Rapid Review of Randomized Clinical Trials of Patient Safety Initiatives in Obstetrics

Preliminary report on findings

Prepared for the World Health Organization (WHO) by BreaKThrough, Knowledge Translation Services, Li Ka Shing Knowledge Institute, St. Michael's Hospital
Submitted October 2, 2015

Prepared By:
Jesmin Antony, MSc
Wasifa Zarin, MPH
Vera Nincic, PhD, MA
Roberta Cardoso, RN, PhD
John D. Ivory, MSc
Marco Ghassemi, MSc
Meaghan Kenny, MA
Charlotte Wilson, MSc
Sanober Motiwala, MSc
Rachel Warren, MA
Inthuja Selvaratnam, HBSc
Sharon Straus, MD, MSc, FRCPC
Andrea C. Tricco, PhD, MSc

Contact:
Dr. Andrea Tricco
Scientist, Knowledge Translation
E: TriccoA@smh.ca
T: 416-864-6060 ext. 77521

TABLE OF CONTENTS

Disclaimer

The information in this report is a summary of available material and is designed to give readers (health systems stakeholders, policy and decision makers) a starting point in considering currently available research evidence. Other relevant scientific findings may have been reported since completion of the review. This report is current to the date of publication and may be superseded by an updated publication on the same topic. You should consult other sources in order to confirm the currency, accuracy and completeness of the information contained in this publication and, in the event that medical treatment is required you should take professional expert advice from a legally qualified and appropriately experienced medical practitioner.

BACKGROUND AND OBJECTIVE

Patient safety is an important issue affecting the quality of healthcare systems around the world[1]. In recent years, there has been an increase in the development of interventions to promote the safety of patients receiving medical care[2-4]. These patient safety initiatives are defined as strategies that reduce the occurrence of preventable adverse events[5,6], thereby improving the quality of care. As such, the approach to improving patient safety outcomes can be viewed as three-pronged: improve the quality of individualized patient care, reduce the occurrence of adverse events, and regulate healthcare spending and costs[7].

A rise in the number of litigation cases and costs is especially apparent in the field of obstetrics[7-9]. Maternity claims estimating a total value of over £5.2 billion were reported in a 10 year analysis conducted by the National Health Services in England, which was more than the value of surgery, medicine, and accident and emergency claims combined[10]. Those working in obstetrical care recognize the need to ensure the safety of patients, and many agencies have taken steps to make this a priority[3,4,7].

However, despite the rise of patient safety initiatives in obstetrics over the years, the impact of these interventions on patient outcomes that can lead to litigation is unclear[11]. Reasons for this uncertainty include the lack of evaluations of patient safety initiatives and the difficulty of measuring change in outcomes of clinical and economical interest[12].

The purpose of our rapid review was to identify randomized clinical trials in the obstetrical care literature that evaluate the impact and cost of patient safety initiatives on maternal and infant health outcomes that can lead to litigation.

METHODS

Definition of a rapid review

In order to provide decision-makers with a summary of the evidence in a short timeframe, we used a rapid review approach. Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner[13].

Protocol

A brief protocol for this rapid review was compiled and revised by systematic review methodologists and clinicians. The final version was approved by members of the WHO and is available upon request. The conduct and reporting of this review follows the guidance outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement[14].

Eligibility criteria

The eligibility criteria were developed a priori and defined using the (PICOST) framework[15], as follows:

P (*population*): Obstetrics patients and their offspring or health practitioners working with obstetrics patients and their offspring (e.g. physician, nurse, midwife, pharmacist, rural medical practitioner, village doctor).

I (*interventions*): Complex interventions with the goal of promoting or ensuring patient safety. Examples of complex interventions include quality improvement interventions, such as patient education, audit and feedback, and clinician education. The definitions for these interventions can be found in Appendix A. For example, drugs that can prevent miscarriage were not included as a patient safety intervention. Also, we excluded interventions on behavioral and psychosocial risks (e.g., smoking, depression, partner violence, obesity).

C (*comparators*): Another patient safety intervention or usual care.

O (*outcomes*): Patient harms (e.g. physical or mental damage or injury to the pregnant woman, fetus or newborn) that can lead to litigation (e.g. lawsuits or other legal action) and their associated costs (e.g. cost of complex intervention, litigation, settlements). We did not include outcomes that occurred after the birth of the child (e.g., psychomotor and cognitive development).

S (*study design*): Randomized clinical trials (RCTs). RCTs that used quasi-randomization methods (e.g., consecutive allocation to treatment and control groups) were excluded.

T *(timeframe)*: RCTs published in the past 10 years (i.e., January 2004 to August 2015).

Other: In addition, only RCTs published in English were eligible for inclusion, to increase the feasibility of this rapid review.

Information sources and literature search

An electronic search of the literature was conducted in MEDLINE (OVID interface), EMBASE (OVID interface), LexisNexis Academic, LegalTrac and the Legal Scholarship Network on August 13, 2015. The search was limited to RCTs (using a validated search filter) published in English in the past 10 years.

The search strategy was developed by an experienced librarian, peer-reviewed by another librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist[16], and refined through team

discussion. The general search terms were related to patient safety initiatives and obstetrical care. The final search strategy for MEDLINE can be found in Appendix B which was modified for use in the other databases, as necessary. The full search strategies for the other databases are available upon request from the last author. The searches were executed and duplicates were removed by the team's information technician.

To supplement the database results, we also searched the websites of the WHO and Canadian Medical Protective Association and scanned the reference lists of included articles for potentially relevant studies. Citations of 1 potentially relevant RCT and 2 systematic reviews identified through scanning the reference lists of included studies are provided in Appendix C.

Study selection

The search results were screened using Synthesi.SR[17], proprietary software available through the Li Ka Shing Knowledge Institute of St. Michael's Hospital.

The inclusion criteria were imported into the software as a questionnaire (Appendix D), which was used for Level 1 screening of citations (i.e., titles and abstracts) and Level 2 screening of potentially relevant full-text articles. For Level 1 screening, a single calibration exercise was conducted on a random sample of 50 citations to ensure reliability in correctly selecting studies for inclusion. All team members independently screened the citations and there were no discrepancies among reviewers (i.e. 100% agreement). The remaining search results were subsequently screened for inclusion by two reviewers independently and discrepancies were resolved by the involvement of a third reviewer.

A similar procedure was used for Level 2 screening. For this calibration exercise, 20 full-text articles were screened by the team and discrepancies among reviewers were discussed and clarified. The team established 90% agreement among all reviewers during the first calibration exercise before proceeding to screen the remaining full-text articles in duplicate. All discrepancies were resolved by the involvement of a third reviewer.

Data abstraction

Data items including RCT characteristics (e.g., author, country of conduct, study period of conduct), patient characteristics (e.g., target population, sample size), description of the patient safety interventions (e.g., case management, clinician education), and outcome results (e.g., patient harms, litigation cases, costs) were collected using a standardized data abstraction form. Two reviewers independently read each article and abstracted relevant information. Differences in abstraction were resolved by discussion and/or the involvement of a third team member.

Quality appraisal

The internal validity of the included RCTs was assessed using the 7-item Cochrane Risk of Bias tool[18]. Two reviewers independently determined the potential risk of selection, performance, detection, attrition, reporting and other (with a focus on funding bias) types of bias present in each of the included studies. All discrepancies were resolved by an independent adjudicator.

Synthesis

Findings from the included RCTs were summarized narratively. The patient and RCT characteristics, patient safety initiative information, outcomes data, and quality appraisal results for each study were reported in detail in the text, tables, and figures.

RESULTS

Literature Search

The literature search of medical and legal databases resulted in 4782 citations (Figure 1). After screening for eligibility at Level 1, 266 potentially relevant full-text articles were identified and screened at Level 2. Studies that were not RCTs with a focus on patient safety initiatives in obstetrics or not published in the last 10 years and not written in English were excluded. As a result, we included 8 relevant RCTs in this rapid review.

Study Characteristics

The study characteristics of the 8 included RCTs are presented in Table 1. Although all RCTs were published in the last 10 years, the eight included RCTs were conducted between the years 1982 and 2011 in Argentina and Uruguay[19], Australia[20], Canada[21], Ireland[22], Senegal and Mali[23], and the United States[24-26]. The RCTs were all publicly funded and included over 400,000 patients in total. Three trials were randomized at the patient level (RCTs)[20,22,24], while 5 were randomized at the hospital or obstetrics unit level (cluster-RCTs)[19,21,23,25,26].

Patient Characteristics

The target populations for each of the included RCTs are described in Appendix E. Two RCTs targeted patient safety initiatives to pregnant women alone[20,22] while one study involved the care of pregnant women and children up to 2 years of age[24]. All of the included cluster-RCTs described interventions aimed at health care providers like clinicians, nurses, midwives and other obstetrical care workers[19,21,23,25,26].

Quality Appraisal

The quality of the included studies was found to be good overall (Figure 2). All 8 studies had low risk of bias with regards to participant and outcome assessor blinding. This was because the outcomes they examined were objective (e.g., mortality, blood loss). As they were all publicly funded, the category of other bias was ranked low across the studies as well. Five of the studies (63%) were assigned a low risk of bias on random sequence generation, incomplete outcome reporting and selective reporting biases. Allocation concealment was the least discernible component of bias as one study was assessed as high risk, one as low risk and the remaining 6 as unclear risk of bias in this category.

Intervention Characteristics

The included complex patient safety interventions, described in Appendix F, were grouped into 7 categories: provider education, provider education with clinician reminders, provider education with team changes, provider education with audit and feedback, case management, case management with team changes and patient education, and case management with team changes and financial incentives. The five studies that described provider education were aimed at improving health care workers knowledge and understanding of obstetrical care, mainly through the use of interdisciplinary training workshops and progress reports[19,21,23,25,26]. In addition to education, a system of reminders for health care workers was implemented in one of the studies[19] and changes in team structure incorporated in another[25]. Chaillet and colleagues[21] describe a cluster-RCT focused on provider education through the implementation of audit and feedback cycles in order to reduce the number of maternal and neonatal adverse events. Case management was described in three trials. In a study by Begley and colleagues[22], midwives provided targeted care before, during and immediately after childbirth to ensure patient safety, while in a study by Lumley and colleagues[20], women were provided support from pre-pregnancy to childbirth, in addition to

education and referrals to specialists, as needed. Olds et al[24] described a multi-arm intervention in which all women received financial incentive by way of free transportation; a subgroup of these women were offered referrals to other specialists (team changes), and another subgroup was offered home visits for the mother and infant after birth (case management).

Outcomes by Intervention

Although we searched for litigation and cost-related outcomes, the studies included in our review only addressed maternal and neonatal patient harms. The findings of each study will be presented by intervention category, as described above and are presented in Table 2. All of the outcomes from each of the included studies can be found in Appendix G.

Provider Education (n=2)

The impact of team and staff training was evaluated in a RCT published by Riley and colleagues in 2011[26]. Labor and delivery staff received interdisciplinary team training to improve nontechnical skills in an attempt to improve patient care. Three hospitals were compared in this trial: one control (no intervention), one using didactic training only, and one full intervention hospital (didactic training with patient simulations). The didactic program was based on an evidence-based teaching plan with a focus on leadership, situation monitoring, mutual support and communication. The full intervention group also received this training, and managed simulated patients from triage through labor and recovery with the opportunity to practice skills and take part in debriefing sessions throughout.

Trends were analyzed for four years after implementation of the intervention, and there were no statistically significant differences in the pre- and post-intervention results in the hospitals administering the control and didactic programs on the WAOS (including 10 adverse outcomes). However, the full intervention hospital reported a statistically significant change in WAOS score, suggesting that a complex intervention including didactic training with situational simulation can improve the safety of obstetrical patients. Regarding the risk of bias, this RCT had an unclear risk of bias on random sequence generation, incomplete outcome reporting, selective reporting bias, and allocation concealment. The other risk of bias item was assessed as being at a low risk.

Earlier this year, Zongo et al[23] reported the effects of a complex intervention involving training on maternal mortality, opinion leaders, educational outreach and audits (death reviews) in a cluster-RCT. The intervention arm was broken into two components. To begin, one physician and one midwife from each of the 23 hospitals (including 95,931 patients) attended a workshop for 6 days where they were trained in evidence-based clinical practice and the clinical audit process. These opinion leaders returned to their respective hospitals and launched maternal death reviews and on-site training workshops, including quarterly educational outreach visits. The control arm was made up of 95,236 patients in 23 hospitals that did not receive any intervention from the research team.

Outcomes assessed at baseline and after 4 years of follow-up on a total of 191,157 patients found that maternal death reviews and on-site training may be beneficial in certain populations. Compared to the control group, the intervention arm resulted in better maternal mortality rates overall. Within the intervention group, women with caesarean deliveries experienced a statistically significant reduction in maternal deaths due to hemorrhage, puerperal infections or sepsis and uterine rupture when compared to those in the control group. This RCT had low risk of bias on all outcomes except random sequence generation and allocation concealment which were both scored as unclear risk of bias using the quality appraisal tool.

Provider Education with Clinician Reminders (n=1)

Althabe et al. 2008[19] published a cluster-RCT exploring a multi-component behavioral intervention including use of opinion leaders, staff training, and staff reminders. Ten hospitals reporting 2114

deliveries acted as the treatment arm. Opinion leaders (physicians, residents, or midwives) from each hospital were selected to attend a 5-day guideline development workshop. Here they focused on critical evaluation of the literature, development of practice guidelines, communication skills, and how to conduct interviews with hospital birth attendants regarding their views on implementation of the intervention. Once these opinion leaders returned to their hospitals, they conducted a workshop to share the new guidelines, train staff, and introduce a system of reminders. Each month, outcome reports were produced and a regional coordinator met with each team of opinion leaders. Nine hospitals with 2185 vaginal deliveries formed the control group and received no intervention besides the standard in-service training.

The outcomes of interest were assessed at baseline and at 18 months in 5,466 patients. When looking specifically at the adverse events to patient, there was a statistically significant reduction in postpartum hemorrhage and blood loss in the intervention arm. Maternal death, maternal admission to the intensive care unit, neonatal death, stillbirths, or Apgar score<4 did not result in a significant difference. An unclear risk of bias was associated with random sequence generation and allocation concealment, while incomplete outcome reporting, selective reporting bias and the other risk of bias items were assessed as being at low risk of bias.

Provider Education with Team Changes (n=1)

Nielsen and colleagues[25] evaluated the effect of staff teamwork training on adverse outcomes in labor and delivery units in a cluster-RCT. Teamwork training was administered in two parts. First, selected clinical staff from 7 hospitals attended a 3 day comprehensive session on teamwork including didactic lessons, video scenarios, interactive training on team structure, problem-solving, communication, workload management, team skills, implementation, and conflict resolution. The trained representatives subsequently returned to their home hospitals to conduct onsite training sessions for 1307 staff members and to structure each unit into core work teams (e.g. nurses, physicians, hospital staff), coordinating teams (i.e. supervisors, clinical leaders, resource personnel) and a multidisciplinary contingency team (i.e. experienced physicians and nurses trained to respond to emergencies). Usual care was provided at 8 control hospital sites.

Analysis was conducted on 28,536 deliveries. The occurrence of individual adverse events of interest was rare, therefore an index measure called the Adverse Outcome Index (AOI) was used. The AOI was equivalent to the proportion of patients with one or more adverse outcomes. Another summary measure called the Weighted Adverse Outcome Score (WAOS) was also used to consider not just the number but also the relative severity of the included adverse outcomes. Some of the adverse events considered in these scores included maternal death, neonatal death, uterine rupture, maternal admission to the ICU, unplanned admission to the NICU, Apgar score <7, and birth trauma. However, no statistically significant differences between groups were observed in these two outcomes or any of the individual adverse outcomes assessed. The risk of bias for this trial was deemed low for all items except allocation concealment, which had an unclear risk of bias.

Provider Education with Audit and Feedback (n=1)

A recently published cluster-RCT by Chaillet et al (2015)[21] conducted across 32 hospitals in Quebec assessed the effect of a multifaceted strategy including staff education, educational outreach and audit and feedback to promote professional onsite training. The intervention involved on-site training, education outreach visits by external facilitators, four 3 month audit and feedback cycles, and post-intervention clinical audits without supervision. The audit and feedback cycles were used to collect and analyze information on recent caesarean deliveries, make recommendations and present formal feedback to health professionals. No intervention was administered to the 16 hospitals of the control arm.

During the 2 year intervention and follow-up period, there were 105,351 deliveries included in the trial. The primary outcome was the number of caesarean births, which showed a small, yet statistically significant reduction in the intervention arm (p=0.04). The intervention group also had statistically

significantly lower major neonatal morbidity (p=0.03) and a statistically smaller increase in minor neonatal morbidity (p<0.001) when compared to the control group. There were no significant differences between groups in maternal morbidity. Overall, this patient initiative was successful in improving safety of the mother and newborn. Regarding the risk of bias, this RCT had a low risk of bias across all components of the assessment tool except allocation concealment, which was unclear.

Case Management (n=1)

In 2011, Begley and colleagues[22] conducted a RCT comparing midwife-led (MLU) care versus consultant-led (CLU) care for 1653 pregnant women aged 16-40 years. The MLU intervention involved care by a team of 19 midwives from before 24 weeks of pregnancy to 7 days after childbirth. Midwives on the hospital and outreach units provided assessments and care during the antenatal and neonatal periods, and followed-up with new mothers through home visits and phone calls during the postpartum period. Women in the CLU received standard care by obstetricians, general practitioners, midwives and other hospital staff from 24 weeks of pregnancy to 2 days after childbirth.

There were no statistically significant differences between the two models of care in many of the maternal primary (e.g., Apgar scores<8, postpartum haemorrhage) and secondary (e.g., at least one antenatal admission, pregnancy complications, fetal loss before 24 weeks, estimated mean blood loss) safety outcomes. Similarly, the number of neonatal adverse events including bag-and mask resuscitation, admission to special care baby units, and early neonatal death did not significantly differ statistically between the groups. As such, the mid-wife led care model was found to be as safe as the consultant-led care model. Regarding the risk of bias, this RCT was consistently assessed as low risk of bias across all components.

Case management with Team Changes and Patient Education (n=1)

Lumley et al (2006)[20] conducted a RCT to assess the impact of a pre-pregnancy advice/counseling service (initiated by two obstetricians) on the well-being of second-born children. The intervention consisted of 6 steps taken by women shortly after the birth of their first child. A midwife worked with 392 women to identify social, health and lifestyle problems, help plan for her next pregnancy, offer referrals to specialists (e.g., dietician, physiotherapist, family planning clinic) as needed, take a family/genetic history, arrange for rubella immunization, and discuss signs to follow before pregnancy. A total of 394 participants in the control arm received a home visit from the midwife with a discussion of their first pregnancy, labor and postpartum experience, and were given the opportunity to ask questions.

Outcomes were assessed after the birth of the second child. Infants born to mothers who received counseling were more likely to be of lower birth weight than those who did not, and there were no differences between the groups in secondary outcomes such as perinatal deaths and congenital malformations. Overall, this pre-pregnancy intervention did not show a statistically significant benefit over the control. With respect to risk of bias assessment, this RCT had a low risk of bias on random sequence generation and the other risk of bias items including unclear risk of selective reporting bias, and high risk of bias on both allocation concealment and incomplete outcome data.

Case Management with Team Changes and Financial Incentives (n=1)

A RCT was conducted to determine the effect of prenatal and infant home visits by nurses on maternal and child mortality by Olds et al (2014)[24]. Participants, mostly African-American women residing in very poor neighborhoods, were randomized to one of four treatment arms during pregnancy and were followed for 2 years. Each treatment arm built upon the one before it. In treatment 1, 166 women received free transportation for prenatal appointments. In addition to transport, 514 treatment 2 women also received developmental screening and referral services for their children. The third treatment arm including 230 women added nurse home visits during pregnancy as well as 2 postpartum home visits, while 228 treatment 4 women received the most comprehensive intervention with transport, screenings, nurse home visits during pregnancy and until the child was 2 years old.

Maternal and infant mortality outcomes were collected for all treatment arms after two years of follow-up. Participants with free transport and screening (treatment 2) had the most natural (i.e. disease-related), external (i.e. injuries, suicide, drug overdose, homicide) and total maternal deaths of all women. In addition, the combined control arm (treatment 1 + treatment 2) had more natural, preventable, and total infant deaths when compared to treatment 3 and 4 combined. Survival curves were created for each of the treatment arms. When projecting to 21 years after randomization, all-cause mortality in mothers was statistically significantly higher in treatment 1 + treatment 2 when compared to treatment 3 alone (p=0.007) or when compared to treatment 3 + treatment 4 combined (P=0.008). Random sequence generation and other risk of bias items were appraised as low for this RCT, while allocation concealment, incomplete outcome data and selective reporting bias were unclear.

DISCUSSION

We conducted a rapid review and identified 8 RCTs written in English and published in the past 10 years on complex interventions that can be used to improve patient safety in obstetrics. Although the included RCTs were published in the past 10 years, their conduct was between 1982 and 2011. Only one of the RCTs was conducted in a low-income and a low-to-middle income economy country[23]. The remainder of the RCTs were conducted in high-income economy countries, suggesting that our results are may only be generalizable to countries with high-income economies but the interventions should be considered in LMICs to determine if they are potentially feasible.

The RCTs focused on a variety of quality improvement strategies, ranging from patient education to audit and feedback. The interventions were targeted at patents, while the cluster-RCTs involved interventions directed towards heath provider training. The most commonly examined intervention was provider education. This is likely because the provider has a great influence on the impact of maternal and infant morbidity and mortality within obstetrics. This was followed by patient education, which is a common quality improvement strategy due to the ease of implementation and low cost.

There are some quality improvement strategies that are promising for obstetrical patients. Results from 1 RCT indicated that a financial incentive, team change, and case management may improve patient safety. As well, audit and feedback and provider education improved patient safety in another RCT compared to usual care. Finally, provider education may improve patient safety, which was found to improve outcomes in most of the RCTs that assessed this intervention. A future systematic review should be conducted on this topic to determine the definitive conclusion on whether these interventions are indeed effective and cost-effective. Such a systematic review can include a meta-analysis of the quality improvement strategies versus usual care, which will allow the quantification of the effectiveness of these interventions. However, such a meta-analysis is challenging, as significant heterogeneity is expected between the studies regarding the delivery and implementation of the quality improvement strategies examined, hampering the interpretation of results.

Although the overall ROB was adequate, there were several limitations identified by the authors of each of the included studies (Appendix F) to be considered when interpreting the findings of these studies. Some of the main concerns revolved around the study of complex interventions using cluster-RCTs. For example, the inconsistent administration and implementation of the patient safety initiatives across settings is unavoidable, especially in the cluster-RCT setting, where each hospital acts as an independent unit. In these cases, consideration should be made of possible confounding effects as a result of the hospital setting and care practices. Blinding of participants and outcome assessors is also difficult to maintain in cluster-RCTs, however many of the outcomes in these studies are of an objective nature (e.g., maternal and neonatal deaths) and therefore the lack of blinding may not significantly impact the results. In addition, it was a challenge to distinguish which aspects of the included mutli-faceted interventions directly contributed to the observed effects across the included RCTs.

In addition to the limitations of the included RCTs, there are some limitations to our rapid review. In order to conduct this within the 6-week time frame, we limited our review to RCTs published in English in the past 10 years. As such, our results are only generalizable to published RCTs in the past 10 years in English. We did not search for unpublished studies and our results might be influenced by publication bias. However, these are quality improvement strategy interventions and may not be as influenced by publication bias as other types of interventions, such as drugs, where most of the RCTs are funded by private industry. Indeed, all of our included RCTs were publicly-funded. As well, we were unable to include an additional potentially relevant RCT that was identified through scanning the reference lists, due to the short timeline for this rapid review. These will be assessed for eligibility at a later date, as we are planning to publish a paper on our rapid review results in the Systematic Reviews journal.

In conclusion, we identified 8 RCTs that assess the effectiveness of patient safety initiatives within obstetrics. The results suggest that some interventions might be more effective than others (e.g., combination of financial incentive, team change, and case management; audit and feedback and provider education; provider education) in improving patient outcomes. A future systematic review could be conducted, including a meta-analysis, to provide more definitive conclusions.

ACKNOWLEDGEMENTS

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS. *To err is human:: building a Safer Health System.* Vol 6: National Academies Press; 2000.
2. Organization WH. Guide for Developing National Patient Safety Policy and Strategic Plan. 2014.
3. Pronovost PJ, Holzmueller CG, Ennen CS, Fox HE. Overview of progress in patient safety. *American journal of obstetrics and gynecology.* 2011;204(1):5-10.
4. American College of Obstetricians Gynecologists. Patient safety in obstetrics and gynecology. ACOG Committee Opinion No. 447. *Obstet Gynecol.* December 2009 2009;114:1424-1427.
5. World Health Organization. Topic 1: What is patient safety. *WHO Patient Safety Curriculum Guide for Medical Schools* http://www.who.int/patientsafety/education/curriculum/who_mc_topic-1.pdf?ua=1. Accessed September 2015.
6. Agency for Healthcare Research and Quality. Patient Safety. *Glossary* https://psnet.ahrq.gov/glossary/p. Accessed September 2015.
7. Pettker CM, Thung SF, Lipkind HS, et al. A comprehensive obstetric patient safety program reduces liability claims and payments. *American journal of obstetrics and gynecology.* 2014;211(4):319-325.
8. National Conference of State Legislatures. Medical malpractice reform. *Health Cost Containment and Efficiencies NCSL, Briefs for State Legislators. Vol 16* October 2011; 71-74. Available at: http://www.ncsl.org/documents/health/IntroandBriefsCC-16.pdf. Accessed July 2015.
9. Knox GE, Simpson KR, Garite TJ. High reliability perinatal units: an approach to the prevention of patient injury and medical malpractice claims. *Journal of Healthcare Risk Management.* 1999;19(2):24-32.
10. NHS Litigation Authority. Ten years of maternity claims-an analysis of NHS litigation authority data. *London: NHS Litigation Authority.* 2012.
11. Pronovost PJ, Miller MR, Wachter RM. Tracking progress in patient safety: an elusive target. *Jama.* 2006;296(6):696-699.
12. Pronovost PJ, Colantuoni E. Measuring preventable harm: helping science keep pace with policy. *Jama.* 2009;301(12):1273-1275.
13. Ganann R, Ciliska D, Thomas H. Expediting systematic reviews: methods and implications of rapid reviews. *Implementation Science.* 2010;5(1):56.
14. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of internal medicine.* 2009;151(4):264-269.
15. Stone P. Popping the (PICO) question in research and evidence-based practice. *Appl Nurs Res.* 2002;15:197-198.
16. Sampson M, McGowan J, Cogo E, Grimshaw J, Moher D, Lefebvre C. An evidence-based practice guideline for the peer review of electronic search strategies. *Journal of clinical epidemiology.* Sep 2009;62(9):944-952.
17. Knowledge Translation Program. Synthesi.SR. 2014; http://knowledgetranslation.ca/sysrev/login.php. Accessed September 2015.
18. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *Bmj.* 2011;343:d5928.
19. Althabe F, Buekens P, Bergel E, et al. A behavioral intervention to improve obstetrical care. *New England Journal of Medicine.* 2008;358(18):1929-1940.
20. Lumley J, Donohue L. Aiming to increase birth weight: a randomised trial of pre-pregnancy information, advice and counselling in inner-urban Melbourne. *BMC Public Health.* 2006;6(1):299.
21. Chaillet N, Dumont A, Abrahamowicz M, et al. A Cluster-Randomized Trial to Reduce Cesarean Delivery Rates in Quebec. *New England Journal of Medicine.* 2015;372(18):1710-1721.
22. Begley C, Devane D, Clarke M, et al. Comparison of midwife-led and consultant-led care of healthy women at low risk of childbirth complications in the Republic of Ireland: a randomised trial. *BMC pregnancy and childbirth.* 2011;11(1):85.

23. Zongo A, Dumont A, Fournier P, Traore M, Kouanda S, Sondo B. Effect of maternal death reviews and training on maternal mortality among cesarean delivery: post-hoc analysis of a cluster-randomized controlled trial. *European Journal of Obstetrics & Gynecology and Reproductive Biology.* 2015;185:174-180.
24. Olds DL, Kitzman H, Knudtson MD, Anson E, Smith JA, Cole R. Effect of home visiting by nurses on maternal and child mortality: Results of a 2-decade follow-up of a randomized clinical trial. *JAMA pediatrics.* 2014;168(9):800-806.
25. Nielsen PE, Goldman MB, Mann S, et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. *Obstetrics & Gynecology.* 2007;109(1):48-55.
26. Riley W, Davis S, Miller K, Hansen H, Sainfort F, Sweet R. Didactic and simulation nontechnical skills team training to improve perinatal patient outcomes in a community hospital. *Joint Commission Journal on Quality and Patient Safety.* 2011;37(8):357-364.

Figure 1. Study Flow

```
Record Identification

  Medline and            LexisNexis Academic,        Websites and
  EMBASE                 Legal Scholarship           other sources
  databases              Network, LegalTrac          (n = 9)
  (n=4573)               (n=200)

              Records after duplicates removed
                       (n =4782)


Level 1 screening

  Records screened    →    Records excluded
  (n =4782)                (n =4516)


Level 2 screening

  Full-text assessed for   →   Full-text articles
  eligibility                  excluded
  (n = 266)                    (n=258)


Included

  Studies included for data abstraction
  (n=8)
```
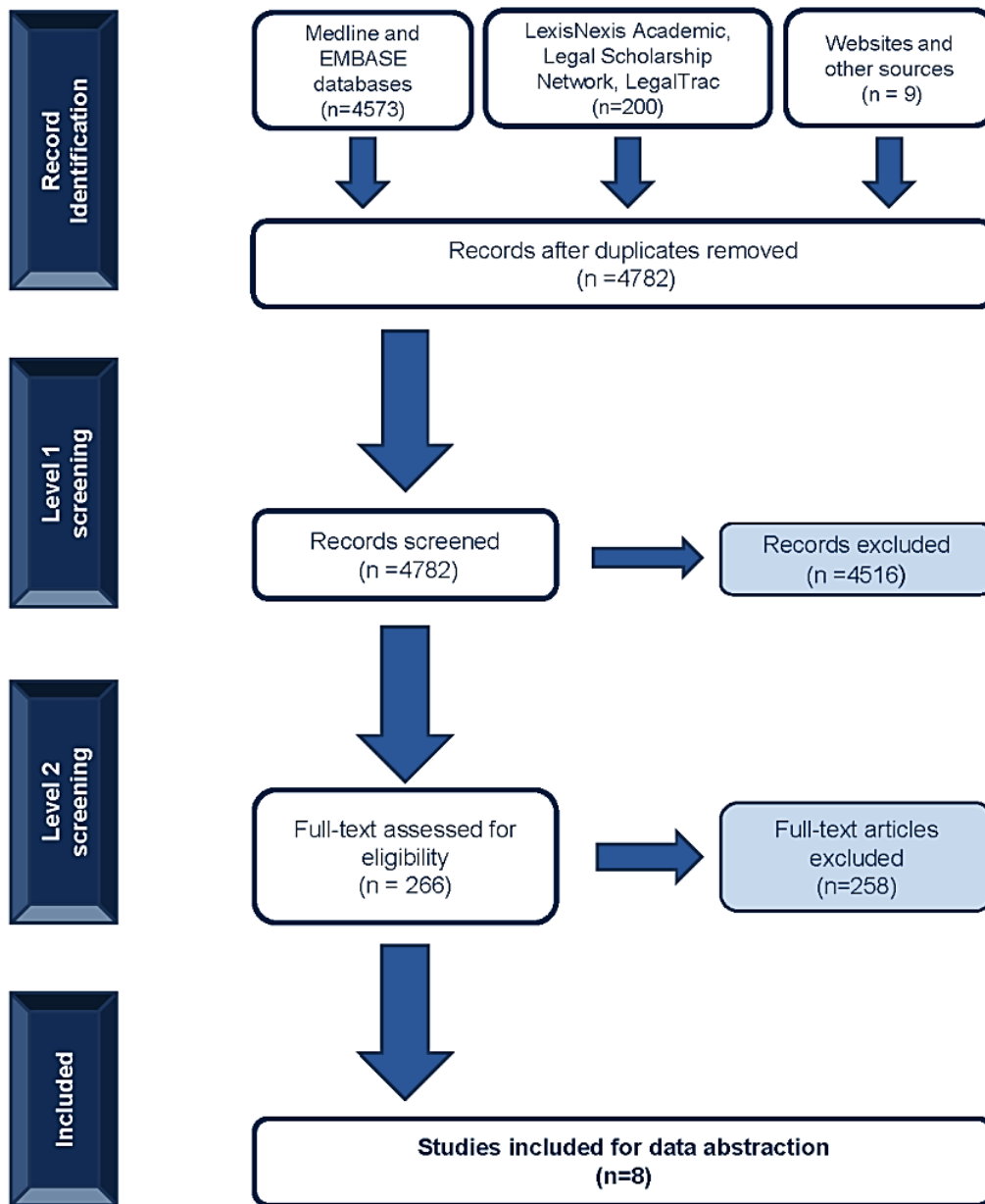
Table 1. Characteristics of included studies

First Author, Year	Country of conduct	Study Discipline	Funding Type	Study design	Study Period	# of Participants (ITT)
Begley, 2011[22]	Ireland	Obstetrics & Gynecology	Publicly Funded	RCT	July 2004 to June 2007	1,653
Lumley, 2006[20]	Australia	Public, Environmental & Occupational Health	Publicly Funded	RCT	May 1982 to December 1994	786
Olds, 2014[24]	USA	Pediatrics	Publicly Funded	RCT	June 1990 to December 2011	1,138
Althabe, 2008[19]	Argentina, Uruguay	Medicine, General & Internal	Publicly Funded	cluster RCT	September 2003 to December 2005	5,466
Chaillet, 2015[21]	Canada	Medicine, General & Internal	Publicly Funded	cluster RCT	April 2008 to October 2011	184,952
Nielsen, 2007[25]	USA	Obstetrics & Gynecology	Publicly Funded	cluster RCT	December 2002 to March 2004	1,307 personnel; 28,536 deliveries
Riley, 2011[26]	USA	Public, Environmental & Occupational Health	Publicly Funded	cluster RCT	2005 to 2008	NR
Zongo, 2015[23]	Senegal, Mali	Obstetrics & Gynecology	Publicly Funded	cluster RCT	2007 to 2011	191,167

Abbreviations: RCT randomized clinical trial, USA United States of America, NR not reported, ITT intention-to-treat
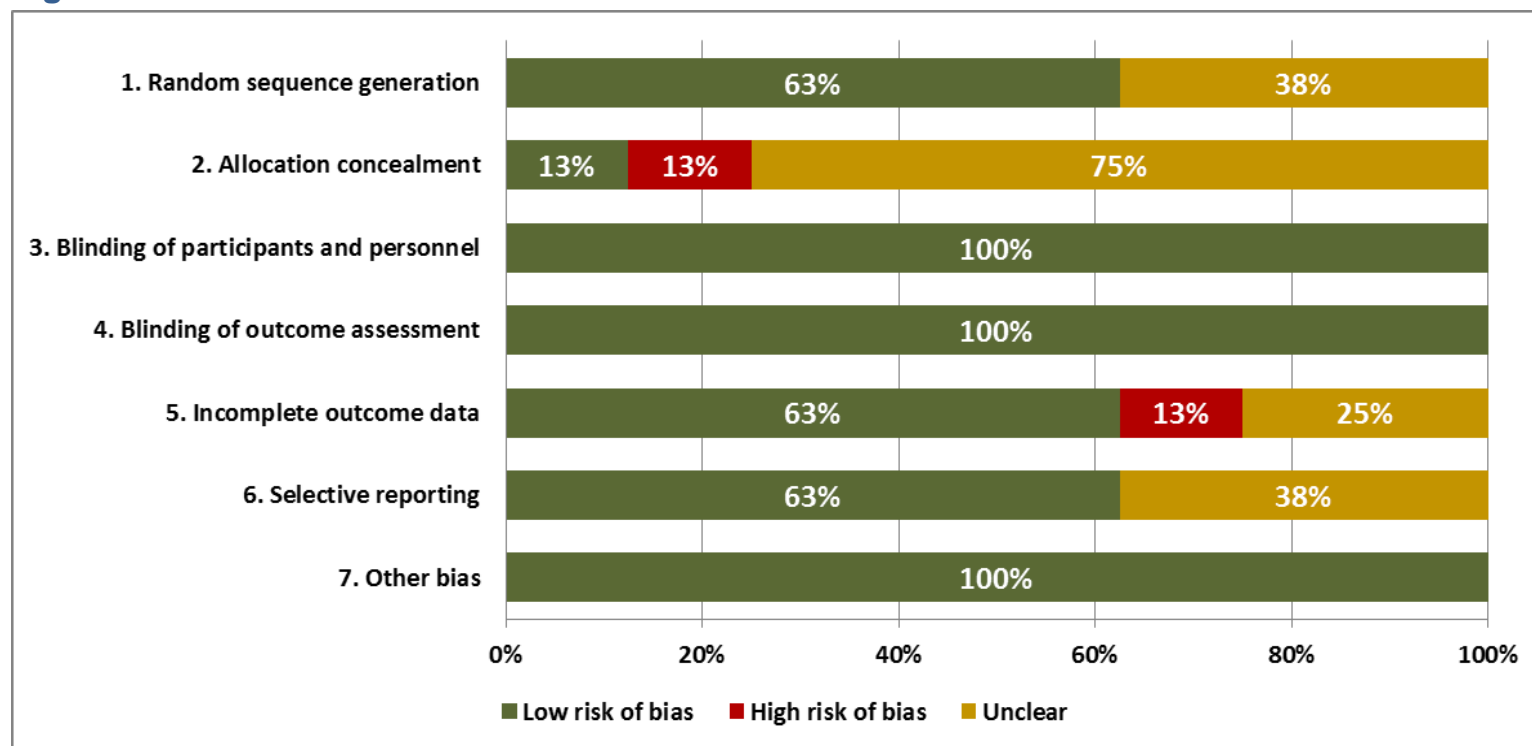
Table 2. Primary Patient Harms Outcomes

First Author, Year	Population and Sample	Intervention	Clinical Patient Harms Result
Randomized Controlled Trials (n=3)			
Begley, 2011[22]	Pregnant women 16-40 years of age Sample size of women (tx vs. control): 1,101 vs. 552	tx: midwife-led (MLU) care control: consultant-led (CLU) care	*MLU vs. CLU* Apgar scores < 8: 10 (0.9%) vs. 9 (1.6%), RR 0.56 (95% CI 0.23, 1.36); Postpartum haemorrhage (PPH): 144(13.1%) vs. 75 (13.6%), RR 0.96 (95% CI 0.74, 1.25); At least one antenatal admission: 487 (44.2%) vs. 229 (41.5%), RR 1.07 (95% CI 0.95, 1.20); Experienced any pregnancy complication: 248 (22.5%) vs. 110 (19.9%), RR 1.13 (95% CI 0.93, 1.38); Fetal loss before 24 weeks: 17 (1.54%) vs. 5 (0.91%), RR 1.70 (95% CI 0.63, 4.60); Estimated mean blood loss: 323 mls (SD 317) vs. 324 mls (SD 401), MD 6.17 (95% CI-32.12, 44.46); Bag-and-mask resuscitation: 23 (2.1%) vs. 12 (2.2%), RR 0.96 (95% CI 0.48, 1.92); Admission to special care baby unit (SCBU): 128 (11.6%) vs. 60 (10.9%), RR 1.07 (95% CI 0.80, 1.43); Early neonatal deaths: 2(0.18%) vs. 2(0.36%); Fetal loss >24 weeks: 1(0.1%) vs. none; Perinatal mortality rates: 2.76 vs. 3.66 per 1,000 live and still-births; Maternal deaths: none
Lumley, 2006[20]	Pregnant women and newborns Sample size of women (tx vs. control):392 vs. 394	tx: pre-pregnancy health intervention group control: usual care	There were seven known perinatal death among the second births, four associated with birth defects and three infants born extremely preterm, including one set of twins.. Infants known to have birth anomalies included two with anencephaly, one with major multiple malformations (not specified), one with multiple heart defects and an absent right kidney, one with a ventricular septal defect, one with aniridia, one with Hirschsprung's disease and one with a fetal heart defect, not otherwise described, and congenital heart block. Five infants with a birth anomaly were in the intervention arm, two in the comparison arm, a combined prevalence of 8.8/1000. The perinatal mortality in the trial was 8.9/1000 births. The perinatal mortality in the State of Victoria (1983–1992) was 8.8/1000 births.

First Author, Year	Population and Sample	Intervention	Clinical Patient Harms Result
Olds, 2014[24]	Pregnant women and newborns Sample size (tx1 vs. tx2 vs. tx3 vs. tx4): 166 vs. 514 vs. 230 vs. 228	tx 1: Transportation for prenatal care, tx 2: Screening and referral for children, tx 3: Prenatal/postp artum home visiting, tx 4: Infant and toddler home visiting	*Maternal deaths (number) tx1 vs. tx2 vs. tx3 vs. tx4* Natural (disease related) 5 vs. 11 vs. 1 vs. 4; External (injuries, suicide, drug overdose, homicide): 0 vs. 11 vs. 0 vs. 1; Total deaths: 5 vs. 22 vs. 1 vs. 5 *Maternal deaths survival curves [mean(SE)} tx1+ tx2 vs. tx3 vs. tx4* All-cause: 3.7(0.74) vs. 0.4 (0.43) vs. 2.2 (0.97) *Child deaths (number) tx1 + tx2 vs. tx3 + tx4* natural (disease related): 5 vs. 2; preventable (SIDS, unintentional injuries, homicide): 9 vs. none; total deaths: 14 vs. 2
Cluster - Randomized Controlled Trials (n=5)			
Althabe, 2008[19]	Pregnant women and newborns sample size (tx vs. control): 2114 vs. 2185	tx: selection of opinion leaders, guideline development workshops, dissemination of the guidelines, clinical management skills for delivery care workshop, implementatio n and maintenance of guidelines, coordination visits; control: usual care	The intervention was associated with a statistically significant reduction in all postpartum hemorrhage indicators — the rate of postpartum hemorrhage of 500 ml or more, the rate of postpartum hemorrhage of 1000 ml or more, and the mean amount of postpartum blood loss. *Intervention effect: Ratio of median rate ratios (95% CI), p-value* Postpartum hemorrhage ≥1000ml (%):0.3 (0.22 to 0.84), p=0.007 Postpartum blood loss (ml): -121.9 (-151.1 to -52.3), p<0.001 Stillbirths (%): 1.19 (0.44 to 2.26), p=0.78 5-min Apgar score <4 (%): 1.86 (0.53 to 2.54), p=0.25 Neonatal death (no): 1.09 (0.55 to 2.55), p=0.78 Maternal admission to the intensive care unit (no): - median baseline rate 3 vs. 1; - median post-intervention rate 3 vs. 3; Maternal death (no): - median baseline rate 1 vs. 1; - median post-intervention rate 1 vs. 1;

First Author, Year	Population and Sample	Intervention	Clinical Patient Harms Result
Chaillet, 2015[21]	Pregnant women and newborns Sample size (tx vs. control): 84, 227 vs. 100,725 pregnant women 105,351 total deliveries	tx: on-site training, educational outreach visits by external facilitators, audit and feedback, post-intervention clinical audits without supervision control: usual care	*major neonatal morbidity: adjusted OR 0.81 (95% CI 0.66, 0.98; P = 0.03);* Tx: (N; %) baseline:1172 (4.7) post-intervention:1070 (4.5) (p=0.03) Cx: (N; %) baseline:1,018 (3.5) post-intervention:1,156 (4.0) *minor neonatal morbidity: adjusted OR 0.88 (95% CI 0.82, 0.94; P<0.001);* Tx: (N; %) baseline:3936 (15.9) post-intervention:4261 (17.8) (p<0.001) Cx: (N; %) baseline:3947 (13.6) post-intervention:5002 (17.1) *Minor maternal complications* Tx: (N; %) baseline:3293 (13.5) post-intervention:3576 (15.2) (p=<0.76) Cx: (N; %) baseline:3869 (13.5) post-intervention:4244 (14.7) *Major maternal complications* Tx: (N; %) baseline:161 (0.66) post-intervention:167 (0.71) (p=<0.71) Cx: (N; %) baseline:138 (0.48) post-intervention:141 (0.49) *Neonatal major trauma* [int vs. cont] ARD −0.23%; 95% CI, −0.40 to −0.01; P = 0.046 *Use of invasive mechanical ventilation* [int vs. cont] ARD −0.38%; 95% CI, −0.60 to −0.09; P = 0.01) *Intrapartum and neonatal deaths* [int vs. cont] ARD −0.06%; 95% CI, −0.08 to −0.03; P<0.001 Rate of blood transfusion: adjusted OR 1.70 (95% CI 1.18, 2.43; P = 0.004)
Nielsen, 2007[25]	Pregnant women and newborns sample size: 1,307 personnel, 28,536 deliveries analyzed	tx 1: instructor-training sessions; on-site training sessions for staff; control: usual care	There were no statistically significant differences between the intervention and control arms for any individual or index measure at baseline. Mean Adverse Outcome Index (%): 8.3 vs. 7.2, ICC 0.015 (95% CI -5.6, 3.2) Mean Weighted Adverse Outcome Score: 2.7 vs. 2.3, ICC 0.008 (95% CI -3.4, 1.4) Mean Severity Index: 31.9 vs. 30.6, ICC 0.017 (95% CI −23.0, 7.0) 3rd-4th degree perineal laceration after vaginal delivery: mean 4.5% (range 3.1–5.4) vs. mean 5.0% (range 1.3–10.0) Unplanned admission to the NICU: mean 4.1% (range 0.2–10.0) vs. mean 4.5% (range 0-19.2)

First Author, Year	Population and Sample	Intervention	Clinical Patient Harms Result
Riley, 2011[26]	Pregnant women and newborns sample size (tx vs. control): patients in one hospital vs. patients another hospital	tx: didactic training, in-situ simulation; control: usual care	Weighted Adverse Outcomes Score (WAOS) *Full Intervention, mean(SD)* [p<0.05] pre-intervention: 1.15 (0.47) vs. post-intervention: 0.72 (0.12); % change: 37.4% *Didactic only, mean (SD)* pre-intervention: 1.46 (1.05) vs. post-intervention: 1.45 (0.82); % change: 1.0% *Control, mean (SD)* pre-intervention: 1.05 (0.79) vs. post-intervention: 1.50 (0.35); % change: 42.7%
Zongo, 2015[23]	Pregnant women with caesarean vs. vaginal deliveries sample size: 95931 patients in 23 hospitals vs. 95236 patients in another 23 hospitals	tx: initial training, trainees as opinion leaders; control: usual care	*Caesarean, Intervention vs. Control [number of maternal deaths (%)]* Hemorrhage, baseline: 65(29.4) vs. 51(31.1), year 4: 65(39.6) vs. 58(32.2); Puerperal infections/sepsis baseline: 32(14.5) vs. 11(6.7), year 4: 11(6.7) vs. 12(6.7); Uterine rupture baseline: 27(12.2) vs. 21(12.8), year 4: 15(9.1) vs. 15(8.3) *Vaginal delivery, Intervention vs. Control [number of maternal deaths (%)]* Hemorrhage, baseline: 79(35.3) vs. 60(34.7), year 4: 57(29.7) vs. 70(34.8) Puerperal infections/sepsis baseline: 9(4.0) vs. 4(2.3), year 4: 10(5.2) vs. 14(7.0) Uterine rupture baseline: 5(2.2) vs. 4(2.3), year 4: 9(4.7) vs. 9(4.5)
Abbreviations: Tx treatment/intervention arm, Cx control are or usual care, vs. versus, RR relative risk or risk ratio, OR odds ratio, SD standard deviation, MD mean difference, CI confidence interval, ARD adjusted risk difference, ICC intracluster correlation coefficient			

Figure 2. Risk of Bias of Included Randomized Clinical Trials

Author, Year	1. Random sequence generation	2. Allocation concealment	3. Blinding participants and personnel	4. Blinding outcome assessor	5. Incomplete outcome data	6. Selective reporting	7. Other bias
Begley, 2011[22]	L	L	L	L	L	L	L
Chaillet, 2015[21]	L	U	L	L	L	L	L
Lumley, 2006[20]	L	H	L	L	H	U	L
Nielsen, 2007[25]	L	U	L	L	L	L	L
Olds, 2014[24]	L	U	L	L	U	U	L
Riley, 2011[26]	U	U	L	L	U	U	L
Althabe, 2008[19]	U	U	L	L	L	L	L
Zongo, 2015[23]	U	U	L	L	L	L	L

Appendix A. Complex Interventions

Complex interventions are important to resolve the common, complex challenges in health care. Quality improvement strategies are considered complex interventions. Complex interventions require detailed descriptions of the intervention to enable researchers to replicate the study, synthesize the results, and implement findings. However, details of complex interventions are often underreported in research. A falls prevention program for seniors is an example of a complex intervention because it often has more than one interacting component administered within the intervention group. For example, the intervention group may receive exercise training with a physiotherapist (exercise training), the physiotherapist may receive training to administer the program specifically to elderly patients (clinician education), and the patients may receive education about falling (patient education). These interventions are challenging to deliver or receive, target more than one level of organization (e.g., both the patient and healthcare provider levels), include multiple dosages and formulations, and allow for the tailoring of interventions across settings (e.g., physiotherapist uses slightly different approaches for different patients in the intervention group).

Examples of QI strategies targeting health systems	
Case management	Any system for coordinating diagnosis, treatment, or routine management of patients (e.g., arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician. If the study called the intervention "case management" we classified it as such.
Team changes	Changes to the structure or organization of the primary health-care team (adding team member, multidisciplinary teams, expansion or revision of professional roles)
Electronic patient registry	General electronic medical record system or electronic tracking. Do not include websites unless patients were tracked over time. To qualify, it had to be a part of the clinical trial as an intervention (i.e., not pre-existing infrastructure unless used more actively)
Facilitated relay of info to clinicians	Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record (excluding conventional means of correspondence between clinicians.)
Continuous QI	Interventions explicitly identified as involving the techniques of continuous QI, total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their effects, and then reassessing the need for further action
Examples of QI strategies targeting health-care providers	
Audit & feedback	Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which was then transmitted back to the clinician. This strategy was strictly based on clinical data and excluded clinical skills. It could include the number of patients with missing tests and dropouts.
Staff education	Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target disorder or population of patients. Includes conferences or workshops, distribution of educational materials (written, video, or other), and educational outreach visits.

Clinician reminders	Paper-based or electronic systems intended to prompt a health professional to recall patient-specific information (e.g., most recent HbA1c value) or to do a specific task (e.g., foot examination).
Financial incentives	Interventions with positive or negative financial incentives directed at providers (eg, linked to adherence to some process of care or achievement of some target outcome). This strategy also includes positive or negative financial incentives directed at patients or system-wide changes in reimbursement
Examples of QI strategies targeting patients	
Promotion of self-management	Provision of equipment or access to resources to promote self-management. If the study called the intervention promotion of self-management, personalized goal-setting, or action-planning, we included it here. We generally thought this a more active strategy than education of patients)
Patient Reminders	Any effort (e.g., postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. If the intervention included case management, reminders to patients needed to be explicit.
Patient education (i.e., written materials, videos, lectures, other)	Patient education related to health
Motivational interviewing	Motivational interviewing ("a directive and client-centered counseling style that relies upon identifying and mobilizing the client's intrinsic values and goals to stimulate behaviour change, thus encouraging client and family involvement in all aspects of care.")

Appendix B. Search Strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
----
1   Obstetrics/
2   "Obstetrics and Gynecology Department, Hospital"/
3   exp Obstetric Surgical Procedures/
4   obstetric$.tw,hw.
5   exp Obstetric Labor Complications/
6   exp "Dilatation and Curettage"/
7   exp Hysterectomy/
8   Sterilization, Tubal/
9   Salpingostomy/
10   exp Pregnancy Complications/
11   cerebral palsy/
12   Asphyxia Neonatorum/
13   (abortion$ or cervical cerclage or colpotomy or culdoscop$ or fetoscop$ or hysteroscop$ or hysterotomy).tw.
14   (paracervical block$ or obstetric$ anesthe$ or obstetric$ anaesthe$).tw.
15   (Cesarean or Episiotom$ or obstetric$ extraction$ or fetal version).tw.
16   ((induc$ or augmentation or premature or pre-term or preterm or obstructed) adj (labour or labor)).tw.
17   (Abruptio Placentae or breech or Cephalopelvic Disproportion or premature rupture of fetal membrane$ or prom or fetal membranes premature rupture or Dystocia or Uterine Inertia or Chorioamnionitis or Placenta Accreta or Placenta Previa or Postpartum Hemorrhage or Uterine Inversion or Uterine Rupture or Vasa Previa).tw.
18   (Fetal Death or Fetal Resorption or Stillbirth or perinatal death or peri-natal death or Maternal Death or Birth Injuri$ or obstetric$ paralys$).tw.
19   (pre-eclampsia or dilatation or Curettage or Vacuum aspiration).tw.
20   (asphyxia neonatorum or cerebral palsy or birth asphyxia or fetal pulmonary embolism or dystocia or ((birth adj (trauma$ or complication$)) or preeclampsia) or ((birth adj (trauma$ or complication$)) or preeclampsia)).tw.
21   exp Dystocia/ or exp Pregnancy Complications, Cardiovascular/
22   or/1-21
23   (safe$.ti,ab. or exp Safety/ or Err$.ti,ab. or Adverse.ti,ab.) and (exp Risk Management/ or exp Quality of Health Care/ or exp Medical Errors/ or Safety Management/ or Medical Audit/)
24   patient safety/
25   (patient safe$ or obstetric$ safe$).tw.
26   22 and (23 or 24 or 25)
27   case reports.pt.
28   Observational Study.pt.
29   (News or Newspaper Article or comment or editorial).pt.
30   or/27-29
31   randomized controlled trial.pt.
32   (randomized or placebo).mp.
33   clinical trial.pt.
34   or/31-33
35   comparative study.pt.
36   26 and 34
37   limit 36 to english
38   limit 37 to yr=2004-2015
39   38 not 30

Appendix C. Potentially relevant citations identified through reference scanning of included studies

Year	Citation
Relevant Randomized Controlled Trials (n=1)	
2013	Dumont A. Fournier P. Abrahamowicz M. et al. Quality of care, risk management, and technology in obstetrics to reduce maternal mortality in Senegal and Mali (QUARITE): a cluster-randomized trial. Lancet. 2013; 382: 146-57
Relevant Systematic Reviews (n=2)	
2006	Chaillet N. Dumont A. Evidence-based strategies for implementing guidelines in obstetrics: a systematic review. Obstet Gynecol. 2006; 108: 1234-45
2010	Van Lonkhuijzen L. Dijkman A. Van Roosmalen J. et al. A systematic review of the effectiveness of training in emergency obstetric care in low-resource environments. BJOG. 2010; 117: 777-87

Appendix D. Questionnaire for study eligibility screening

Questions	Response Options
Question 1: Does the citation describe or evaluate the use of complex interventions with the goal of promoting or ensuring patient safety?	☐Yes ☐No ☐Unclear
Question 2: Are the patient safety initiatives targeted at obstetrics patients and their offspring or health practitioners working with obstetrics patients and their offspring (e.g., physician, nurse, midwife, pharmacist, rural medical practitioner, village doctor)?	☐Yes ☐No ☐Unclear
Question 3: Is the report a randomized controlled trial (RCT)?	☐Yes ☐No ☐Unclear
Question 4: Does the trial evaluate at least one of the following outcomes: Patient harms (e.g., physical or mental damage or injury to the pregnant woman, fetus or newborn) that can lead to litigation (e.g., lawsuits or other legal action) and their associated costs (e.g. cost of complex intervention, litigation, settlements)	☐Yes ☐No ☐Unclear
Question 5: Was the trial published in English?	☐Yes ☐No ☐Unclear
Question 6: Was the trial published between 2004 and 2015 (inclusive)?	☐Yes ☐No ☐Unclear

Appendix E. Patient Characteristics

Author, Year	Setting	Target population	Treatment			Control		
			Intervention [Name]	Duration	Sample Size	Intervention [Name]	Duration	Sample Size
Randomized Controlled Trials (n=3)								
Begley, 2011[22]	Two maternity hospitals with 1,300-3,200 births annually in Ireland	Pregnant women (16-40 years of age)	Midwife-led (MLU) care	Antenatal care: prior to 24 weeks of pregnancy to throughout pregnancy; Intrapartum care: throughout birth; Postnatal: up to two days; Home visits: up to the seventh postpartum day; Telephone support up to the seventh postpartum day	1,101	Consultant-led (CLU) care	Prior to 24 weeks of pregnancy until 2-3 days in hospital (postpartum care), when care was transferred to the Public Health Nursing service.	552
Lumley, 2006[20]	A newly established pre-pregnancy service (PPIS) in inner urban Melbourne, Australia	Pregnant women attending local MCH Centres	Pre-pregnancy health intervention group	From the early months after the first birth until the birth of the second child	392	Comparison group	One home visit from the Pre-pregnancy Information and Counselling Service Midwife with a discussion of their first pregnancy, labour and birth and the postpartum experience.	394

Author, Year	Setting	Target population	Treatment			Control		
			Intervention [Name]	Duration	Sample Size	Intervention [Name]	Duration	Sample Size
Olds, 2014[24]	A public system of obstetric and pediatric care in Memphis, Tennessee	tx1 and tx2: pregnant women tx3: pregnant women and newborns, tx4: pregnant women, newborns to toddlers	tx 1: Transportation for prenatal care; tx 2: Screening and referral for children; tx 3: Prenatal/ postpartum home visiting; tx 4: Infant and toddler home visiting	tx 1:free transportation for duration of prenatal care tx 2:transportation for prenatal care and developmental screening and referral services for their children at ages 6, 12, and24 months tx 3: Mean of 7 prenatal visits and 2 postpartum visits; tx 4: Mean of 7 prenatal visits + 26 visits after delivery	tx 1: 166; tx 2: 514; tx 3: 230; tx 4: 228;	NA	NA	NA
Clustered Randomized Controlled Trials (n=5)								
Althabe, 2008[19]	19 public maternity hospitals in Argentina and Uruguay that had at least 1000 vaginal deliveries annually: 10 in intervention and 9 in control	birth attendants	Selection of Opinion Leaders ; Guidelines development workshops; Dissemination of the Guidelines; Clinical management skills for delivery care workshop; Implementation and maintenance of guidelines; Coordination visits	NR ; 5 days ; NR (intervention lasted in total 18 months) ; 1 day workshop ; NR (intervention lasted in total 18 months) ; once a month	10 hospitals, 2114 deliveries	Usual care	18 months	9 hospitals, 2185 deliveries

Author, Year	Setting	Target population	Treatment			Control		
			Intervention [Name]	Duration	Sample Size	Intervention [Name]	Duration	Sample Size
Chaillet, 2015[21]	32 hospitals in Quebec (16 in intervention, 16 in control group), with at least 300 deliveries in the year; (4 community, 22 regional, and 6 tertiary hospitals); Canada	Health professionals of the maternity unit; the audit committee; Physicians and nurses;	On-site training; Educational outreach visits by external facilitators; Audit and feedback; Post-intervention: clinical audits without supervision	The study included a 1-year pre-intervention (baseline) period, a 1.5-year intervention period, and a 1-year post-intervention period	16 hospitals	Usual care	NA	16 hospitals
Nielsen, 2007[25]	Hospital labor and delivery units at 15 U.S. hospitals (military and civilian hospitals). Seven hospitals in the INT group and 8 hospitals in the control arm	Labor and delivery room personnel ; Labor and delivery staff	Instructor-training sessions ; On-site training sessions for staff	3-day instructor training session for 4 hours; on-site training duration NR	7 hospitals with 1307 staff, 28536 deliveries	Usual care	NA	8 hospitals

| Author, Year | Setting | Target population | Treatment | | | Control | | |
			Intervention [Name]	Duration	Sample Size	Intervention [Name]	Duration	Sample Size
Riley, 2011[26]	Three small-sized community hospitals (50 to 66 beds) serving comparable rural/suburban patient populations in the Midwest: two are intervention sites, one is control	NA	Didactic Training; In-Situ Simulation	A 30-minute audiovisual webinar, a 10-item test at the conclusion of the training ; Simulation: 30 to 45 minutes, followed by a 2 hour debriefing session. In total, 11 simulation training sessions	2 hospitals	Usual care	NA	1 hospital
Zongo, 2015[23]	Twenty-four health care facilities in Senegal and 22 in Mali were stratified by level of care and randomly assigned after a 1-year baseline period to either an intervention or a control group.	Physicians and midwives; health-care professionals who were involved in obstetric care: doctors, midwives and nurses	Initial training of opinion leaders; Opinion leaders trained hospital staff	Training of opinion leaders for 6 days, training of staff for 2 years	23 hospitals; 95,931 patients analyzed	Usual care	2 years	23 hospitals; 95,236 patients analyzed

Abbreviations: Tx, Treatment; Cx, Control; NA, Not applicable; NR, Not reported
Note: Usual care – no external intervention in addition to standard practice

Appendix F. Interventions Examined

Author, Year	Name of Intervention	Description of Intervention	Limitations
Randomized Controlled Trials (n=3)			
Begley, 2011[22]	Midwife-led (MLU) care	▪ Antenatal care (including assessment) was provided by midwives in the unit, or in an outreach clinic and, if desired, by the woman's GP. Where complications arose, women were transferred to CLU based on agreed criteria. Following obstetric assessment women transferred back to MLU or remained in CLU as appropriate, where they received the usual care described above. ▪ Intrapartum care was provided by midwives in the MLU with transfer to CLU if necessary, based on agreed criteria. ▪ Postnatal care - by midwives in the MLU for up to two days, with transfer of women or neonates to CLU if necessary (and back, as appropriate), based on agreed criteria. ▪ On discharge, MLU midwives visited at home, up to the seventh postpartum day, when care was transferred to the Public Health Nursing service. Care in the MLUs was provided by the full team of midwives (12 in OLOL and 7 in CGH), so women did not necessarily have the degree of continuity of care that might be expected from case-load models of midwife-led care. ▪ Telephone support, up to the seventh postpartum day, when care was transferred to the Public Health Nursing service. Care in the MLUs was provided by the full team of midwives (12 in OLOL and 7 in CGH), so women did not necessarily have the degree of continuity of care that might be expected from case-load models of midwife-led care.	**NO BLINDING OF PARTICPANTS/GROUPS** Lack of blinding of participants and carers as all women attending MLU were known to be in the study intervention group. Those allocated to CLU care were not masked either, as the blinding of participants allocated to control groups in such situations has been criticised. Unavoidable potential bias thus exists for both randomised groups. **SUBJECTIVE OUTOME ASSESSMENT** The outcome 'blood loss' was estimated, as per hospital protocols, and amounts are thus imprecise in both groups. **INTERVENTION NOT CONSISTENTLY ADMINISTERED ACROSS SETTINGS** The focus of this study was on the relative effects of midwife-led care provided in the setting of an alongside MLU. As such, this study combines elements of midwife- led care including continuity of care in pregnancy and birth with settings for birth i.e. the MLU. We acknowledge that not all midwife-led models of care will take place in an alongside MLU nor, indeed, in a homelike environment. Further, not all alternative settings for birth will provide midwife-led care. **CONFOUNDING EFFECTS OF INTERVENTION ARE COMPLEX** Differentiating the effects of midwife-led care from the setting of that care is not possible within this study, a limitation that is not unique to our study. The potential confounding effect of practice settings such as MLU on the outcomes of midwife-led care is complex as are the interrelationships between philosophy and continuity of care. **CONTAMINATION - TRANSFERS BETWEEN GROUPS** In this study, the percentage of women transferring from MLU to CLU care in the antenatal period, in particular, is higher (at 45%) than quoted rates of 24% in some UK centres. The permanent transfer rates of 13% intrapartum and 0.5% postnatally are approximately the same as the 12-15% and up to 8% reported in the UK. Some of the reasons for permanent transfer such as induction of labour and premature labour should not automatically preclude women from being transferred back to MLU care in the postnatal period, if appropriate. Quality reviews and audits of reasons for transfer would assist in reducing these high rates to more normal levels.
	Consultant-led (CLU) care	Women randomised to CLU received standard care: antenatal care provided by obstetricians and, if desired, by the woman's GP, supported by the hospital medical team with assistance from midwives, who did not usually perform assessment; intrapartum care provided by midwives unless complications developed, with consultant overview; and postpartum care (2-3 days in hospital) provided by midwives, overseen by consultants. Women were discharged into the care of Public Health Nurses.	
Lumley, 2006[20]	Pre-pregnancy health intervention group	Pre-pregnancy health intervention that consisted of mid-wife led: ▪ Identification of any current social, health or lifestyle	**SLOW RECRUITMENT (STAFF TURNOVER)** Limitations of the trial included slow recruitment. It occurred at half the rate planned, extending the duration of the trial and making it harder to

Author, Year	Name of Intervention	Description of Intervention	Limitations
		problems. ▪ Discussion of timing, planning and preparation for the next pregnancy ▪ Offers of referral for any specific problem identified (e.g. to a dietician, relaxation group, physiotherapist, family planning clinic, general practitioner) all available at the Community Health Centre or nearby, or at a local hospital clinic; linkage with appropriate community resources (e.g. language-specific play-group) and networks. ▪ Taking a family/genetic history and arranging a referral if necessary. ▪ Arranging for rubella immunisation if not immune ▪ Discussion of the points summarised on a WAIT, STOP, and GO reminder card. The card was headed Signs to follow before pregnancy, and designed to mimic traffic lights.	maintain local interest and Maternal and Child Health Nurses' enthusiasm. Another factor slowing recruitment was staff turnover. A common work pattern at the time was moving to a new position after two years, to get a broad experience in community settings. Each new staff member needed a familiarization and training period: many were unfamiliar with randomised trials at the time of recruitment. POPULATION AT LOWER RISK FOR ADVERSE EVENTS Greater limitation was the research team's lack of recognition that the women participating were of lower, rather than higher risk of adverse pregnancy outcomes. The decision to recruit women through existing services for mothers and infants failed to take into account the fact that women who had adverse outcomes in their first pregnancy (a perinatal death, an infant with a major congenital anomaly or a very preterm infant) would be underrepresented. Mothers whose infants had died would not be part of MCH services and mothers of infants requiring on-going care from hospitals or specialist services were likely to have been using those services, or visits to private paediatricians, for routine health advice and support as an alternative to their local MCHN.
	Comparison group	All women recruited received a home visit from the Pre-pregnancy information counseling service midwife with a discussion of their first pregnancy, labour and birth and the postpartum experience. Any questions asked by the women were answered.	DIFFICULT TO FOLLOW-UP None of the first-born infants included in the PPIS trial was born before 30 weeks gestation. More than 50% of participants moved house before the birth of their second child, making follow-up a much larger part of the midwives' role than originally planned The average interval between the first and second births was a mean of 39 months compared with the predicted two years. This extended the time required for follow- up and made follow-up more difficult.
Olds, 2014[24]	tx 1: transportation for prenatal care	Free transportation for prenatal care appointments	COULD NOT ASSESS MORTALITY The effect of the program on mortality was not hypothesized because of the infrequency of death among most groups in this age range. LIMITED SAMPLE SIZE AND SPARENESS OF DATA The sparseness of the data and limited sample size for a study of mortality mean that the findings are sensitive to relatively small changes in the numbers of deaths in the intervention and control conditions. Apparent differences between treatments 3 and 4 in maternal mortality are likely sampling artifacts.
	tx 2: Screening and referral for children	Free transportation for prenatal care appointments and developmental screening and referral services for their children at ages 6, 12, and 24 months	
	tx 3: Prenatal/ postpartum home visiting	Free transportation, nurse home visits during pregnancy plus 2 postpartum visits. The Nurse-Family Partnership (NFP) nurses are charged with (1) improving the outcomes of pregnancy by helping women improve their prenatal health, (2) improving children's subsequent health and development by helping mothers provide more competent care of their babies, and (3) improving women's health and development by helping them develop self-care practices, plan subsequent pregnancies, complete their educations, and find employment. The program guidelines include specific activities to support women's protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships;	

Author, Year	Name of Intervention	Description of Intervention	Limitations
		engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.	
	tx 4: Infant and toddler home visiting	Free transportation for prenatal care appointments and developmental screening, nurse home visits during pregnancy and through child age 2 years. The NFP nurses are charged with (1) improving the outcomes of pregnancy by helping women improve their prenatal health, (2) improving children's subsequent health and development by helping mothers provide more competent care of their babies, and (3) improving women's health and development by helping them develop self-care practices, plan subsequent pregnancies, complete their educations, and find employment. The program guidelines include specific activities to support women's protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.	
Clustered Randomized Controlled Trials (n=5)			

Author, Year	Name of Intervention	Description of Intervention	Limitations
Althabe, 2008[19]	Selection of Opinion Leaders Guidelines development workshops Dissemination of the Guidelines Clinical management skills for delivery care workshop Implementation and maintenance of guidelines Coordination visits	▪ Teams of three to six birth attendants (physicians, residents, or midwives) were identified as opinion leaders by their peers at each intervention hospital with the use of a previously validated sociometric questionnaire ▪ Each team was trained in a 5-day workshop to develop and disseminate evidence-based guidelines on management of the third stage of labor and the use of episiotomy. The workshops focused on critical evaluation of the medical literature, development of clinical practice guidelines, communication skills, and methods of conducting one-on-one academic detailing visits with hospital birth attendants to discuss their views regarding implementation of the intervention at the hospital. ▪ The teams then disseminated the guidelines, trained and visited birth attendants, and developed reminders to be placed in labor and delivery wards, inside surgical packages for birth attendants, and on clinical records. The teams also produced monthly reports on rates of use of episiotomy and prophylactic oxytocin based on hospital clinical data. ▪ One day workshop at each hospital for opinion leaders. ▪ Placing reminders of the recommended practices in labor and delivery wards, clinical records, and surgical packages; monthly reports of hospital episiotomy and active management rates to be distributed to every birth attendant; each hospital received a computer, all the intervention materials, developed guidelines, and the WHO Reproductive Health Library and Clinical Evidence as sources of evidence-based interventions for pregnancy and delivery care ▪ A regional coordinator met once a month with each team of opinion leaders to assess whether the components were completed as planned	NR
	Usual care	During the intervention period, the control hospitals received no intervention other than standard in-service training. During the 1-year follow-up period, we offered the control hospitals all components of the intervention except the visits by the coordinators	

Author, Year	Name of Intervention	Description of Intervention	Limitations
Chaillet, 2015[21]	On-site training, Educational outreach visits by external facilitators, Audit and feedback, Post-intervention clinical audits without supervision	- Initial onsite training in evidence-based clinical practices by instructors from the Society of Obstetricians and Gynecologists of Canada - Support the committee in the audit process, and in the implementation of evidence-based recommendations - During the year after the training period, four 3-month audit cycles were implemented by audit committees, with the support of external facilitators who made quarterly educational outreach visits. Each cycle included five standardized steps: the identification of women who had caesarean deliveries during the first month of each cycle; the collection of data, with the use of standardized forms, regarding the management of labor and delivery; the assessment by the local audit committee, with the use of clinical algorithms, of the relevance of the indications for caesarean delivery; the formulation of recommendations for best practices and the evaluation of previous recommendations, both performed by the committee; and the provision of informal and formal feedback to health professionals. - During the 1-year post intervention period, health professionals in the intervention group were encouraged to continue performing clinical audits, but without supervision, in order to assess the program's sustainability. The mean time required by the audit committee members to conduct each audit session, to formulate and produce recommendations, and to provide feedback and ensure the implementation of the recommendations (through regular staff meetings, training sessions, and informal discussions) was approximately 2 days per 3-month cycle.	BASELINE CHARACTERISTICS NOT CONSISTENT Since hospitals were the unit of randomization, and the number of deliveries varied across hospitals, there were differences in the distribution of certain hospital characteristics across groups at baseline. These differences were adjusted a priori in multivariable analyses. INTERVENTION NOT CONSISTENTLY ADMINISTERED The intervention was not fully implemented at four intervention hospitals. CONFOUNDING EFFECTS OF COMPLEX INTERVENTION Because we tested a complex, multifaceted intervention, it is not possible to determine which of its components were primarily responsible for the observed effect.
	Control	No intervention was planned for the control group. In order to assess contamination bias, quality-improvement programs were reviewed annually in control hospitals	

Author, Year	Name of Intervention	Description of Intervention	Limitations
Nielsen, 2007[25]	instructor-training sessions, on-site training sessions for staff	▪ Clinical staff from the seven intervention hospitals attended a 3-day instructor training session comprising 4 hours of didactic lessons, video scenarios, and interactive training covering team structure and processes, planning and problem solving, communication, workload management, team skills, and implementation. Conflict resolution strategies were included to provide a means of enhancing team behavior. Teamwork training also included assistance with creation and structure of teams at each intervention hospital. ▪ Trainers returned to their respective hospitals to conduct onsite training sessions for staff members from obstetrics, anesthesiology, and nursing and to structure each unit into core work teams made up of those nurses, physicians, and staff in direct contact with patients and coordinating teams composed of immediate supervisors, clinical leaders, and unit resource personnel. In addition, a contingency team, a multidisciplinary group of experienced physicians and nurses drawn from practitioners that are on call during a 24-hour period, were trained to respond in a coordinated way to obstetric emergencies. The group was also empowered to draw on additional hospital-wide resources.	SHORT TIMELINE TO TRAIN AND IMPLEMENT Short time of training (4 hours) and implementation (4 months); team training may simply not have been effective LACKING POWER Power to detect important intervention effects may have been lacking; INCOMPLETE ASCERTAINMENT OF OUTCOMES Incomplete ascertainment of outcomes; HAWTHORNE EFFECT the influence of collecting data on the results; POTENTIAL CONTAMINATION OR UNCERTAINTY OF CAUSAL EFFECT Due to other quality control initiatives and procedural changes made at the institutions to improve care; NO ACCEPTED MEASURE OF ERROR No national measures of error in obstetrics, so the process measures used as surrogates for teamwork behaviors do not capture teamwork behavior or medical errors in obstetrics; maybe the Adverse Outcome Index did not captured teamwork behavior or medical errors in obstetrics
	Usual care	NA	
Riley, 2011[26]	Didactic Training	Didactic training was based on the Team-STEPPS training curriculum, an evidence-based teamwork curriculum developed by the U.S. Department of Defense and the Agency for Healthcare Research and Quality with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. In previous research, we found that four key behaviors are responsible for the majority of team and communication failures during critical events. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop communication, and shared mental model. The full format and techniques of our condensed curriculum are explained elsewhere. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The	DIFFERENCES IN FREQUENCY OF INTERVENTION The improved outcomes in the full-intervention hospital were the result of 11 simulation sessions. In contrast, only one didactic TeamSTEPPS session was held, and we did not examine whether the success achieved with multiple simulations could also be achieved with repetitive didactic sessions without the use of simulation; HIRING AND TRAINING OF NEW STAFF THROUGH DURATION OF STUDY In addition, personnel departed and were hired during the course of this study at all three settings, and there was no assessment of the impact of these changes in professional staff. BASELINE CHARACTERISTICS OF SETTINGS INCONSISTENT Although the hospitals randomly were assigned to each intervention, there were some differences that might have affected the outcomes, as suggested by a cluster analysis, such as number of births for obstetricians as compared to those for family practitioners. The improved outcomes could be related to the greater willingness of a smaller, less busy obstetrical unit in which care is predominantly provided by obstetricians more willing to embrace the team concepts

Author, Year	Name of Intervention	Description of Intervention	Limitations
		webinar used a combination of visual prompts, audio narration of key elements, and a video of simulated scenarios. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviors from the didactic training. Previous work describes the development, categorization and validation of an evaluation tool for assessing near misses and active failures by collecting, analyzing, and validating simulations of emergency C-sections in a 390-bed community hospital. Following Reason's model, these "breaches" in patient safety barriers were categorized according to active failures (standardized communication, situational awareness and shared mental model) and latent conditions (process design and compliance with policy and procedure).	irrespective of the in-situ simulation intervention. This study was conducted in three smaller hospitals in suburban/ outer rural areas, and the application of these findings to other settings is limited. CONFOUNDING EFFECTS OF STUDY There is no way to know whether the reported effects can be attributed to other influences in this study. CONTAMINATION Given the difficulties of this type of design, there may be possible contamination effects (such as change of policy or change in personnel). NOT GENERALIZABLE TO LARGE HOSPITALS Many features of larger hospitals, including less consistency between teams, more complex care processes, and higher-risk patients, were not explored in the settings where this study occurred. QUESTION AUTHENTCITY OF SIMULATION Moreover, the in-situ simulation is by definition, a replication of a critical event, not the event itself. No post simulation assessment of the participants was conducted to determine the extent of perceived authenticity of the simulation experience. POSSIBLE CONFOUNDERS Finally, although there were no other safety initiatives going on in the obstetrics units of the participating hospitals, we are unaware of broader hospital-level safety initiatives that could have affected the perception of COS or the outcome data. MEASURES NOT APPROPRIATE In addition, it is possible that the didactic TeamSTEPPS curriculum, which represented an abbreviated version of the four-to-six-hour workshop provided in a conventional TeamSTEPPS training session, did not constitute an adequate test of the TeamSTEPPS program.
	In-Situ Simulation	The in-situ simulation for perinatal critical events consisted of five components: (a) briefing, (b) in-situ simulation, (c) debriefing, (d) rapid-cycle follow-through with process improvements, and (e) repetition to reinforce skills and create resiliency. During the briefing, participants who were directly involved in the simulation were educated about the simulation scenarios. The simulated patient was followed from triage, through labor and the operating room (OR), and then to the recovery area. The simulation, which typically ran 30 to 45 minutes, was initiated in a manner similar to a typical handoff, with a brief history from one provider to the next. A two-hour debriefing session, with the use of advanced debriefing techniques, was held immediately following each simulation. Eleven simulation training sessions were conducted at the simulation treatment hospital from September 2007 through February 2008. Scenarios and triggers were taken from actual occurrences in the hospital unit. We used an event-set methodology to develop scenarios for uterine rupture, placental abruption, and post-partum hemorrhage. The event sets specified phases for each of the three scenarios. Five clinical triggers were designed to prompt NTS behaviors: situational awareness, shared mental model, closed-loop and SBAR-R29 communication, leadership and teamwork, and latent conditions.	
	Usual care	No Intervention	

Author, Year	Name of Intervention	Description of Intervention	Limitations
Zongo, 2015[23]	Initial training of opinion leaders, Opinion leaders training hospital staff	▪ Training session on evidence-based clinical practices and on clinical audit of one physician and one midwife per hospital, using the Advances in Labour and Risk Management (ALARM) international program and provided by certified instructors. ▪ The trainees then played the role of local opinion leaders (without financial incentives) in their own hospitals and launched MDR and on-site training workshops with the support of the local audit committees and external facilitators during their quarterly educational outreach visits. The audit committees made various quality improvement suggestions during the audit sessions. The most recurrent actions implemented were: organizational changes to improve 24 hour service availability and patient monitoring. Training topics were selected by the audit committees depending on the principal causes of maternal mortality in a given hospital, as identified during the reviews. The most recurrent topics were the management of pre-eclampsia and post-partum hemorrhage.	OVERALL SAMPLE SIZE NOT SUFFICIENT TO DETECT HETEROGENIETY Tests of interaction typically have low statistical power, and the sample size calculation for this trial did not take into account the power to detect heterogeneity of intervention effects by delivery mode. However, there were sufficient large numbers within each subgroup to allow adequate analysis. Risk of false-positive results increases with multiple subgroup testing; therefore, the analysis was restricted to primary outcome (hospital-based maternal mortality), thus minimizing the probability of type 1 errors. BASELINE CHARACTERISTICS NOT CONSISTENT Some maternal characteristics among women with vaginal and caesarean delivery were not balanced between intervention and control arms at baseline. This could partly explain the differences in baseline maternal mortality between allocation groups. Thereby, we adjusted for well known risk factors for hospital-based maternal mortality, in accordance with publications from African countries. This method combined with the difference-in-difference approach, allowed us to assess additional reduction of the risk that a mother in the intervention group would die before being discharged from hospital, relative to the
	Usual care	Not receiving any intervention from the research team.	reduction in the control group, adjusting for maternal characteristics and clustering. However, subgroup analyses that are not pre-specified should be treated as exploratory. The hypotheses that we have generated should be confirmed by other randomized controlled studies. HIGH RISK OF TYPE 1 ERROR We reported the tests of interaction separately for each hospital type, because intervention effects in the primary analysis of the QUARITE trial differed across these subgroups. Given, the multiplicity of interaction tests, the risk of type I error remains high. However, the differential effects by hospital type in these secondary analyses are consistent with the findings of the primary analysis. The effect of the intervention was limited to capital and district hospitals.
Abbreviations: General Practitioner, GP; Maternal and Child Health (MCH); Maternal and Child Health Nurses , MCHN; Tx, treatment;			

Appendix G. All Patient Harms Outcomes

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
Randomized Controlled Trials (n=3)			
Begley, 2011[22]	pregnant women and neonates	caesarean birth 163 [14.8%]; induction of labour 248 [22.5%] ; episiotomy (126 [11.4%] ; instrumental birth (139 [12.6%] ; Apgar scores less than 8 (10 [0.9%] ; postpartum haemorrhage (PPH) (144 [13.1%] ; initiation of breastfeeding (616 [55.9%]; MLU women were significantly less likely to receive continuous EFM (available only in CLU) (397 [36.1%] or have labour augmented by amniotomy or with oxytocin (436 [39.6%], at least one antenatal admission (487 [44.2%], experienced any pregnancy complication (248 [22.5%], fetal loss before 24 weeks (17 [1.54%], spontaneous vaginal birth (761 [69.1%], intact perineum (421 [38.2%], estimated mean blood loss (323 mls (SD 317) ; Women randomised to MLU had significantly fewer mean ultrasound examinations (1.98 (SD 1.37) mean difference (MD) -0.51, 95% CI -0.68, -0.34) and antenatal cardiotocographs (2.38 (SD 3.6); Significantly fewer MLU women chose to have epidurals (for which they had to transfer to CLU) (202 [18.3%]. Alternative methods of pain relief included transcutaneous electrical nerve stimulation (TENS) (64 [16%] and hydrotherapy (birthing pool in MLU, bath in CLU) (257 [23.3%]; ≤ 2 caregivers in labour (n, %): 297(27%) MLU women had a longer mean length of labour (4.6 hours (SD 3.27); MLU women more frequently used spontaneous pushing (726 [65.9%], upright positions for birthing (300 [27.2%] , physiological management of third stage of labour (137 [12.4%]; More MLU women stayed only one postnatal day or less (184 [16.7%]; Neonatal outcomes showed no statistically significant difference between MLU and CLU in paediatric care required (292 [26.5%]; facial oxygen (130 [11.8%] ; bag-and-mask resuscitation (23 [2.1%];admission to special care baby unit (SCBU) (128 [11.6%]; There were two early neonatal deaths in MLU (0.18%), two (0.36%) in CLU, and one (0.1%) fetal loss at > 24 weeks in MLU. ; Perinatal mortality rates in MLU 2.76 per 1,000 live and still-births. There were no maternal deaths.	caesarean birth 84 [15.2%]; induction of labour 138 [25.0%] ; episiotomy 68 [12.3%] ; instrumental birth 79 [14.3%] ; Apgar scores less than 8 (9 [1.6%]) ; postpartum haemorrhage (PPH) 75 [13.6%] ; initiation of breastfeeding 317 [57.4%] ; MLU women were significantly less likely to receive continuous EFM (available only in CLU) 313 [56.7%] or have labour augmented by amniotomy or with oxytocin 314 [56.9%] or have at least one antenatal admission 229 [41.5%], experienced any pregnancy complication 110 [19.9%], fetal loss before 24 weeks 5 [0.91%], spontaneous vaginal birth 372 [69%], intact perineum 225 [40.8%], estimated mean blood loss 324 mls (SD 401) ; Alternative methods of pain relief included transcutaneous electrical nerve stimulation (TENS) 170 [12%] and hydrotherapy (birthing pool in MLU, bath in CLU) 18 [3.3%]; ≤ 2 caregivers in labour (n, %): 94(17%) MLU women had a longer mean length of labour 4.0.hours (SD 2.41); MLU women more frequently used spontaneous pushing 308 [55.8%], upright positions for birthing 55 [10.0%], physiological management of third stage of labour 1 [0.2%]; More MLU women stayed only one postnatal day or less 57 [10.3%]; Neonatal outcomes showed no statistically significant difference between MLU and CLU in paediatric care required 150 [27.2%]; facial oxygen 63 [11.4%]; bag-and-mask resuscitation 12 [2.2%]; admission to special care baby unit (SCBU) 60 [10.9%]; There were two early neonatal deaths in MLU (0.18%), two (0.36%) in CLU, and one (0.1%) fetal loss at > 24 weeks in MLU. ; Perinatal mortality rates in CLU were 3.66 per 1,000 live and still-births. There were no maternal deaths.
Lumley, 2006[20]	pregnant women and newborns ; Control: pregnant women	Birth interval (months): Mead (SD)= 40.0 (30) [F 0.89, p 0.35; unequal variance in birth interval] Missing= 2 Birth weight:	Birth interval (months): Mead (SD)= 38.1 (26) Missing= 1 Birth weight: Mean (SD)=3500 (504)

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
		Mean (SD)=3403 (509) Missing data=3 Low birth weight (<2500 g)=25/393 [OR (exact) 1.85 [0.91, 3.91] Birth weight <10thpercentile= 40/378 (11%) OR (exact) 1.14 [0.55, 2.38] Low birth weight <1000 g = 6 Low birth weight 1000–1499= 3 Low birth weight 1500–1999= 7 Low birth weight 2000–2499= 9 All with birth weight (≥ 2,500 g) = 367 Missing data = 3 All births= 395 Gestation Mean (SD) = 39.3 (2.2) Preterm birth (<37 weeks) = 24 (6%) [OR (exact) 1.44 (0.73, 2.91)] Preterm birth 20–27 weeks=4 Preterm birth 28–31 weeks=6 Preterm birth 32–36 weeks=14 All with gestations ≥ 37 weeks=366 Missing data = 2 All gestations=392 Infants with a birth anomaly = 5	Missing data=2 Low birth weight (<2500 g)=14/394 Birth weight <10thpercentile= 31/382(8%) Low birth weight <1000 g = 0 Low birth weight 1000–1499= 0 Low birth weight 1500–1999= 2 Low birth weight 2000–2499= 12 All with birth weight (≥ 2,500 g) = 380 Missing data = 2 All births= 396 Gestation Mean (SD) = 39.5 (1.5) Preterm birth (<37 weeks) = 17 (4%) Preterm birth 20–27 weeks=0 Preterm birth 28–31 weeks=1 Preterm birth 32–36 weeks=16 All with gestations ≥ 37 weeks=374 Missing data = 3 All gestations=394 Infants with a birth anomaly = 2
Olds, 2014[24]	pregnant women and newborns ; Control: pregnant women, newborns, infant, toddlers	Maternal deaths No[a]: Natural (disease related) = 1 External (unintentional injuries, suicide, drug overdose, homicide) = 0 21 years following randomization, the mean (SE) all-cause mortality rate =0.4%(0.43%) 21 years after randomization, the external-cause mortality rate = 0.0% (SE not calculable) external-cause survival analysis contrast of treatments with treatments 3 and 4 combined was significant (post hoc P = .02). Maternal deaths No[b]: Natural (disease related) = 4 External (unintentional injuries, suicide, drug overdose, homicide) =1 Child deaths, No.: Natural (disease related) =2 Preventable (SIDS, unintentional injuries, homicide): 0 21 years following randomization, the mean (SE) all-cause mortality rate =2.2%(0.97%) 21 years after randomization, the external-cause mortality rate = 0.4% (0.44%) all-cause mortality rate =0.9%(0.65%) preventable-cause mortality death rate= 0.0% (SE not calculable) preventable-cause survival contrast of treatment 2with treatment 4, = significant (P = .04).	Maternal deaths No[a]: Natural (disease related) = 5 External (unintentional injuries, suicide, drug overdose, homicide) = 0 21 years following randomization, the mean (SE) all-cause mortality rate (treat. 1 +treat 2)=3.7% (0.74%). The survival contrast of treatments 1 and 2 with treatment 3 was significant (P = .007), the contrast of treatments 1 and 2 combined with treatment 4 was not significant (P = .19), and the contrast of treatments 1 and 2 combined with treatments 3 and 4 combined was significant (post hoc P = .008). 21 years after randomization, the external-cause mortality rate was 1.7% (0.51%) in treatments 1 and 2 combined. external-cause survival analysis contrast of treatments 1 and 2 combined with treatment 3 was marginally significant (P = .053) external-cause survival analysis contrast of treatments 1 and 2 combined with treatment with treatment 4 was not significant (P = .18) Maternal deaths No[b]: Natural (disease related) = 11 External (unintentional injuries, suicide, drug overdose, homicide) = 11 Child deaths, No.: Natural (disease related) = 5 Preventable (SIDS, unintentional injuries, homicide): 9 all-cause mortality rate =2.7%(0.73%) preventable-cause mortality death rate = 1.6% (0.57%)

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
Clustered Randomized Controlled Trials (n=5)			
Chaillet, 2015[21]	women and newborns: 84,227; Control: 100,725	caesarean delivery (N; %) baseline: 5484 (22.5) post-intervention: 5128 (21.8) (p=0.04) Low risk level of pregnancy - total number (N) baseline:11,478 post-intervention:10,067 Low risk level of pregnancy - caesarean delivery (N; %) baseline:971 (8.5) post-intervention: 763 (7.6) (p=0.03) High risk level of pregnancy - total number (N) baseline:12,910 post-intervention:13,417 High risk level of pregnancy - caesarean delivery (N; %) baseline:4513 (35.0) post-intervention: 4365 (32.5) (p=0.35) All deliveries - Planned caesarean delivery (N; %) baseline:2,939 (12.1) post-intervention:2,872 (12.2) (p=0.42) All deliveries-Pharmacologic induction of labor (N; %) baseline:4,345 (17.8) post-intervention:5,501 (23.4) (p=<0.001) All deliveries-Artificial rupture of membranes (N; %) baseline:11,563 (47.4) post-intervention:11,972 (51.0) (p=0.87) Number of women who attempted labor - Total no. baseline:21,449 post-intervention:20,612 Number of women who attempted labor - Intrapartum caesarean delivery (N; %) baseline:2,545 (11.9) post-intervention:2,256 (10.9) (p=0.14) Number of women who attempted labor -assisted vaginal delivery (N; %) baseline:2,535 (11.8) post-intervention:2,223 (10.8) (p=0.04) Number of women who attempted labor -use of oxytocin during labour (N; %) baseline:7,652 (35.7) post-intervention:6,205 (30.1) (p=<0.001) Number of women who attempted labor -Epidural analgesia (N; %) baseline:14,416 (67.2) post-intervention:14,004 (67.9) (p=0.75) Number of women who attempted labor -Episiotomy (N; %) baseline:3,762 (17.5) post-intervention:2,953 (14.3) (p=0.87) Noncephalic presentation, prolonged labor, abnormal pattern in fetal heart rate (Table S1-not available) # of adherence to the protocol = 12 (75%)	caesarean delivery (N; %) baseline: 6671 (23.2) post-intervention: 6767 (23.5) Low risk level of pregnancy - total number (N) baseline:14,717 post-intervention:13,019 Low risk level of pregnancy - caesarean delivery (N; %) baseline:1256 (8.5) post-intervention: 1172 (9.0) High risk level of pregnancy - total number (N) baseline:13,981 post-intervention:15,762 High risk level of pregnancy - caesarean delivery (N; %) baseline:5415 (38.7) post-intervention: 5595 (35.5) All deliveries - Planned caesarean delivery (N; %) baseline:3,701 (12.9) post-intervention:3,907 (13.6) All deliveries-Pharmacologic induction of labor (N; %) baseline:5,235 (18.2) post-intervention:7,872 (27.4) All deliveries-Artificial rupture of membranes (N; %) baseline:13,495 (47.0) post-intervention:14,534 (50.5) Number of women who attempted labor - Total no. baseline:24,997 post-intervention:24,874 Number of women who attempted labor - Intrapartum caesarean delivery (N; %) baseline:2,970 (11.9) post-intervention:2,860 (11.5) Number of women who attempted labor -assisted vaginal delivery (N; %) baseline:2,574 (10.3) post-intervention:2,605 (10.5) Number of women who attempted labor -use of oxytocin during labour (N; %) baseline:9,932 (39.7) post-intervention:7,572 (30.4) Number of women who attempted labor -Epidural analgesia (N; %) baseline:18,364 (73.5) post-intervention:18,339 (73.7) Number of women who attempted labor -Episiotomy (N; %) baseline:4,777 (19.1) post-intervention:3,871 (15.6) Noncephalic presentation, prolonged labor, abnormal pattern in fetal heart rate (Table S1-not available) # of adherence to the protocol = 12 (75%)

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
		Change in the rate of assisted vaginal delivery (adjusted odds ratio [intervention vs. control] = 0.88; 95% CI, 0.77 to 0.99; P = 0.04; adjusted risk difference, −1.1%; 95% CI, −2.2 to −0.1), Composite risk of maternal morbidity - Minor morbidity: (N; %) baseline:3293 (13.5) post-intervention:3576 (15.2) (p=<0.76) Composite risk of maternal morbidity - Major morbidity: (N; %) baseline:161 (0.66) post-intervention:167 (0.71) (p=<0.71) Composite risk of neonatal -Total no. of births (N) baseline:24,823 post-intervention:23,902 Composite risk of neonatal - Minor morbidity: (N; %) baseline:3936 (15.9) post-intervention:4261 (17.8) (p=<0.001) Composite risk of neonatal - Major morbidity: (N; %) baseline:1172 (4.7) post-intervention:1070 (4.5) (p=0.03) Rate of blood transfusion -[int vs cont] (adjusted odds ratio = 1.70; 95% CI,1.18 to 2.43; P = 0.004). neonatal major trauma [int vs cont] (adjusted risk difference) = −0.23%; 95% CI, −0.40 to −0.01; P = 0.046) use of invasive mechanical ventilation [int vs cont] (adjusted risk difference) = −0.38%; 95% CI, −0.60 to −0.09; P = 0.01) intrapartum and neonatal deaths [int vs cont] (adjusted risk difference =−0.06%; 95% CI, −0.08 to −0.03; P<0.001) Effect of the intervention on major neonatal morbidity remained significant after exclusion of preterm births (adjusted odds ratio, 0.82; 95% CI, 0.70 to 0.96; P = 0.02)	Change in the rate of assisted vaginal delivery (adjusted odds ratio [intervention vs. control] = 0.88; 95% CI, 0.77 to 0.99; P = 0.04; adjusted risk difference, −1.1%; 95% CI, −2.2 to −0.1), Composite risk of maternal morbidity - Minor morbidity: (N; %) baseline:3869 (13.5) post-intervention:4244 (14.7) Composite risk of maternal morbidity - Major morbidity: (N; %) baseline:138 (0.48) post-intervention:141 (0.49) Composite risk of neonatal -Total no. of births (N) baseline:29,107 post-intervention:29,211 Composite risk of neonatal - Minor morbidity: (N; %) baseline:3947 (13.6) post-intervention:5002 (17.1) Composite risk of neonatal - Major morbidity: (N; %) baseline:1,018 (3.5) post-intervention:1,156 (4.0) Rate of blood transfusion -[int vs cont] (adjusted odds ratio = 1.70; 95% CI,1.18 to 2.43; P = 0.004). neonatal major trauma [int vs cont] (adjusted risk difference) = −0.23%; 95% CI, −0.40 to −0.01; P = 0.046) use of invasive mechanical ventilation [int vs cont] (adjusted risk difference) = −0.38%; 95% CI, −0.60 to −0.09; P = 0.01) intrapartum and neonatal deaths [int vs cont] (adjusted risk difference =−0.06%; 95% CI, −0.08 to −0.03; P<0.001)
Nielsen, 2007[25]	Women with a pregnancy of 20–43 weeks of gestation and newborns ; Control: Pregnant women	Caesarean deliveries mean (range). = 28.2 (23.9–40.8) Gestational age less than 37 weeks (%) = 13.3 (9.6–27.4) Birth weight less than 2,500 g (%) = 9.7 (5.2–24.7) Adverse Outcome Index (%) = 8.3 [ICC=0.015] Weighted Adverse Outcome Score = 2.7 [ICC=0.008] Severity Index = 31.9 [ICC=0.017] Process measures (time elapsed) in hours: Registration to provider assessment = 1.1 [ICC=0.268] Registration to maternal-fetal assessment (min) = 17.8 [ICC=0.031] Scheduled registration to induction= 3.3 [ICC=0.268] GBS antibiotic order to first dose (min) = 42.9 [ICC= 0.015] Epidural request to initiation (min)= 32.5 [ICC=0.036] Scheduled caesarean delivery start time to incision = 2.0 [ICC=0.203] Immediate caesarean delivery decision to incision (min)=21.2 [ICC=0.039] (P= .03) Urgent caesarean section decision to incision (min)= 77.0	Caesarean deliveries mean (range). =24.8 (11.9–41.2) Gestational age less than 37 weeks (%) = 11.7 (5.6–18.7) Birth weight less than 2,500 g (%) = 8.6 (3.9–14.6) Adverse Outcome Index (%) = 7.2 Weighted Adverse Outcome Score = 2.3 Severity Index = 30.6 Process measures (time elapsed) in hours: Registration to provider assessment = 1.0 Registration to maternal-fetal assessment (min) = 14.9 Scheduled registration to induction= 3.3 GBS antibiotic order to first dose (min) = 42.5 Epidural request to initiation (min)= 33.1 Scheduled caesarean delivery start time to incision = 2.0 Immediate caesarean delivery decision to incision (min)=33.3 Urgent caesarean section decision to incision (min)= 65.8 Registration to delivery – nullipara =14.4 Registration to delivery – multipara = 8.1 Delivery to end of care in labor and delivery =3.4

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
		[ICC=0.034] Registration to delivery – nullipara = 13.8 [ICC=0.042] Registration to delivery – multipara = 8.3 [ICC=0.021] Delivery to end of care in labor and delivery =3.3 [ICC=0.141] third- or fourth-degree perineal laceration after vaginal delivery: 4.5% (range 3.1–5.4) range of the Adverse Outcome Index across the sites= 4.1–16.5% The mean Adverse Outcome Index (range) was 9.0 (5.9 –14.7) in the intervention arm. unplanned admission to the NICU: mean 4.1% (range 0.2–10.0),	third- or fourth-degree perineal laceration after vaginal delivery: mean 5.0% (range 1.3–10.0) range of the Adverse Outcome Index across the sites= 4.7–12.6% The mean Adverse Outcome Index (range) was 9.4 (6.5–16.6) in the control arm unplanned admission to the NICU: mean 4.5% (range 0–19.2)
Riley, 2011[26]	pregnant women and newborns	Pre-intervention Mean (SD)=1.15 (0.47) Post-intervention WAOS Means (and Standard Deviations)= 0.72 (0.12) [% Change (Pre to Post)=−37.4%, significant at the .05 level] Didactic-Only pre-1.46 (1.05) post-1.45 (0.82)% change 1.0% The results show no change in safety attitudes during the two-year period of the study for either the control group or didactic-only condition, with an increase in teamwork for the full-intervention hospital at the .05 level. However, the statistical significance no longer held when a Bonferroni adjustment was applied to the level of significance.	Pre-intervention Mean (SD)=1.05 (0.79) Post-intervention WAOS Means (and Standard Deviations)= 1.50 (0.35)) [% Change (Pre to Post)= +42.7%]
Althabe, 2008[19]	pregnant women and newborns	Prophylactic oxytocin — %: Median Baseline Rate = 2.1 Median Post-intervention Rate= 83.6 (P=0.01) Nine of the 10 intervention hospitals increased their rate of prophylactic use of oxytocin by more than 50% Episiotomy — %: Median Baseline Rate = 41.1 Median Post-intervention Rate= 29.9 (P=<0.001) Episiotomy in primiparous women: Median Baseline Rate =84.8 Median Post-intervention Rate=66.5 (P=0.02) Episiotomy in multiparous women: Median Baseline Rate = 18.4 Median Post-intervention Rate= 12.4 (P=0.01) The intervention was associated with a statistically significant reduction in all postpartum hemorrhage indicators — the rate of postpartum hemorrhage of 500 ml or more, the rate of postpartum hemorrhage of 1000 ml or more, and the mean amount of postpartum blood loss. Postpartum hemorrhage ≥500 ml (%): Median Baseline Rate = 18.6 Median Post-intervention Rate= 6.9 (P=0.03) Postpartum hemorrhage≥1000 ml (%) (%): Median Baseline Rate = 3.0 Median Post-intervention Rate= 0.8 (P=0.007) median rate ratio 0.26 Postpartum blood loss (ml):	Prophylactic oxytocin — %: Median Baseline Rate = 2.6 Median Post-intervention Rate= 12.3 Nine of the 10 intervention hospitals increased their rate of prophylactic use of oxytocin by more than 50% Episiotomy — %: Median Baseline Rate = 43.5 Median Post-intervention Rate= 44.5 Episiotomy in primiparous women: Median Baseline Rate =84.1 Median Post-intervention Rate=84.6 Episiotomy in multiparous women: Median Baseline Rate = 16.2 Median Post-intervention Rate= 19.3 Postpartum hemorrhage ≥500 ml (%): Median Baseline Rate =9.8 Median Post-intervention Rate= 8.1 Postpartum hemorrhage≥1000 ml (%) (%): Median Baseline Rate = 1.5 Median Post-intervention Rate= 0.6 median rate ratio 0.88 Postpartum blood loss (ml): Median Baseline Rate = 211.9 Median Post-intervention Rate=215.3 median rate ratio 0.4 Manual extraction of placenta (%): Median Baseline Rate = 0.5

Author, Year	Outcomes measured	Treatment patient harms results	Control patients harms results
		Median Baseline Rate = 274.2 Median Post-intervention Rate=167.8 (P=<0.001) median rate ratio -121.5 Manual extraction of placenta (%): Median Baseline Rate = 1.0 Median Post-intervention Rate=1.4 (P=0.36) Perineal sutures (%): Median Baseline Rate = 54.6 Median Post-intervention Rate=48.6 (P=0.08) Perineal tears (%)-2nd degree (tears and episiotomies): Median Baseline Rate = 44.2 Median Post-intervention Rate=33.3 (P=0.03) Perineal tears (%)-3rd or 4th degree: Median Baseline Rate = 0.5 Median Post-intervention Rate=0.5 (P=0.60) Stillbirths (%): Median Baseline Rate =0.8 Median Post-intervention Rate=0.7 (P=0.78) median rate ratio 1.04 5-min Apgar score <4 (%): Median Baseline Rate =1.1 Median Post-intervention Rate=1.0 (P=0.25) median rate ratio 0.90 Neonatal death (%): Median Baseline Rate =1.3 Median Post-intervention Rate=1.1 (P=0.78) median rate ratio 0.61 Maternal admission to the intensive care unit (no.): Median Baseline Rate =3 Median Post-intervention Rate=3 Maternal death (no.): Median Baseline Rate =1 Median Post-intervention Rate=1	Median Post-intervention Rate=0.6 Perineal sutures (%): Median Baseline Rate = 55.2 Median Post-intervention Rate=55.9 Perineal tears (%)-2nd degree (tears and episiotomies): Median Baseline Rate = 45.3 Median Post-intervention Rate=46.4 Perineal tears (%)-3rd or 4th degree: Median Baseline Rate = 0.4 Median Post-intervention Rate=0.5 Stillbirths (%): Median Baseline Rate =0.7 Median Post-intervention Rate=0.6 median rate ratio 0.88 5-min Apgar score <4 (%): Median Baseline Rate =1.5 Median Post-intervention Rate=0.8 median rate ratio 0.49 Neonatal death (%): Median Baseline Rate =2.0 Median Post-intervention Rate=10.9 median rate ratio 0.55 Maternal admission to the intensive care unit (no.): Median Baseline Rate =1 Median Post-intervention Rate=3 Maternal death (no.): Median Baseline Rate =1 Median Post-intervention Rate=1
Zongo, 2015[23]	pregnant women with caesarean vs. vaginal deliveries	*Caesarean Intervention* Hemorrhage, baseline: 65(29.4); year 4: 65(39.6) ; Pre-eclampsia /eclampsia baseline: 65(29.4)); year 4: 65(39.6) ; Puerperal infections/sepsis baseline: 32(14.5); year 4: 11(6.7) ; Uterine rupture baseline: 27(12.2); year 4: 15(9.1) ; Obstructed labor baseline: 4(1.8); year 4: 1(0.6) ; *Vaginal Delivery Intervention* Hemorrhage , baseline: 79(35.3); year 4: 57(29.7) ; Pre-eclampsia / eclampsia baseline: 41(18.3); year 4: 34(17.7) ; Puerperal infections/sepsis baseline: 9(4.0); year 4: 10(5.2) ; Uterine rupture baseline: 5(2.2); year 4: 9(4.7); Obstructed labor baseline: 1(0.4); year 4: 1(0.5)	*Caesarean Control* Hemorrhage, baseline: 51(31.1); year 4: 58(32.2) ; Pre-eclampsia / eclampsia baseline: 51(31.1); year 4: 58(32.2) ; Puerperal infections/sepsis baseline: 11(6.7); year 4: 12(6.7) ; Uterine rupture baseline: 21(12.8); year 4: 15(8.3) ; Obstructed labor baseline: 3(1.8); year 4: 1(0.6); *Vaginal Delivery Control* Hemorrhage, baseline: 60(34.7); year 4: 70(34.8); Pre-eclampsia / eclampsia baseline: 31(17.9); year 4: 32(15.9) ; Puerperal infections/sepsis baseline: 4(2.3); year 4: 14(7.0) ; Uterine rupture baseline: 4(2.3); year 4: 9(4.5) ; Obstructed labor baseline: 1(0.6); year 4: 2(1.0)]
Abbreviations: int, Intervention; cont, control; vs, versus			