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Effects of combinations of diagnostic and treatment strategies for postpartum haemorrhage: a network meta-analysis (Review)

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[Intervention Review]

Effects of combinations of diagnostic and treatment strategies for postpartum haemorrhage: a network meta-analysis

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ABSTRACT

Rationale

Postpartum haemorrhage (PPH) is a major cause of maternal mortality worldwide. The combination of accurate diagnosis and effective treatment is necessary to improve outcomes. There is uncertainty about which combination of diagnostic and treatment strategies is most effective.

Objectives

To assess the comparative effectiveness of various combinations of 'diagnostic and treatment' strategies for PPH in women giving birth, and rank them.

To explore the relative effects of various diagnostic strategies, when the treatment strategies are the same or similar.

To explore the relative effects of various treatment strategies, when the diagnostic strategies are the same or similar.

Search methods

We searched CENTRAL, MEDLINE, Embase, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform to 18 October 2024.

Eligibility criteria

Randomised controlled trials or cluster-randomised trials comparing the effects of different combinations of 'diagnostic and treatment' strategies for PPH were eligible. We included studies of women having vaginal or caesarean birth in any setting.

Outcomes

Critical outcomes were: PPH ≥ 500 mL within 24 hours after birth; additional blood loss of ≥ 500 mL following diagnosis of PPH and within 24 hours after birth; PPH ≥ 1000 mL within 24 hours after birth; need for blood transfusion; use of additional uterotonics, and PPH treatment rate. Important outcomes included maternal death.

Risk of bias

We used the Cochrane risk of bias tool (RoB 1).

Synthesis methods

At least two review authors independently assessed trials for inclusion, trustworthiness, risk of bias, and certainty of the evidence using GRADE. We calculated direct and indirect effect estimates, where possible, for critical and important outcomes. Due to limited data, we were unable to perform pairwise meta-analyses and network meta-analyses for the available combinations, or generate rankings.

Included studies

We included five trials (10 trial arms, 236,771 women); all included women giving birth vaginally and four had a hospital setting.

The combinations of diagnostic and treatment strategies were: visual estimation-based diagnosis plus usual care for treatment; 3-option trigger PPH diagnosis with calibrated drape (1. clinical concern, or 2. blood loss ≥ 300 mL to < 500 mL plus abnormal observations, or 3. blood loss ≥ 500 mL) plus MOTIVE (uterine **M**assage, **O**xytocics, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care) treatment bundle; 2-option trigger PPH diagnosis with calibrated drape (1. clinical concern, or 2. blood loss ≥ 500 mL) plus MOTIVE treatment bundle; calibrated drape-based diagnosis plus usual care for treatment; gravimetric method-based diagnosis plus usual care for treatment; MaternaWell tray-based diagnosis plus usual care for treatment.

Synthesis of results

3-option trigger PPH diagnosis plus MOTIVE bundle versus visual estimation-based diagnosis plus usual care (direct evidence; 1 study, 170,956 participants) reduces PPH ≥ 500 mL (RR 0.48, 95% CI 0.39 to 0.58; high-certainty evidence), and PPH ≥ 1000 mL (RR 0.34, 95% CI 0.26 to 0.44; high-certainty). Moderate-certainty evidence suggests it probably makes little or no difference to the need for blood transfusion (RR 0.82, 95% CI 0.62 to 1.08) or additional uterotonics (RR 1.19, 95% CI 0.94 to 1.50), and maternal death (RR 0.73, 95% CI 0.36 to 1.48).

2-option trigger PPH diagnosis plus MOTIVE bundle versus visual estimation-based diagnosis plus usual care (direct evidence; 1 study, 39,176 participants) reduces PPH ≥ 500 mL (RR 0.73, 95% CI 0.60 to 0.89; high-certainty). It probably makes little or no difference to PPH ≥ 1000 mL (RR 0.88, 95% CI 0.69 to 1.12; moderate-certainty), and the need for blood transfusion (RR 1.06, 95% CI 0.55 to 2.04; moderate-certainty), and may make little or no difference to maternal death (RR 1.01, 95% CI 0.00 to 4.0×10^7; low-certainty). High-certainty evidence suggests it increases the need for additional uterotonics (RR 3.54, 95% CI 2.27 to 5.52).

3-option trigger PPH diagnosis plus MOTIVE bundle versus 2-option trigger PPH diagnosis plus MOTIVE bundle (indirect evidence) reduces PPH ≥ 500 mL (RR 0.65, 95% CI 0.49 to 0.86; high-certainty), PPH ≥ 1000 mL (RR 0.38, 95% CI 0.27 to 0.55; high-certainty), and the need for additional uterotonics (RR 0.34, 95% CI 0.20 to 0.55; high-certainty). It probably makes little or no difference to the need for blood transfusion (RR 0.78, 95% CI 0.38 to 1.59; moderate-certainty), and may make little or no difference to maternal death (RR 0.72, 95% CI 0.00 to 2.9×10^7; low-certainty).

Calibrated drape-based diagnosis plus usual care (in a European setting (E)) versus visual estimation-based diagnosis plus usual care (E) (direct evidence; 1 study, 25,381 participants) probably makes little or no difference to the need for blood transfusion (RR 0.83, 95% CI 0.57 to 1.21; moderate-certainty).

Gravimetric method-based diagnosis plus usual care versus calibrated drape-based diagnosis plus usual care (direct evidence; 1 study, 1195 participants) reduces PPH ≥ 500 mL (RR 0.54, 95% CI 0.32 to 0.90; high-certainty), and may make little or no difference to need for blood transfusion (RR 1.00, 95% CI 0.06 to 15.94; low-certainty).

MaternaWell tray-based diagnosis plus usual care versus calibrated drape-based diagnosis plus usual care (direct evidence; 1 study, 63 participants) may make little or no difference to PPH ≥ 500 mL (RR 0.61, 95% CI 0.11 to 3.38; low-certainty), and PPH ≥ 1000 mL (RR 0.30, 95% CI 0.01 to 7.19; low-certainty).

Gravimetric method-based diagnosis plus usual care versus MaternaWell tray-based diagnosis plus usual care (indirect evidence) may make little or no difference to PPH ≥ 500 mL (RR 0.89, 95% CI 0.15 to 5.35; low-certainty).

No data were available for other critical and important outcomes.

Authors' conclusions

Both 3-option trigger PPH diagnosis plus MOTIVE bundle and 2-option trigger PPH diagnosis plus MOTIVE bundle were more effective than visual estimation-based diagnosis plus usual care (direct evidence).

3-option trigger PPH diagnosis plus MOTIVE bundle was more effective than 2-option trigger PPH diagnosis plus MOTIVE bundle (indirect evidence). As the treatment strategy (MOTIVE bundle) is the same in these combinations, the increased effectiveness is likely due to the 3-option trigger PPH diagnosis, which adds blood loss of ≥ 300 mL to < 500 mL in the drape plus abnormal clinical observations as a PPH diagnostic trigger.

None of the comparisons demonstrated differences in blood transfusion or maternal mortality outcomes.

Future research should assess the effectiveness of combination diagnostic and treatment strategies in non-hospital settings, and for women having a caesarean birth. Studies should provide more data on side effects, and maternal experience of care.

Funding

Gates Foundation

Registration

PROSPERO (CRD42024600189)

PLAIN LANGUAGE SUMMARY

Which combinations of ways to diagnose and treat excessive bleeding after childbirth (postpartum haemorrhage) are most effective?

Key messages

- We found the combination of using a diagnosis with 1) birth-attendant clinical concern, or 2) 300 mL to 500 mL of drape-measured blood loss (blood is collected in a plastic drape with markings indicating the volume) with observations (e.g. heart rate, blood pressure, the tone of the womb, and flow of blood), or 3) 500 mL or more of drape-measured blood loss to diagnose postpartum haemorrhage (PPH), plus a treatment bundle, was more effective than using visual estimation for diagnosis plus usual care for treatment.
- When using the same treatment bundle for PPH treatment, using a diagnosis with 1) birth-attendant clinical concern, or 2) 300 mL to 500 mL of drape-measured blood loss with observations, or 3) 500 mL or more of drape-measured blood loss was more effective than a diagnosis using 1) birth-attendant clinical concern, or 2) 500 mL or more of drape-measured blood loss.

What is PPH?

PPH is commonly defined as blood loss of 500 mL or more in the first 24 hours after childbirth.

Why is this review important?

PPH is a common reason why mothers die in childbirth around the world. Reducing PPH harm requires a combination of accurate diagnosis and effective treatment. Our study aimed to determine which combinations are most effective.

What did we want to find out?

We aimed to find out which combinations of ways to diagnose and treat PPH are most effective.

What did we do?

We looked at relevant studies to find out which combinations of ways to diagnose and treat PPH are most effective. We included women having a normal or caesarean birth in any setting (community delivery units, hospitals, home births).

Examples of ways to diagnose PPH include the assessor: having clinical concern; looking at the blood loss and estimating the blood volume (visual estimation); measuring the volume of blood loss in a drape or tray with markings indicating the volume (volumetric method); measuring the blood loss in a drape along with observations (such as heart rate and blood pressure), and weighing blood loss using scales (gravimetric method).

Examples of ways to treat PPH include 'usual care' (normal hospital practice), and treatment 'bundles' with various treatments given at the same time, such as the MOTIVE bundle (**M** – Massage of the womb to help it contract, **O** – giving medicines like Oxytocin to contract the womb, **T** – giving Tranexamic acid (a medicine given to slow bleeding), **IV** – intravenous fluids: fluids given through a drip to help maintain blood pressure, **E** – Examination and Escalation: if bleeding does not stop, calling for help and considering other treatments).

What did we find out?

We found five studies involving 236,771 women.

We are confident that diagnosis using 1) birth-attendant clinical concern, or 2) 300 mL to 500 mL of drape-measured blood loss with observations, or 3) 500 mL or more of drape-measured blood loss, plus the MOTIVE bundle is more effective than visual estimation plus usual care in reducing PPH of 500 mL or more and PPH of 1000 mL or more, but probably makes little or no difference to the need for blood transfusion or other drug treatments, and the risk of mothers dying.

We are confident that diagnosis using 1) birth-attendant clinical concern, or 2) 500 mL or more of drape-measured blood loss, plus the MOTIVE bundle is more effective than visual estimation plus usual care for reducing PPH of 500 mL or more, but probably makes little or

no difference to PPH of 1000 mL or more and the need for blood transfusion, and may make little or no difference to the risk of mothers dying. We are confident that it increases the need for additional drug treatments.

We are confident that diagnosis using 1) birth-attendant clinical concern, or 2) 300 mL to 500 mL of drape-measured blood loss with observations, or 3) 500 mL or more of drape-measured blood loss, plus the MOTIVE bundle is more effective than diagnosis using 1) birth-attendant clinical concern, or 2) 500 mL or more of drape-measured blood loss, plus the MOTIVE bundle in reducing PPH of 500 mL or more, PPH of 1000 mL or more, and the need for additional drug treatments. It probably makes little or no difference to the need for blood transfusion, and may make little or no difference to the risk of mothers dying.

Drape-based diagnosis plus usual care (E) (this is usual care in a European healthcare setting, which may be different to usual care in a low-income setting because of access to, for example, more effective treatments) versus visual estimation plus usual care (E) probably makes little or no difference to the need for blood transfusion.

We are confident that the gravimetric method-based diagnosis plus usual care versus drape-based diagnosis plus usual care is more effective in reducing PPH of 500 mL or more, but may make little or no difference to the need for blood transfusion.

Tray-based diagnosis plus usual care versus drape-based diagnosis plus usual care may make little or no difference in reducing PPH of 500 mL or more and PPH of 1000 mL or more.

Gravimetric method-based diagnosis plus usual care versus tray-based diagnosis plus usual care may make little or no difference in reducing PPH of 500 mL or more.

What are the limitations?

All our studies involved women giving birth normally and most were in hospitals. We would like more information about women giving birth by caesarean, and in other settings such as home births. We would also like more information about unwanted effects and women's experience of care.

How up to date is the evidence?

This evidence is current to 18 October 2024.

SUMMARY OF FINDINGS

Summary of findings 1. 3-option PPH trigger plus MOTIVE bundle versus visual estimation plus usual care

Patient or population: women in the third stage of labour (1 cluster-RCT, 170,956 participants)

Intervention test and treat combination: 3-option PPH trigger plus MOTIVE bundle

Comparison/reference test and treat combination: visual estimation plus usual care

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Direct Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty
PPH (≥ 500 mL)	79 per 1000	165 per 1000	86 fewer per 1000 (from 100 fewer to 69 fewer)	0.48 (0.39 to 0.58)	⊕⊕⊕⊕ HIGH
Severe PPH (≥ 1000 mL)	15 per 1000	43 per 1000	28 fewer per 1000 (from 32 fewer to 24 fewer)	0.34 (0.26 to 0.44)	⊕⊕⊕⊕ HIGH
Blood transfusion	25 per 1000	31 per 1000	6 fewer per 1000 (from 12 fewer to 2 more)	0.82 (0.62 to 1.08)	⊕⊕⊕⊖ MODERATE[a]
Additional uterotonics	129 per 1000	108 per 1000	21 fewer per 1000 (from 7 fewer to 54 more)	1.19 (0.94 to 1.50)	⊕⊕⊕⊖ MODERATE[a]
Maternal death	Absolute risks incalculable due to low event rates			0.73 (0.36 to 1.48)	⊕⊕⊕⊖ MODERATE[a]

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; MOTIVE (uterine **M**assage, **O**xytocics, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care); PPH: postpartum haemorrhage; RCT: randomised controlled trial; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Direct evidence downgraded by one level due to serious imprecision.

Summary of findings 2. 2-option PPH trigger plus MOTIVE bundle versus visual estimation plus usual care

Patient or population: women in the third stage of labour (1 cluster-RCT, 39,176 participants)

Intervention test and treat combination: 2-option PPH trigger plus MOTIVE bundle

Comparison/reference test and treat combination: visual estimation plus usual care

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Direct Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty
PPH (≥ 500 mL)	129 per 1000	176 per 1000	48 fewer per 1000 (from 71 fewer to 19 fewer)	0.73 (0.60 to 0.89)	⊕⊕⊕⊕ HIGH
Severe PPH (≥ 1000 mL)	33 per 1000	37 per 1000	4 fewer per 1000 (from 12 fewer to 4 more)	0.88 (0.69 to 1.12)	⊕⊕⊕⊖ MODERATE[a]
Blood transfusion	16 per 1000	15 per 1000	1 more per 1000 (from 7 fewer to 16 more)	1.06 (0.55 to 2.04)	⊕⊕⊕⊖ MODERATE[a]
Additional uterotonics	222 per 1000	63 per 1000	159 more per 1000 (from 80 more to 284 more)	3.54 (2.27 to 5.52)	⊕⊕⊕⊕ HIGH
Maternal death	Absolute risks incalculable due to low event rates			1.01 (0.00 to 4.0×10^7)	⊕⊕⊖⊖ LOW[b]

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; MOTIVE (uterine **M**assage, **O**xytocics, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care); PPH: postpartum haemorrhage; RCT: randomised controlled trial; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Direct evidence downgraded by one level due to serious imprecision.
[b]Direct evidence downgraded by two levels due to very serious imprecision.

Summary of findings 3. 3-option PPH trigger plus MOTIVE bundle versus 2-option PPH trigger plus MOTIVE bundle

Patient or population: women in the third stage of labour

Intervention test and treat combination: 3-option PPH trigger plus MOTIVE bundle

Comparison/reference test and treat combination: 2-option PPH trigger plus MOTIVE bundle

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Indirect Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty**
PPH (≥ 500 mL)	79 per 1000	121 per 1000	42 fewer per 1000 (from 62 fewer to 17 fewer)	0.65 (0.49 to 0.86)	⊕⊕⊕⊕ HIGH
Severe PPH (≥ 1000 mL)	11 per 1000	28 per 1000	17 fewer per 1000 (from 20 fewer to 13 fewer)	0.38 (0.27 to 0.55)	⊕⊕⊕⊕ HIGH
Blood transfusion	5 per 1000	7 per 1000	2 fewer per 1000 (from 4 fewer to 4 more)	0.78 (0.38 to 1.59)	⊕⊕⊕⊖ MODERATE[a]
Additional uterotonics	48 per 1000	141 per 1000	93 fewer per 1000 (from 113 fewer to 63 fewer)	0.34 (0.20 to 0.55)	⊕⊕⊕⊕ HIGH
Maternal death	Absolute risks incalculable due to low event rates			0.72 (0.00 to 2.9×10^{7})	⊕⊕⊖⊖ LOW[b]

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

**The certainty of the indirect estimates was not further downgraded for indirectness due to the "similarity assumption" (factors in the design of the trial and the methodological quality are not sufficiently different to result in different effects) [1].

CI: confidence interval; MOTIVE (uterine **M**assage, **O**xytocics, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care); PPH: postpartum haemorrhage; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Indirect evidence downgraded by one level due to serious imprecision.
[b]Indirect evidence downgraded by two levels due to very serious imprecision.

Summary of findings 4. Calibrated drape plus usual care (E) versus visual estimation plus usual care (E)

Patient or population: women in the third stage of labour (1 cluster-RCT, 25,381 participants)

Intervention test and treat combination: calibrated drape plus usual care (E)

Comparison/reference test and treat combination: visual estimation plus usual care (E)

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Direct Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty
PPH (≥ 500 mL)	–	–	–	No data available for this outcome.	–
Severe PPH (≥ 1000 mL)	–	–	–	No data available for this outcome.	–
Blood transfusion	8 per 1000	9 per 1000	2 fewer per 1000 (from 4 fewer to 2 more)	0.83 (0.57 to 1.21)	⊕⊕⊕⊖ MODERATE[a]
Additional uterotonics	–	–	–	No data available for this outcome.	–
Maternal death	–	–	–	No deaths.	–

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; E: Europe; PPH: postpartum haemorrhage; RCT: randomised controlled trial; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Direct evidence downgraded by one level due to serious imprecision.

Summary of findings 5. Gravimetric method plus usual care versus calibrated drape plus usual care

Patient or population: women in the third stage of labour (1 RCT, 1195 participants)

Intervention test and treat combination: gravimetric method plus usual care

Comparison/reference test and treat combination: calibrated drape plus usual care

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Direct Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty
PPH (≥ 500 mL)	47 per 1000	87 per 1000	40 fewer per 1000 (from 59 fewer to 9 fewer)	0.54 (0.32 to 0.90)	⊕⊕⊕⊕ HIGH
Severe PPH (≥ 1000 mL)	–	–	–	No data available for this outcome.	–
Blood transfusion	2 per 1000	2 per 1000	0 fewer per 1000 (from 2 fewer to 33 more)	1.00 (0.06 to 15.94)	⊕⊕⊖⊖ LOW[a]
Additional uterotonics	–	–	–	No data available for this outcome.	–
Maternal death	–	–	–	No data available for this outcome.	–

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; PPH: postpartum haemorrhage; RCT: randomised controlled trial; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Direct evidence downgraded by two levels due to very serious imprecision.

Summary of findings 6. MaternaWell tray plus usual care versus calibrated drape plus usual care

Patient or population: women in the third stage of labour (1 RCT, 63 participants)

Intervention test and treat combination: MaternaWell tray plus usual care

Comparison/reference test and treat combination: calibrated drape plus usual care

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Direct Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty
PPH (≥ 500 mL)	61 per 1000	100 per 1000	39 fewer per 1000 (from 89 fewer to 238 more)	0.61 (0.11 to 3.38)	⊕⊕⊖⊖ LOW[a]
Severe PPH (≥ 1000 mL)	10 per 1000	33 per 1000	23 fewer per 1000 (from 33 fewer to 206 more)	0.30 (0.01 to 7.19)	⊕⊕⊖⊖ LOW[a]
Blood transfusion	–	–	–	No data available for this outcome.	–
Additional uterotonics	–	–	–	No data available for this outcome.	–
Maternal death	–	–	–	No data available for this outcome.	–

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; PPH: postpartum haemorrhage; RCT: randomised controlled trial; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Direct evidence downgraded by two levels due to very serious imprecision.

Summary of findings 7. Gravimetric method plus usual care versus MaternaWell tray plus usual care

Patient or population: women in the third stage of labour

Intervention test and treat combination: gravimetric method plus usual care

Comparison/reference test and treat combination: MaternaWell tray plus usual care

Outcome: multiple outcomes

Outcome	Anticipated absolute effects* (95% CI)			Indirect Evidence	
	Risk with intervention	Risk with reference	Risk difference with intervention	RR (95% CI)	Certainty**
PPH (≥ 500 mL)	54 per 1000	61 per 1000	7 fewer per 1000 (from 52 fewer to 265 more)	0.89 (0.15 to 5.35)	⊕⊕⊖⊖ LOW[a]
Severe PPH (≥ 1000 mL)	–	–	–	No data available for this outcome.	–
Blood transfusion	–	–	–	No data available for this outcome.	–
Additional uterotonics	–	–	–	No data available for this outcome.	–
Maternal death	–	–	–	No data available for this outcome.	–

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison/reference group and the relative effect of the intervention (and its 95% CI).

**The certainty of the indirect estimates was not further downgraded for indirectness due to the "similarity assumption" (factors in the design of the trial and the methodological quality are not sufficiently different to result in different effects) [1].

CI: confidence interval; PPH: postpartum haemorrhage; RR: risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

[a]Indirect evidence downgraded by two levels due to very serious imprecision.

BACKGROUND

Description of the condition

Postpartum haemorrhage (PPH) is a leading cause of maternal deaths worldwide. The majority of these deaths occur in low- and middle-income countries (LMICs) [2]. Mothers who survive may still be affected by serious morbidity, such as the need for blood transfusion, and surgery such as hysterectomy [3].

The common definition of PPH is blood loss of ≥ 500 mL in the first 24 hours after birth. Severe PPH is defined as blood loss of ≥ 1000 ml in the same time period [4]. The commonest cause of PPH is uterine atony (failure of the uterus to contract adequately), but other causes include trauma, retained tissue and coagulopathies [5, 6]. Risk factors include maternal anaemia, prolonged labour and multiple gestation [5, 6]. The causes and risk factors may not always be easily identifiable.

PPH is a treatable condition, but this requires both timely and accurate diagnosis, and the provision of effective treatments to account for the different causes. There is uncertainty about which combination of diagnostic and treatment strategies is most effective.

Description of the intervention and how it might work

Description of the intervention

The interventions for this review are combinations of PPH diagnostic and treatment strategies at vaginal or caesarean birth.

The diagnostic strategies include the use of different definitions for identifying PPH (e.g. based on volume of blood loss or change in haemoglobin), different thresholds for defining PPH (e.g. volume of blood loss of ≥ 500 mL or ≥ 1000 mL), or different measurement methods for diagnosing PPH (e.g. visual estimation of blood loss, calibrated blood collection drape, calibrated tray, or gravimetric assessment of blood loss).

The treatment strategies include 'usual care' according to local guidelines, sequential treatment approaches (e.g. uterotonic treatment, followed by tranexamic acid, further followed by uterine balloon, as necessary), or bundled treatment approaches, such as the MOTIVE bundle used in the E-MOTIVE intervention [7].

How might the intervention work?

Accurate diagnosis and effective treatment are both essential for improving outcomes. Accurate diagnosis requires both a clear and actionable definition and an accurate and implementable diagnostic strategy. Using a PPH definition that fails to identify women who later develop poor outcomes, or a PPH diagnostic strategy that results in missed or delayed diagnosis, could mean women in need of PPH treatment go without timely treatment. Thus, both a clinically meaningful PPH definition that is closely related to prognosis and a sound diagnostic strategy that accurately identifies PPH are necessary. However, accurate diagnosis alone is not sufficient. Unless effective treatment is provided for those with a diagnosis of PPH, outcomes are unlikely to improve. The combination of an accurate diagnostic strategy and an effective treatment strategy is likely to be more effective than either of these elements alone. The combination of diagnosis and treatment strategies is the focus of this review.

Why it is important to do this review

Studies have evaluated the combination of a diagnostic strategy and a treatment strategy for PPH. However, there is substantial heterogeneity in the diagnostic strategies and treatment strategies used, and it is currently unclear which combinations of diagnostic and treatment strategies result in the greatest benefit. This review aims to bring together all the evidence into one coherent analysis and, if possible, rank the available options in order of their effects.

OBJECTIVES

- To assess the comparative effectiveness of various combinations of 'diagnostic and treatment' strategies for PPH in women giving birth, and rank them.
- To explore the relative effects of various diagnostic strategies, when the treatment strategies are the same or similar.
- To explore the relative effects of various treatment strategies, when the diagnostic strategies are the same or similar.

METHODS

We followed the Methodological Expectations of Cochrane Intervention Reviews (MECIR) when conducting the review (8), and PRISMA 2020 guidance for the reporting (9).

Criteria for considering studies for this review

Types of studies

All randomised controlled trials or cluster-randomised trials comparing the effects of different combinations of 'diagnostic and treatment' strategies for PPH were eligible for inclusion. Randomised trials published only as abstracts were eligible if sufficient information could be obtained, including by contacting study authors. We excluded quasi-randomised trials (e.g. trials which randomise by day of week). There were no date or language restrictions applied.

Types of participants

The review included studies of women having vaginal or caesarean birth in any location and setting.

Types of interventions

Trials were eligible for inclusion if they evaluated a combination of a diagnostic strategy and treatment strategy for PPH against another combination of a diagnostic strategy and treatment strategy. When the treatment strategies across the comparisons were the same or very similar, we explored the relative effects of the various diagnostic strategies. Conversely, when the diagnostic strategies across comparisons were the same or very similar, we explored the relative effects of the various treatment strategies.

Combinations of diagnostic and treatment strategies included the following.

- **Visual estimation-based diagnosis plus usual care for PPH treatment**. The visual estimation-based diagnosis involves birth attendants estimating blood loss by seeing to what extent drapes and sheets are soaked with blood, along with blood collected in non-calibrated collection devices such as drapes and bowls. Usual care includes interventions to treat PPH in accordance with local or national guidelines as reported by the

trialists. We differentiated between 'usual care' in high-income country (HIC) settings and low- and middle-income country (LMIC) settings as they are not equivalent.

- **3-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle**. The 3-option trigger PPH diagnostic strategy diagnoses PPH if: 1) there is concern based on clinical judgement, or 2) ≥ 300 mL to < 500 mL of blood is collected in the drape plus one abnormal clinical observation or vital sign (heart rate (tachycardia > 100 beats per minute (bpm) or an increase of 20 bpm from baseline), blood pressure (systolic blood pressure < 100 mmHg or a decrease of 20 mmHg from baseline), soft uterine tone, heavy vaginal flow of blood), or 3) ≥ 500 mL of blood is collected in the drape (regardless of other observations or vital signs). The 'MOTIVE' PPH treatment bundle consists of uterine **M**assage, **O**xytocic drugs, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care).
- **2-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle**. The 2-option trigger PPH diagnostic strategy diagnoses PPH if: 1) there is concern based on clinical judgement, or 2) ≥ 500 mL of blood is collected in the drape (regardless of other observations or vital signs).
- **Calibrated drape-based diagnosis plus usual care for PPH treatment**. For the calibrated drape-based diagnostic strategy, a calibrated blood collection drape or bag is placed under the woman giving birth. The graduations indicate the volume of blood gathered.
- **Gravimetric method-based diagnosis plus usual care for PPH treatment**. The Gravimetric method-based diagnosis involves the use of scales to weigh collected blood loss, as well as weighing blood-soaked gauze, pads, and sheets, and subtracting their dry weight.
- **MaternaWell tray-based diagnosis plus usual care for PPH treatment**. For the MaternaWell tray-based diagnostic strategy, the MaternaWell tray is placed underneath the woman after the birth of the baby. The placenta is delivered onto the tray and then removed. The attendant measures the blood volume in the tray in accordance with the calibrations and instructions of the tray. The tray is removed once the bleeding has stopped or when 30 minutes have passed after placement.

We excluded trials which did not have clear diagnostic and treatment strategies.

Outcome measures

We estimated the relative effects (and would have estimated the rankings had there been sufficient data) of the competing interventions (combinations of diagnostic and treatment strategies) according to the following critical and important outcomes.

Critical outcomes

The critical outcomes of the review were as follows.

- PPH ≥ 500 mL within 24 hours after birth
- Additional blood loss of ≥ 500 mL following diagnosis of PPH and within 24 hours after birth (as reported by the study)
- PPH ≥ 1000 mL within 24 hours after birth
- Need for blood transfusion
- Use of additional uterotonics
- PPH treatment rate

Important outcomes

The important outcomes of the review were as follows.

- Maternal deaths
- Severe morbidity (defined as maternal deaths or severe morbidity events adapted from World Health Organization (WHO) "near miss" criteria [10], to include major surgery (laparotomy, uterine artery ligation, internal iliac artery ligation, B-Lynch suture, hysterectomy, extensive vaginal repair), admission to the intensive care unit, or vital organ failure (temporary or permanent))
- Side-effects, e.g. fever (> 38 °C), nausea, vomiting, diarrhoea, hypertension, headache, shivering, abdominal pain
- Maternal satisfaction as reported by the study
- Maternal sense of wellbeing as reported by the study
- Breastfeeding at discharge
- Postpartum anaemia (haemoglobin < 9 g/dL)

Search methods for identification of studies

The search methods are detailed in Supplementary material 1.

Electronic searches

The search strategies were developed and run in collaboration with the Cochrane Information Specialist (Supplementary material 1).

We identified relevant trials through searches of the following databases.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2024, Issue 9 of 12), in the Cochrane Library
- MEDLINE (Ovid) (1946 to 18 October 2024)
- Embase (Ovid) (1974 to 18 October 2024)

We did not impose restrictions on language of publication or publication status.

We searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for ongoing and unpublished studies.

A randomised control trial (RCT) filter was applied: Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2023 revision)([11]).

We also handsearched the references of relevant systematic reviews published since 2019.

We checked the status of included and eligible studies for post-publication amendments, expressions of concern, errata, corrigenda and retractions. This was done in the corresponding journals and on retractiondatabase.org [12].

Searching other resources

We aimed to retrieve additional relevant references cited in papers identified through the above search strategy and searched for the full texts of trials initially identified as abstracts. For randomised trials published only as abstracts, we aimed to seek information from primary authors to investigate whether these studies would

meet our eligibility criteria for inclusion. We did not apply any language or date restrictions.

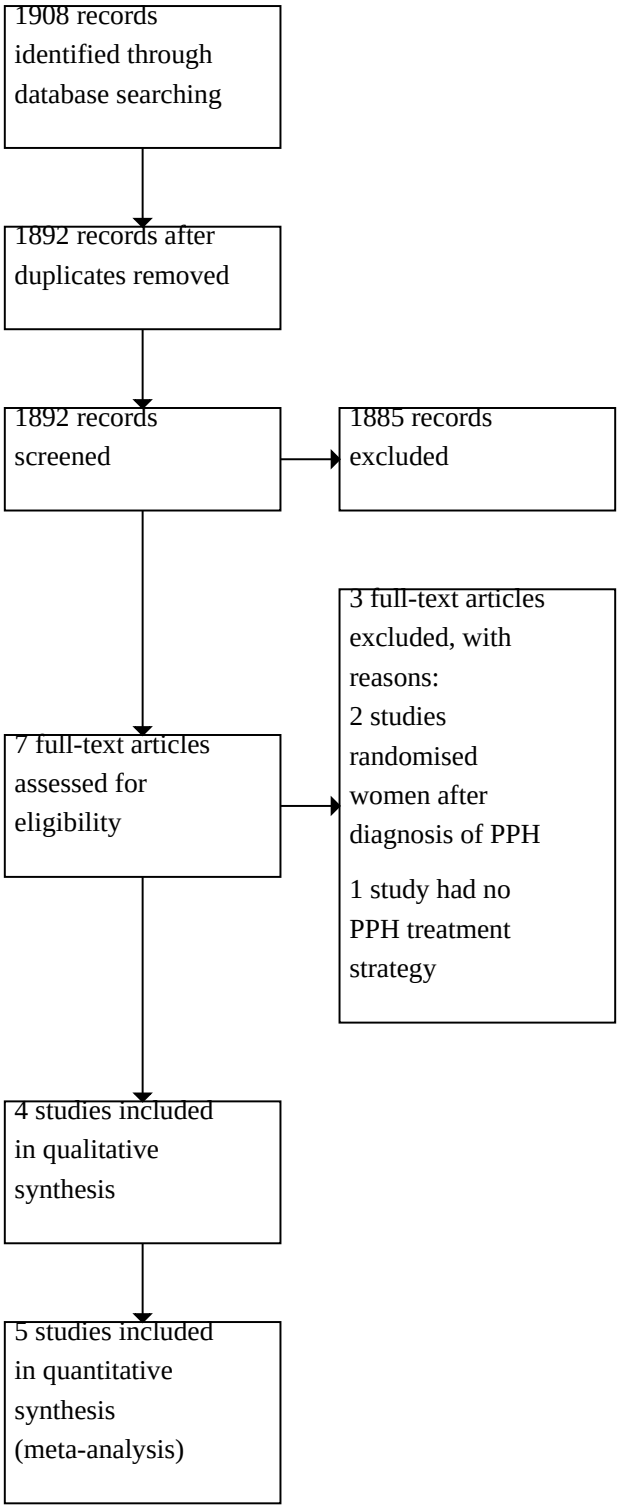
Data collection and analysis

Review authors who were also authors of any potentially eligible study made no study eligibility decisions about, extracted data from, carried out the risk of bias assessment for, or performed GRADE assessments for that study.

Selection of studies

At least two review authors independently assessed the studies identified for possible inclusion (IY and AD, or KV and MP where IY and AD were conflicted). Disagreements were resolved through consensus or input from another review author. Figure 1 shows the results of the study selection process.

Figure 1. PRISMA flow diagram



Trustworthiness screening of eligible studies

At least two authors (IY and AD, or KV and MP where IY and AD were conflicted) undertook trustworthiness assessments of all eligible studies, according to Cochrane Pregnancy and Childbirth editorial guidelines and using the Cochrane Pregnancy and Childbirth's trustworthiness screening tool (CPC-TST) [13]. Disagreements were resolved through consensus discussion or input from another review author. The trustworthiness screening tool consists of the following four domains.

- Governance,
- Baseline data,
- Feasibility
- Results

We adapted the trustworthiness tool for each domain, to account for historical differences in expectations of reporting and research methodology. These adaptations are described below. Data from abstracts would only have been included if the authors confirmed that it came from the final analysis and would not change subsequently.

We assessed the trustworthiness domains as follows.

Governance

- Are there retraction notices or expressions of concern on the Retraction Watch Database [12]?
- Was the study prospectively registered (post 2010)? If not, is there a satisfactory reason?
- Did the authors provide a copy of the protocol?
- Did the authors provide details of patient consent and ethics approval?
- Are there sufficient details about the recruitment of participants and trial dates?
- If contacted, did the authors correspond with requests for further information in the specified timeframe?
- Did the authors provide individual patient data (IPD) if requested to do so?
- Are there fewer than three study authors, and is the reason given for this?

Baseline characteristics

- Are participant baseline characteristics available?
- Are the characteristics too similar (distribution of mean)?
- Are the recalculated standard deviations (SD) and P values correct?

Feasibility

- Is there concern that the characteristics are implausible, e.g. a large number of participants recruited in a short time frame in a single centre?
- Are details about randomisation provided?
- Is there less than a six-month period between the trial ending and its publication, and is there a reason for this?
- If a placebo was used, and sourced without industry sponsorship, how was this achieved?

Results

- Is there concern that the results are implausible, e.g. a large risk reduction with a small sample size or no complications?
- Are the results very different to those found in other included studies?
- Are the recalculated SDs and P values correct?

Historical differences in expectations of reporting and research methodology

We would not have contacted authors of studies published before 1980 due to the age of the authors and publications. We made trustworthiness screening assessments based on the available data and information. Studies which were published before 1990 were deemed trustworthy even if trial dates, ethics and consent information and randomisation and blinding details were not explicitly detailed. Studies published before 2010 did not require prospective trial registration, and either the trial dates, consent details, or ethics information could be left out of the manuscript.

Data extraction and management

At least two review authors independently extracted the data from eligible studies using blank electronic forms designed in Microsoft Excel (IY and AD, or KV and MP where IY and AD were conflicted). Disagreements were resolved through consensus or input from another review author, if required. We entered data into STATA [14] and Review Manager [15]. Had the information been unclear, we would have contacted study authors to provide further details.

Study data

We extracted the following data for each included study.

- The number of participants
- Any exclusion criteria
- The interventions (combinations of diagnostic and treatment strategies) being compared and their available outcomes as given above
- All relevant arm-level data (e.g. number of events and number of participants for binary outcomes, and means and standard deviations per study arm for continuous outcomes)
- PPH treatment rate

Data on potential effect modifiers

We extracted the following study and population characteristics that may act as effect modifiers from each included study.

- Mode of birth (vaginal or caesarean birth)
- Prior risk of PPH (as defined by the study and categorised as low, high, mixed or not stated)
- Setting of the study (community, hospital or home birth)

Other data

We also extracted the following additional information for each included study.

- Country or countries in which the study was performed
- Resource level (LMIC versus HIC)
- Date of publication and dates of recruitment

- Type of publication (full-text publication, abstract, unpublished data)
- Reference for trial registration

Risk of bias assessment in included studies

At least two review authors (IY and KV, or MP where IY was conflicted) independently assessed the risk of bias for outcomes in the included studies using the original Cochrane RoB 1 tool for randomised trials [16]. Any disagreements would have been resolved by consensus discussion or by involving another review author, if required.

Random sequence generation (selection bias)

We excluded studies that were found to be at high risk of bias for random sequence generation (any non-random process, e.g. odd or even date of birth, or hospital or clinic record number). For each included study, we described the method used to generate the allocation sequence to allow an assessment of whether it produced comparable groups.

The methods were assessed as follows.

- Low risk of bias (any truly random process, e.g. random number table, or computer random number generator)
- Unclear risk of bias

Allocation concealment (selection bias)

We described for each included study the method used to conceal allocation to combined diagnostic and treatment strategy prior to assignment and assessed whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment.

The methods were assessed as follows.

- Low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes)
- High risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth)
- Unclear risk of bias

Blinding of participants and personnel (performance bias)

For each included study, we described the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to have affected the results.

The methods were assessed as follows.

- Low, high or unclear risk of bias for participants
- Low, high or unclear risk of bias for personnel

Blinding of outcome assessment (detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received.

We assessed methods used to blind outcome assessment as follows.

- Low, high or unclear risk of bias. We considered studies to be at low risk if we judged that the lack of blinding would be unlikely to affect the results.

Incomplete outcome data (attrition bias)

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

We assessed methods to handle incomplete outcome data as follows.

- Low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups and less than 10% of outcome data missing)
- High risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation or more than 10% of outcome data missing)
- Unclear risk of bias

Selective reporting (reporting bias)

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

We assessed the methods as follows.

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

Other bias

We described any important concerns about other possible sources of bias, such as the source of funding and possible conflicts of interest.

These were assessed as follows.

- Low risk of other bias (public funding or no funding, and no significant conflicts of interest identified)
- High risk of other bias (industry funding or significant conflicts of interest identified)
- Unclear risk of other bias

Measures of treatment effect

Relative treatment effects

For dichotomous outcomes, we summarised the relative treatment effects as risk ratios (RR) with 95% CIs (Supplementary material

5). For continuous outcomes, we would have summarised the treatment effects using the mean difference (MD) with 95% CIs. If different scales had been used for continuous outcomes, we would have used standard mean differences with 95% CIs [17].

Relative treatment ranking

With sufficient data, we would have estimated the cumulative probabilities of each diagnostic and treatment strategy combination being at each possible rank and obtained a diagnostic and treatment strategy combination hierarchy using the surface under the cumulative ranking curve (SUCRA). The larger the SUCRA, the higher its rank amongst all available diagnostic and treatment strategy combinations [18]. The probabilities to rank the diagnostic and treatment strategy combinations would be estimated under a Bayesian model with flat priors, assuming that the posterior distribution of the parameter estimates is approximated by a normal distribution with mean and variance equal to the frequentist estimates and variance–covariance matrix. Rankings would be constructed by drawing 1000 samples from their approximate posterior density. For each draw, the linear predictor would be evaluated for each study, and the largest linear predictor would be noted [19].

Unit of analysis issues

Cluster-randomised trials

We included three cluster-randomised trials in this review (Gallos 2023a [20]; Gallos 2023b [21]; Zhang 2010 [22]). In the case of Gallos 2023a and Gallos 2023b, the authors provided estimates and 95% confidence intervals for outcomes not reported by the paper. These estimates were produced using the same methods as used for the analyses they reported in the study. In the case of Zhang 2010, the intracluster correlation coefficients (ICCs) were provided in the study manuscript. The standard errors were adjusted using the methods detailed in the *Cochrane Handbook for Systematic Reviews of Interventions* [1]. If the ICCs had not been provided, we would have estimated them from the trials themselves, or from similar trials conducted in similar populations [1]. In this case, we would have conducted sensitivity analyses to investigate the effects of variations in the ICCs. We would have considered it reasonable to combine the results from individually randomised trials and cluster-randomised trials if there was little heterogeneity between the study designs, and any interaction between the relative effects of diagnostic and treatment strategy combinations and the choice of randomisation unit was thought to be unlikely. We would also have assessed the effect of the unit of randomisation in sensitivity analysis [1].

Multi-arm trials

We did not find any multi-arm trials to include in this review. We would have treated multi-arm trials as multiple independent comparisons in pairwise meta-analyses. We would account for the correlation between the effect sizes in the network meta-analysis.

Dealing with missing data

The levels of attrition were noted for each included study as described in 'Incomplete outcome data' in 'Assessment of risk of bias in included studies' (Supplementary material 2). Where possible, all participants randomised to each group were included in the analyses, and all participants were analysed in the group to which they were allocated, whether they received the allocated intervention or not. The denominator for each outcome in each trial was the number of participants randomised minus any participants whose outcomes were known to be missing.

Reporting bias assessment

Assessment of reporting bias, such as publication bias, was not undertaken in this review due to the limited number of included studies. If there had been 10 or more studies in the meta-analysis, we would have investigated reporting bias by generating funnel plots, and visually assessing them for asymmetry.

Synthesis methods

Network meta-analysis was not possible due to the paucity of included studies and data.

Methods for direct comparisons of combinations of PPH diagnostic and treatment strategies

The review presents direct pairwise analyses of comparisons of PPH diagnostic and treatment strategy combinations with ICC adjustments for the included cluster-randomised trials (Supplementary material 5).

Pairwise meta-analyses using a random-effects model in STATA and Review Manager [14, 15] would have been performed for every comparison of combinations of PPH diagnostic and treatment strategies had there been at least two studies for each of those comparisons of combinations [23].

Methods for indirect comparisons

We performed indirect comparisons where two competing diagnostic and treatment strategy combinations could be compared indirectly through a common comparison. To produce indirect comparisons, we used the method described by Bucher and colleagues [24]. We estimated the indirect comparisons using Microsoft Excel, as per the methods described by Tobias and colleagues [25].

Methods for network comparisons

We generated network diagrams and assessed them to determine if a network meta-analysis was feasible. We were unable to undertake network comparisons due to the limited number of studies and data. Had there been sufficient studies, we would have performed the network meta-analysis within a frequentist framework using multivariate meta-analysis estimated by restricted maximum likelihood. The analyses would have been undertaken using STATA [14]. We would have used the network suite of STATA commands designed for this purpose [26].

Assessment of transitivity across network comparisons

We would expect the assumption of transitivity across diagnostic and treatment strategy combination comparisons to hold, provided: 1) diagnostic and treatment strategy combinations are similar in different trials (e.g. visual estimation plus usual care is implemented in a similar way regardless of the competing diagnostic and treatment strategy combination), and 2) no pairwise comparisons differ with respect to the distribution of effect modifiers (e.g. similar study designs and characteristics). The assumption of transitivity is assessed by comparing the clinical and methodological characteristics of the studies within the comparisons.

Investigation of heterogeneity and subgroup analysis

Investigation of heterogeneity and subgroup analyses were not possible due to the paucity of included studies and data.

Assessment of statistical heterogeneity

Assumptions when estimating the heterogeneity

Heterogeneity for each comparison would be estimated in pairwise meta-analyses. A common estimate for the heterogeneity variance across all the different comparisons would be assumed in network meta-analysis.

Measures and tests for heterogeneity

The presence of heterogeneity within each pairwise comparison for the outcomes would be assessed, statistically, using the I^2 statistic. This measures the percentage of variability that cannot be attributed to random error [27]. The certainty of the evidence would be downgraded for inconsistency according to the GRADE approach [28]. The magnitude of the heterogeneity variance parameter estimated from the multivariate meta-analysis would be used to assess statistical heterogeneity in the entire network.

Assessment of statistical inconsistency

We would use the 'design-by-treatment' interaction model, described by Higgins and colleagues (2012) [29], to check the assumption of consistency in the entire network. This method accounts for a different source of inconsistency that can occur when studies with different designs (two-arm trials versus three-arm trials) give different results, as well as disagreement between direct and indirect evidence. We would employ this approach and use a Chi^2 test to indicate the presence of inconsistency from any source in the entire network.

Investigation of heterogeneity and inconsistency

We would explore the possible sources of heterogeneity and inconsistency for outcomes. Had sufficient studies been available, we would have performed multivariate meta-analyses for subgroups and sensitivity analyses by using potential effect modifiers as possible sources of inconsistency and heterogeneity.

Subgroup analysis

We were unable to undertake subgroup analyses due to the limited number of included studies and data.

We had planned to carry out the following subgroup analyses for the critical outcomes.

- Mode of birth (vaginal or caesarian)
- Resource level (LMIC or HIC)

We would assess subgroup differences by comparing the network diagram for each subgroup. Next, we would perform a pairwise and network meta-analysis for each subgroup, then compare their relative effects and relative ranking. We would examine the subgroups for qualitative interactions where the direction of effect could be reversed, i.e. if a diagnostic and treatment strategy combination was harmful in one subgroup but beneficial in another.

If these subgroup analyses explained any heterogeneity/inconsistency, we would treat the results with caution.

Equity-related assessment

The deleterious consequences of PPH, such as death and severe morbidity, disproportionately affect LMICs, despite the incidence of PPH being similar around the world. We recognise that the resource setting may influence the implementation of diagnostic and treatment strategy combinations. For this reason, we described the countries in which trials were conducted as a proxy for the resource setting (Supplementary material 2; Table 1). We considered this information when interpreting the results and their applicability.

Sensitivity analysis

We were unable to undertake sensitivity analyses due to the limited number of included studies and data. We would undertake sensitivity analyses for each comparison for the randomisation unit (cluster versus individual). For each comparison, the analyses would be limited to the critical outcomes.

Certainty of the evidence assessment

Our review presents one summary of findings table for each diagnostic and treatment strategy combination comparison and includes the outcomes for that comparison. The outcomes include: PPH ≥ 500 mL, severe PPH ≥ 1000 mL, blood transfusion, the use of additional uterotonics and maternal death.

We used the GRADE approach to rate the certainty of the evidence for the available direct, indirect and network estimates [28, 30, 31]. Where available, we assessed the certainty of the preliminary direct evidence for an outcome by considering: limitations in study design (risk of bias), inconsistency, indirectness and publication bias [1]. This preliminary certainty assessment was used to inform subsequent indirect and network certainty ratings (had they been available) as appropriate [31]. The final certainty assessment for the direct evidence was reported in the summary of findings tables following incorporation of the imprecision domain [31]. The thresholds for assessing imprecision are available in Supplementary material 6. The network diagrams for the outcomes with the comparisons show the certainty of the final direct evidence.

Next, we rated the preliminary certainty of the indirect evidence where this was available. We used the lower of the preliminary direct certainty ratings of the two arms forming the dominant ‘first-order’ loop in the network diagram for the outcome, then assessed intransitivity [31]. The final certainty rating for the indirect evidence was reported in the summary of findings tables following incorporation of the imprecision domain [31].

Had there been network evidence available, we would have gone on to assess the certainty of this. This would be based on, firstly, the higher certainty rating of the preliminary direct or indirect estimate, or the preliminary rating of the estimate that contributes the most, or the preliminary rating of the direct estimate [31], secondly, assessment of coherence between direct and indirect effect estimates and, finally, the precision of the network effect estimate itself [31].

Two review authors (IY and AD, or KV and MP where IY and AD were conflicted) independently appraised the certainty ratings of the evidence. Disagreements were resolved through consensus, or input from a third author if needed.

We rated the certainty of the evidence for each estimate as 'high', 'moderate', 'low' or 'very low'.

- **High-certainty:** we are very confident that the true effect lies close to that of the effect estimate.
- **Moderate-certainty:** we have some confidence in the effect estimate. The true effect is likely to be close to the effect estimate, but it may be different.
- **Low-certainty:** our confidence in the effect estimate is low. The true effect may be very different from the effect estimate.
- **Very low-certainty:** we have very little confidence in the effect estimate. The true effect is very likely to be different from the effect estimate.

The summary of findings tables include the anticipated absolute effects. These are based on the available direct or indirect effect estimates for each comparison of combinations of diagnostic and treatment strategies. The baseline rates are derived from the trials themselves.

Consumer involvement

We sought consumer involvement to provide critical feedback on the plain language summary. The consumer was from a nonmedical background, had a personal interest in PPH, and had expertise in writing (see Acknowledgements). In particular, feedback was given on the language used to make the plain language summary accessible and easy to understand for non-specialist readers.

RESULTS

Description of studies

Results of the search

The search was undertaken on 18 October 2024. The results of the search strategy are summarised in the PRISMA flow diagram Figure 1.

The search strategy retrieved 1908 records. After the removal of duplicates, we reviewed 1892 records by title and abstract screening, and excluded 1885 of these as they failed to meet the inclusion criteria. We reviewed seven full-text articles. The final analysis included four records (five trials) Supplementary material 2, with three records being excluded for not meeting the inclusion criteria Supplementary material 3. The publication by Gallos 2023 [7], although a single published record, contains two separate comparisons of combinations of diagnostic and treatment strategies, so we treated this as two separate trials (Gallos 2023a; Gallos 2023b).

There were no trials identified as 'ongoing studies', or classified as 'studies awaiting classification'.

We included five trials in the analysis after screening for eligibility and trustworthiness, as detailed below.

Trustworthiness assessment of eligible studies

We used the CPC-TST to assess the five studies that we identified for inclusion in this review. All the studies assessed on first screening were deemed trustworthy Supplementary material 2. The study by Ambardekar 2014 [32] was registered retrospectively despite being published in 2014. However, we judged it to be trustworthy as the trial itself was conducted between 2006 and 2007 when prospective trial registration was not a requirement.

Included studies

This review includes five two-arm randomised trials, involving 236,771 women (Table 1). All studies were reported in English, and included women giving birth vaginally. The studies were conducted in various countries and some (60%, 3/5) involved more than one country (Gallos 2023a; Gallos 2023b; Zhang 2010). Most trials (80%, 4/5) were conducted in a hospital setting (Ambardekar 2014; Gallos 2023a; Gallos 2023b; Zhang 2010), with a single trial (20%, 1/5) conducted in a midwife birthing unit (Esau 2024 [33]). Most trials (80%, 4/5) included women at both low and high risk of PPH (Ambardekar 2014; Gallos 2023a; Gallos 2023b; Zhang 2010), with a single trial (20%, 1/5) including only women at low risk (Esau 2024). Three of the trials were cluster-randomised (Gallos 2023a; Gallos 2023b; Zhang 2010).

In the five trials (10 trial arms), the following diagnostic and treatment strategy combinations were used.

- Visual estimation-based diagnosis plus usual care for PPH treatment was used in two trial arms (20%).
- Visual estimation-based diagnosis plus usual care for PPH treatment (Europe (E)) was used in one trial arm (10%).
- 3-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle was used in one trial arm (10%).
- 2-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle was used in one trial arm (10%).
- Calibrated drape-based diagnosis plus usual care for PPH treatment was used in two trial arms (20%).
- Calibrated drape-based diagnosis plus usual care (E) for PPH treatment was used in one trial arm (10%).
- Gravimetric method-based diagnosis plus usual care for PPH treatment was used in one trial arm (10%).
- MaternaWell tray-based diagnosis plus usual care for PPH treatment was used in one trial arm (10%).

Excluded studies

Our review excluded three studies Supplementary material 3: two involved randomisation of participants after the diagnosis of PPH, and one did not explicitly detail a PPH treatment strategy.

Risk of bias in included studies

The risk of bias assessment is summarised in Figure 2 and Figure 3. Details of the individual assessments are available in Supplementary material 2.

Figure 2.

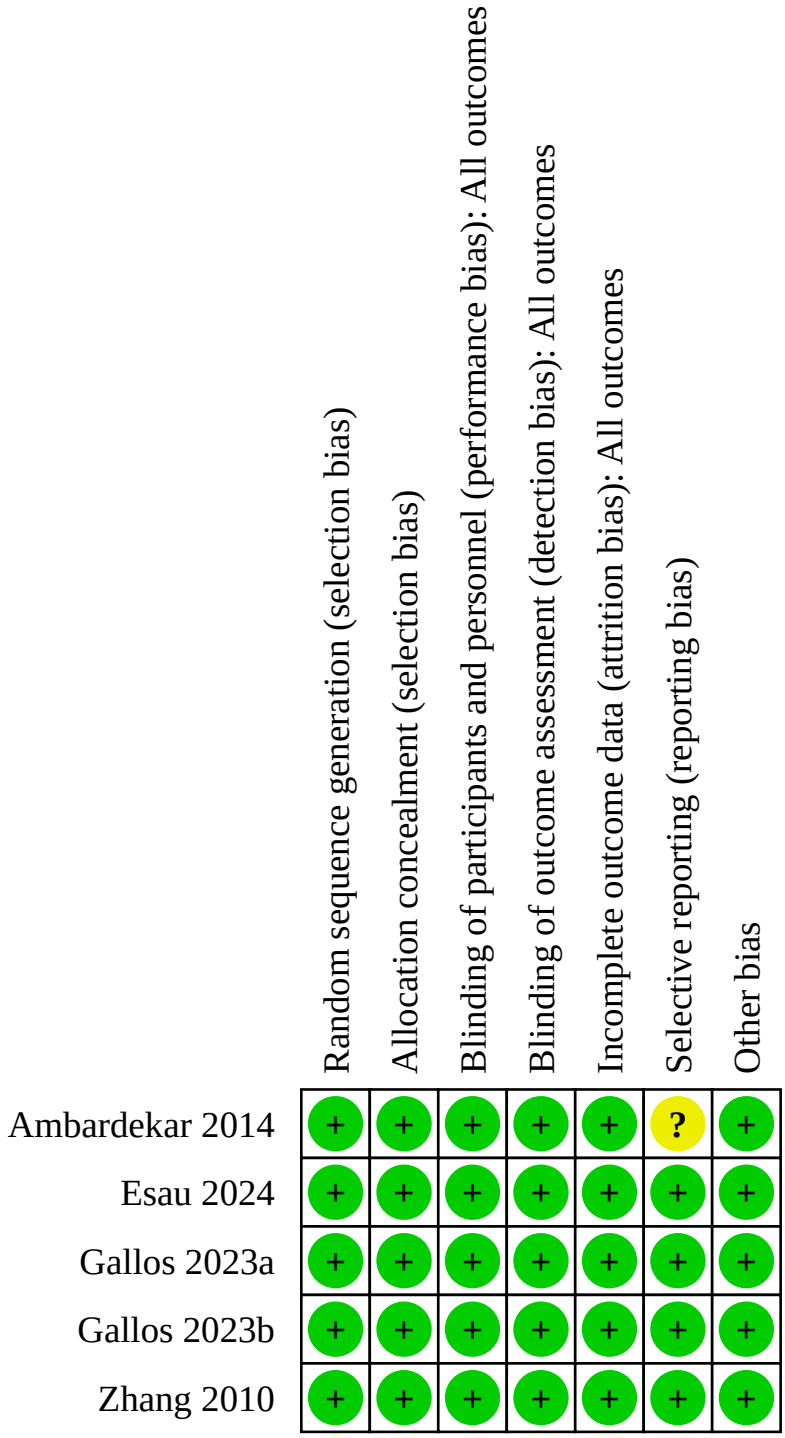
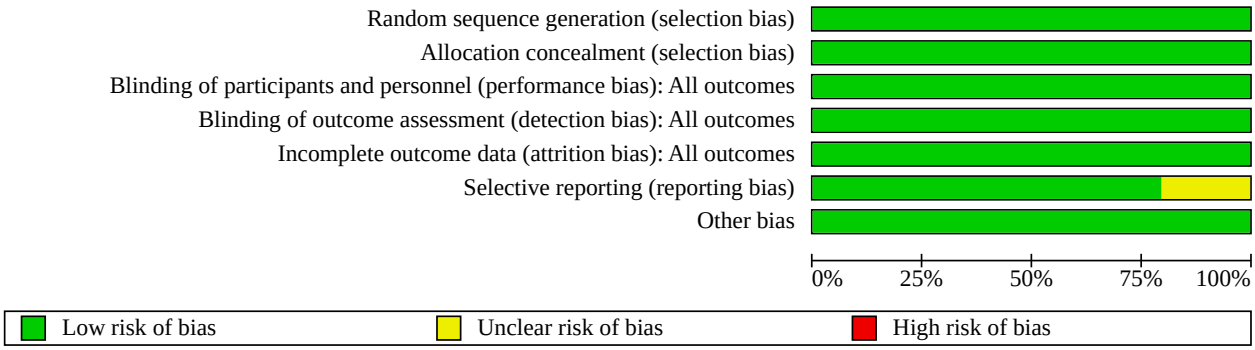


Figure 3.



Allocation

We excluded any trials with evidence of inadequate random sequence generation. All the included trials used an adequate method of random sequence generation, and we judged them to be at low risk of bias.

For the allocation concealment domain, we judged all included trials to be at low risk of bias.

Blinding

We judged all the included trials to be at low risk of bias for the 'blinding of participants and personnel', and 'blinding of outcome assessment' domains.

Incomplete outcome data

All the included trials were at low risk of bias for the 'incomplete outcome data' domain. In these trials, missing outcome data were less than 10% for the critical outcomes, and balanced in numbers across intervention groups with similar reasons for missing data across groups.

Selective reporting

All the trials prespecified all outcomes in publicly available trial protocols and reported them. However, one of the included trials (20%, 1/5) was retrospectively registered, so we judged the risk of bias to be unclear for this trial (Ambardekar 2014). We judged the remaining four trials (80%, 4/5) to be at low risk of bias.

Other potential sources of bias

We judged all the included trials to be at low risk of bias for this domain.

Publication bias

We were unable to assess publication bias due to the paucity of included studies.

Synthesis of results

The analyses for the available direct and indirect comparisons are presented in Supplementary material 5. We were unable to present these analyses in the 'Analyses' section due to the large number of results requiring ICC adjustments and calculations.

For each outcome, the network diagrams showing the available comparisons of combinations of diagnostic and treatment strategies are shown in Figure 4, Figure 5, Figure 6, Figure 7, and Figure 8.

Figure 4. Network Diagram for PPH ≥ 500ml. The nodes represent an intervention and their size is proportional to the number of trials comparing this intervention to any other in the network. The lines connecting each pair of interventions represent a direct comparison and are drawn proportional to the number of trials making each direct comparison. The colour of the line is green for high-certainty evidence and red for low-certainty evidence.

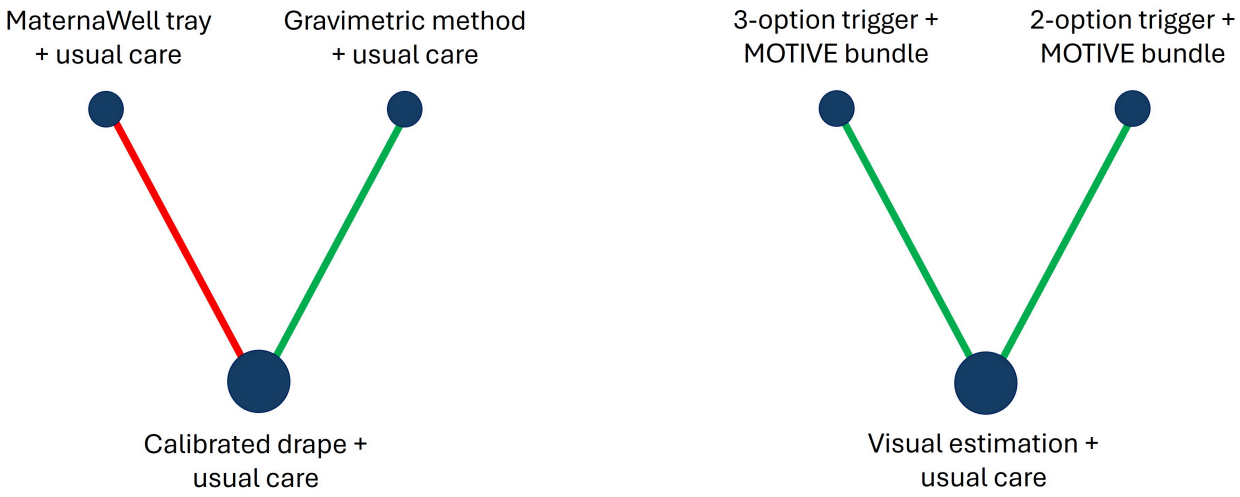


Figure 5. Network Diagram for PPH ≥ 1000ml. The nodes represent an intervention and their size is proportional to the number of trials comparing this intervention to any other in the network. The lines connecting each pair of interventions represent a direct comparison and are drawn proportional to the number of trials making each direct comparison. The colour of the line is green for high-certainty evidence, orange for moderate-certainty evidence, and red for low-certainty evidence.

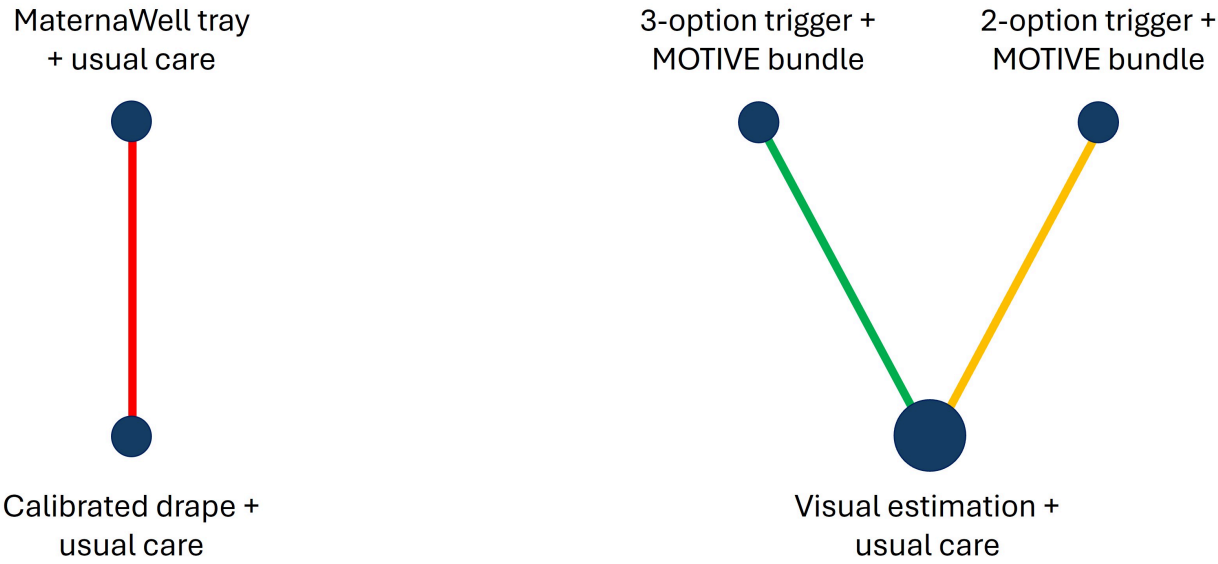


Figure 6. Network Diagram for blood transfusion. The nodes represent an intervention and their size is proportional to the number of trials comparing this intervention to any other in the network. The lines connecting each pair of interventions represent a direct comparison and are drawn proportional to the number of trials making each direct comparison. The colour of the line is orange for moderate-certainty evidence and red for low-certainty evidence.

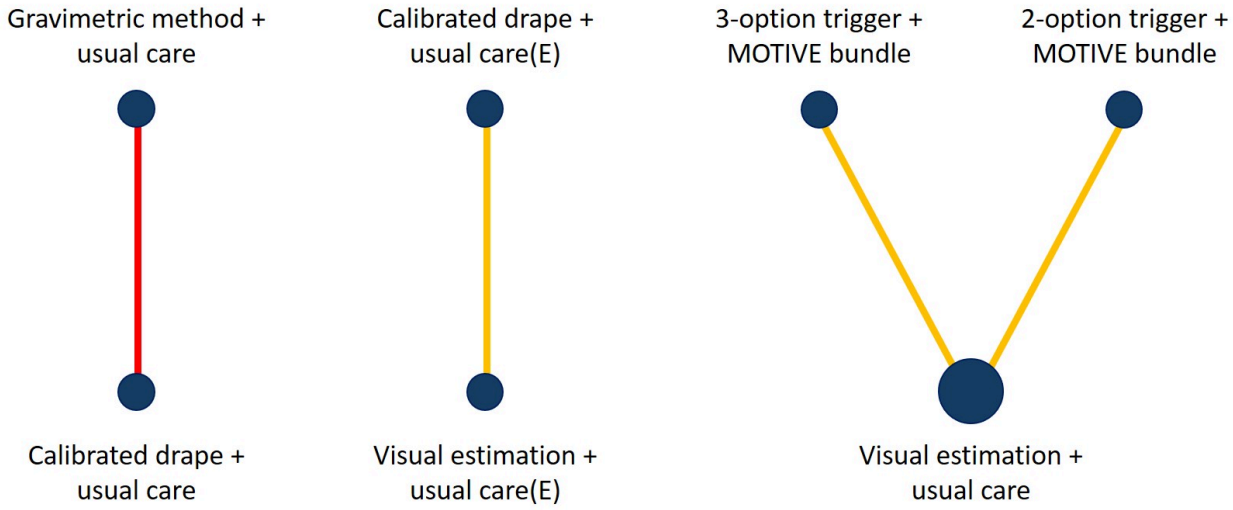


Figure 7. Network Diagram for use of additional uterotonics. The nodes represent an intervention and their size is proportional to the number of trials comparing this intervention to any other in the network. The lines connecting each pair of interventions represent a direct comparison and are drawn proportional to the number of trials making each direct comparison. The colour of the line is green for high-certainty evidence and orange for moderate-certainty evidence.

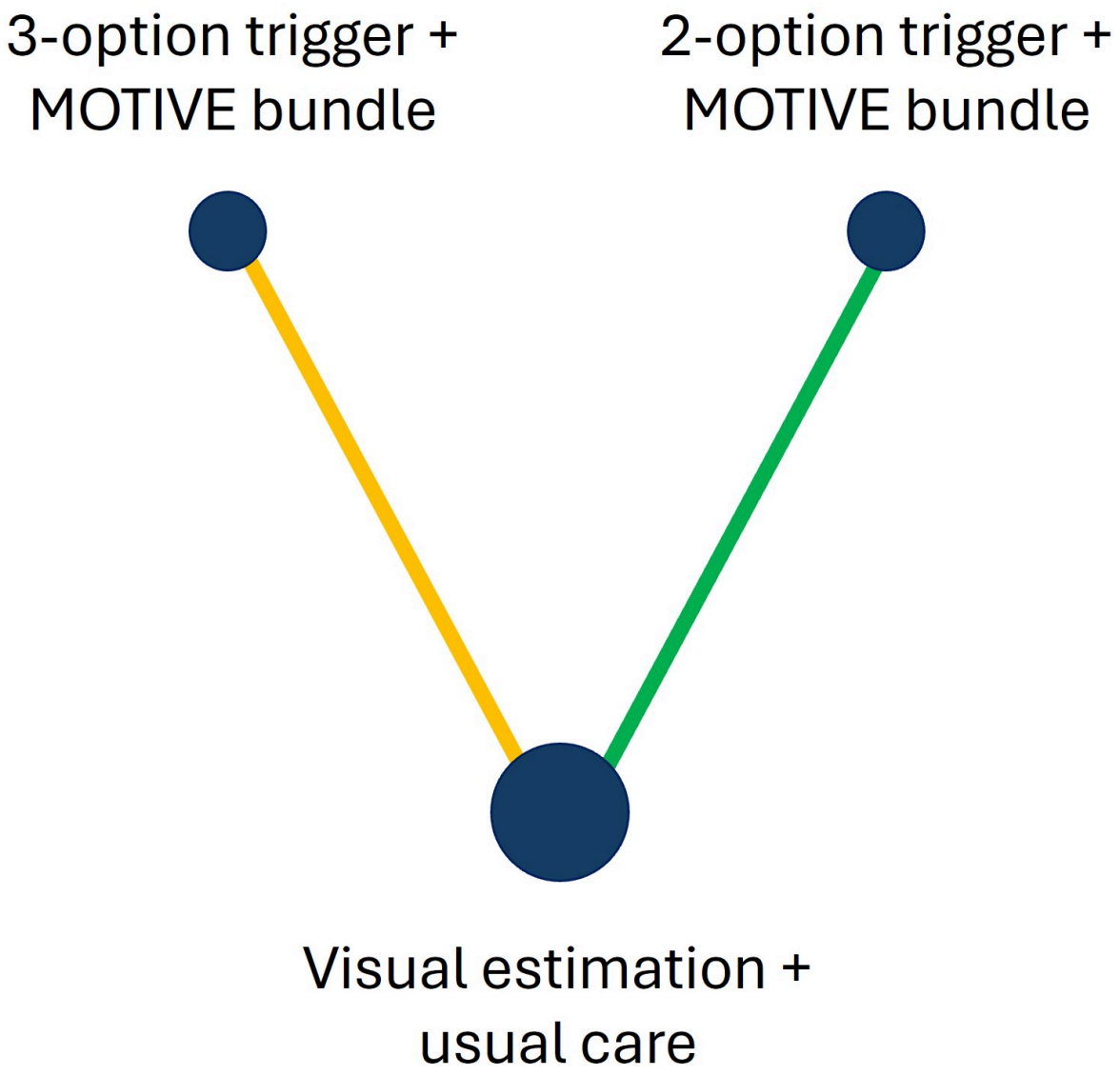
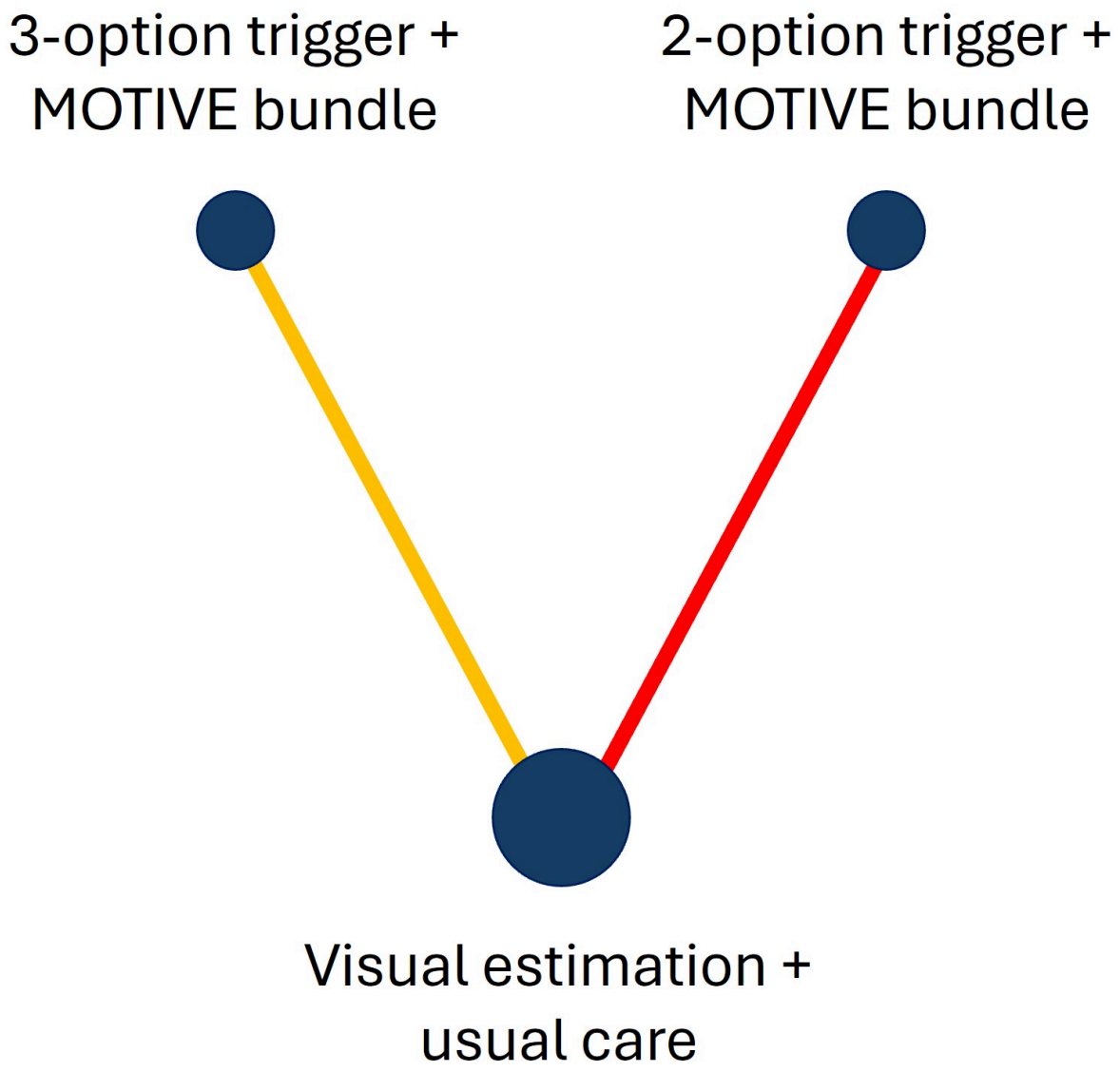


Figure 8. Network Diagram for maternal death. The nodes represent an intervention and their size is proportional to the number of trials comparing this intervention to any other in the network. The lines connecting each pair of interventions represent a direct comparison and are drawn proportional to the number of trials making each direct comparison. The colour of the line is orange for moderate-certainty evidence and red for low-certainty evidence.



3-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle versus visual estimation-based diagnosis plus usual care for PPH treatment

Direct evidence (1 study, 170,956 participants) suggests that, compared with visual estimation-based diagnosis plus usual care, the combination of 3-option trigger PPH diagnosis plus MOTIVE bundle reduces the outcome of PPH ≥ 500 mL from 165 per 1000 women in the control group to 79 per 1000 women in the intervention group (RR 0.48, 95% CI 0.39 to 0.58; high-certainty evidence). It also reduces the outcome of PPH ≥ 1000 mL from 43 per 1000 women in the control group to 15 per 1000 women in the intervention group (RR 0.34, 95% CI 0.26 to 0.44; high-certainty evidence). See Summary of findings 1.

Moderate-certainty evidence suggests that, compared with visual estimation-based diagnosis plus usual care, the combination of 3-option trigger PPH diagnosis plus MOTIVE bundle probably makes little or no difference to the outcomes of need for blood transfusion (RR 0.82, 95% CI 0.62 to 1.08), need for additional uterotonics (RR 1.19, 95% CI 0.94 to 1.50), and maternal death (RR 0.73, 95% CI 0.36 to 1.48). See Summary of findings 1.

2-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle versus visual estimation-based diagnosis plus usual care for PPH treatment

Direct evidence (1 study, 39,176 participants) suggests that, compared with visual estimation-based diagnosis plus usual care, the combination of 2-option trigger PPH diagnosis plus MOTIVE

bundle reduces the outcome of PPH ≥ 500 mL from 176 per 1000 women in the control group to 129 per 1000 women in the intervention group (RR 0.73, 95% CI 0.60 to 0.89; high-certainty evidence). See Summary of findings 2.

When compared with visual estimation-based diagnosis plus usual care, the combination of 2-option trigger PPH diagnosis plus MOTIVE bundle probably makes little or no difference to the outcomes of PPH ≥ 1000 mL (RR 0.88, 95% CI 0.69 to 1.12; moderate-certainty evidence) and need for blood transfusion (RR 1.06, 95% CI 0.55 to 2.04; moderate-certainty evidence). It may make little or no difference to the outcome of maternal death (RR 1.01, 95% CI 0.00 to 4.0×10^7; low-certainty evidence). The CI for maternal death is very wide due to the very low number of events. See Summary of findings 2.

High-certainty evidence suggests that, compared with visual estimation-based diagnosis plus usual care, the combination of 2-option trigger PPH diagnosis plus MOTIVE bundle increases the need for additional uterotonics from 63 per 1000 women in the control group to 222 per 1000 women in the intervention group (RR 3.54, 95% CI 2.27 to 5.52). See Summary of findings 2.

3-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle versus 2-option trigger PPH diagnosis with calibrated drape plus MOTIVE treatment bundle

Indirect evidence suggests that, compared with 2-option trigger PPH diagnosis plus MOTIVE bundle, the combination of 3-option trigger PPH diagnosis plus MOTIVE bundle reduces the outcome of PPH ≥ 500 mL from 121 per 1000 women in the control group to 79 per 1000 women in the intervention group (RR 0.65, 95% CI 0.49 to 0.86; high-certainty evidence). It also reduces the outcome of PPH ≥ 1000 mL from 28 per 1000 women in the control group to 11 per 1000 women in the intervention group (RR 0.38, 95% CI 0.27 to 0.55; high-certainty evidence), and the need for additional uterotonics from 141 per 1000 women in the control group to 48 per 1000 women in the intervention group (RR 0.34, 95% CI 0.20 to 0.55; high-certainty evidence). See Summary of findings 3.

The evidence suggests that, compared with 2-option trigger PPH diagnosis plus MOTIVE bundle, the combination of 3-option trigger PPH diagnosis plus MOTIVE bundle probably makes little or no difference to the outcome of need for blood transfusion (RR 0.78, 95% CI 0.38 to 1.59; moderate-certainty evidence), and may make little or no difference to the outcome of maternal death (RR 0.72, 95% CI 0.00 to 2.9×10^7; low-certainty evidence). The CI for maternal death is very wide due to the very low number of events. See Summary of findings 3.

Calibrated drape-based diagnosis plus usual care (E) for PPH treatment versus visual estimation-based diagnosis plus usual care for PPH treatment (E)

Moderate-certainty direct evidence (1 study, 25,381 participants) suggests that, compared with visual estimation-based diagnosis plus usual care (E), the combination of calibrated drape-based diagnosis plus usual care (E) probably makes little or no difference to the outcome of need for blood transfusion (RR 0.83, 95% CI 0.57 to 1.21). See Summary of findings 4.

Gravimetric method-based diagnosis plus usual care for PPH treatment versus calibrated drape-based diagnosis plus usual care for PPH treatment

Direct evidence (1 study, 1195 participants) suggests that, compared with calibrated drape-based diagnosis plus usual care, the combination of gravimetric method-based diagnosis plus usual care reduces the outcome of PPH ≥ 500 mL from 87 per 1000 women in the control group to 47 per 1000 women in the intervention group (RR 0.54, 95% CI 0.32 to 0.90; high-certainty evidence). Low-certainty evidence suggests that, compared with calibrated drape-based diagnosis plus usual care, the combination of gravimetric method-based diagnosis plus usual care may make little or no difference to the outcome of need for blood transfusion (RR 1.00, 95% CI 0.06 to 15.94; low-certainty evidence). See Summary of findings 5.

MaternaWell tray-based diagnosis plus usual care for PPH treatment versus calibrated drape-based diagnosis plus usual care for PPH treatment

Direct evidence (1 study, 63 participants) suggests that, compared with calibrated drape-based diagnosis plus usual care, the combination of MaternaWell tray-based diagnosis plus usual care may make little or no difference to the outcomes of PPH ≥ 500 mL (RR 0.61, 95% CI 0.11 to 3.38; low-certainty evidence), and PPH ≥ 1000 mL (RR 0.30, 95% CI 0.01 to 7.19; low-certainty evidence). See Summary of findings 6.

Gravimetric method-based diagnosis plus usual care for PPH treatment versus MaternaWell tray-based diagnosis plus usual care for PPH treatment

Indirect evidence suggests that, compared with MaternaWell tray-based diagnosis plus usual care, the combination of gravimetric method-based diagnosis plus usual care may make little or no difference to the outcome of PPH ≥ 500 mL (RR 0.89, 95% CI 0.15 to 5.35; low-certainty evidence). See Summary of findings 7.

There were no data available for the critical and important outcomes not presented in this section. In particular, there were no data available for the critical outcomes: additional blood loss of ≥ 500 mL following diagnosis of PPH and within 24 hours after birth (as reported by the study), and PPH treatment rate.

Subgroup analyses

We were unable to undertake subgroup analyses due to the limited number of included studies and data.

Sensitivity analyses

We were unable to undertake sensitivity analyses due to the limited number of included studies and data.

Equity assessment

The only study in our review conducted in a HIC setting was Zhang 2010. The remaining four studies were conducted in LMICs (Ambardekar 2014; Esau 2024; Gallos 2023a; Gallos 2023b) (Supplementary material 2; Table 1).

DISCUSSION

Summary of main results

Our review identified five studies evaluating a range of comparisons of diagnostic and treatment strategy combinations. We assessed all the identified studies to be trustworthy.

The direct evidence from the single study that compared 3-option trigger PPH diagnosis plus MOTIVE bundle versus visual estimation-based diagnosis plus usual care suggests that 3-option trigger PPH diagnosis plus MOTIVE bundle reduces the outcome of PPH ≥ 500 mL (high-certainty evidence). It also suggests that it reduces the outcome of PPH ≥ 1000 mL (high-certainty evidence), but probably makes little or no difference to the outcomes of need for blood transfusion (moderate-certainty evidence), need for additional uterotonics (moderate-certainty evidence), and maternal death (moderate-certainty evidence).

The direct evidence from the single study that compared 2-option trigger PPH diagnosis plus MOTIVE bundle versus visual estimation-based diagnosis plus usual care suggests that 2-option trigger PPH diagnosis plus MOTIVE bundle reduces the outcome of PPH ≥ 500 mL (high-certainty evidence), but probably makes little or no difference to the outcomes of PPH ≥ 1000 mL (moderate-certainty evidence), and need for blood transfusion (moderate-certainty evidence). It may make little or no difference to the outcome of maternal death (low-certainty evidence). The study suggests that 2-option trigger PPH diagnosis plus MOTIVE bundle increases the need for additional uterotonics (high-certainty evidence).

The indirect evidence that compared 3-option trigger PPH diagnosis plus MOTIVE bundle versus 2-option trigger PPH diagnosis plus MOTIVE bundle, suggests that 3-option trigger PPH diagnosis plus MOTIVE bundle reduces the outcomes of PPH ≥ 500 mL (high-certainty evidence), PPH ≥ 1000 mL (high-certainty evidence), and the need for additional uterotonics (high-certainty evidence). However, it probably makes little or no difference to the need for blood transfusion (moderate-certainty evidence), and may make little or no difference to maternal death (low-certainty evidence). For both these combinations of diagnostic and treatment strategies, the treatment strategy is the same, i.e. the MOTIVE bundle. This suggests that the 3-option trigger PPH diagnosis is responsible for the reduction in PPH ≥ 500 mL, PPH ≥ 1000 mL, and the need for additional uterotonics. The 3-option trigger PPH diagnosis differs from the 2-option trigger PPH diagnosis by adding blood loss of ≥ 300 mL to < 500 mL in the drape plus one abnormal clinical observation as a PPH diagnostic trigger.

The direct evidence from the single study that compared calibrated drape-based diagnosis plus usual care (E) versus visual estimation-based diagnosis plus usual care (E), suggests that calibrated drape-based diagnosis plus usual care (E) probably makes little or no difference to the outcome of need for blood transfusion (moderate-certainty evidence).

The direct evidence from the single study that compared gravimetric method-based diagnosis plus usual care versus calibrated drape-based diagnosis plus usual care suggests that gravimetric method-based diagnosis plus usual care reduces the outcome of PPH ≥ 500 mL (high-certainty evidence), but may make little or no difference to the need for blood transfusion (low-certainty evidence).

The direct evidence from the single study that compared MaternaWell tray-based diagnosis plus usual care versus calibrated drape-based diagnosis plus usual care suggests that MaternaWell tray-based diagnosis plus usual care may make little or no difference to the outcomes of PPH ≥ 500 mL (low-certainty evidence) and PPH ≥ 1000 mL (low-certainty evidence).

The indirect evidence that compared gravimetric method-based diagnosis plus usual care versus MaternaWell tray-based diagnosis plus usual care, suggests that gravimetric method-based diagnosis plus usual care may make little or no difference to the outcome of PPH ≥ 500 mL (low-certainty evidence).

There were no data available for the other critical outcomes: additional blood loss of ≥ 500 mL following diagnosis of PPH and within 24 hours after birth (as reported by the study), and PPH treatment rate.

Due to the low number of identified studies for each comparison of diagnostic and treatment strategy combinations, we were unable to perform subgroup analyses or sensitivity analyses.

Limitations of the evidence included in the review

We did not identify sufficient studies to determine network estimates or produce rankings as per our protocol. We were also unable to undertake subgroup or sensitivity analyses.

Our review found no data on the critical outcomes of additional blood loss of ≥ 500 mL and PPH treatment rate, and important outcomes such as severe morbidity (e.g. intensive care unit admission), side effects, breastfeeding at discharge, postpartum anaemia, and maternal sense of wellbeing and satisfaction.

We used the GRADE methods to assess the certainty of the evidence for the direct and indirect estimates in our review. The effect estimates ranged in certainty from high to low and varied across comparisons and outcomes. The main reasons for downgrading were concerns about imprecision.

In the 3-option trigger PPH diagnosis and 2-option trigger PPH diagnosis, one of the triggers (i.e. collected blood loss ≥ 500 mL) was also an outcome. This means that the outcome is more likely to reflect the other triggers, such as clinical concern and ≥ 300 mL to < 500 mL of collected blood plus abnormal clinical observations. This information might be useful for exploring different thresholds of blood loss for PPH diagnosis.

Some of the data we found concerning treatment strategies were for initial treatments and first response treatments for PPH. This was not our intention, but a consequence of the data which were available. However, the MOTIVE bundle, which includes examination and escalation, does move beyond initial first response treatments.

'Usual care' was not always well-defined by the included studies and this might limit our understanding of the actual treatments in these studies. It also limits our ability to potentially isolate effective initial treatments given the numerous options available. Our 'Characteristics of included studies' table gives as much detail about 'usual care' as the included studies made available (Table 1).

The majority of the trials included in our review were conducted in a hospital setting, with one trial conducted in a midwife birthing

unit. There were no trials conducted in the home-birth setting. None of the trials we included evaluated women giving birth by caesarean section. One trial was conducted in a HIC, European setting, whereas the remaining trials were undertaken in LMIC settings.

Limitations of the review processes

Due to the limited number of studies we found, we were unable to undertake network estimates, determine rankings, or undertake subgroup or sensitivity analyses.

We made adjustments for historical changes in methodological and reporting standards when applying the CPC-TST to screen studies. This meant that the criteria for older studies were more relaxed for requirements such as prospective trial registration. We minimised bias by applying the tool as other Cochrane reviews have done [34].

Some authors of this review were also authors of eligible and potentially eligible studies. They did not make decisions about study eligibility, extract data, or undertake risk of bias or GRADE assessments for those studies. Other review authors, without such conflicts, undertook these tasks.

The baseline rates we used to calculate the anticipated absolute effects in the summary of findings tables are derived from the relevant trials themselves. As these are from trial settings, they may be lower than rates expected in a 'real-world' setting.

The clinical characteristics of women recruited to the studies included in this review varied. The level of detail given by study authors about the inclusion criteria also varied.

The level of detail given about 'usual care' as a treatment strategy varied from trial to trial. We made a distinction between 'usual care' given in the European setting and 'usual care' given in the LMIC setting, as they are unlikely to be equivalent.

Agreements and disagreements with other studies or reviews

We did not find any other reviews comparing combinations of diagnostic and treatment strategies for PPH in the context of randomised trials.

A recent review highlighted the accuracy of objective measures of measuring blood loss by using a calibrated drape and combining these with clinical variables to diagnose postpartum haemorrhage (PPH) [35]. Another review highlighted the effectiveness of first response treatment bundles as the treatment strategy [36]. However, there is no firm guidance on which combination of diagnostic and treatment strategies is best. Our review provides evidence for the effectiveness of a range of combinations of diagnostic and treatment strategies.

AUTHORS' CONCLUSIONS

Implications for practice

Both 3-option trigger PPH diagnosis plus MOTIVE bundle and 2-option trigger PPH diagnosis plus MOTIVE bundle, when compared with visual estimation-based diagnosis plus usual care, showed some benefit (direct evidence). 3-option trigger PPH diagnosis plus MOTIVE bundle reduced the outcomes of PPH ≥ 500 mL and PPH ≥ 1000 mL, and 2-option trigger PPH diagnosis plus MOTIVE bundle reduced the outcome of PPH ≥ 500 mL.

Indirect evidence showed that 3-option trigger PPH diagnosis plus MOTIVE bundle, when compared with 2-option trigger PPH diagnosis plus MOTIVE bundle, reduced the outcomes of PPH ≥ 500 mL, PPH ≥ 1000 mL, and the need for additional uterotonic. These results suggest that 3-option trigger PPH diagnosis plus MOTIVE bundle is more effective than 2-option trigger PPH diagnosis plus MOTIVE bundle for some outcomes. As the treatment strategy in both these combinations is the same, i.e. the MOTIVE bundle, 3-option trigger PPH diagnosis is likely to be more effective than 2-option trigger PPH diagnosis.

Our study findings highlight the importance of objective volumetric blood loss measurement with assessment of clinical signs to diagnose PPH. Gravimetric blood loss measurement is an alternative when volumetric measurement is not available.

Reducing the adverse outcomes of PPH requires both early and accurate diagnosis, and effective treatment availability and delivery. Knowledge of the effectiveness of different combinations of diagnostic and treatment strategies can help policymakers prioritise the most effective ones. Protocols which focus on effective combinations of diagnostic and treatment strategies should be encouraged. However, consideration needs to be given to cost-effectiveness, acceptability to stakeholders, and the feasibility of implementing combination strategies in routine care, particularly in low-resource settings.

Implications for research

Future research should focus on comparing other combinations of diagnostic and treatment strategies. An example would be comparing the combination of 3-option trigger PPH diagnosis plus usual care with 3-option trigger PPH diagnosis plus MOTIVE bundle to assess the potential effects of the different treatment strategies. This may give greater insights into the impact of different treatment strategies when the diagnostic strategy is the same.

There is a need to evaluate diagnostic and treatment strategy combinations in the context of risk factors. For example, we found no studies which evaluated the combinations by risk stratifying for factors such as maternal anaemia. In some high-income countries, the use of intravenous iron therapy for anaemia is becoming more common to reduce the rates of blood transfusion. This could be investigated as an outcome in future research.

Information about the effect of combinations of diagnostic and treatment strategies on side effects experienced by women remains under-reported. There are also limited data on priorities for women and families, such as breast-feeding at discharge, and maternal satisfaction and sense of wellbeing. Future studies should include these outcome data.

The majority of our included studies were undertaken in the hospital setting. None of our studies evaluated caesarean birth. Future research should evaluate combinations of diagnostic and treatment strategies in both hospital and non-hospital settings, and for women having a caesarean birth, to allow generalisability across setting and mode of birth.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: 10.1002/14651858.CD016259.

Supplementary material 1 Search strategies

Supplementary material 2 Characteristics of included studies

Supplementary material 3 Characteristics of excluded studies

Supplementary material 4 Data package

Supplementary material 5 Analyses

Supplementary material 6 Thresholds for assessing imprecision

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article.

- Sign-off Editor (final editorial decision): David Haas, Indiana University School of Medicine (Sign-off Editor)
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Liz Bickerdike, Cochrane Central Editorial Service
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments and supported editorial team): Leticia Rodrigues, Cochrane Central Editorial Service
- Copy Editor (copy editing and production): Andrea Takeda, Cochrane Central Production Service
- Peer-reviewers (provided comments and recommended an editorial decision): Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods); Jo Platt, Central Editorial Information Specialist (search); Dr Sadia Malick FRCOG Consultant Gynaecologist King Faisal Specialist Hospital & Research Centre, Riyadh Saudi Arabia (clinical); Maria Fernanda Escobar, Head of the Global Health Equity Unit and leader of the Hospital Padrino Strategy, Fundacion Valle del Lili, Cali – Colombia (clinical).

Contributions of authors

Coordination: IY

Writing of manuscript: IY

Conception and design: IY, AC

Search and selection of studies for inclusion: IY, AD, AC (KV and MP when other authors were conflicted)

Data extraction: IY, AD (KV and MP when other authors were conflicted)

Assessment of the risk of bias: IY, AD (KV and MP when other authors were conflicted)

Analysis of data: IY, MP, AT, AC

Assessment of the certainty of evidence: IY, AD (KV and MP when other authors were conflicted)

Data interpretation: IY, AC

Declarations of interest

Idnan Yunas: no relevant interests were disclosed.

Malcolm Price: no relevant interests were disclosed.

Kugajeevan Vigneswaran: no relevant interests were disclosed.

Aurelio Tobias: no relevant interests were disclosed.

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Registration and protocol

The protocol for this review was prospectively registered with PROSPERO (CRD42024600189).

Data, code and other materials

Supplementary material 4

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ADDITIONAL TABLES

Table 1. Characteristics of included studies

Study	Population and setting	Diagnostic and treatment strategy combination 1	Diagnostic and treatment strategy combination 2	Outcomes
Ambardekar 2014	India (LMIC) RCT N = 1195 Hospital Vaginal birth All women aged 18 and older presenting for an imminent vaginal delivery	Gravimetric method-based diagnosis (Weight and measurement of blood and blood-soaked materials following the cessation of bleeding. A sheet with plastic backing was placed under the buttocks just after delivery and cord clamping. The sheet drained into a metal basin placed on a shelf below the delivery table. Blood loss was collected in the basin for at least one hour or, if bleeding continued after one hour, until active bleeding stopped. After bleeding stopped, all blood-soaked gauze pieces and mops were counted and then placed in the collection basin. The basin was placed on an electronic scale and weighed. The weight of the blood was assessed by subtracting the initial weight of the basin, gauzes and mops from the total weight of the soaked materials,	Calibrated drape-based diagnosis (Using the Excellent BRASS-V Drape. Blood loss was measured for at least one hour or, if bleeding continued after one hour, until active bleeding stopped. When active bleeding stopped, providers examined the drape and recorded the level indicated.) Plus usual care (Provider actions related to the prevention or treatment of PPH (including blood loss interpretation) were as per provider preference and standard hospital practice and not dic-	PPH (≥ 500 mL) Blood transfusion

Table 1. Characteristics of included studies *(Continued)*

		assuming that one gram is equivalent to 1 mL.) Plus usual care (Provider actions related to the prevention or treatment of PPH (including blood loss interpretation) were as per provider preference and standard hospital practice and not dictated by the study protocol.)	tated by the study protocol.)	
Esau 2024	South Africa (LMIC) RCT N = 63 Midwife birthing unit Vaginal birth Included pregnant women older than 18 years presenting with low-risk pregnancies at a gestational age of 36 weeks and more, planning to have a vaginal birth.	MaternaWell tray-based diagnosis (The birth attendants placed the tray underneath the parturient after the birth of the baby. The placenta was delivered onto the tray and then removed. The midwife measured the blood volume in the tray in accordance with the instructions of the tray. The tray was removed once the bleeding had stopped or when 30 minutes had passed after placement.) Plus usual care (This could include additional intravenous or intramuscular oxytocin, uterine massage, suturing of vaginal tears and transfer to a hospital in the case of blood loss > 1000 mL.)	Calibrated drape-based diagnosis (The birth attendants placed the calibrated drape underneath the parturient after the birth of the baby. The placenta was delivered onto the blood collection device and then removed. The midwife measured the blood volume in the drape. The drape was removed once the bleeding had stopped or when 30 minutes had passed after placement. The measurement was read directly on the calibrations in accordance with the instructions of the drape.) Plus usual care (This could include additional intravenous or intramuscular oxytocin, uterine massage, suturing of vaginal tears and transfer to a hospital in the case of blood loss > 1000 mL.)	PPH (≥ 500 mL) Severe PPH (≥ 1000 mL)
Gallos 2023a	Kenya, Nigeria, Tanzania (LMIC) Cluster-RCT N = 170,956 Hospital Vaginal birth Included hospitals that were geographically and administratively distinct from each other, had between 1000 and 5000	3-option trigger PPH diagnosis with calibrated drape (PPH was diagnosed if: 1) there was concern based on clinical judgement, or 2) ≥ 300 mL to < 500 mL of blood was collected in the drape plus one abnormal clinical observation or vital sign (heart rate, blood pressure, uterine tone, vaginal flow of blood), or 3) ≥ 500 mL of blood was collected in the drape, regardless of other observations or vital signs.) Plus MOTIVE treatment bundle	Visual estimation-based diagnosis (Uncalibrated drapes, without alert or action lines, were used to visually estimate blood loss. The drape was placed under the woman's buttocks following vaginal delivery of the baby. The blood was collected for one hour, or two hours if the bleeding continued beyond one hour.) Plus usual care	PPH (≥ 500 mL); Severe PPH (≥ 1000 mL) Blood transfusion Additional uterotonic use Maternal death

Table 1. Characteristics of included studies *(Continued)*

	vaginal births per year, and were able to provide comprehensive obstetrical care with the ability to perform surgery for postpartum haemorrhage. Excluded hospitals if they had already implemented a bundle for treatment for PPH.	(The 'MOTIVE' PPH treatment bundle consists of uterine **M**assage, **O**xytocic drugs, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care.)	(Interventions to treat PPH were used in accordance with local or national guidelines.)	
Gallos 2023b	South Africa (LMIC) Cluster-RCT N = 39,176 Hospital Vaginal birth Included hospitals that were geographically and administratively distinct from each other, had between 1000 and 5000 vaginal births per year, and were able to provide comprehensive obstetrical care with the ability to perform surgery for postpartum haemorrhage. Excluded hospitals if they had already implemented a bundle for treatment for PPH.	2-option trigger PPH diagnosis with calibrated drape (PPH was diagnosed if: 1) there was concern based on clinical judgement, or 2) ≥ 500 mL of blood was collected in the drape, regardless of other observations or vital signs.) Plus MOTIVE treatment bundle (The 'MOTIVE' PPH treatment bundle consists of uterine **M**assage, **O**xytocic drugs, **T**ranexamic acid, **I**ntra**V**enous fluids, and **E**xamination and **E**scalation of care.)	Visual estimation-based diagnosis (Uncalibrated drapes, without alert or action lines, were used to visually estimate blood loss. The drape was placed under the woman's buttocks following vaginal delivery of the baby. The blood was collected for one hour, or two hours if the bleeding continued beyond one hour.) Plus usual care (Interventions to treat PPH were used in accordance with local or national guidelines.)	PPH (≥ 500 mL) Severe PPH (≥ 1000 mL) Blood transfusion Additional uterotonic use Maternal death
Zhang 2010	European countries (13) (HIC) Cluster-RCT N = 25,381 Hospital Vaginal birth Included maternity units if they had more than 200 vaginal deliveries annually (excluding water births), no previous policy for routine use of collector bags and complied with the EUPHRATES consensus statement	Calibrated drape-based diagnosis (The collector bag was placed under the mother's pelvis as soon as the baby was born and before delivery of the placenta. The bag was transparent and graduated, allowing continuous monitoring of blood loss. The bag was to be left in situ until the birth attendant was no longer concerned about blood loss, such as when a sanitary towel was applied to the vulva.) Plus usual care (E) (As per individual hospital protocol.)	Visual estimation-based diagnosis (No collector bag was used. Postpartum blood loss was assessed visually.) Plus usual care (E) (As per individual hospital protocol.)	Blood transfusion Maternal death

Table 1. Characteristics of included studies *(Continued)*

			on the prevention and management of PPH.		
			All units included women giving vaginal birth except those in Denmark which enrolled women if the midwife agreed to participate.		

BMI: body mass index ;bpm: beats per minute; E: Europe; Hb: haemoglobin; HIC: high-income country; IQR: interquartile range; LMIC: low- or middle-income country; PPH: postpartum haemorrhage; RCT: randomised control trial; SBP: systolic blood pressure; SD: standard deviation