use; Panaretto et al. (2005) acknowledge the poor recording and missing data in hospital databases; five do not provide any information about the validity or reliability of databases/data collection (Jan et al., 2004; Julnes, 1994; Nel and Pashen, 2003; Mason, 1990; Panaretto et al., 2007); and Jewell and Russell (2000) acknowledge the risk of incomplete, inconsistent and imprecise data in the birth certificates used to collect data on antenatal care access; in the other studies it is unclear from where data are extracted. In three studies there is likely selection bias due to self-selection to the intervention (Nel and Pashen, 2003; Mason, 1990; Panaretto et al., 2005 & 2007), and in all others selection of control and exposure groups was dependent on birth certificates, client records or lists, or databases that were previously existing and the accuracy/reliability of data largely unknown. Some studies attempted to control for confounders in the design by stratification of one variable (Panaretto et al., 2005 & 2007), matching of demographic variables or other

Use of ANC (1 or 4 visits) (continued)

variables where data were available (Jan et al., 2004; Jewell and Russell, 2000), or at analysis through multivariate regression and adjustment of results (Kildea et al., 2012; Panaretto et al., 2007).

- ⁸ **Indirectness:** All studies were conducted in high-income countries with ethnic minority women: five in Australia with Indigenous Aboriginal or Torres Strait Islander populations; three in the USA with minority groups including pregnant adolescents at high risk of poor outcomes; two in the United Kingdom with Asian and Turkish women; and one in Israel with Bedouin women. Interventions are similar in that they all included multiple culturally appropriate services and components alongside antenatal/clinical care services; these included health advocacy, liaison, linkage or brokerage for women, Indigenous health staff, group or individual support, home or clinic-based visits, and sometimes transport services. It would be difficult to replicate the interventions as they are so diverse and probably implemented differently by all staff involved; also difficult to isolate which component is responsible for the outcomes. Comparison groups tend to be standard care, no intervention or historical and contemporary controls. All studies reported number of ANC visits albeit slightly differently: some report median number of visits (Panaretto et al., 2005 & 2007); mean number of visits (Jan et al., 2004; Jewell and Russell, 2000; Mason, 1990); non-use (Parsons and Day, 1992); more than six visits (Julnes, 1994); Bilenko, Hammel and Belmaker (2007) and Nel and Pashen (2003) provide ANC use data before and after the new clinic intervention; and Kildea et al. (2012) presents use data as a range. Some use the APCNU index and/or the Kessener index to report adequacy of antenatal care visits (Jewell and Russell, 2000; Thompson, Curry and Burton, 1998); others report inadequacy as fewer than for visits (Panaretto et al., 2005 & 2007).
- ⁹ **Inconsistency:** Overall results indicate a positive effect of culturally appropriate interventions on ANC use; eight studies showed a greater number of ANC visits among women receiving an intervention designed to improve culturally appropriate skilled maternity care (outcome reported variously), three report no difference in ANC use between those receiving the intervention and controls; three reported more adequate ANC use in women receiving the intervention (Jewell and Russell, 2000; Panaretto et al., 2005; Panaretto et al., 2007).

Postpartum care visit mother

- ¹⁰ **Risk of bias:** Described as a randomized controlled group design (Marsiglia, Bermudez-Parsai and Coonrod, 2010), eligible participants who agreed to participate were assigned randomly to a study group but generation of allocation sequence and concealment is unclear, leading to possible bias in assignment to groups. Although randomization should control for confounders, there is a lack of information on baseline characteristics of both the experimental groups so impossible to know if groups are balanced. In addition, there is no information about the validity or reliability of the medical records used to obtain data on this outcome.

RECOMMENDATION 8

Companion of choice at birth

Question: Does allowing a woman to have a companion of choice to accompany her during labour and birth in the facility/or in the presence of a skilled birth attendant lead to an increase in births with a skilled birth attendant/institutional births and to improvements in perceptions of quality of care?

Author(s): Ellen D Hodnett, Simon Gates, G Justus Hofmeyr, Carol Sakala

Date: 2014-06-23

Question: Continuous support versus usual care – all trials for women during childbirth

Settings: Low, middle and high-income settings

Bibliography: Hodnett ED, Gates S, Hofmeyr GJ, Sakala C. Continuous support for women during childbirth. Cochrane Database of Systematic Reviews, 2013; (7):CD003766.

QUALITY ASSESSMENT							NUMBER OF PATIENTS		EFFECT		QUALITY	IMPORTANCE
NUMBER OF STUDIES	DESIGN	RISK OF BIAS	INCONSISTENCY	INDIRECTNESS	IMPRECISION	OTHER CONSIDERATIONS	CONTINUOUS SUPPORT VERSUS USUAL CARE - ALL TRIALS	CONTROL	RELATIVE (95% CI)	ABSOLUTE		
Subsequent birth with an SBA												
0												
Negative rating of/negative feelings about birth experience (assessed with: Interviews or questionnaires ^a)												
11	Randomized trials	No serious risk of bias ¹	No serious inconsistency ²	Serious ³	No serious imprecision ⁴	None ⁵	653/5583 (11.7%)	982/5550 (17.7%)	RR 0.69 (0.59 to 0.79)	55 fewer per 1000 (from 37 fewer to 73 fewer)	⊕⊕⊕○ MODERATE ^b	CRITICAL
								24.8%		77 fewer per 1000 (from 52 fewer to 102 fewer)		

^a All used either questionnaires or interviews.

^b For this outcome quality was assessed as 'low' in the WHO guideline, *WHO recommendations for augmentation of labour*. Geneva: World Health Organization; 2014.

¹ Checking for possible selection bias. Random sequence generation: five trials were at unclear risk of bias (Breart et al., 1992 Belgium; Breart et al., 1992 France; Dickinson et al., 2002; Hofmeyr et al., 1991; Kennell et al., 1991) because they did not describe the method of random assignment. Six trials described using a computer random number generator or referred to a random number table (Bruggemann et al., 2007; Campbell et al., 2006; Hodnett et al., 2002; Langer et al., 1998; Morhason-Bello et al., 2009; Torres et al., 1999) and were assessed as low risk of bias. Allocation concealment: the risk of selection bias was high in one small trial (Bruggemann et al., 2007); women picked their treatment allocation from an opaque container. In five trials (Campbell et al., 2006; Hodnett et al., 2002; Kennell et al., 1991; Torres et al., 1999; Morhason-Bello et al., 2009), risk of selection bias was low with allocation described as either using central allocation, e.g. Hodnett et al. (2002) used a central, computerized randomization service accessed by telephone or other trials described using sequentially numbered, opaque, sealed envelopes. In the remaining trials (Breart et al., 1992 Belgium; Breart et al., 1992 France; Dickinson et al., 2002; Hofmeyr et al., 1991; Langer et al., 1998), risk of selection bias was unclear. Blinding (performance bias and detection bias) performance bias: neither those providing nor receiving care could be blinded to the presence/absence of a person providing continuous support. Hodnett et al. (2002) provided evidence to discount contamination and co-intervention as serious threats to validity. In four trials group assignment was known and no attempt to blind outcome assessment was apparent and so these were assessed as being at high risk of bias (Bruggemann et al., 2007; Campbell et al., 2006; Hofmeyr et al., 1991; Morhason-Bello et al., 2009). Detection bias: in the trials which sought participants' evaluations of their birth experiences, efforts were made to reduce response bias through use of an interviewer blinded to the woman's group allocation or self-administered questionnaires. Two trials were assessed as being at low risk of bias because some blinding of outcome assessment was performed (Hodnett et al., 2002; Langer et al., 1998). In the remaining trials, risk of bias for blinding (performance and detection bias) was unclear (Breart et al., 1992 Belgium; Breart et al., 1992 France 1992; Dickinson et al., 2002; Kennell et al., 1991; Torres et al., 1999). Incomplete outcome data (attrition bias): the review authors did not include data for outcomes assessed in hospital in a comparison if there was more than 20 percent loss to follow-up; they did not include longer-term outcome data if there was more than 25 percent loss to follow-up. Based on these criteria, one trial was assessed as being at high risk of bias for attrition bias (Campbell et al., 2006). Selective reporting

(reporting bias): all outcomes appear to have been reported upon in the majority of trials. Other potential sources of bias: there were no other sources of bias apparent in any of the trials. In summary, the methodological quality of the trials was generally good with low risk of bias. Comparisons of fixed-effect and random-effects analyses did not yield material differences in the results. Thus neither the risk of bias nor heterogeneity should be of concern when interpreting results.

- ² Women who had continuous, one-to-one support during labour were less likely to have reported negative rating of/negative feelings about childbirth experience (11 trials, n=11,133, average RR 0.69, 95% CI 0.59 to 0.79, I² 63%, τ² 0.03). Outcome: negatives ratings of/negative views about the birth experience 1. Policies about companions: in five trials (n=8639) companions were permitted; RR 0.70, 95% CI 0.62 to 0.78. In six trials (n=2539) companions were not permitted; RR 0.62, 95%CI 0.56 to 0.69. Chi² for the subgroup comparison=2.03, P=0.15. 2. Availability of epidural analgesia: in nine trials (n=10,404) epidural analgesia was routinely available; RR 0.70, 95% CI 0.64 to 0.77. In two trials (n=774) epidural analgesia was not routinely available; RR 0.55, 95% CI 0.48 to 0.63. Chi² for the subgroup comparison=7.92, P 0.0005. 3. Routine use of EFM: four trials (n=7467) were conducted in settings with routine EFM; RR 0.67, 95% CI 0.60 to 0.76. Four trials (n=1710) were conducted in settings in which EFM was not routine; RR 0.60, 95% CI 0.53 to 0.68. Three trials (n=1977) were in settings in which the use of routine EFM is not known; RR 0.84, 95% CI 0.65 to 1.08. Chi² for the subgroup comparison=5.55, P=0.06. 4. Provider characteristics: in four trials (n=8145) support providers were hospital staff; RR 0.87, 95% CI 0.73 to 1.03. In three trials (n=1325) the providers were not hospital staff and not part of the woman's social network; RR 0.66, 95% CI 0.57 to 0.77. In four trials (n=1708), providers were part of the woman's social network; RR 0.57, 95% CI 0.51 to 0.64. Chi² for the subgroup comparison=16.47, P=0.0003. Thus the effectiveness of continuous support in reducing the likelihood of dissatisfaction with or negative views of the childbirth experience appeared to be stronger in settings in which epidural analgesia was not routinely available, and when the provider was neither a staff member nor part of the woman's social network.
- ³ There were similarities in participants across studies: all studies included low-risk women; nine of which stated women were nulliparous at term, the remaining two (Morhason-Bello et al., 2009; Torres et al., 1999) studies did not state parity. Two studies required women to be either less than 5 cm (Dickinson et al., 2002) or 6 cm (Langer et al., 1998) dilation. Studies were

performed in a number of settings; six in high-income (Breart et al., 1992 Belgium; Breart et al., 1992 France; Campbell et al., 2006; Dickinson et al., 2002; Hodnett et al., 2002; Kennell, 1991), and five in low-income (Bruggeman et al., 2007; Hofmeyr et al., 1991; Langer et al., 1998; Torres et al., 1999; Morhason-Bello et al., 2009) settings. Continuous support was either provided by a health care professional (midwife/nurse) (Hodnett et al., 2002; Dickinson et al., 2002; Breart et al., 1992 Belgium; Breart et al., 1992 France), a doula/layperson trained in the intervention (Campbell et al., 2006; Torres et al., 1999; Langer et al., 1998; Hofmeyr et al., 1991) or not (Kennell et al., 1991), or a companion identified by the woman herself without training (Morhason-Bello et al., 2009; Bruggemann et al., 2007). The control group varied somewhat: five studies compared continuous support with intermittent support (Kennell et al., 1991; Hodnett et al., 2002; Hofmeyr et al., 1991; Breart et al., 1992 Belgium; Breart et al., 1992 France), two with routine care (not fully described) (Langer et al., 1998; Morhason-Bello et al., 2009), or no companion present (Bruggemann et al., 2007; Torres et al., 1991), one study (Dickerson, 2002) stipulated no midwife and the women were encouraged to have an epidural. In the final study women were allowed to have a support person of their own choosing (Campbell et al., 2006).

- ⁴ Women who had continuous, one-to-one support during labour were less likely to have reported negative rating of/negative feelings about childbirth experience (11 trials, n=11,133, average RR 0.69, 95% CI 0.59 to 0.79, I² 63%, τ² 0.03). Smallest trial n=118 (Hofmeyr, et al 1991), largest trial n=5,569 (Hodnett et al., 2002). In five trials (Breart et al., 1992 Belgium; Breart et al., 1992 France; Dickinson et al., 2002; Hodnett et al., 2002; Torres et al., 1991) the CI included the value of no difference between treatments therefore indicating that continuous, one-to-one support during labour was not significantly different from the control. Control interventions of these trials comprised: intermittent support from a nurse who had not received labour support training (Hodnett et al., 2002), no midwifery support, women encouraged to have an epidural (Dickinson et al., 2002), varying degrees of midwifery presence in addition to fathers (Breart et al., 1992 Belgium; Breart et al., 1992 France), and no companion present (Torres et al., 1991). The sample sizes of the studies ranged from 188 (Hofmeyr et al., 1991) to 5569 (Hodnett et al., 2002).
- ⁵ Risk of bias was unclear in one study (Campbell et al., 2006) and no other sources of bias were apparent in the remaining trials.

RECOMMENDATION 9

Community mobilization through facilitated participatory learning and action cycles with women's groups

Question: What are the impacts on MNH of community mobilization through facilitated participatory learning and action cycles with women's groups?

Question: What are the impacts on maternal and newborn health of community mobilization through participatory learning and action cycles with women's groups?

Settings: In low and middle-income countries

Bibliography: Prost et al. (2013). Women's groups practicing participatory learning and action to improve maternal and newborn health in low-resource settings: a systematic review and meta-analysis. *The Lancet*, Volume 381, Issue 9879, Pages 1736-1746; Colbourn T and Prost A. (2013) Supplementary meta-analysis of women's group trials for WHO meeting - 29 July 2013. unpublished

QUALITY ASSESSMENT							NUMBER OF PATIENTS		EFFECT		QUALITY	IMPORTANCE
NUMBER OF STUDIES	DESIGN	STUDY LIMITATIONS	INCONSISTENCY	INDIRECTNESS	IMPRECISION	OTHER CONSIDERATIONS	MOBILIZATION THROUGH PARTICIPATORY LEARNING AND ACTION CYCLES WITH WOMEN'S GROUPS	CONTROL	RELATIVE (95% CI)	ABSOLUTE		
Maternal mortality (follow-up 7-11.5 months; ^a assessed with death of a woman while pregnant or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes. Confirmed using verbal autopsies.)												
7	Randomized trials ¹	No serious risk of bias	No serious inconsistency ³	Serious ⁴	Serious ⁵	None	162/57413 (0.28%)	190/56501 (0.34%)	OR 0.63 (0.32 to 0.94) ⁶	1 fewer per 1000 (from 0 fewer to 2 fewer)	⊕⊕○○ LOW	IMPORTANT
Neonatal mortality (follow-up 2-9.5 weeks; assessed with death of a live born infant within 28 complete days of birth. Confirmed using verbal autopsies.)												
7	Randomized trials ¹	No serious risk of bias	No serious inconsistency ⁷	Serious ⁴	No serious imprecision	None	1657/57413 (2.9%)	1969/56501 (3.5%)	OR 0.77 (0.65 to 0.9) ⁸	8 fewer per 1000 (from 3 fewer to 12 fewer)	⊕⊕⊕○ MODERATE	IMPORTANT
Stillbirths (follow-up 2-9.5 weeks; assessed with verbal autopsies in which no sign of breathing, heartbeat or any other evidence of life was reported at birth)												
7	Randomized trials ¹	No serious risk of bias ²	No serious inconsistency	Serious ⁴	Serious ⁹	None ¹⁰	1605/57413 (2.8%)	1576/56501 (2.8%)	OR 0.91 (0.79 to 1.03) ¹¹	2 fewer per 1000 (from 6 fewer to 1 more)	⊕⊕○○ LOW	IMPORTANT

^a Assessment from seven months of gestation to 2.5 months after birth (postpartum). A majority of studies assessed outcomes at six weeks after birth.

QUALITY ASSESSMENT							NUMBER OF PATIENTS		EFFECT		QUALITY	IMPORTANCE
NUMBER OF STUDIES	DESIGN	STUDY LIMITATIONS	INCONSISTENCY	INDIRECTNESS	IMPRECISION	OTHER CONSIDERATIONS	MOBILIZATION THROUGH PARTICIPATORY LEARNING AND ACTION CYCLES WITH WOMEN'S GROUPS	CONTROL	RELATIVE (95% CI)	ABSOLUTE		
Institutional delivery (follow-up 2-9.5 weeks; assessed with number. of deliveries at a health facility assessed using questionnaires and interviews)												
6	Randomized trials ¹	Serious ²	No serious inconsistency	Serious ¹²	No serious imprecision	None	—	—	OR 1.03 (0.91 to 1.16) ¹¹	—	⊕⊕○○ LOW	CRITICAL
Giving birth with a skilled birth attendant (follow-up 2-9.5 weeks; assessed with questionnaires and interviews)												
5	Randomized trials ¹	Serious ²	No serious inconsistency	Serious ¹³	Serious ⁹	None	—	—	OR 0.98 (0.83 to 1.14) ¹¹	—	⊕○○○ VERY LOW	CRITICAL
Receiving any antenatal care (follow-up 2-9.5 weeks; assessed with questionnaires and interviews)												
5	Randomized trials ¹	Serious ²	No serious inconsistency	Serious ¹⁴	Serious ⁹	None	—	—	OR 1.11 (0.81 to 1.41) ¹¹	—	⊕○○○ VERY LOW	IMPORTANT
Receiving the recommended number of antenatal care visits (follow-up 2-9.5 weeks; assessed with: 3 or more ANC visits; assessed using questionnaires and interviews)												
5	Randomized trials ¹	Serious ²	No serious inconsistency	Serious ¹⁴	Serious ⁹	None	—	—	OR 0.94 (0.73 to 1.16) ¹¹	—	⊕○○○ VERY LOW	CRITICAL

- 1 Cluster RCTs.
- 2 Serious study-level limitations as participants and those responsible for recruitment and evaluation of individuals after cluster randomization were not blind to allocation status. There was incomplete outcome reporting in most trials; outcome data was obtained directly from the authors.
- 3 Statistically significant, moderate heterogeneity of results, $I^2=58.8\%$, $p=0.024$. The heterogeneity might be explained by the different proportions of pregnant women participating in groups in the different trials because examining the trials in two groups, those with over 30 percent of pregnant women participating and those with under 30 percent, reduces the heterogeneity. The GDG accepted the different proportions of pregnant women as a plausible explanation for the heterogeneity so there is no downgrading on this criterion. Note, however, that this association between proportions of pregnant women participating and the heterogeneity, while plausible, may have arisen by chance and so this explanation should be treated with caution.
- 4 Potential risk of indirectness as six out of seven studies in the meta-analysis were undertaken in rural settings and only one trial assessed the impact of the intervention on the urban poor. Separate recommendations should be made for each group to reduce indirectness. If the recommendation were to consider the evidence only in terms of rural areas, it could be upgraded as this would address the limitations due to indirectness of the evidence.
- 5 Wide confidence intervals.
- 6 Exposure to women's group is associated with a 37 percent reduction in maternal mortality.
- 7 Statistically significant, substantial heterogeneity of results, $I^2=64.7\%$, $p=0.009$. The heterogeneity might be explained by the different proportions of pregnant women participating in groups in the different trials because examining the trials in two groups, those with over 30 percent of pregnant women participating and those with under 30 percent, reduces the heterogeneity. The GDG accepted the different proportions of pregnant women as a plausible explanation for the heterogeneity so there is no downgrading on this criterion. Note, however, that this association between proportions of pregnant women participating and the heterogeneity, while plausible, may have arisen by chance and so this explanation should be treated with caution.
- 8 Exposure to women's group is associated with a 23 percent reduction in neonatal mortality.
- 9 Recommendation may differ if the lower versus the upper boundary of the CI represented the truth.
- 10 One study does not report stillbirth outcomes in the paper. However, the Prost et al. (2013) meta-analysis uses results obtained directly from the authors.
- 11 No evidence of effect ($p>0.05$).
- 12 Potential risk of indirectness as five out of six studies in the meta-analysis were undertaken in rural settings and only one trial assessed the impact of the intervention on the urban poor.
- 13 Potential risk of indirectness as all five studies in the meta-analysis were undertaken in rural settings.
- 14 Potential risk of indirectness as four out of five studies in the meta-analysis were undertaken in rural settings and only one trial assessed the impact of the intervention elsewhere.

RECOMMENDATION 10

Community participation in maternal death surveillance and response (MDSR)

Question: What interventions to involve communities in the analysis and dissemination of information from maternal and perinatal death reviews are effective in improving key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	Study design likely cohort with control at high risk of bias. Very serious¹	PICO addresses the review question. Intervention was multiple and included community mobilization as well as quality of care interventions; not possible to disaggregate the effect of each. No serious indirectness²	Birth in a facility is reported and implies significant increases in facility births in the intervention and comparison areas but not in the control area. Errors in outcome data, unclear how many women were surveyed, no denominators presented. Not applicable	Very low
Care with skilled birth attendant or facility in case of maternal complications/ illness	n=1	Study design likely cohort with control at high risk of bias. Very serious	PICO addresses the review question. Intervention was multiple and included community mobilization as well as quality of care interventions; not possible to disaggregate the effect of each. No serious indirectness	Results imply significant increases in number of women expected to have complications who actually receive care in an EmOC facility in the intervention and comparison areas, but not the control area. Errors in outcome data, unclear how many women were surveyed, no denominators presented. Not applicable	Very low

Birth with a skilled birth attendant or facility birth

- ¹ **Risk of bias:** Poorly reported study which probably equates with poor conduct and methods (Hossain and Ross, 2006). Study design is not stated but seems to be a cohort (pre and post) with control but pre and post are not comparable due to different sampling; cannot determine which data collection methods are used or their validity/reliability; selection of women within each study group is unclear; no information on confounders; and blinding not described.
- ² **Indirectness:** Population is women and families in a two districts in Bangladesh. The intervention area received multiple activities including a community support intervention which included involving the community in death review, through collecting information on maternal deaths, community diagnoses, and dissemination and discussion of the community diagnoses, as well as facility upgrades and improved quality of care. Because the intervention is multiple it is not possible to identify which activity (i.e. if it was community involvement in death review) produced the outcomes. There were two comparison areas: one received facility upgrades only, the other no intervention. The study reports on facility births (percentage of total births in facilities).

RECOMMENDATION 11

Community participation in quality-improvement processes

Question: What interventions to involve communities in quality-improvement processes for maternity care services are effective in increasing birth with a skilled birth attendant/institutional birth and improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=1	One cluster RCT of moderate quality. Serious¹	Participants, intervention, comparison and outcome directly address the review question. Single intervention community participation in quality improvement via report cards. No serious indirectness	The cluster trial reports a significant increase in facility births, reported as additional deliveries at the facility on average, per month. Consider the RoB when interpreting. Not applicable	Moderate
	n=4	Four observational studies all of weak methodological quality. Very serious²	Some direct comparisons. Population is similar across studies, but intervention differs. Serious³	Some similarity in results across studies. Four studies report increases in facility births; in three studies the increase is significant. One study reports improvements in use of skilled birth attendants following implementation of the quality-improvement intervention, compared with data in the period before. Serious⁴	Very low
	n=1 ^a	One quasi-experimental study rated weak. Serious⁵	Participants, intervention, comparison and outcome directly address review question. No serious indirectness⁶	Study reports significant increases in the intervention and comparison groups but not the control group. Not applicable	Very low
Care with skilled birth attendant or facility in case of maternal complications/illness	n=1 ^a	A quasi-experimental study of weak methodological quality. Serious⁷	Participants, intervention, comparison and outcomes directly address the review question. No serious indirectness⁸	The study reports significant increases in the intervention and comparison groups; control group also shows very small increase but there is an error in the reporting of confidence intervals. Consider the RoB when interpreting. Not applicable	Very low

^a This study (Hossain and Ross, 2006) was of an intervention specifically aiming to increase access to skilled care in case of complications. Consequently the messages are different and the intervention also contributed to ensure safe birth practices at home.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Use of ANC	n=1	One cluster RCT of moderate quality. Serious⁹	Participants, intervention, comparison and outcome directly address the review question. Single intervention community participation in quality improvement via report cards. No serious indirectness	Reports a non-significant increase in use of ANC, reported as additional ANC visits at the facility on average, per month. Not applicable	Moderate
	n=3	Three observational studies of weak methodological quality. Serious¹⁰	Some direct comparisons. Population is similar across studies, but intervention differs and outcomes are reported differently. Serious¹¹	Some similarity in results across studies. All studies report increases in ANC visits; in one study the difference in number of women who made at least one or more than three visits is significant between baseline and endline. Serious¹²	Very low
Postpartum visit visits for women	n=1	One retrospective before and after study of weak quality. Serious¹³	Participants, intervention, comparison and outcome directly address the review question. No serious indirectness¹⁴	Reports coverage of postnatal care within 72 hours of birth increased over time. Not applicable	Very low

Birth with a skilled birth attendant or facility birth

- 1 **Risk of bias:** The method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses) (Bjorkman and Svensson, 2009).
- 2 **Risk of bias:** An ITS that uses routine facility-based data likely to be valid; no information on reliability; selection bias possible and likely that participants aware of research question as communities/providers were involved in formative research; designing the new delivery model and implementation activities and this could lead to providers changing reporting behaviour; also possible confounders not mentioned (Gabrysch et al., 2009). One controlled before and after study the control group was matched by geographical location and congruence between intervention and control groups was confirmed at baseline (but this data is not presented), but bias is possible through self-reported data and there is no description of blinding (Kaseje et al., 2010). In the pre and post programme evaluation (Sinha, 2008) validity/reliability of survey tool unknown and it changed baseline to follow-up; selection bias is possible, and no information about possible confounding factors. Purdin, Khan and Saucier (2009) is a retrospective before and after at high risk of bias as there is a risk that surveillance data/databases are incomplete or unreliable, potential for selection bias, and the lack of control group means that the changes could be due to other external factors or trends rather than the community participation component of the interventions.
- 3 **Indirectness:** Studies conducted in a low-income country (Kenya) and middle-income countries (Peru, India, Pakistan) and in communities and/or providers in rural and poor areas, and specifically with Afghan refugee women (Purdin, Khan and Saucier, 2009). The community participation interventions are diverse: in some studies community participation in QI is just one component of larger safe motherhood or maternal and newborn health programmes (Gabrysch et al., 2009; Purdin, Khan and Saucier, 2009; Sinha, 2008), while in others community participation in QI was the main focus of the intervention, i.e. community dialogue (Kaseje et al., 2010). All report on facility birth and one on SBA (Gabrysch et al., 2009).
- 4 **Inconsistency:** Some similarity in results: the ITS study reports increase in deliveries in the health centre between baseline and follow-up, and an increase in SBA, but with no control group the changes in outcome observed may not be due to the new delivery model intervention alone (Gabrysch et al., 2009); controlled before and after study reports significant increases

in facility births at intervention sites (Kaseje et al., 2010); the pre and post study (Sinha, 2008) reports significant increases in births at primary health centres and government hospitals. Purdin, Khan and Saucier (2009) report the proportion of births in an EmOC facility increased following the intervention in a refugee population.

- 5 **Risk of bias:** Data collection is poorly described, selection bias is unclear, blinding is not described and there is no information on confounding factors (Hossain and Ross, 2006).
- 6 **Indirectness:** Target population was women and families and providers/facilities in rural Bangladesh. Intervention was multiple: community participation in QI one component; stakeholder committee formed to obtain community views on improving services – the committee monitored cleanliness and client perspectives of services. Reports on percentage of total births in facilities.

Care with skilled birth attendant or facility in case of maternal complications/illness

- 7 **Risk of bias:** Data collection is poorly described, selection bias is unclear, blinding is not described and there is no information on confounding factors (Hossain and Ross, 2006).
- 8 **Indirectness:** Target population was women and families and providers/facilities in rural Bangladesh. Intervention was multiple: community participation in QI one component; stakeholder committee formed to obtain community views on improving services (the committee monitored cleanliness and client perspectives of services). Reports on met need for emergency obstetric care pre and post intervention.

Use of ANC

- 9 **Risk of bias:** Method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses) (Bjorkman and Svensson, 2009).
- 10 **Risk of bias:** One controlled before and after study, the control group was matched by geographical location and congruence between intervention and control groups was confirmed at baseline (but this data is not presented), but bias is possible through self-reported data and there is no description of blinding (Kaseje et al., 2010). In the pre and post programme evaluation (Sinha, 2008), validity/reliability of survey tool unknown and it changed baseline to follow-up, selection bias is possible, and no

information about possible confounding factors. Purdin, Khan and Saucier (2009) is a retrospective before and after at high risk of bias as there is a risk that surveillance data/databases are incomplete or unreliable, potential for selection bias, and the lack of control group means that the changes could be due to other external factors or trends rather than the community participation component of the interventions.

- 11 **Indirectness:** Studies conducted in a low-income country (Kenya) and middle-income countries (India, Pakistan) and in all studies the population was communities and/or providers in rural and poor areas, and specifically with Afghan refugee women (Purdin, Khan and Saucier, 2009). The community participation interventions are diverse: in two studies community participation in QI was just one component of larger safe motherhood programme (Purdin, Khan and Saucier 2009; Sinha, 2008), while in the other community participation in QI was the main focus of the intervention via community dialogue (Kaseje et al., 2010). All report on ANC visits, slightly differently: had at least one visit or more than three (Sinha, 2008); four or more visits (Kaseje et al., 2010); and three or more visits (Purdin, Khan and Saucier, 2009).
- 12 **Inconsistency:** The controlled before and after study reports increases but no significant differences between control and intervention sites (Kaseje et al., 2010) and the pre and post evaluation reported improved ANC practices with significant differences between baseline and endline in women who made at least one or more than three visits (Sinha, 2008). The retrospective before and after study reported increased ANC use following the intervention, but no analysis of change (Purdin, Khan and Saucier, 2009).

Postpartum visit visits for woman

- 13 **Risk of bias:** Risk that surveillance data/databases are incomplete or unreliable, potential for selection bias, and the lack of control group means that the changes could be due to other external factors or trends rather than the community participation component of the interventions (Purdin, Khan and Saucier, 2009).
- 14 **Indirectness:** Conducted in Pakistan in a refugee camp setting with Afghan refugee women; the community participation in QI intervention was just one component of larger safe motherhood programme. Reports on postnatal coverage within 72 hours of birth; appears to be visits for women.

RECOMMENDATION 12

Community participation in programme planning and implementation

Question: What interventions to involve communities in MNH programme planning are effective in increasing birth with a skilled birth attendant/institutional birth and improving other key maternal and newborn health outcomes?

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Birth with a skilled birth attendant or facility birth	n=4	Two cluster RCTs and one quasi-experimental study of moderate quality. Serious¹	Evidence of indirectness in relation to participants, interventions and outcomes. Very serious²	Wide variation in results across studies. Both cluster trials report increased facility births, one significant, one not; the quasi-experimental study reports an increase in facility births at both sites, but greater increase at the control site than the study site. Very serious³	Very low
	n=5	All observational studies of weak methodological quality. Very serious⁴	Evidence of indirectness in relation to participants, interventions and outcomes. Very serious⁵	Some similarity in results across studies. Controlled before and after studies report significant increases in facility birth; before and after report increases following the intervention; and a follow-up study reports significant increases over the three years. Serious⁶	Very low
	n=1 ^a	One pre and post intervention study of weak quality. Very serious⁷	Participants, intervention, comparison and outcome directly address the review question. Intervention was multiple and community mobilization a small component; no control group but comparison with baseline. No serious indirectness	The post-intervention follow-up study reports significant increases in deliveries assisted by a trained person and occurring at a health facility over a three-year follow-up period. Not applicable	Very low

^a This study (Ahluwalia, 2010) was of an intervention specifically aiming to increase access to skilled care in case of complications. Consequently the messages are different and the intervention also contributed to ensure safe birth practices at home.

OUTCOME	NUMBER OF STUDIES	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	OVERALL QUALITY OF THE EVIDENCE (HIGH, MODERATE, LOW, VERY LOW)
Care with skilled birth attendant or facility in case of maternal complications/ illness	n=1 ^b	A pre and post intervention study of weak methodological quality. Very serious ⁸	Participants, intervention, comparison and outcome directly address the review question. Intervention was multiple and community mobilization a small component; no control group but comparison with baseline. No serious indirectness ⁹	Study reports an increase in the number of pregnant women attending the district hospital treated for obstetric complications. Due to the design limitations, this could be due to other factors such as increased demand, referrals or better reporting at the hospitals. Not applicable	Very low
Use of ANC	n=4	Two cluster RCTs and one quasi-experimental study of moderate quality. Serious ¹⁰	Evidence of indirectness in relation to participants, interventions and outcomes. Very serious ¹¹	The cluster trials report non-significant increases in ANC use; the quasi-experimental study reports a decrease in use of ANC. Very serious ¹²	Very low
	n=7	All observational studies of weak methodological quality. Very serious ¹³	Evidence of indirectness in relation to participants, interventions and outcomes. Very serious ¹⁴	All studies report increased ANC use. In the before and after studies the changes in the outcome could be due to other external factors or trends. Serious ¹⁵	Very low
Postpartum visits for woman	n=1	One retrospective before and after study of weak quality. Serious ¹⁶	Participants, intervention, comparison and outcome directly address the review question. No serious indirectness ¹⁷	Reports coverage of postnatal care within 72 hours of birth increased over time. Not applicable	Very low

^b This study (Ahluwalia, 2003) was of an intervention specifically aiming to increase access to skilled care in case of complications. Consequently the messages are different and the intervention also contributed to ensure safe birth practices at home.

Birth with a skilled birth attendant or facility birth

- ¹ **Risk of bias:** Randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but data for the outcome were self-reported and the assessors were not blind to intervention status (Bhutta et al., 2011). The method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses) (Bjorkman and Svensson, 2009). In the quasi-experimental study (one intervention reported in two papers), there was a risk of selection bias as rural and urban areas were chosen for the study and control sites and were more developed than typical rural/urban settings in Nepal, blinding is not described, and data are self-reported in household and adolescent surveys (Malhotra et al., 2005; Mathur, Mehta and Malhotra, 2004)
- ² **Indirectness:** Both cluster randomized studies conducted in rural communities, but one in a middle-income country (Pakistan; Bhutta et al., 2011) and one in a low-income country (Uganda; Bjorkman and Svensson, 2009); the quasi-experimental study was conducted with adolescents in Nepal. In one study community participation was just one small component of larger maternal and newborn health programme (Bhutta et al., 2011), one was a specific community-based monitoring intervention using report cards (Bjorkman and Svensson, 2009), and the other was a client-centred participatory approach (Malhotra et al., 2005; Mathur, Mehta and Malhotra, 2004). All studies report facility birth (Bhutta et al., 2011; Bjorkman and Svensson, 2009; Malhotra et al., 2005; Mathur, Mehta and Malhotra, 2004).
- ³ **Inconsistency:** Both cluster trials report increased facility births, one significant (Bjorkman and Svensson, 2009), one not (Bhutta et al., 2011); the quasi-experimental study reports an increase in facility births at both sites, but a greater increase at the control site than the study site (Malhotra, 2005).
- ⁴ **Risk of bias:** Two controlled before and after studies: in one the control group was matched by geographical location and congruence between intervention and control groups was confirmed at baseline (but this data is not presented), but bias is possible through self-reported data and there is no description of blinding (Kaseje et al., 2010); in the other, controls were not matched, differences between study groups at baseline were not described, data were collected by survey with no discussion of validity/reliability, and blinding is not described (Kaufman, Liu and Fang, 2012). In the remaining three one group before

and after evaluations (Harkins et al., 2008; Purdin, Khan and Saucier, 2009; Sood et al., 2004) there is a risk that surveillance data/databases are incomplete or unreliable (Purdin, Khan and Saucier, 2009) or the survey tools are not valid or reliable (Harkins et al., 2008; Sood et al., 2004); there is potential for selection bias in all four studies, and the lack of control groups in these studies mean that the changes could be due to other external factors or trends rather than the community participation component of the interventions. Sood et al. (2004) included a control group at endline assessment, but no information on any difference between the exposed/unexposed groups.

- ⁵ **Indirectness:** Studies are conducted in a low-income country (Kenya) and a middle-income country (Indonesia, China, India, Peru) and with varying populations including rural poor communities (Kaseje et al., 2010; Kaufman, Liu and Fang, 2012; Sood et al., 2004), peri-urban migrant poor (Harkins et al., 2008), and Afghan refugee women (Purdin, Khan and Saucier, 2009). The community participation interventions are diverse and the level of participation in planning, implementing and evaluating programmes varies across the studies. All studies report on facility births, and two report on SBAs (Harkins et al., 2008; Sood et al., 2004); in Sood et al. (2004) SBA includes a doctor, obstetric specialist, midwife puskesmas, village midwife and private midwife.
- ⁶ **Inconsistency:** The controlled before and after studies report significant increases in facility births at intervention sites (Kaseje et al., 2010; Kaufman, Liu and Fang, 2012). The before and after studies report increased facility birth following the intervention (Harkins et al., 2008; Purdin, Khan and Saucier, 2009) but no analysis of change except in Sood et al. (2004), where endline data suggests facility births were significantly more likely in the group exposed to the intervention.
- ⁷ **Risk of bias:** One group before and after evaluation, at high risk of bias: there is a risk that surveillance data/databases are incomplete or unreliable (Ahluwalia et al., 2010); there is potential for selection bias, and the lack of control groups in these studies mean that the changes could be due to other external factors or trends rather than the community participation component of the interventions.

Care with skilled birth attendant or facility in case of maternal complications/illness

- ⁸ **Risk of bias:** Weak design; one group pre and post design using formative baseline assessment and follow-up data (Ahluwalia et al., 2003). No information provided about the recruitment or selection of participants for baseline or endline assessments, so cannot tell if selected individuals are representative. Although data collection for this outcome was through CARE-implemented monitoring systems, there is no indication of reliability of these systems. As there is no control group, impossible to judge whether changes in the outcome due to the complex intervention, or any other secular trends or factors.
- ⁹ **Indirectness:** No serious indirectness. Study conducted in rural, poor communities in Tanzania, a low-income country. The intervention being evaluated was multiple and complex. The study reports percentage change in number of obstetric complications attended at district hospitals.

Use of ANC

- ¹⁰ **Risk of bias:** In Bhutta et al. (2011) randomization was by computer-generated number, there is no risk of selection bias and confounding was controlled for in the design by stratification but data for the outcome were self-reported and the assessors were not blind to intervention status; in Bjorkman and Svensson (2009) the method of randomization was not described, blinding was not described, and data were self-reported in a household survey (although where possible patient records were used to validate responses). In the quasi-experimental study there was a risk of selection bias as rural and urban areas were chosen for the study and control sites and were more developed than typical rural/urban settings in Nepal, blinding is not described, and data are self-reported in household and adolescent surveys (Malhotra et al., 2005; Mathur, Mehta and Malhotra, 2004).
- ¹¹ **Indirectness:** Both cluster randomized studies conducted in rural communities, but one in a middle-income country (Pakistan; Bhutta et al., 2011) and one in a low-income country (Uganda; Bjorkman and Svensson, 2009); the quasi-experimental study was conducted with adolescents in Nepal. In one study community participation was just one small component of larger maternal and newborn health programme (Bhutta et al., 2011), one was a specific community-based monitoring intervention using report cards (Bjorkman and Svensson, 2009), and the other was a client-centred

Use of ANC (continued)

participatory approach (Malhotra, 2005; Mathur, Mehta and Malhotra, 2004). Outcomes also reported differently: four or more visits in Bhutta et al. (2011), number of ANC visits at the facility per month in Bjorkman and Svensson (2009) and mean percentage of women receiving prenatal care (Malhotra et al., 2005; Mathur, Mehta and Malhotra, 2004).

- ¹² **Inconsistency:** The two cluster RCTs report non-significant increases in ANC use (Bhutta et al., 2011; Bjorkman and Svensson, 2009); the quasi-experimental study reports a decrease in women receiving ANC (Malhotra et al., 2005).
- ¹³ **Risk of bias:** In one the control group was matched by geographical location and congruence between intervention and control groups was confirmed at baseline (but this data is not presented), but bias is possible through self-reported data and there is no description of blinding (Kaseje et al., 2010); in the other, controls were not matched, differences between study groups at baseline were not described, data were collected by survey with no discussion of validity/reliability, and blinding is not described (Kaufman, Liu and Fang, 2012). Five studies are one group before and after evaluations, there is a risk that surveillance data/databases are incomplete or unreliable (Ahluwalia et al., 2010; Purdin, Khan and Saucier, 2009) or the survey tools are not valid or reliable (Harkins et al., 2008; Paxman et al., 2005; Sood et al., 2004); there is potential for selection bias in all five studies, and the lack of control groups in these studies mean that the changes in ANC use could be due to other external factors or trends rather than the community participation component of the interventions. Sood et al. (2004) included a control group at endline assessment, but no information on any difference between the exposed/unexposed groups.
- ¹⁴ **Indirectness:** Studies are conducted in a range of countries from low income (Tanzania, Kenya) to middle income (Pakistan, Indonesia, China, India, Peru), and with varying populations including rural poor communities (Ahluwalia et al., 2010; Kaseje et al., 2010; Kaufman, Liu and Fang, 2012; Paxman et al., 2005; Sood et al., 2004), peri-urban migrant poor (Harkins et al., 2008), and Afghan refugee women (Purdin, Khan and Saucier, 2009). The community participation interventions are diverse and the level of participation in planning, implementing and evaluating programmes varies across the studies: in some studies community participation is just one small component of larger safe motherhood or maternal and newborn health programmes (Ahluwalia et al., 2010; Harkins et al., 2009;

Paxman et al., 2005; Purdin, Khan and Saucier, 2009; Sood et al., 2004), while in others community participation was the main focus of the intervention, specifically community-based monitoring via report cards (Bjorkman and Svensson, 2009), community dialogue (Kaseje et al., 2010), or more general participatory approaches to improve services for specific groups (Kaufman, Liu and Fang, 2012). All studies report ANC use but with different measures: some report number of women reporting four or more visits (Harkins et al., 2009; Kaseje et al., 2010; Sood et al., 2004), others report complete ANC (defined as three or more visits) (Paxman et al., 2005; Purdin, Khan and Saucier, 2009), one reports prenatal care before 20 weeks (Ahluwalia et al., 2010), and other descriptive measures (Kaufman, Liu and Fang, 2012).

- ¹⁵ **Inconsistency:** The controlled before and after studies report increases but no significant differences between control and intervention sites (Kaseje et al., 2010; Kaufman, Liu and Fang, 2012). The before and after studies all report increased ANC use following the intervention, but no analysis of change.

Postpartum visits for woman

- ¹⁶ **Risk of bias:** Purdin, Khan and Saucier (2009) is a retrospective before and after at high risk of bias as there is a risk that surveillance data/databases are incomplete or unreliable, potential for selection bias, and the lack of control group means that the changes could be due to other external factors or trends rather than the community participation component of the interventions.
- ¹⁷ **Indirectness:** Conducted in Pakistan in a refugee camp setting with Afghan refugee women; the community participation in quality-improvement intervention was just one component of larger safe motherhood programme. Reports on postnatal coverage within 72 hours of birth; the visits appear to be for women.

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