Protocol for Systematic Review

Review title: A systematic review of strategies to evaluate maternal blood loss during childbirth.

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BACKGROUND

Description of the issue

Primary postpartum haemorrhage (PPH), or excessive maternal bleeding, is defined as visually estimated blood loss of 500 millilitres (mls) or more within twenty-four hours of childbirth (World Health Organization [WHO], 1998). In the United Kingdom (UK), the Royal College of Obstetricians and Gynaecologists (RCOG) have offered an additional range of definitions that reflect the severity of PPH. In addition, they suggest that action for 500mls blood loss with no maternal signs of shock, can be restricted to 'basic measures' such as physiological monitoring; with full resuscitation commencing when the estimated loss reaches 1000mls (Arulkumaran et al., 2009).

The most common cause of primary PPH is uterine atony, or failure of the uterine muscle to contract adequately after birth to control bleeding. Other main causes include retained products of conception, trauma to the genital tract and clotting disorders. Primary PPH from uterine atony is a major factor in a quarter of maternal deaths worldwide and is the leading cause of maternal death in low-income countries (Khan et al., 2006; WHO, 2012). The rate of severe PPH is reported to be rising in high-income countries (Joseph et al., 2007) and is the most frequent cause of severe maternal morbidity in the United Kingdom (Lewis, 2007; Lennox and Marr, 2013).

The amount of blood loss that is detrimental to individual women will vary depending on their general health, socioeconomic status and the amount and rate of the loss (Lalonde et al., 2006). Maternal adaptation to pregnancy, which includes a forty per cent increase in maternal circulating blood volume, also means that healthy women can compensate physiologically for blood losses up to 1000mls. They will often show no obvious signs of shock until compensatory mechanisms begin to fail (Stables and Rankin, 2005). Visual estimation of blood loss is the most common and practical method of quantifying blood loss following childbirth and is currently used as the basis for diagnosing and treating PPH. However, this method is known to underestimate blood losses of 500 mls or more by thirty to fifty per cent (Sloan et al., 2010). Underestimation of blood loss can lead to delayed or missed diagnosis and treatment of PPH, directly contributing to rates of morbidity and mortality. The contrasting problem is that an awareness of the tendency to underestimate blood loss may lead to health professionals over-estimating amounts and initiating treatment in women for whom it is not required. This will carry with it the risks and costs associated with unnecessary use of drugs, anaesthesia and blood transfusion as well as impacting on women's choices in subsequent pregnancies.

Description of the intervention

It is important to ensure prompt recognition and treatment of PPH in order to reduce or prevent maternal mortality and morbidity (Lalonde, 2006; Lewis, 2007; CMACE, 2011). In response to the large body of evidence that has demonstrated that visual estimation of blood loss is unreliable, numerous strategies have been developed in an attempt to improve blood loss estimation. These include tools such as blood collection drapes to assist clinicians in the practical estimation of blood loss, and strategies such as the use of guidelines and training to improve health professionals' skills of PPH management.

How the intervention might work

Intervention strategies are primarily aimed at assisting clinicians to quantify blood loss more accurately than visual estimation, to promote timely recognition of PPH. For example, calibrated blood collection drapes are positioned to capture the blood lost during birth so that it is more easily quantified.

Why it is important to do this review

No systematic reviews of this evidence have been carried out to date, so while there are a plethora of strategies available to assess blood loss, there is no consensus on whether they are successful in their aims. As PPH is increasing, identifying the most appropriate method of quantifying blood loss will inform practice and policy and may contribute to early recognition and treatment of excessive blood loss. A systematic review is required to summarise the available evidence on strategies that are used to evaluate blood loss during childbirth, and to answer the review question:

How successful are strategies used to evaluate blood loss during childbirth?

OBJECTIVES

The primary objective of this systematic review is to assess the success of strategies developed to evaluate blood loss during the first twenty-four hours following childbirth.

METHODS PART ONE

Inclusion criteria for considering quantitative studies for this review

Types of studies

Randomised controlled trials (RCTs), cluster RCTs, quasi-experimental studies including non-randomised controlled trials and controlled before and after studies will be considered for inclusion.

Types of participants

Participants will include those people involved in the evaluation of blood loss during the third stage of labour and the twenty four hours following completion of the third stage. This includes but is not restricted to: women, their birth partners, trained and untrained birth attendants, midwives, nurses, support workers, obstetricians, anaesthetists, and laboratory staff.

Types of Interventions

Studies conducted in real or simulated environments comparing visual estimation of blood loss to any of the following strategies including but not restricted to:

- PPH focussed staff education / training strategies
- Protocols, guidelines and algorithms (pictorial or written)
- Calibrated and un-calibrated under-buttock blood collection drapes.
- Gravimetric methods (measurement by weight)
- Volumetric measurement (calibrated jugs, receivers)
- Laboratory based methods
- Physiological response-based estimation
- Emerging technologies

Exclusion criteria

Studies focussing on secondary postpartum haemorrhage, definition of risk factors for PPH, and trials comparing treatment regimens for PPH will be excluded.

Types of outcome measures

Primary outcomes

The primary outcome measures will be success of the strategy for evaluating blood loss as defined by the authors of included studies. For example,

1. Improvement in the accuracy of blood loss estimation

2. Frequency of PPH or associated clinical outcomes as defined by authors of included studies (e.g. drop in haematocrit; need to administer blood transfusion; admission to intensive care unit).

The secondary outcome measures will include:

1. Health care professionals' responses to, and management of, blood loss
2. Health care professionals' skills in evaluating blood loss
3. Cost effectiveness of strategy
4. Clinical practicality of employing the strategy
5. Number and types of adverse effects of strategy

Search methods for the identification of studies

The search strategy will use text and keywords / MESH terms identified in the first stage of a three step search strategy, modified as required by each database. Search terms are shown below:

Search terms

1. Postpartum blood loss/
2. Postpartum bleed*/
3. Postpartum h?emorrhage*/
4. Obstetric* blood loss*/
5. Obstetric bleed*/
6. Obstetric h?emorrhage*/
7. Maternal blood loss*/
8. Maternal bleed*/
9. Maternal h?emorrhage*/
10. (*Birth) adj3 (blood loss*/)
11. (*Birth) adj3 (bleed*/)
12. (*Birth) adj3 (h?emorrhage*/)
13. Estimat*
14. Measur*
15. Quantif*
16. Assess*
17. Accura*
18. Prevent*
19. Diagnos*
20. Gravimetric
21. Photospectrometry
22. Alkaline h?ematin method
23. Blood collect* drape*
24. Blood collect* bag*
25. Train*
26. Guideline*
27. Protocol*
28. Technolog*
29. Procedure*
30. Scenario*
31. Simulat*

32. Recogni*
33. Manage*
34. Decision?making
35. Practice
36. Competen*
37. Third stage of labo?r
38. Search will be conducted using: 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 **AND** 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37

Electronic searches

The electronic databases to be searched include: MEDLINE, CINAHL Plus, EMBASE, the British Nursing Index, Maternity and Infant Care and PsycINFO. Studies published in all languages will be considered for inclusion and no date restrictions will be imposed. The reference lists of all included studies will be searched to identify additional studies.

Data collection and analysis

Selection of studies

Two authors, AH and TL, will independently review the titles and abstracts of potentially relevant studies using the inclusion / exclusion criteria described. Where there is no abstract but the title implies suitability for inclusion the full publication will be retrieved and suitability for inclusion assessed. Any disagreement that arises regarding suitability will be resolved through discussion. If the two reviewers are unable to resolve the disagreement the opinion of a third reviewer (AW) will be sought. Studies deemed eligible for inclusion will be imported into the reference management system, EndNote X5. Full publications of all included studies will be obtained. Where publications are only available as an abstract, attempts will be made to contact the authors to obtain the full reports. If full reports are not available these studies will be excluded.

Data extraction and management

Two reviewers (AH and TL) will extract data independently. Data extraction will be conducted using The 'Cochrane Public Health Group (CHPG) Data Extraction and Assessment Template', CPHG Data extraction template.docx (CPHG, 2011) which will adapted for this review and piloted to ensure consistency between authors in assessment and grading of studies. The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and objectives.

Assessment of risk of bias

This risk of bias on included studies will be assessed using the Cochrane 'Effective Practice and Organisation of Care (EPOC) RoB Tool, Risk of Bias 05-01-2009.doc (Higgins and Green, 2011) which is suitable for RCTs as well as other non-randomised designs that include a control group.

Measures of effect

Continuous outcomes will be recorded and compared using the weighted mean difference, or standardised mean difference, when different studies have used different scales to report the same outcome. Where a number of outcome measures are identified, the ratio of means will be used. Dichotomous outcomes and categorical data will be expressed as relative risks. 95% confidence intervals will be calculated for each category (Higgins and Green, 2011).

Unit of analysis issues

If unit of analysis issues arise from included studies, advice will be sought from the fourth reviewer (MC) about how to treat them.

Assessment of heterogeneity

If studies are sufficiently similar in terms of participants, interventions and outcomes, pooling and statistical meta-analysis of the data will be considered. The level of statistical heterogeneity will be quantified using the I^2 statistic. The I^2 statistic shows the level of variation in the intervention effects across the included studies, which are due to differences between the studies rather than chance. The value is expressed as a percentage and above 30% the level of heterogeneity may be important and should be interpreted carefully, as above this level meta-analysis may not be appropriate (Higgins and Green, 2011).

Data synthesis

Meta-analysis will be considered if the included studies are sufficiently similar, with low levels of heterogeneity (<30%), and where pooling of results will provide meaningful results. In the event that statistical pooling is not appropriate the findings will be presented in narrative form. Tables and figures will be used to aid data presentation where appropriate. The presentation of the synthesis will be organised by grouping together the results of studies that have tested the same or similar blood loss assessment strategy. Within each subgroup, findings will be organised by study design. The outcomes for all groups will be

considered overall and a narrative summary will be used to describe and discuss the success of each strategy.

Missing data

Attempts will be made to contact authors for missing data or for clarification of any issues regarding the study.

METHODS PART TWO

Criteria for considering qualitative studies for this review

Types of studies

Qualitative studies including, but not limited to, methodologies such as grounded theory, ethnography, phenomenological research, action research and feminist research will be considered for inclusion. Studies using mixed-methods that include a qualitative element and sufficient data will also be considered.

Types of participants and phenomenon of interest

Participants will include health professionals who have experience of blood loss assessment during childbirth, and the use of strategies to assist them in the process. This includes but is not restricted to obstetricians, anaesthetists, midwives, nurses, support workers and laboratory staff. Participants will also include the women and their birth partners who have experience of care received by health professionals using blood loss assessment strategies during their care.

Context

Experiences in real or simulated births will be included.

Search methods for the identification of studies

The search strategy will use text and keywords / terms identified in the first stage of a three step search strategy, modified as required by each database.
Search terms are shown (next page) and will be applied to the electronic databases used the SPIDER approach (Cooke et al., 2012).

Electronic searches

The electronic databases to be searched include MEDLINE, CINAHL Plus, EMBASE, the British Nursing Index, Maternity and Infant Care, PsycINFO. Studies published in all languages will be considered for inclusion and no date restrictions will be imposed. The reference lists of all included studies will be searched to identify additional studies. Where research is only available as an abstract, attempts will be made to contact the authors to obtain the full reports. If full reports are not available these studies will be excluded. A search of key organizations including the World Health Organization; Royal College of Obstetricians and Gynaecologists; International Federation of Gynecology and Obstetrics;

and the International Confederation of Midwives will be conducted through the World Wide Web to identify guidelines, project and policy documents.

Search terms

Sample (Population)	Phenomenon of Interest	Design	Evaluation	Research type
Postnatal	H?emorrhage*	Questionnaire	Experienc*	Qualitative
Postpartum	Blood loss	Survey	Diagnos*	Mixed method*
Maternal	Bleeding	Focus group*	Decision?making	
Obstetric*		Case stud*	View*	
*Birth		Observ*	Quantif*	
		Interview*	Know*	
		Phenomenology	Feel*	
		Grounded theory	Understand*	
		Ethnography	Recogni*	
		Feminist research	Manag*	
		Action research	Attitude*	
			Practic*	
			Competen*	
			Estimat*	
To search use: [S AND P of I] AND [(D OR E) AND R]				

Data collection and analysis

Selection of studies

Two authors, AH and TL, will independently review the titles and abstracts of potentially relevant studies using the inclusion / exclusion criteria described. Where there is no abstract but the title implies suitability for inclusion the full publication will be retrieved and suitability for inclusion assessed. Any disagreement that arises regarding suitability will be resolved through discussion. If the two reviewers are unable to resolve the disagreement the opinion of a third reviewer (AW) will be sought. Studies deemed eligible for inclusion will be imported into the reference management system, EndNote X5. Full publications of all included studies will be obtained. Where publications are only available as an abstract, attempts will

be made to contact the authors to obtain the full reports. If full reports are not available these studies will be excluded.

Data extraction and management

Two reviewers (AH and TL) will extract data independently. The critical appraisal instrument for qualitative studies from the Critical Appraisal Skills Programme (CASP, 2010), CASP_Qualitative_Appraisal_Checklist_14oct10.pdf, will be used to extract and record data. The data extracted will be assessed for methodological validity and will include specific details about the phenomena of interest, populations, study methods and outcomes of significance to the review question and specific objectives. The reviewers will independently assign a quality score to studies which will be recorded on the table Qualitative Appraisal Scoring Table.docx. Any disagreement that arises between AH and TL will be resolved through discussion. If the two reviewers are unable to resolve the disagreement the opinion of a third reviewer (AW) will be sought.

Data Synthesis

After the qualitative studies have been rated according to their quality they will be categorised according to their similarity in meaning. If appropriate the categorised studies will be pooled to create a set of statements that represent that aggregation. This data will then be subjected to a meta-synthesis in order to produce a single comprehensive set of synthesised findings that can be used as a basis for evidence-based practice. In the event that textual pooling is not possible the findings will be presented in narrative form (The Joanna Briggs Institute, 2004).

SYNTHESIS OF QUANTITATIVE AND QUALITATIVE DATA

A narrative synthesis of the quantitative and qualitative evidence included in this review will be undertaken. The purpose will be to reach an understanding of how successful blood loss assessment strategies are in achieving the intended outcomes of individual studies. It is also important to gain an understanding of the factors that may affect the implementation of these strategies in practice. The four main elements of narrative synthesis identified by Popay et al (2006, p.11) will provide the framework for this process. These include:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in the data
- Assessing the robustness of the synthesis

This process will allow for conclusions and recommendations to be drawn from the data.

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