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The Recognition of Excessive blood loss At Childbirth (REACT) Study: A two-phase exploratory, sequential mixed methods inquiry using focus groups, interviews, and a pilot, randomised crossover study.

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ABSTRACT

Objectives: To explore how childbirth-related blood loss is evaluated and excessive bleeding recognised; and develop and test a theory of postpartum haemorrhage (PPH) diagnosis.

Design: Two-phase, exploratory, sequential mixed methods design using focus groups, interviews and a pilot, randomised crossover study.

Setting: Two hospitals in North West England.

Sample: Women (following vaginal birth with and without PPH), birth partners, midwives and obstetricians.

Methods: Phase 1 (qualitative): 8 focus groups and 20 one-to-one, semi-structured interviews were conducted with 15 women, 5 birth partners, 11 obstetricians, 1 obstetric anaesthetist and 19 midwives (n=51). Phase 2 (quantitative): 11 obstetricians and 10 midwives (n=21) completed two simulations of fast and slow blood loss using a high-fidelity childbirth simulator.

Results: Responses to blood loss were described as automatic, intuitive reactions to the speed, nature and visibility of blood flow. Health professionals reported that quantifying volume was most useful *after* a PPH diagnosis, to validate intuitive decisions and guide on-going management. During simulations, PPH treatment was initiated at volumes at or below 200ml (fast mean blood loss 79.6ml, SD 41.1; slow mean blood loss 62.6ml, SD 27.7). All participants treated fast, visible blood loss, but only half treated slow blood loss, despite there being no difference in volumes (difference 18.2ml, 95% CI -5.6 to 42.2ml, p=0.124).

Conclusions: Experience and intuition, rather than blood loss volume, inform recognition of excessive blood loss after birth. Women and birth partners want more information and open communication about blood loss. Further research exploring clinical decision-making and how to support it is required.

Tweetable Abstract: During a PPH, clinical decision-making is intuitive with clinicians treating as soon as excessive loss is recognised.

INTRODUCTION

Primary postpartum haemorrhage (PPH) is the most common single cause of maternal death worldwide, mainly in low-income countries.^{1,2} In high-income countries, where maternal deaths from PPH are rare, severe PPH is increasing.³⁻⁵ In the United Kingdom (UK), PPH is the second leading cause of direct

maternal deaths and the leading cause of maternal collapse and severe maternal morbidity.^{4,6-8} Delayed diagnosis and treatment are linked to the increasing incidence and severity of PPH⁹ with experts suggesting that most deaths could be avoided by more 'appropriate diagnoses'.¹⁰

Visual estimation is commonly used to assess blood loss volume following birth¹¹ but is universally acknowledged as inaccurate.¹² Traditionally, research has focused on improving clinicians' skills in volume estimation, but retention of skills and improved clinical outcomes have not been demonstrated.¹² A large cluster randomised trial¹³ showed that blood collection bags facilitated more accurate volume measurement, but did not improve the timing of PPH diagnosis, or reduce its severity. A recent Cochrane review¹⁴ found that there was insufficient evidence to support the use of one method of estimating blood loss volume over another, following vaginal birth, as none of the methods had any impact on diagnostic accuracy. We postulated that this may be because they are not actually used to inform diagnosis during clinical decision-making.¹² We found that there was little research aimed at understanding the decision-making processes involved in the evaluation of blood loss. To address this, phase one of our study used qualitative methods to explore how childbirth-related blood loss is evaluated, by those involved in the process. During analysis we developed a theory of PPH diagnosis which informed the design of the second phase of the study. Phase two used clinical simulation and quantitative methods to test the hypothesis that health professionals react to the nature, speed and visibility of blood loss. This is contrary to current opinion that suggests that blood loss is primarily assessed as a volume and health professionals react when the amount reaches a threshold indicative of PPH, according to standard definitions, such as blood loss exceeding 500ml.¹

METHODS

The REACT Study was completed between June 2014 and October 2017, in two large National Health Service (NHS) hospitals in North West England (study sites one and two), using a two-phase, exploratory, sequential, mixed methods design.^{15,16} The intent of this design is to facilitate qualitative exploration followed by quantitative follow-up.¹⁶ In our study, qualitative results were used to design simulation scenarios which were administered and measured through quantitative methods. The effect of mixing the methods in this design is that one dataset builds on the results from the other.¹⁶ Phase one of our study explored blood loss-related decision-making and developed a theory of PPH diagnosis. This theory was tested in phase two.

Permissions were obtained from the Greater Manchester (East) Research Ethics Committee (14/NW/0052) and both NHS organisations. The study was presented using the 'Consolidated Criteria for Reporting Qualitative Research' (COREQ)¹⁷ and the 'Consolidated Standards of Reporting Trials' (CONSORT)¹⁸.

Participants

Purposive sampling was used to recruit women, midwives and obstetricians with a wide range of views and experiences of the phenomenon being explored.¹⁹ All grades of health professionals, and postnatal women with varying degrees of blood loss at birth, were invited to participate. Snowball sampling, a strategy where the acquaintances of participants already recruited are approached and invited, was used to recruit the birth partners of women participants.²⁰ All participants gave written, informed consent and provided basic demographic information (Table 1).

Health professionals

All grades of obstetricians and midwives (health professionals) were eligible to participate, with a total of 52 recruited to both phases of the study. Recruitment was facilitated by key clinicians (gatekeepers), who provided information and forwarded an invitation email to eligible staff, and displayed posters in clinical areas. Interested staff contacted the research team for further information. AH was also regularly available in clinical areas to provide eligible staff and women with information about the study.

Postnatal women

English-speaking women, aged 18 years and over (with and without PPH), were eligible to participate in phase one following vaginal birth of their well babies. Women were introduced to AH (an experienced midwife) by postnatal ward midwives or completed 'Consent-to-Contact' forms with their contact preferences. Fifteen women participated within three months of their most recent birth experience. A further six women expressed interest but did not participate.

Birth partners

Participating women received 'Consent-to-Contact' forms for their birth partners to return to AH, if interested, with five agreeing to participate.

Patient and public involvement

Women from the recruiting hospitals' Maternity Patient and Public Involvement (PPI) panels informed the study design and reviewed the protocols and data collection tools associated with the study. Women and their birth partners from study site 2 were participants in phase one.

Study design

Phase one – Qualitative data collection

Participants chose to complete a one-to-one interview or focus group, allowing privacy and flexibility. Eight focus groups and 20 one-to-one, semi-structured interviews were conducted with 11 obstetricians, one obstetric anaesthetist and 19 midwives from study site one, and 15 women and five birth partners from study site two (n=51). Women attended focus groups in a community Children's Centre or completed interviews in their homes. Birth partners completed interviews in their homes or at the study site's antenatal clinic. Health professionals participated in their workplace.

Discussions lasting 20 to 77 minutes, facilitated by AH using a topic guide as an aide-memoir (Figure S1), were audio-recorded, transcribed verbatim and anonymised. Topic guides were developed based on best practice principles.²¹ A dual moderator (research midwife) attended the women's focus groups.

Transcripts were annotated with observations from field notes to aid interpretation. Data saturation was determined when no new information was discussed by participants.¹⁹

Qualitative data analysis

Analysis and interpretation were led by AH using the 'Framework' approach.^{22,23} Preliminary themes and subthemes, a mixture of emerging themes and a-priori themes derived from the research questions and topic guides,²³ were refined and used to code the data. This started inductively at the data level, progressing to more abstract ideas through an iterative process of coding, linking ideas and testing relationships.²⁴ In the final stage, 'data summary and display',²³ data were summarised (retaining participants' phrases) and displayed in matrices to facilitate interpretation.

Trustworthiness

AH led the project, ensuring thorough immersion in the data. Peer and ethical review and pilot testing of the tools used ensured that the study design and rationale were scrutinised and modified, as appropriate. An independent qualitative researcher (CF) with expertise in 'Framework' guided AH's analysis. The use of NVivo 10 software²⁵ promoted transparency enabling all members of the research team to contribute to coding, analysis and interpretation. An active and on-going process of researcher reflexivity enabled

AH to remain as neutral as possible.²⁶ In keeping with the study design, phase two was designed following preliminary analysis of the qualitative data, requiring additional approvals of a phase two protocol and study documents. This phase tested the validity of suggestions in the qualitative discussions that responses to blood loss were automatic and relied on the nature, speed and visibility of bleeding, rather than volume.

Phase 2 – Quantitative data collection

A theory of PPH diagnosis, developed during qualitative analysis, was tested in a pilot, randomised crossover study, using clinical simulation of fast and slow blood loss with the NOELLE® S575.100 Birthing Simulator (Gaumard Scientific®, Miami).²⁷ As the qualitative data suggested that clinicians responded automatically to speed of visible blood flow, rather than volume of blood loss, it was decided that two scenarios would be used to simulate fast and slow bleeding,. The main outcome was to explore the ‘trigger point’ for eliciting a PPH response from the participant. Creating scenarios that broadly focused on the third stage of labour minimised the possibility of participants guessing the scenario topic as there were several possible clinical outcomes to the histories described.

Ten midwives and 11 obstetricians from study site two completed two clinical simulations focusing on management of the 3rd stage of labour, subsequently complicated by continuous fast or slow blood loss. The order in which the scenarios were presented was determined by randomisation with participants randomised to ‘fast blood loss followed by slow blood loss’ or ‘slow blood loss followed by fast blood loss’ (Figure 1). ‘Fast blood loss’ was simulated, using Gaumard artificial blood solution, at a rate of 125 millilitres (ml) per minute (500ml over 4 minutes) via the mannequin’s integrated bleeding function. Due to the inability to vary the flow rate of bleeding from the mannequin, ‘slow blood loss’ was delivered via a modification to the mannequin’s integrated bleeding function using an infusion pump and additional tubing, hidden from participants. This delivered blood loss at a rate of 999ml per hour (500ml over 30 minutes). Blood loss was activated remotely by a second research midwife acting as the birth partner in the scenario. The random allocation sequences, generated by an administrator using StatsDirect software (StatsDirect Ltd, Cambridge),²⁸ were placed in consecutively numbered, sealed, opaque envelopes and opened immediately prior to participation. Stratification by professional group and block randomisation prevented allocation bias and ensured balanced groups. The scenarios ended when participants either initiated PPH management/ treatment or concluded that no further actions or treatment were necessary. At this point the total volume of blood loss was calculated and recorded by the researcher on a data collection form.

Sample size calculation

To our knowledge there have been no previous similar studies upon which to base a sample size calculation. We hypothesised that there would be a 40% reduction in blood loss between the fast and slow groups (from 250ml to 150ml) at the point when treatment was initiated. Assuming a common standard deviation of 75ml, 10 participants would be needed in each group to detect this difference at the 5% level with 80% power via an unpaired t-test using nQuery Advisor (Statistical Solutions Ltd, Ireland).²⁹ This was used as a conservative justification for a total sample size of 20 participants to cover paired and unpaired comparisons for this pilot study, data from which could be used to inform the sample size for further studies. The crossover design allowed each participant to complete two clinical scenarios and act as their own controls, allowing for differences between the scenarios to be measured.³⁰ A potential confounding factor, that data from the second scenario may reflect a residual (learning) effect from the first scenario ('carry-over'), was considered during analysis.^{31,32}

Quantitative data analysis

Data analysis was completed by AH and MC. Descriptive statistics were estimated using SPSS v23 (IBM, New York).³³ For each scenario, differences between the mean values for midwives and obstetricians were compared within and across the randomisation groups, as well as overall between the randomised groups. The four-stage method of crossover analysis³⁴ was completed using StatsDirect software.²⁸ Two-sided t-tests and 95% confidence intervals, for differences between means, facilitated further interpretation of the data.

RESULTS

Phase one - Qualitative

Analyses of the data for the 'health professionals' and 'women and birth partners' were conducted separately, before synthesising into three major themes and sub-themes (Table S1). It is beyond the scope of this paper to discuss the separate analyses for health professionals and women and birth partners in detail. An overview of the whole study findings which relate specifically to clinical decision-making and recognition of excessive blood loss are therefore presented. Detailed findings relating to women and birth partners will be addressed in a further publication. Verbatim quotes of participants are numbered within the text and displayed in Table 2.

Theme 1 - Normal and normalised blood loss

All participants agreed that some bleeding following childbirth was normal. Descriptions of normal blood loss often included a volume and a time frame (Quote 1) and varied according to mode of birth (Quote 2).

At study site one, objective measurement was routine at all operative births in theatre, using swab weight and volume of suctioned blood loss; and during instrumental births and perineal repair, using under-buttock drapes. In these circumstances, quantification was widely accepted by staff as more accurate and useful for informing on-going management. Similarly, weighing blood loss at normal births was practised by some midwives, who felt that it facilitated PPH diagnoses that might otherwise have been missed (Quote 3). Expectation also appeared to increase vigilance, with midwives describing being 'zoned in' (Midwife 5/Focus Group/T5) and more likely to measure and treat blood loss, in women who had, or developed risk factors for PPH. However, many midwives felt that for most women, routine weighing was an impractical, time-consuming, unnecessary medical intervention (Quote 4) that should be reserved for blood losses judged to be 'more than normal' (Midwife 3/Focus Group/T6). While some participants were able to judge blood loss as a volume, using knowledge of the saturation level of swabs and incontinence sheets, others described simply 'knowing' what constituted a normal or abnormal amount (Quote 5)

Discussions highlighted that objective measures of blood loss could be increased or decreased ('normalised') depending on whether the amount was judged to be 'normal' or 'abnormal' for each woman/mode of birth. This was described as a subconscious action, linked to expectations that most women have a normal amount of blood loss (Quote 6). Others felt that it involved conscious decisions to avoid treatment that was not clinically justified or to secure treatment and observation of women with borderline blood losses, which they might not otherwise have received (Quote 7).

Most health professionals described this process of regularly modifying both estimated and quantified blood loss volumes, by 'always doing a bit of subtracting' (Obstetrician 3/Focus Group/T29). This was to allow for the presence of liquor and to reflect professional judgment about whether the blood loss would be tolerated by individual women. It was acknowledged that this could lead to normalisation of a borderline estimate of blood loss, which would otherwise have crossed over the diagnostic threshold for PPH.

Theme 2 – Reacting to blood loss

Fast, visible and continuous blood loss was referred to as a 'proper PPH', which 'automatically raised alarm bells' (Midwife 1/Focus Group/T5) and was the main trigger (Trigger 1 – Figure 2) for eliciting a PPH

response (management, treatment and/or escalation). Descriptions, such as 'pouring' and 'pumping out continuously', often depicted the speed and nature of blood loss (Quote 8). Sometimes, the extent of bleeding was delayed and only recognised once a woman became unwell (Quote 9) or collapsed (Quote 10) (Trigger 2 – Figure 2). Other reasons cited for delayed diagnosis included a lack of regular vital signs measurement in the early postnatal period, especially if the woman appeared well or if staff were reassured by a normal blood pressure reading.

Initial reactions to blood loss were described by participants as an instinctive 'gut reaction' (Quote 11), explained as a sense of unease, or a response to a 'feeling of shock'. Experienced health professionals also referred to 'intuition', informed by past experiences (Quote 12). Although most women stated that they were unable to comprehend much detail about their blood loss, accounts suggested that they were highly perceptive to events, often alerted to a problem by the non-verbal cues of the people around them (Quote 13).

Theme 3 - Managing and escalating excessive blood loss

Organisational factors also appeared to influence how objective values were viewed and treated. It was suggested that a recent (local) increase in the volume threshold used to define PPH, from 500ml to 750ml, along with a 'reportable PPH' threshold of 1500ml, may have had the effect of normalising large blood losses (Quote 14). It was felt that this, along with frequent exposure to larger blood losses in practice at this study site, may also have had the effect of desensitising staff and extending their reaction times (Quote 15).

Once alerted to a problem, through gut feeling and intuition, health professionals described a decision-making process that was methodical and practised, described by one midwife as 'military' (Midwife 1/Focus Group/T6). This was the point at which health professionals gathered additional clinical information to confirm PPH diagnosis and inform and justify their decisions. This included calculating cumulative blood loss and instigating regular measurement and recording of vital signs and early warning scores.

Phase two - Quantitative

The main theory derived from qualitative analysis, that health professionals respond automatically to the speed and nature of visible bleeding, rather than volume of blood loss, was tested in phase two with 10 midwives and 11 obstetricians. Data were analysed to test the hypothesis that, compared to slow blood

loss, fast blood loss is associated with a faster PPH response from health professionals. Analyses examined whether there were any differences in responses to fast and slow blood loss between the two professional groups and whether responses were influenced by the order in which the scenarios were presented.

Actual blood loss (ABL) and duration of bleeding

Tables S2 and S3 show descriptive statistics for actual blood loss (ml) and duration of bleeding (minutes).

Slow blood loss

When the slow blood loss scenario was viewed first, duration of blood loss was longer and ABL values higher, for the obstetricians than the midwives. When the slow scenario was viewed second, ABL values and duration of bleeding were similar between the midwives and obstetricians. The highest volume of slow blood loss triggering a PPH response by midwives (acknowledged trickle and stated they would watch and wait) was 136.2ml, compared to 84.2ml for obstetricians (recognised bleeding vessel in vagina [bleeding port], applied pressure and requested suturing equipment).

Fast blood loss

During fast blood loss, obstetricians reacted at similar volumes in the two randomised groups, but ABL values were lower than those of the midwives and always less than 100ml. Midwives took longer to respond to fast blood loss compared to obstetricians, leading to higher volumes, particularly when viewing the fast scenario second. The highest volume of fast blood loss triggering a PPH response by midwives (2nd dose of oxytocic) was 200ml, compared to 76ml for obstetricians (rubbed up a contraction and requested syntocinon infusion).

Tables S4 and S5 show crossover analyses for actual blood loss (ml) and duration of bleeding (minutes). There was no evidence of a difference in actual blood loss between the fast scenario (mean 79.6ml, SD 41.1) and the slow scenario (62.6ml, SD 27.7) (difference 18.2ml, 95% CI -5.6 to 42.2ml, $p=0.124$). There was also no evidence of a difference in actual blood loss between the first and second time periods ($p=0.392$). Duration of bleeding was shorter in the fast scenario compared with the slow scenario (difference -2.91 minutes, 95% CI -3.75 to -2.06 minutes, $p<0.001$). Allowing for scenario, there was no evidence of a difference in duration of bleeding between the first and second time periods ($p=0.196$).

Responses to blood loss

The ABL volumes triggering a PPH response were low and, in all but one case, below 200ml (range for obstetricians 19ml [fast] to 84.2ml [slow]; range for midwives 33.1ml [slow] to 200ml [fast]). The findings show that, irrespective of the order that participants completed the scenarios, PPH responses were initiated more quickly, and by all participants, in all the fast blood loss scenarios. Conversely, despite there being no difference in actual blood loss between the fast and slow scenarios, 6 out of 21 participants (3 midwives, 3 obstetricians) concluded the slow blood loss scenario without treatment, whilst the mannequin was still bleeding. The six participants who did not initiate a PPH response in the slow group either did not see the on-going blood loss or did not consider it a problem. Responses included applying a sanitary pad and stating that they were happy to conclude; stating that there was no continuing blood loss; or, in one case, recognised the on-going bleeding but after checking the maternal antenatal haemoglobin, concluded that it was of no concern.

Less than half of the participants chose to estimate blood loss as a volume (7/21 slow; 9/21 fast), and only one estimate was over 500ml. This appears to support the theory that speed and visibility of blood loss are more important than volume in determining PPH responses. Health professionals in our study treated blood loss as soon as they perceived it as abnormal rather than waiting for a specific volume.

DISCUSSION

Although a small number of studies³⁵⁻³⁹ have explored PPH recognition, this is the first study in a high-resource setting. The three key messages from this study are first, that health professionals initiate treatment as soon as they recognise bleeding as abnormal, not at any predetermined volume; second, measuring blood loss will not improve reaction speed in obvious rapid blood loss, but may ensure that PPH is not missed with slow loss; and third, at the study sites, measurements of blood loss are currently used retrospectively for recording purposes rather than to initiate and guide initial management. If blood loss measurement is to be effective, there needs to be continuous on-going evaluation as the PPH situation evolves. Only a small number of health professionals used knowledge of saturation points of commonly used items to gauge blood loss volume to make a diagnosis.

Current guidelines define PPH by volume^{1,40,41} and assume that treatment is commenced after a volume-based diagnosis. Such guidelines assume that measuring blood loss volume is commonly used as a way to ensure that heavy blood loss is rapidly responded to, to ensure that therapy is correctly initiated at 500mls for all women, and to accurately determine blood loss to guide management. However, our study showed that this does not reflect clinical practice, as treatment was initiated as soon as blood loss was clinically diagnosed as abnormal, with volume measured to support the clinical diagnosis. Values were

often 'normalised' if the measured amount contradicted clinical perceptions. We would argue that blood loss measurement is important for insidious bleeding, to ensure that a slow cumulative loss is not missed, and to determine the severity of loss. However, this can only be done if the measurement process is changed so that it is continuous and on-going throughout the immediate postnatal period / PPH, which is not usually done.

Our findings concurred with those from low-resource settings³⁵⁻³⁹ where language used to describe excessive blood loss reflected the nature and speed of blood flow;³⁸ and maternal condition, such as 'faintness' or 'unconsciousness', was important for judging the severity of the loss.³⁵ While local methods of quantification were used,³⁶ most participants described simply 'knowing' when blood loss was too much, based on an intuitive, gut reaction.³⁹ Experience was used to interpret intuitive feelings and inform responses to them.³⁹

The theory of PPH diagnosis, developed in phase one of this study and tested in phase two, confirmed that volume is not routinely used to make a PPH diagnosis but becomes important after a PPH diagnosis to validate intuitive responses, guide management, and to justify on-going decisions. We have considered these findings in context with psychological theories of decision-making and⁴² found that that, in studies exploring recognition and diagnosis of similarly dynamic and complex phenomenon, such as active labour,⁴³ dying,⁴⁴ and physiological deterioration,^{45,46} decision-making was predominantly intuitive, with objective measures used to validate intuitive decisions. Similarly, in our study, quantified blood loss, maternal vital signs and early warning scores were often used to confirm rather than inform diagnoses. In relation to objective measurement of blood loss, many midwives in our study expressed reluctance to routinely measure cumulative blood loss following normal birth, as this might 'medicalise' an otherwise normal situation. Furthermore, although not statistically significant, midwives were also found to respond at higher volumes of blood loss to obstetricians, a finding that may be worthy of further investigation.

Although the detailed findings of the women and birth partners data will be presented elsewhere, it is relevant to note here that we found that women and their birth partners were highly perceptive to blood loss and, like women in studies focussing on severe PPH,⁴⁷ clearly recalled the details of their experiences and of knowing 'instinctively' that something was wrong. In relation to supporting clinical decision-making, particularly during insidious blood loss, we found that women wanted more information to enable them to recognise excessive postnatal bleeding and contribute to decision-making processes.

Strengths and limitations

The main strength of this study was the mixed methods approach, with participants recruited from two large NHS maternity hospitals in the UK. While the fact that both hospitals were in the same geographical region may limit transferability of the findings to other settings, it is a strength that the qualitative data were supported by the quantitative findings. Selection bias was a possibility in both phases of the study, as those who felt confident discussing their clinical practice may have been more likely to participate. Similarly, because qualitative discussions captured participants' tacit knowledge and verbal accounts of previous experiences of evaluating blood loss, recall bias is another possibility. However, these limitations were minimised by the relatively large sample size for a qualitative study. Due to the difficulties of participating in a group discussion through an interpreter, non-English-speaking women were excluded from this study. This inevitably limits transferability of findings, as the views of these women are not represented. In phase two, while the sample size was relatively small, the cross-over technique maximised data collection from the sample and important issues were highlighted which will inform future studies. A limitation of using a mannequin is that subtle cues associated with maternal physiological responses to blood loss were absent, which may have affected participants' responses. There is a possibility with the use of a cross-over design that responses to the second simulation scenario reflected a learning effect from the first scenario ('carry-over'). Duration of bleeding was found to be longer in the slow scenario. This may reflect that some obstetricians believed that this was a retained placenta scenario, with the associated actions prolonging the bleeding time. It may also indicate a learning effect, with obstetricians slower to react to the slow blood loss unless they had seen the fast scenario first and learned that a PPH response was required. Some participants also commented that they had treated insidious blood loss that in normal practice they would have observed, because they were 'in a false situation' and felt the need 'to do something'. While this may imply a learning effect, it may also suggest that more participants, than the six reported, would have left the insidious bleeding untreated if they had not felt / learned that a PPH treatment response was required.

Future research

Further research to explore decision-making in more detail, is essential for informing strategies to reduce delays in PPH diagnosis and treatment. Future research should also consider the appropriate ways of providing education and information to women, to enable them to contribute to decision-making, particularly during insidious, compensated blood loss, which may otherwise go unrecognised.

Conclusions

Our study found that recognition of excessive blood loss and PPH is often an automatic reaction to the speed and nature of visible blood loss, or condition of the woman, rather than a response to a volume measurement. Experience and intuition play an important role in the recognition and response processes, as well as informing actions taken in treatment and management.

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Disclosure of interests

No conflicts of interest have been disclosed by any of the authors.

Contribution to Authorship

AH conceived the study. The study design was refined with input from TL, ADW and MC. AH collected all the data apart from the final two simulation participants, whose contribution was facilitated by research midwife CC and research manager DL. Qualitative data analysis was completed by AH, supported by CF. TL and ADW contributed to qualitative data analysis and interpretation. Quantitative data analysis was completed by AH and MC. AH wrote the manuscript and all authors have contributed to each draft and reviewed the final manuscript.

Details of Ethics Approval

A favourable ethical opinion was received from the National Research Ethics Service Committee North West – Greater Manchester East (REC Reference: 14/NW/0052) on 10th March 2014. Management permissions were also granted from the two participating NHS R&D offices prior to commencement. The University of Manchester acted as research sponsor, as defined in the Research Governance Framework for Health and Social Care Version 2 (DoH2005) and the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031).

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Table 1: Demographic information of participants and methods of participation

PHASE 1 – QUALITATIVE								
Women (n=15) and Birth Partners (n=5)								
Study site: 2								
Participant Group (incl. mode of birth for women)	Number of Participants	Range of Years in Practice (mean)	Method of Participation		Age Range in Years (mean)	Parity	Range of Estimated Blood Loss in ml (mean)	Birth Partner Participants
			Focus Group	1:1 Interview				

Women (spontaneous)	7	-	5	2	26-36 (33.3)	1 (n=2) 2 (n=4) 3 (n=1)	200-600 (383) (Unavailable for 1 woman)	1
Women (ventouse)	4	-	0	4	32-40 (37.5)	1 (n=1) 2 (n=1) 3 (n=2)	600-1250 (838)	0
Women (forceps)	4	-	2	2	25-35 (29.8)	1 (n=3) 2 (n=1)	400-1000 (675)	4
Health Professionals (n=31)								
Study site: 1								
Grade 5 midwives	4	0.25-2 (1)	4	0				
Grade 6 midwives	7	3-29 (12.4)	7	0				
Grade 7 midwives	8	5-24 (17.5)	8	0				
ST1 - ST2 doctors	4	1-4 (2.25)	2	2				
ST3 –ST5 doctors	0	0	0	0				
ST6-7 doctors	2	8-9 (8.5)	1	1				
Consultants	6	12-33 (23.7)	2	4				
PHASE 2 – QUANTITATIVE								
Health professionals (n=21)				Randomisation Group				
Study site: 2				Slow / Fast	Fast / Slow			
Grade 5 midwives	0	0	0	0				
Grade 6 midwives	6	8-29 (17)	5	1				
Grade 7 midwives	4	15-26 (20.5)	0	4				

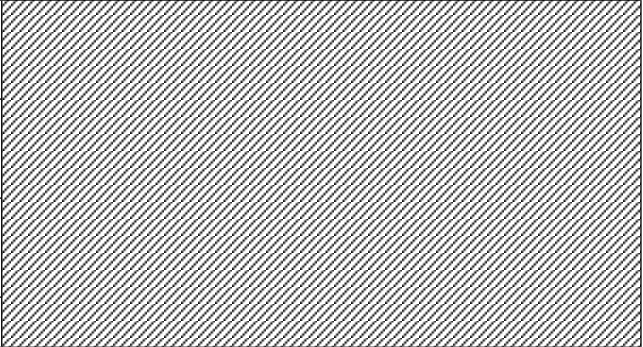
ST1 - ST2 doctors	0	0	0	0	
ST3 –ST5 doctors	4	5-15 (8.25)	1	3	
ST6-7 doctors	6	5-12 (7.3)	4	2	
Consultants	1	23	0	1	

Table 2: Participants' verbatim quotes from qualitative data

Quote Nº	Participant ID	Verbatim quote	Method of Participation/ Transcript (T) Nº
1	Midwife 3	<i>Well, something that's not too heavy. I suppose less than five hundred ml, a steady loss in the first twenty-four hours, becoming lighter the next few days.</i>	Focus Group/T8
2	Obstetrician	<i>I suppose it depends on the type of delivery, so ideally - well, less than probably two or three hundred ml in a normal delivery but less than - or around - there's this mythical 500ml (laughs) mark for a caesarean section that everybody runs to.</i>	Interview/T28
3	Midwife 2	<i>I had a woman the other day who I thought lost about 500mls...I took the inco (incontinence) pad off and weighed it, and it was 800.</i>	Focus Group/T18
4	Midwife 1	<i>It's an intervention, isn't it? You're saying that from day one, all women have a PPH if you're saying that you'd introduced something like measuring each pad...</i>	Focus Group/T5
5	Midwife 1	<i>I know the difference between...something that I think is normal for a normal delivery because I've seen enough of them to know what is abnormal (Emphasis on 'know' noted in field notes)</i>	Focus Group/T5
6	Midwife 1	<i>I absolutely agree with what (name) says about...tempering your estimation of blood loss according to how, clinically, you feel the woman is... I would always say what I thought it was, but I think, subconsciously, people...you estimate it to be less when you're expecting less.</i>	Focus Group/T6
7	Obstetrician	<i>I'm sure there's an element in some practice...if you've got a number that activates them staying in HDU or getting a 6-hour Hb...people can estimate a blood loss that's either just under that because they think they'll be alright. Or they're a bit anxious and want closer follow-up.</i>	Interview/T32
8	Obstetrician 1	<i>I think a massive blood loss is very obvious. Whenever she's absolutely pouring, you can tell that she's losing a lot of blood and she's going to lose a lot of blood quite quickly.</i>	Focus Group T29

9	Karen (woman)	<i>My pulse went really high and they weren't sure what was causing it ...I remember the consultant saying that they weren't too sure whether I'd lost a bit more than...they'd estimated just because of the, the way my pulse had gone (Spontaneous birth, estimated Blood Loss [EBL] 600ml)</i>	Interview/T16
10	Midwife 5	<i>There was a woman...upstairs in the birth centre, trickle, trickle, trickle, trickle. All of a sudden, she came down to delivery unit, straight into theatre in a collapsed state with a Hb of 4.</i>	Focus Group/T5
11	Chris (birth partner)	<i>It was only when I saw blood dripping onto the floor... I felt worried and that's when I thought, you know...it was too much...that...that's not normal</i>	Interview/T27
12	Obstetrician	<i>I guess the difficulty with experience is that, you're tempted to do that 'so it's more than you're used to, or it's less than you're used to'. But I think...experience is good at that pre-calculating stage. It's that whole, am I worried...do I need to get some extra help now, before you've even thought about how much has been lost.</i>	Interview/T32
13	Helen (woman)	<i>...more people seemed to be migrating that way, and there was some concerned looking faces kind of looking at me, and then looking down again. (Forceps delivery, EBL 1000ml)</i>	Focus Group/T11
14	Midwife 2	<i>So, if they're raising the bar then that's kind of normalising...isn't it?</i>	Focus Group/T8
15	Obstetrician	<i>I think, in a busier unit that deals with PPHs frequently, there can be a complacency, which may have resulted in a drift of the thresholds and trigger points, um, you know, which may, undermine the severity of the situation.</i>	Interview/T21

TABLE / FIGURE LIST

Table 1: Demographic information of participants and methods of participation

Table 2: Participants' verbatim quotes from qualitative data

Figure 1: CONSORT Flow Diagram of Phase 2 simulation study participants

Figure 2: A theoretical model of PPH diagnosis, management and treatment

Supporting Information Figure S1: Topic Guides

Supporting Information Table S1: Final main themes and subthemes for qualitative data

Supporting Information Table S2: Descriptive statistics for actual blood loss (ml) for professional group by randomised group in each blood loss scenario

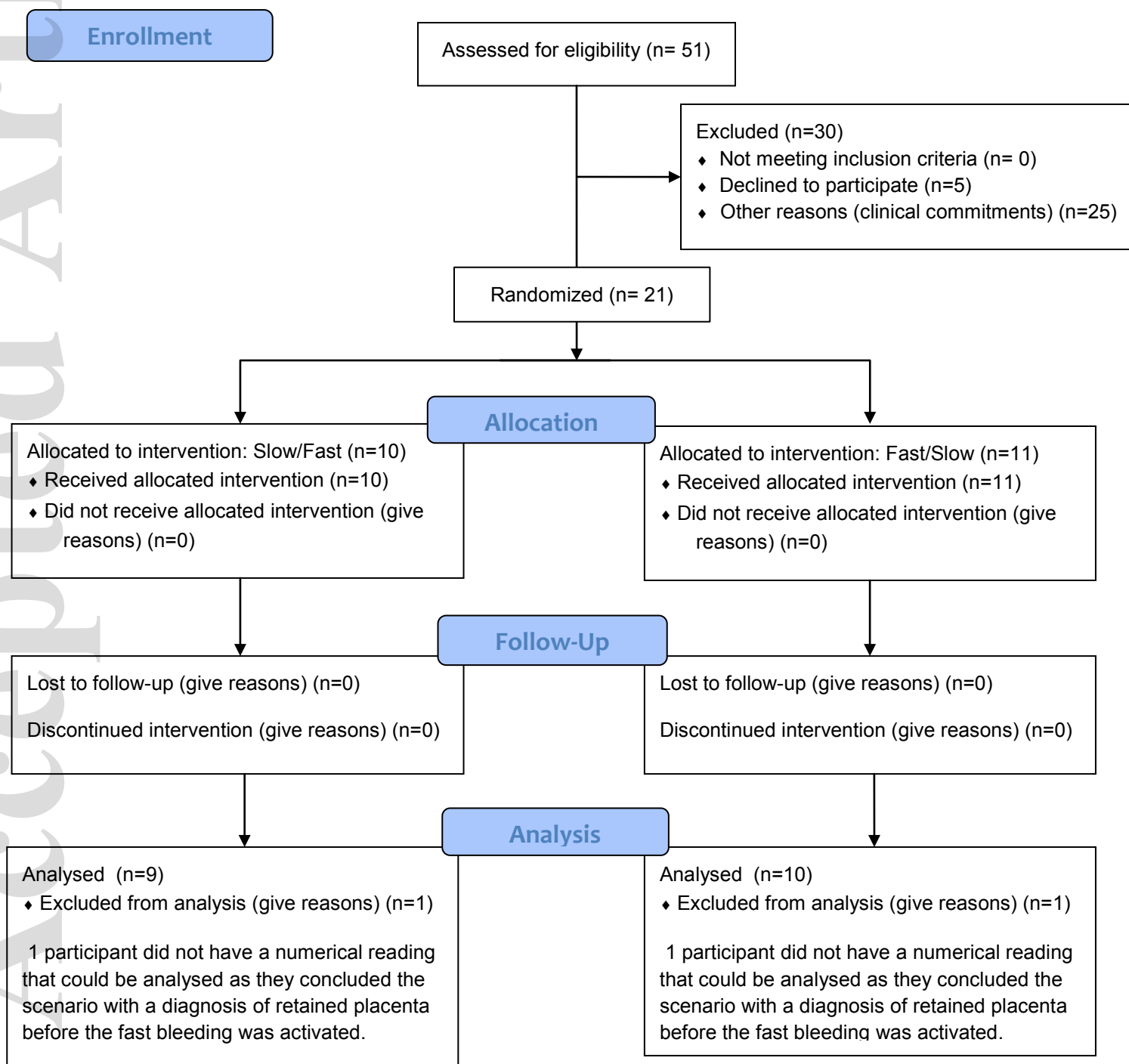
Supporting Information Table S3: Descriptive statistics for duration of bleeding (minutes) for professional group by randomised group in each blood loss scenario

Supporting Information Table S4: Crossover analysis for actual blood loss (ml)

Supporting Information Table S5: Crossover analysis for duration of bleeding (minutes)

Supporting Information Table S6: GRIPP2-SF

Flow Diagram of Phase 2 simulation studies participants



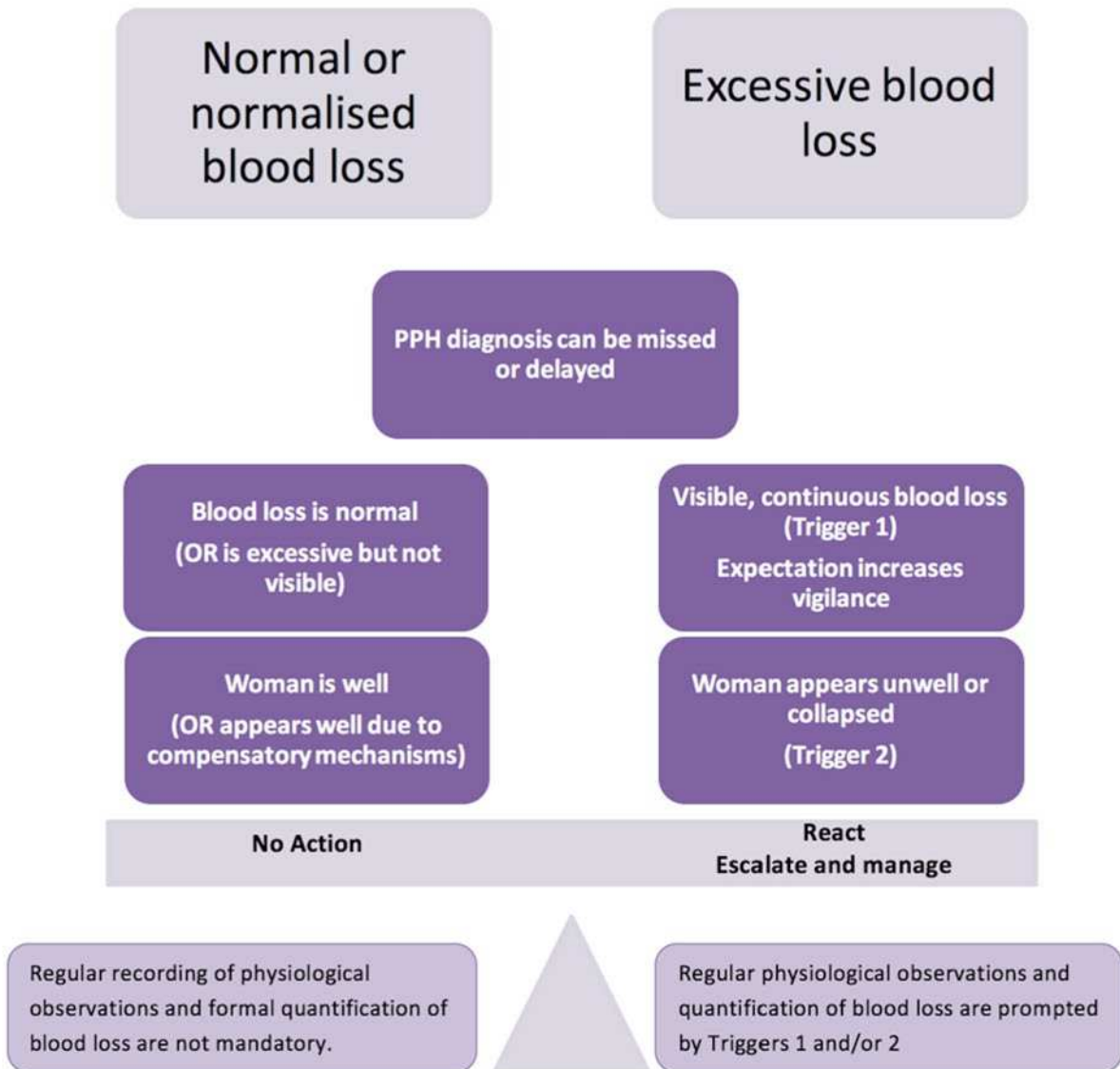


Figure 2: A new theoretical model of PPH diagnosis, based on the findings of the REACT study