

**Women's experience of the consent process in a  
randomised controlled trial of emergency treatment  
for postpartum haemorrhage.**

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## **Thesis summary**

This thesis has been written in the format of three papers: a systematic review, empirical study and a critical reflection. Paper 1 presents a systematic review and thematic synthesis which explores patients lived experience of consenting to research during a life-threatening emergency. Four studies met the inclusion criteria. Themes highlighted the importance of communication, the patient-professional relationship and decision-making paradigms in increasing patient's confidence in emergency medicine research and their role in the consent process. Further implications for clinical and research practice are discussed.

Paper 2 presents a qualitative study that aimed to explore women's experiences and views on the acceptability of consenting to a randomised controlled trial for the treatment of postpartum haemorrhage. 14 women and their partners were interviewed. Framework analysis was used to interpret the data and four central themes emerged highlighting the influence of individual and systemic factors on women's comfort with the overall consent process. Women's views of the acceptability of consenting to research during a postpartum haemorrhage are contingent on both individual and systemic factors. An understanding of these factors can inform future research protocols but also clinical practice. Improvements to future obstetric consent strategies are discussed.

Paper 3 presents a critical reflection on the process of conducting the thesis and therefore it is not intended for publication. The implications of the research for clinical practice and the relevance to and role of clinical psychology in research, emergency medicine and obstetric care are discussed. Reflections on personal and professional development are also discussed.

## **Acknowledgments**

Firstly, I would like to thank my supervisors for their knowledge and guidance. Dr Sue Channon, thank you for providing the opportunity to take on this project and for your invaluable support, time and commitment in helping me through this process. Dr Lucy-Brookes-Howell, thank you for your guidance during the data collection and support in using framework analysis.

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## **Paper 1: Systematic review**

### **How do patients with a life-threatening medical condition experience and view consenting to take part in emergency research trials? A literature review and thematic synthesis.**

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Paper 1 has been prepared for submission to the International European Journal of Emergency Medicine (see Appendix 1 for submission guidelines). For ease of reading, figures have been included in the text rather than in appendices as per journal guidelines.

Word count = 6,600  
(excluding tables, figures and references)

## **Abstract**

**Objective** - To synthesise patients' experiences and views on consenting to research in emergency medicine settings.

**Method** - A literature review was conducted. EMBASE, CINAHL, MEDLINE and PsychINFO databases were systematically searched, in addition to hand searching of reference lists, to identify relevant papers. Papers were included if they were published in a peer reviewed journal, written in the English language and investigated patients experiences of consenting to an emergency research trial using a qualitative or mixed method design. Following the identification of relevant studies a thematic synthesis was conducted to explore key themes within and across studies to answer the review question.

**Results** – Four papers matched the eligibility criteria. Patient populations included cardiac, stroke and obstetrics. Five analytical themes were generated from the literature; saving lives, risks and delays, professional-patient communication, capacity to decide and confusion about decision-making paradigms. Clinical and research implications of the themes are explored.

**Conclusion** – The five themes highlight the importance of communication and the patient-professional relationship and clarification of decision-making paradigms in increasing patient's confidence in emergency medicine research and understanding their role in research consent processes. Consent in research needs to be conceptualised not only as a legal event but also an ethical patient-centred process that requires shared information and discussion. The findings can be used to guide improvements in patients experience and understanding of consent protocols and policies in emergency research and, more broadly, across research and clinical practice.

**Keywords:** *informed consent, emergency medicine research, patient views, clinical research, research participation*

## **Background**

Biomedical research is necessary to develop evidence-based treatments in emergency medical settings (1-3), however it poses significant legal and ethical challenges (4,5) and continues to be a topic of debate (6). Legal and ethical frameworks (7-9) are in place to ensure that the four pillars of medical ethics; autonomy, beneficence, non-maleficence and justice, are upheld to protect patient's rights both within standard clinical practice and research (4). 'Informed' consent is embedded within the moral pillar of self-determination and is central to research and clinical ethics. The process of gaining informed consent for a proposed intervention should be an open and ongoing dialogue between the patient and the professional (10) where the patient is supported to understand disclosed information on risks, benefits and requirements and is able to retain and use this information to make and communicate a reasoned and voluntary decision (4). Informed consent is not just signing a form (11,12). The value-base and process of informed consent overlaps with the concept of shared-decision making in clinical practice (11).

In both clinical practice and research, professionals are obligated to not only ask for patients' consent but evidence how they conducted this process. Delany's 'iceberg' framework of consent highlights systems that influence the process of gaining informed consent and the difficulties integrating these in clinical practice (13). The framework describes the tip of the iceberg as the actions taken by the professional to obtain consent (e.g. what information is given? how is it communicated? completion of documentation). The second and third sections, which are still visible, are professional guidelines to support practitioners and legislation which governs the overall process. The fourth section of the iceberg, lying below the surface and often not explicitly considered during the process, comprises the ethical theories underpinning the concept of autonomy. Legally, professionals are obligated to disclose information regarding possible risks and benefits, but there is no legal requirement for them to have an in-depth understanding of the ethics and values-base underpinning the concept of informed consent (14).

This review explores the process of consent in emergency research trials from the perspective of patients with a life-threatening condition. Whilst patients are often treated in emergency medical settings for non-life threatening conditions, gaining informed consent for clinical procedures and research is inherently different in this situation to those of medical emergency. In the later there is a need for rapid assessment of patient symptoms (15) and treatment decision-making, rendering these situations time-pressured, fraught, with patients often temporarily lacking capacity due to loss of consciousness, physical pain, psychological distress

or cognitive confusion (16). In addition, when patient's lives are under threat the significance of clinical decisions is heightened. Acknowledging these substantive differences, this review focuses on situations of medical emergency and uses the terms emergency medicine/medical emergencies to refer to the treatment of life-threatening conditions.

The processes of gaining consent in emergency medicine hold ethical and practical challenges (16). Legislation safeguards patients' right to autonomy but in doing so can be a barrier to the evolution of future medical interventions (17). Without the progression of emergency medical interventions professionals risk contravening the principles of beneficence and non-maleficence through no fault of their own (1,15). In the last decade, quantitative and qualitative research exploring patients' attitudes to consent to research in medical emergencies has increased in response to this need for progress. Several studies have reported patient views and experiences of aspects of emergency medical research, including views on the necessity of emergency research (18-21); perceived understanding of trial and research terminology; perceived capacity to give informed consent and internal and external barriers and motivators for agreeing to research in this context (22-27). In addition, researchers have investigated the acceptability of different consent paradigms such as surrogate consent, deferred consent or exception from informed consent for patients (28-30).

Despite the increase in primary research on this topic, only two reviews have been conducted (16,31) and only the latter used a systematic search strategy. The most recent systematic review highlighted patient's motivations and reservations about emergency research. However, the review included studies which assessed the attitudes of patients who were treated for non-life threatening conditions in emergency settings; used emergency department convenience samples and used hypothetical trial scenarios. As such the review did not explore in detail the experiences and views of patients who had lived experience of being admitted to hospital with a life-threatening condition and enrolled in an emergency research trial.

The aim of this review is to synthesise study findings on patients' lived experiences of participating in emergency research trials, to advance current practice in emergency research and clinical settings.

## **Method**

### **Search Strategy**

The development of the search strategy and database selection were informed by prior scoping searches. Subject headings and text words relating to ‘consent for research in emergency medical conditions’ were applied using Boolean operators. Search terms were deliberately broad to enable a high sensitivity search to review all potentially relevant papers. Qualitative methodology was not used as a search term due to reportedly poor indexing of qualitative studies and titles that lack the keywords describing the article (32). EMBASE (1947-), CINAHL (1984-), MEDLINE (1946-) and PsychINFO (1806-) databases were searched on 31st December 2016, in addition to hand searching of reference lists, to identify relevant papers. Examples of the search strategies used in each database are provided in Appendix 2.

### **Study Selection**

Duplicate citations were removed and titles and abstracts of the retrieved papers were screened for relevance. Abstracts that did not provide enough information regarding the eligibility criteria were kept for full-text review. The full texts of potentially relevant papers were read and evaluated by the author and a peer healthcare professional against the criteria checklist. Discrepancies between reviewer’s ratings were discussed and resolved.

### **Inclusion/exclusion criteria**

Papers were included if they were reported in the English Language; a peer-reviewed journal; used a qualitative or mixed methodology; used an adult population; and reported patients experience/views/attitudes of emergency research consent processes during treatment for a life-threatening condition. Papers were excluded if they were review articles; used populations from non-emergency settings or patients who attended emergency departments for non-life threatening conditions; used solely quantitative outcomes; or used paediatric populations. The U.S. Department of Health and Human Services Food and Drug Administration Office (FDA) criteria of a life-threatening condition “a disease or condition where the likelihood of death is high unless the course of the disease or condition is interrupted” (33) was used to distinguish between life-threatening and non-life threatening conditions. A paper selection criteria checklist was developed using the PICOS (Population, Intervention, Comparators, Outcomes, Study designs) template as guidance (refer to Appendix 3).

## **Search results**

Initial searches identified 777 studies. Following de-duplication across databases, 662 studies were screened for relevance using the titles and abstracts. 10 additional papers were found through hand searching. 27 full texts were read and assessed against the review criteria and four studies were judged as eligible for inclusion in the synthesis. Figure 1 shows a PRISMA (preferred reporting items for systematic reviews) diagram detailing the results and paper selection process for the systematic search (34).

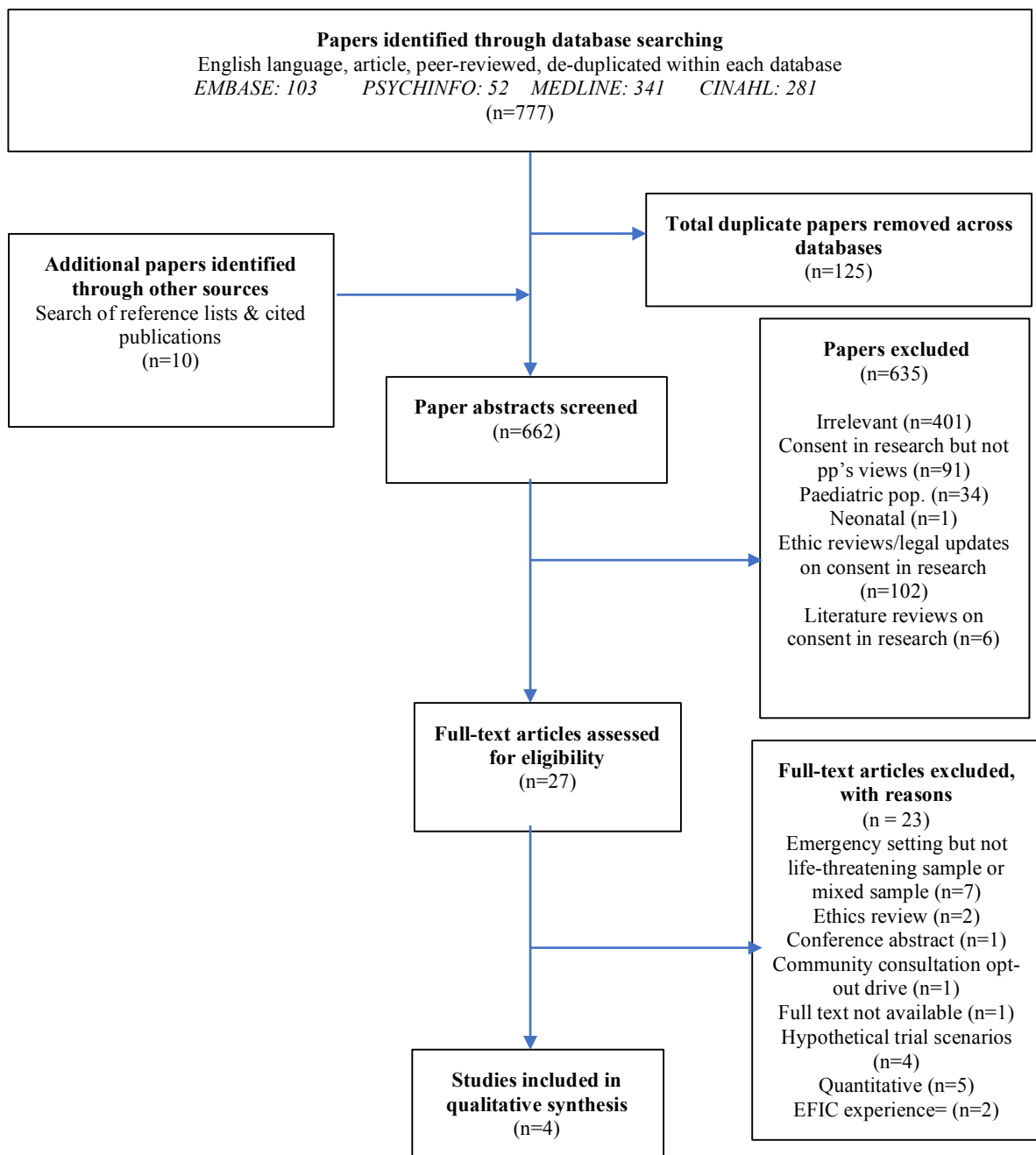
## **Quality Assessment**

Included studies were quality assessed by the author. Qualitative studies were assessed using the CASP (Critical Appraisal Skills Programme checklist; (35)). The CASP was designed by a multidisciplinary working group to help develop an evidence-based approach in health and social care (36). Mixed method studies were critically assessed using the MMAT (Mixed Method Assessment Tool; (37)), specifically developed to provide quality appraisal criteria for studies included in systematic mixed studies reviews (38). Although in development, evaluations have shown that the MMAT meets the agreed standard for content validity (39) and reliability (40, 41). The MMAT is one of a limited selection of tools for assessing the methodological quality of mixed method studies. Two reviewers conducted quality assessment of the full text papers: the first author and a peer health professional. Relevant data from each paper was extracted to support and evidence quality rating decisions. Although the CASP does not have a scoring system, the first author translated the CASP answers into numbers (e.g. 'Yes' =1, 'Can't tell' and 'No' = 0) to gain a score that could be converted to a percentage to aid interpretation across the two tools. Quality ranges were not stipulated by either tool; therefore, the first author considered 80-100% = high quality, 50-80% = moderate and <49% = as low quality.

## **Data synthesis and analysis method**

After reviewing several approaches including meta-synthesis (42); narrative synthesis; and framework synthesis (43), both researchers agreed that thematic synthesis, as described by Thomas and Harden (44) was the best fit for the research objectives. Thomas and Harden developed the approach for use in health promotion and public health; to explore stakeholder's views on the appropriateness and acceptability of specific health interventions to inform practice and policy.

Figure 1: PRISMA detailing systematic review process



This corresponded with the objectives of the systematic review question which were two-fold: to identify individuals lived experience and views on consenting to research in a life-threatening emergency setting and to use this information to consider improvements to the way in which research consent pathways are implemented in emergency clinical practice. Thematic synthesis has been widely utilised in other systematic reviews synthesising primary qualitative studies in medical settings (45-47). Critics state that reviewers should be cautious that they do not violate the integrity of the qualitative primary studies (48). A further rationale for using

thematic synthesis was it is considered “epistemologically-neutral” (49) and as such it can be applied to aggregative, configurative and mixed approaches to synthesis (50). In addition, the stages of thematic synthesis have been reported in published papers as well as process examples, thereby providing transparency (44).

Data synthesis was conducted by CP using the method described by Thomas & Harden (44). The qualitative findings section of each paper, including quotations and authors’ interpretive narratives were extracted and transferred verbatim into a Word document. The views of carers or staff were excluded from the analysis. The synthesis consisted of 3 stages; 1) free line-by-line coding; 2) the development of descriptive themes and 3) the generation of analytical themes. Multiple readings of the extracted data were conducted to achieve immersion. The author developed initial codes inductively to ensure true representation of the data; as such they evolved through the process. The final codes were then grouped according to comparable or contrary concepts and descriptive themes were developed to provide context. Finally, descriptive themes, which represented the original findings of the primary studies, were translated into analytical themes to address the review question. The process was iterative and involved the author’s interpretation and inference of the relative meaning of descriptive themes in relation to the review question. The evolution of the thematic findings was regularly discussed with the second author during supervision.

## **Results**

### **Study characteristics**

A summary of the characteristics of the studies is outlined in Table 1. Four studies with a total of 85 patients were included (24, 51-53). Publication dates ranged from 2003-2016. Two of the four studies were conducted in the last two years. The remaining two studies were dated and were included in Limkakeng et al.’s 2014 systematic review (30). However, Limkakeng et al. conducted a meta-summary rather than an in-depth qualitative synthesis.



Table 1: Characteristics of included studies

Reference	Country	N (patients only)	Gender	Age <sup>1</sup>	Medical pop.	Design	Data Analysis	Quality score
Dickert et al. (2015) (24)	USA	20	F (5) M (15)	$\bar{x}$ 56.5	Acute Myocardial Infarction	Mixed Methods	Descriptive statistics & inductive coding	50% MM (quali: 75% & quant: 50%)
Gammelgaard et al. (2004) (51)	Denmark	32	M (26) F (6)	43-78	Acute Myocardial Infarction	Qualitative Method	Grounded Theory	70% CASP
Lawton et al. (2016) (52)	UK	22	F	$\bar{x}$ 30.7	Retained placenta (peripartum)	Qualitative Method	Constant comparison	90% CASP
Mangset et al. (2003) (53)	Norway	11	M (8) F (3)	$\bar{x}$ 69.9	Stroke	Qualitative Method	Phenomenological method	70% CASP

### Critical appraisal

Critical appraisal scores ranged from 50-90% (see Table 1 above), showing moderate to high quality across studies (see Appendix 4 for detailed notes). There were minor discrepancies between the two reviewer's scores but overall quality ratings categories were the same. Dickert et al.'s study was given a total score of 50% because the overall quality score of a mixed method study cannot exceed the quality of its weakest component, which was the quantitative part of the study. It is important to note that the qualitative part of the study scored 75%.

### Inclusion of studies

No papers were excluded from the analysis and synthesis due to quality rating, instead the quality assessment process was used to inform the interpretation of the findings and highlight contribution of studies to the overall review findings. The aim of the review was to consider a range of patient experiences across emergency medical settings and therefore each qualitative study was deemed to hold information that could be meaningful for the review question.

### ***Ethical considerations***

Ethical approval was reported in three of the studies (24, 52-53). In Gammelgaard's published paper (51), ethical approval was reported for the randomised controlled trial 'DANAMI-2' but not for the qualitative sub-study. It is interesting, given the focus of the studies that only one study reported gaining informed consent for the qualitative study. The issue of confidentiality was not discussed in any paper (52).

### ***Research aims, methodology and design***

All four studies provided a clear statement of aims with justification of the relevance to research and clinical practice. Three studies used a single method qualitative design (51-53) and the remaining study (25) used a mixed method design (closed-ended questions and open-ended questions). Only three studies gave a rationale for their chosen design (51-53). The aim of the review was to synthesise qualitative data, therefore only the qualitative section of Dickert et al.'s study was analysed (25).

### ***Populations and trial details***

Populations within the four studies were as follows: myocardial infarction (24, 51); stroke (53) and peripartum (52). Lawton et al.'s participants were involved in the Got-it trial, a UK-wide randomised controlled trial (RCT) for women with a retained placenta. The trial investigated whether use of glyceryl trinitrate (GTN) spray as compared to placebo, facilitated delivery of the placenta without having to attend theatre for manual or surgical intervention. Mangset et al. (53) interviewed patients who were eligible for the Third International Stroke Trial (IST-3), a randomised controlled trial (RCT) of thrombolytic drug treatment within the first 6 hrs after a stroke. Both the remaining studies focused on medical treatment for myocardial infarction (24, 51). Dickert et al. participants were part of a trial of coronary ischemic post-conditioning in patients with ST-elevation myocardial Infarction (STEMI). The population in Gammelgaard et al.'s (51) study were candidates for the second DANish Acute Myocardial Infarction study (DANAMI-2) which compared primary angioplasty with fibrinolysis (usual practice) in the management of acute myocardial infarction.

### ***Sampling and data collection***

All but one study gave detailed information about the recruitment of participants (51-53). Two studies only recruited individuals who had consented to take part in the trials (24, 52). Sampling methods were reported in all studies. Two studies reported using purposive sampling (24, 52),

although Gammelgaard et al. referred to this as ‘strategic’ sampling. The remaining two studies used convenience sampling (24, 53). Dickert et al. (24) reported that all individuals who had participated in the parent AMI trial were eligible for the qualitative study; excluding those who were non-English speaking, were not the individual who had been asked for consent initially and were unable to answer interview questions. Similarly, Mangset et al. (53) recruited individuals who had been asked to participate in the IST-3 and the only other exclusion parameters were patients with severe aphasia, severely reduced consciousness and dementia.

Only one study referred to a form of saturation (52). Lawton et al. (52) stated that data collection ceased following data saturation which they reported as ‘no new findings or themes identified in new data collection’. Having used a phenomenological method, Mangset et al. (53) would not be expected to report data saturation as the philosophy of the method is to capture rich personal accounts from the sample and explore commonalities, rather than saturation of themes. It would be expected that Gammelgaard et al. (51) report on theoretical saturation given grounded theory as the choice of method and as such this reduces the credibility of the findings. Dickert et al. (24) did not highlight how data collection was ceased. Due to this and use of convenience sampling there a risk of sampling bias. Sample size ranged from 11 to 32, all of which are adequate numbers for the methodologies. As such, most studies had small patient samples, although this is expected in qualitative studies. Both Dickert et al. (24) and Gammelgaard et al.’s (51) studies were biased towards male participants likely due to the naturally higher prevalence of this medical condition in men. Each of the four studies used interviews as the method of collecting data. Lawton et al. (52) was the only study that also interviewed staff involved in the clinical trial.

### ***Data analysis***

Reports of the data analysis process were varied. Both Mangset et al. (53) and Lawton et al. (52) described this in detail; referencing the use of in-depth coding and multiple analysts to aid triangulation and provide credibility checks. Gammelgaard (51) reported adhering to grounded theory protocol but no examples were given and it was unclear who conducted the data analysis. The use of participants quotes to illustrate findings were diverse across the studies. Given Dickert et al. (24) conducted a mixed method study, it was expected that there would be fewer quotes reported in comparison to the three single qualitative studies.

### ***Data findings***

All papers were considered to contribute relevant information to the literature base on patients lived experienced and views on providing informed consent during a medical emergency, and to each specialist emergency medical domain (24, 51-53). However, some studies presented more in-depth findings than others (52-53). Dickert et al. (24) provided a highly descriptive rather than interpretative account of patients' views in line with the mixed method study design utilised. Gammelgaard et al. (51) despite stating adherence to grounded theory principles, they did not report findings in relation to a developing theory which brings in to question the credibility of the data analysis and subsequent findings.

### ***Capacity to consent***

All studies discussed issues around patients' capacity to consent to emergency research. Some studies emphasised patients perceived level of capacity by using direct verbatim quotes. In others, authors inferred patients' level of capacity. In Mangset et al.'s study (53), authors deduced that patients did not appear to have capacity to make an informed decision to enrol in research given that they had no understanding of the trial nor did they understand the conditions of research (e.g. randomisation). Gammelgaard et al. (51) highlighted because of post-consent interviews it was impossible to test whether patients fulfilled competence criteria during the emergency. However, authors explored patients perceived level of competency given their physical, emotional and cognitive state at the time of the emergency. Authors inferred that patients perceived level of competence was attributed to their physical and emotional wellbeing at the time of the emergency (51). However, even patients who were alert and pain-free misinterpreted research terminology and pathways. Patients in 'Dickert et al.'s study (24) reported limited understanding of the trial and research processes, believing that they could choose between treatment arms. Patients described being in pain, under stress and feeling time-pressured. Authors concluded that patients did not appear to have had capacity to make an 'informed' decision at the time of the emergency (24). Women in Lawton et al.'s study (52) described making 'snap decisions' without knowing or understanding the full facts of the research. Lawton et al. (52) suggested that women appeared unable to make an 'informed' decision due to lacking capacity because of pain and exhaustion.

### ***Researcher bias***

Two studies reported limited details about potential researcher bias (51-52) and accounted for the role of authors in the research process. The remaining two studies (24, 53) did not report any statement on the influence of the researcher – participant relationship. In addition, authors did not

discuss reflexivity; the influence of researcher preconceptions and values. This again brings in to question the reliability of the findings in these studies.

### **Thematic synthesis**

The thematic synthesis of the studies generated 40 initial codes; 14 descriptive themes; and five analytical themes, see Table 2 for the link between the data analysis and the development of the themes. The analytical themes are summarised below using primary and secondary evidence. The contribution of each study to the themes and sub-themes is detailed in Table 3.

#### **Saving Lives**

The first analytical theme centred on the motivators for patients' enrolment in emergency research: underpinned by the descriptive sub-themes of **trust in medical profession and system**, **advance medical treatments** and **increase own chances of survival**. Individuals believed that the trial provided a chance to save their life and potentially future lives. They reported a strong belief in the competency of medical professionals and trusted the hospital system to manage critical situations safely: *"I assume that there are well-trained, professional people who are in charge, so I feel safe"* (53). Some individuals reasoned that if doctors thought it was a risk worth taking to test new interventions then they were happy to take part: *"...then I might as well participate because after all they needed somebody to take part in this trial to find out about it"* (51). These individuals recognised the need for participation in research to advance treatment and were encouraging of this societal role, believing it was their "duty" (53). Others reported the more serious their condition was the more likely they were to enrol in research as a chance to save their life: *"...for me the most important thing was that I was given treatment and nothing else, what else they did, makes no difference"* (53) and *"I'd have done anything to sort of avoid having to go to theatre"* (52).

#### **Risks and delays**

In contrast to the more societal-focused motivators of participation, the reasons for declining emergency trial enrolment were self-focused. The three sub-themes were: **urgency - wanting immediate treatment**, **"I don't want to risk my life for an experiment"** and **treatment "lottery"**. Individuals reported that receiving immediate treatment was the most important thing to them: *"I was in a panic and for me the most important thing was that I was given some treatment"* (53).

Analytical themes	Descriptive Themes	Initial free codes
<b>Saving Lives</b>	Trust in medical profession	If doctors think it is ok Explanation for trial Time taken to explain information (1) <sup>1</sup>
	To advance medical treatments	People need to take part to find out new things Benefitted from past research To save future lives
	Increase own chances of survival	Adequacy of existing treatment Severity of condition: last option Grateful to have options
<b>Risk &amp; Delays</b>	Urgency - wanting immediate treatment	Trial would require waiting Priority = immediate treatment
	“I don’t want to risk my life for an experiment”	Fear of research being prioritised over patient well-being Fear of dying Risks considered to outweigh benefits Severity of condition: reluctance to take risks Media coverage of trials
	Treatment “lottery”	Blinding = the right to know! Treatment ‘lottery’ is unfair Science needs randomisation but discomfort of being part of it Life is precious
<b>Professional-patient communication</b>	Interaction during consent-gaining	Not the right time to ask Influence of past negative experiences of healthcare Time taken to explain information (2)
<b>Capacity to decide</b>	What risks?	Not able to process risks Told there were ‘no’ risks
	Information processing reduced	Emotionally overwhelmed Lack of time to decide Unable to read or retain the information Lack of understanding of research terms
	I’ll try anything!	Anything to get rid of the physical pain Prevent more invasive procedures
	Can I say no?	The right to say no! Not a good time to object
	Making a snap decision	Life and death situation Unsure of own capacity - on reflection Anxiety after making the decision
<b>Decision-making paradigms</b>	RCT - So I choose between the emergency treatments?	Belief the patient decides between treatments Belief that experimental treatment must be better
	The Doctor should decide – they know best!	Experts should make decisions Belief that professionals ‘chose’ treatment based on clinical need

Research trial involvement often involved, or was perceived to involve, waiting which was deemed unacceptable and provoked emotions such as anger, disbelief and fear. Randomising to treatment arms and transferring to another ward or even hospital were reported as obstacles to rapid treatment (51). Following on from this theme, many individuals did not want to take what

<sup>1</sup> One initial code was considered relevant to two descriptive themes it was categorised under both themes. Number 1 or 2 representing duplication.

they perceived to be a risk to their life for the sake of research due to anxieties about dying, research goals being prioritised over patient wellbeing and deliberation of risk-benefit ratios: *“Anything that can benefit myself or anybody else, I don't have a problem with it as long as there is no detriment to me”* (24). Most individuals recognised the need for research in medical emergencies to develop new treatments but reported ambivalence about their own role in this process due to treatment “lottery” (51). Several individuals believed they had the right to know what treatment they would be receiving and felt a placebo option was unnecessary (53).

### **Professional-patient communication**

Some individuals did not feel that professionals recognised the difficulty in deciding to partake in research during a medical emergency: *“She [the physician] said ‘I know’, and I said ‘you can’t be serious; I said I can’t possible decide...And she said ‘But I have to ask you, I know it’s not fair but I have to ask...’”* (51). Others felt supported by professionals, believing they recognised the difficult decision they were asking patients to consider and had done their best: *“I think they genuinely probably told me everything about the trial, but my head was elsewhere”* (52). A minority of individuals commented on how a doctor’s request to read trial information, may in itself feel like pressure to enrol: *“I think it should be both (physician and patient), but I don't think it should be a pressured decision. The patient shouldn't feel pressured. Nine times out of ten when a person of authority speaks, that's pressure within itself”* (24).

### **Capacity to decide**

The fourth analytical theme identified that patients appeared to have reduced capacity to make an ‘informed’ decision regarding partaking in emergency research. Five descriptive sub-themes supported this analytic theme: **what risks; reduced ability to process any information; I’ll try anything; can I say no; making a snap decision**. Many individuals reported not reading or processing information on possible risks: *“I don’t think I read anything about any risks”* (51). Some individuals reported being told by professionals that in fact there were “no” risks involved and this impacted on their decision (51). Some individual’s felt confused and unable to make an informed decision due to lack of time to read and process the information fully as a result of their medical condition: *“at that point I was cross-eyed and it was just about all I could take in”* (52).

Table 3: Studies contribution to the themes

<b>Analytical Themes</b> <i>Descriptive Themes (sub-themes)</i>	Dickert et al.	Gammelgaard et al.	Lawton et al.	Mangset et al.
<b>Saving Lives</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
<i>Trust in medical profession</i>		√	√	√
<i>To advance medical treatments</i>		√	√	√
<i>Increase own chances of survival</i>	√	√	√	√
<b>Risks and Delays</b>	<b>Yes</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>
<i>Urgency – wanting immediate treatment</i>		√		√
<i>“I don’t want to risk my life for an experiment”</i>	√	√		√
<i>Treatment “Lottery”</i>		√		√
<b>Professional-patient communication</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>
<i>Interaction during consent-gaining</i>		√		√
<b>Capacity to decide</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
<i>What risks?</i>	√	√	√	√
<i>Information processing reduced</i>	√	√	√	√
<i>I’ll try anything!</i>	√	√	√	
<i>Can I say no?</i>	√	√		√
<i>Making a snap decision</i>	√	√	√	√
<b>Decision-making paradigms</b>	<b>Yes</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>
<i>RCT – so I choose between the emergency treatments?</i>	√	√		√
<i>Doctors should decide – they know best!</i>	√	√		√

A medical emergency can be an extremely stressful and distressing time and some individuals appeared to find being asked to decide exacerbated their sense of distress: “*It was introduced at a stage in a condition that was for me critical...I was in a panic...*” (53). Further to this, a minority felt that a life and death situation was not the time to ask someone to consent to a research trial: “*I couldn’t make any decisions whatsoever because my head was spinning; I was having a heart attack!*” (51). Several individuals found that they were physically and emotionally unable to attend and comprehend information: “*I don’t remember because everything was going so fast and I was, like, freaking out myself*” (24). Many individuals re-counted that at the point of being asked to take



part in emergency research they were willing to try anything to gain immediate treatment, relieve the pain, prevent longer treatment or reduce emotions such as fear and panic: *“the only thing I can tell you is, when that pain hit, you don't want to talk about nothing; you don't want to hear about scientific this or that. All you want to do is get this resolved right away”* (24). A few individuals reported believing that research trials were normal and that to object would be considered irrational and they would be looked upon unfavourably: *“I don't think it's normal to react negatively, in other words not a good time to object, either”* (53). Many individuals reported making an impulsive decision without considering the risks and benefits of the trial: *I just said yes straightaway, I didn't want to mess around, I just wanted to hold my baby... ”* (52).

### **Confusion about treatment decision-making paradigms**

A further analytical theme was confusion about treatment decision-making paradigms (e.g. emergency research randomised controlled trial (RCT) vs. usual emergency care), underpinned by two descriptive sub-themes: **RCT - so I choose between the emergency treatments?** and **Doctors should decide – they know best**. Several patients were confused about the trial design and what was required of them, believing that they had to choose between treatments arms (51). Other individuals believed that they should not be asked to make the decision, but rather medical professionals as they were the experts could establish clinical need (24, 53). Furthermore, some individuals felt that it was ridiculous to be asked to decide about research when they had no foundation medical knowledge to base their decision on: *“They are supposed to know aren't they? I don't know anything about what treatment I needed”* (51). Individuals appeared confused between the relationship between the doctor and patient in emergency research trials, as opposed to standard emergency care believing that treatment was individualised: *“...they would see which is the right treatment...I think it is a decision of the doctor who is doing the treatment.”* (24).

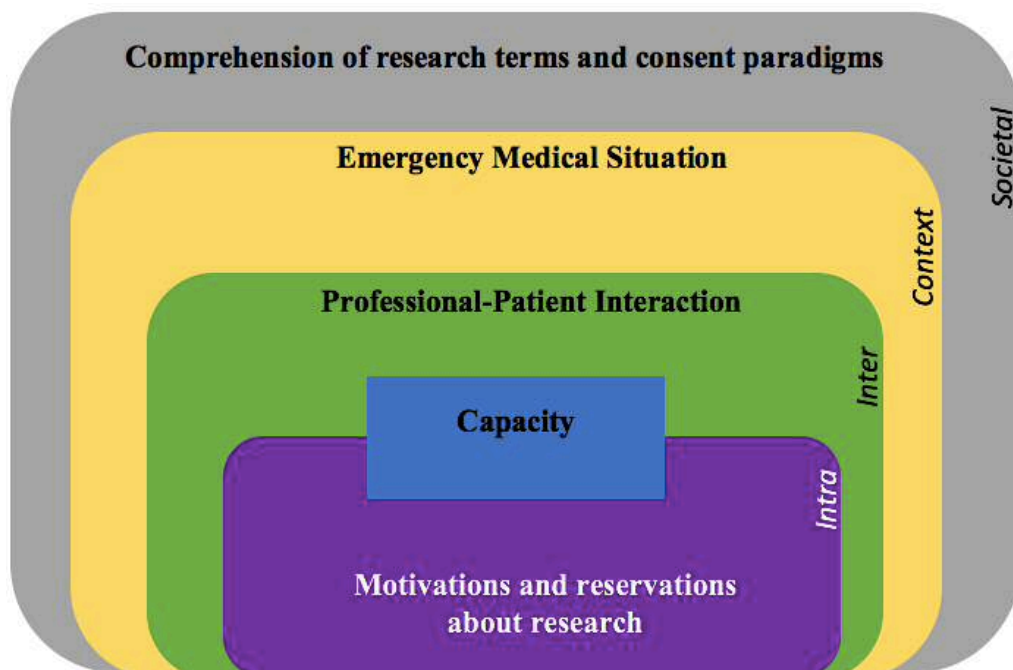
## **Discussion**

### **Summary of findings**

Five analytical themes were generated from the synthesis, underpinned by 14 descriptive themes and 40 initial codes. The findings are tentative given the small number of papers in the synthesis. Patients recognised the necessity of emergency research but several were ambivalent about their own role in this process. This appeared to be related to a lack of understanding of trial requirements, consent paradigms and ethical concerns centred on risk of harm. Patients who demonstrated understanding of the above concepts gave balance to risk and possible benefits. However, several patients considered it impossible to make ‘informed’ decisions regarding

research during an emergency due to the impact of physical pain, psychological distress and the time-pressured nature of the environment. Most patients considered professionals to be doing their best in broaching the topic during an emergency, but some felt that the process itself put them in an impossible dilemma. A diagram was created to highlight the connection between the five analytical themes (see Figure 2). It highlights the influence of contextual factors on patients' decision-making regarding research during a medical emergency.

Figure 2: A schematic representation of the findings of the themes



Patients' decisions regarding reasons and reservations (intrapersonal) for enrolment in emergency research are influenced by interactions with professionals (interpersonal), the emergency environment (context) and comprehension of research designs, language and consent pathways (societal). Gaining informed consent in a medical setting is a relational process between patient and professional as it requires sharing information, an active discussion and a judgment of a patient's capacity to make a balanced decision. Of importance is the influence of professional's approach to the consent process and the patient's actual or felt sense of ability to make an informed decision during a medical emergency. Further to this, the emergency environment generates recruitment challenges regarding time, management style, sense of safety, condition severity and resources which may influence patient's decisions to enrol in research. The final theme and factor influencing enrolment in research is patient, family, medical professional and public

comprehension of research designs, language and consent pathways. Poor comprehension is likely to act as a barrier to successful recruitment in emergency research trials.

The synthesis highlights areas for improving patient understanding and decision-making in emergency medical research. Despite ongoing research over the last 20 years and multiple legal and clinical procedural changes, many patients continue to feel ambivalent about enrolling in research trials in emergency settings (19-20, 51, 53). The concerns identified in this synthesis continue to underpin patients' decisions to engage or decline entry into emergency research trials.

### ***The importance of the 'relational' component of gaining consent***

A factor in the acceptability of the informed consent process in emergency research for patients appears to be the relationship between the patient and the asking professional. Gaining informed consent in a medical setting is a relational process between patient and professional as it requires active discussion and a judgment of a patient's capacity to make a balanced decision. This is important as medical professionals appear to be focused on the procedural duties associated with gaining patient consent e.g. the visible tip of the iceberg model 'what professionals say and do' (13) as highlighted in the analytical theme of professional-patient communication. The label of 'informed' consent does not appear to support the application of consent-gaining as professionals appear to see it as a matter of delivering information rather than sharing and discussing information with the patient. As such consent-gaining appears to be viewed as an event rather than both a legal event and ethical patient-centred process. The 'delivery' of the information is likely to be the priority during medical emergencies when time is critical in preventing morbidity and mortality. Patients are likely to be in acute physical and psychological distress and therefore it is imperative that medical professionals are skilled in validating the patients emotional state in addition to sensitively 'sharing' and discussing trial information in the limited time frame. Although patients are required to make an independent decision in research, the values and process of discussing consent could be seen to be parallel to shared decision-making frameworks in clinical practice (10).

### ***Clinical vs. research – the role of the medical professional***

It is also necessary for professionals consider the influence and power they may inadvertently have on patients' decisions to partake in research (54) due to confusion between standard clinical practice and research (therapeutic misconception; (55)) and the differing role of medical professionals in these contexts. In clinical settings in western societies, medical professionals are considered 'experts' whom patients trust to make healthcare decisions. As highlighted by the

theme of ‘confusion between decision-making paradigms’ in this synthesis, patients often believe the role of the medical professional to be the same within a research context, particularly emergency research where there is high chance of morbidity and mortality. Yet the roles of professionals are different in accordance with the aims that govern each context. Standard clinical practice aims to promote the health of individual patients and patient-centred care (56). Clinical research on the other hand aims to generate useful knowledge for future patients and therefore the role of the professional is to prioritise the needs of the community over individuals. For recruitment purposes, it is important that patients are given clear and succinct verbal and written documentation that denotes the difference between clinical practice and research decision-making. Not only could this provide clarity on terminology but also promote patient decision-making, which in healthcare is often passive in nature (57). In addition, it is crucial that medical professionals can critically reflect on the influence of their position and beliefs and subsequent interaction with the patient during the informed consent process.

### ***Complexity of research terminology & consent documentation***

Informed consent documentation is often extensive and burdened with complex terminology to cover a vast array of eventualities, making it difficult for patients to understand (58). This is the case in non-emergency clinical settings but is heightened in emergency medical situations due to the additional factors of acute pain, psychological distress, cognitive confusion and levels of consciousness (59-60). Patients often do not fully read or understand the consent forms (46-48). For patients who have limited literacy skills, being asked to consider reading trial information during a stress-inducing emergency medical situation is likely to exacerbate comprehension difficulties. Although difficult to facilitate during medical emergencies, it is important for professionals to clarify patient understanding of trial processes for consent to be as informed as possible in this context.

### **Strengths and limitations of the review**

Strengths of the review include the application of a systematic and iterative search strategy to access a comprehensive data set; a second reviewer at the full-text screening stage; and application of thematic synthesis, a well-documented approach developed for analysing qualitative data (44). Published critical appraisal tools, reported in health systematic reviews were used to assess the quality of the included studies.

The main limitation of the review is the substantial shortage of primary qualitative literature on this topic and methodological limitations within studies. Only four studies were found to be relevant to the review question, highlighting a shortage of studies in this area. All studies had small samples although this is to be expected in qualitative research. Studies were conducted in western countries and predominantly with individuals' over the age of 45; this could be considered a natural bias of conditions such as stroke and cardiac arrest. Further to this, study populations were limited to a small number of specialities (e.g. stroke, cardiology, general emergency and obstetrics) and one study utilised a mixed method design and therefore provided limited data on contextual factors underpinning individual beliefs and behaviours in emergency research. The Confidence in the Evidence from Reviews of Qualitative Research (CERQual) tool (61) could have been used in an additional analysis to assess the levels of confidence to place in the findings.

### **Implications for future research**

There is limited up-to-date literature on patients' in-depth views and experiences of being part of an emergency trial for a broad range of life-threatening conditions. There is also a lack of literature on the in-depth views of patients who decline to partake in these emergency trials. As a result, continued research is needed in this area, not only to contextualise patient decisions regarding research enrolment but to provide a platform to discuss the evolving nature of emergency medicine research and influence legal, ethical and clinical protocols. This would improve the legitimacy and credibility of emergency research for patients and promote shared decision-making and inclusivity.

### **Conclusion**

Five analytical themes were highlighted in the thematic synthesis of qualitative studies exploring patients' views and experiences of consent processes in emergency research. These included motivators and inhibitors underpinning patient's decisions to accept or decline trial involvement; a lack of understanding of the distinctions between clinical practice and clinical research; differences in professional-patient communication and interaction and the ability of the patient to make an 'informed' decision. The themes identify areas of opportunity to promote patient understanding and comfort during consent processes in emergency research, several of which are also relevant for supporting the broader process of informed patient consent across clinical settings.

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## **Paper 2: Empirical study**

### **Using framework analysis to explore women's experience of the consent process in a randomised controlled trial of emergency treatment for postpartum haemorrhage.**

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Paper 2 has been prepared for submission to the BMC Pregnancy and Child Birth journal (see Appendix 5 for submission guidelines). For the purpose of the thesis the additional abbreviations section is excluded.

Word count: 9,500  
(excluding tables, figures and references)

## **Abstract**

**Objective:** To explore the experiences of patients and their partners who participated in a trial of treatment for postpartum haemorrhage and the acceptability of the research consent process to inform the implementation of acceptable consent pathways in emergency obstetric research.

**Method:** Semi-structured face-to-face interviews were conducted with fourteen women and two partners. Framework analysis was used to interpret the data.

**Results:** Four central themes emerged from women's birth, PPH, and subsequent OBS2 enrolment narratives; the birth before the bleed; losing blood; women's perceived ability to make an informed decision and preferences for future research consent pathways.

**Conclusion:** Women's views of the acceptability of consenting to research during a postpartum haemorrhage are contingent on both individual and systemic factors. An understanding of these factors can inform future research protocols but also clinical practice. Improvements to future obstetric consent strategies are discussed.

**Trial registration:** ISRCTN ref: ISRCTN46295339 (01.07.2013); EudraCT: 2012-005511-11 (28.11.2012), UKCRN ref: 13940.

**Keywords:** consent, emergency medicine research, postpartum haemorrhage, clinical research, research participation, childbirth, intrapartum trials

## **Background**

### ***Postpartum Haemorrhage (PPH)***

Postpartum haemorrhage (PPH) is the most common form of major obstetric haemorrhage (1) and a leading cause of maternal mortality in developing countries (2). In the UK, PPH accounts for 10% of all direct maternal deaths (3) and between 2004-2013 prevalence rates of PPH in England have increased from 7% to 13.8% (3, 4). PPH is defined as blood loss of  $\geq 500\text{ml}$  after vaginal delivery or  $\geq 1000\text{ml}$  after caesarean section (5). Blood loss over 1000ml is considered major and subdivided into two categories: moderate  $\geq 1000\text{-}2000\text{ml}$  and severe  $\geq 2000\text{+}$  (3). PPH is categorised as primary and secondary depending on onset of bleeding: primary =  $\geq 24\text{hrs}$  post birth and secondary =  $\geq 12$  weeks post birth (6). Origins of postpartum haemorrhage are uterine atony, trauma, retained placenta, and coagulopathy often referred to as the four T's: tone, trauma, tissue and thrombin (7,8). The management of PPH includes four mechanisms: communication, resuscitation, monitoring and investigation and measurements to control the bleeding (9). In the last decade, there has been an increase in the conduct of clinical trials investigating the effectiveness of different medical interventions for the treatment of PPH across the world (the WOMAN trial (10); FIB-PPH (11)).

### ***The experience and impact of having a PPH***

Although a normal and natural process, childbirth can lead to not only physical but psychological trauma (12,13). Birth trauma defined as belief of 'actual or threatened injury or death to the mother or her baby' (14) can result in psychological difficulties such as posttraumatic stress disorder (PTSD) and depression (15,16). Prevalence rates of PTSD following childbirth are between 1-3% in Western countries (16). Studies have found that birth-related risk factors associated with the development of PTSD are negative experiences pre-and during delivery, obstetric emergencies, operative birth, fear of losing the baby and a lack of perceived staff support during the birth (15,17). Individual factors identified as increasing the risk of women experiencing PTSD following birth include previous experiences of trauma (e.g. sexual abuse), mental health difficulties and lack of social support. For some women, experiencing a blood loss during birth may lead to psychological distress and the association between PPH and PTSD is currently being explored (18). Previous research conducted with women who experienced a PPH of 1500ml+ found no increased risk of experiencing postpartum depression or PTSD (19). Most qualitative PPH studies have focused on women who have experienced severe blood loss (2,000ml+) and required invasive treatment (20,21). These studies have highlighted that factors such as blood loss management, reduced communication from professionals, separation from family and fearing

death, increases psychological distress during and following a PPH. These themes have recurred in recent studies of women's experience of PPH with a mild-moderate (500-2000ml) blood loss suggesting these factors are associated with psychological impact rather than blood loss severity per se (22). Therefore, it is important to acknowledge that regardless of the presence or absence of risk factors, trauma is in the 'eye of the beholder' (23) and research exploring women's experience of birth complications can provide useful information to inform future clinical management of birth complications.

### ***Research in obstetric settings***

The nature of obstetric practice means that emergency situations are relatively frequent (24) and conducting intrapartum research in obstetric settings is invariably complex. Childbirth involves considerable physical and psychological exertion and pain (25) and can inhibit a woman's capacity to make informed decisions about standard clinical procedures and research (26). Further factors such as fear of labour, antenatal health complications and prior traumatic birth experiences can influence labour management and ability to give informed consent. In addition, analgesics used in labour have been shown to reduce cognitive functioning, specifically short term memory retrieval (27). Historically, pregnant women have been excluded from clinical trials due to being viewed as a 'vulnerable' population in research governance (28) but research during antenatal, intrapartum and postpartum care is essential for the development and implementation of evidence-based medical treatment. Distinguishing the difference between clinical treatment and research is an inherent problem in medical research, resulting in misplaced patient beliefs that doctors in research trials prioritise individual best interests and that treatment will always benefit the individual (29, 30). During intrapartum emergency trials, women may be more susceptible to this "therapeutic misconception" (29) due to the limited time to comprehend the nature of the research, preoccupation with fear of harm to baby or own death, confusion on details of emergency treatment and cultural belief about the doctor's role. Therapeutic misconception can therefore compromise the legitimacy and acceptability of intrapartum research.

### ***Research consent pathways***

Although ethically ideal, true informed consent can be difficult to obtain in many medical settings. Broad obstacles to informed consent include patient literacy, research and health literacy, cultural differences, communication and recruitment strategies and professional understanding and comfort with research trials (31). Informed consent is further compromised in medical emergencies due to factors such as time pressure, treatment window, reduced cognitive

functioning, pain levels and fear of death. The requirement to obtain consent prior to study procedures in trials of emergency care reduces recruitment and introduces delays in treatment that would not occur outside the confines of the trial (32). The need to provide evidence based care to patients in emergency situations is therefore compromised by an inability to deliver trials that test timely interventions. To mitigate this, alternative consent processes have been proposed for clinical trial research: proxy consent and exception from informed consent (33,34).

### ***Obstetric specific consent pathways***

Midwifery associations have highlighted the importance of research being conducted “with women, not on women” (35) and therefore, finding optimum obstetric research consent pathways remains a priority. Obstetric research has the additional consent pathway of antenatal information. Obstetric guidelines have advised that information given is in line with the suspected risk of occurrence e.g. it would be unethical to give all pregnant women detailed information on complications that occur in less than 1/100 women e.g. uterine inversion (36). Antenatal information given as part of a staged consent pathway and in line with level of suspected risk is supported by consumer groups and professional bodies (35,36).

Intrapartum studies have mainly opted for brief antenatal information so as not to cause undue distress and fear pre-labour, followed by full study information at time of trial eligibility (WOMAN Trial, (10); Release Trial, (37)). However, during an obstetric emergency it may not be ethical or practical to provide full research information due to capacity issues or limited treatment window. A recent development to obstetric research has been the oral consent pathway (36): provided women have been given antenatal information, brief oral consent can take place at the time of the complication and full written consent obtained at a later stage (34).

To date, no qualitative research has been conducted on exploring women’s experience and views of consenting to research during a postpartum haemorrhage. The closest relevant research conducted by Lawton et al. investigated womens’ experiences of being invited to partake in a peripartum trial for the treatment of a retained placenta (38). Health professionals were also interviewed to explore their experiences and views of the consent-gaining process. Findings highlighted that women and professionals had different views on whether ‘informed’ consent was gained, with women reporting the influence of antenatal and intrapartum events on their decision-making ability and staff focusing on disclosure of information about risks. The women in the study suggested the implementation of antenatal trial information to increase awareness, however

professionals were reluctant to include this pathway due to the belief that it would cause undue distress to women in pregnancy.

### **Rationale and aims**

Qualitative research can provide valuable insight into stakeholder's experience of health complications and medical research, which can help improve future clinical care and advance research procedures. PPH provides an apposite context for exploring consent as it is an anticipated obstetric emergency condition that requires treatment within a limited timeframe. Obstetric emergencies are distinctive in that professionals are responsible for the welfare of two individuals: the mother and baby. Further to this obstetric care is reliant on connected services e.g. antenatal clinics, delivery wards, post-natal community follow-up. Evidence based treatment and understanding of stakeholder's experiences is essential to enable the delivery of patient-centred care. Regarding specific PPH trials, most have sampled homogeneous groups due to the variation of causation and treatment, using categories such as method of delivery and level of blood loss as exclusion criteria. In addition, the OBS2 trial utilised an antenatal information pathway. The OBS2 trial aimed to contextualise women's experience of the consent process within an emergency obstetric setting e.g. PPH and evaluate the acceptability of this process to inform consent protocol in future PPH trials. Therefore, the aims of the OBS2 qualitative study were two-fold:

- (i) To explore the experiences, views and preferences of women who gave consent to participate in a trial of treatment for postpartum haemorrhage.
- (ii) To explore the acceptability of the consent process (e.g. antenatal information pathway and intrapartum consent) and how future clinical trials of PPH can be optimised.

### **Method**

#### **Ethical approval**

Full ethical approval for the OBS2 trial was obtained from the Research Ethics Committee for Scotland (Ref: 13/SS/0008) in March 2013. Local Trust Research and Development approvals were obtained prior to the start of the study. The qualitative sub-study was granted approval via a substantial ethics amendment in December 2015 (see Appendix 6).



## Study Design

The qualitative study was a sub-study of the Obstetrics Bleeding Study Two (OBS2), a prospective, randomised, double-blind, placebo controlled trial that took place between June 2013-16 and investigated whether early infusion of fibrinogen concentrate during a major PPH reduced the total number of allogeneic blood products transfused compared to placebo (39). Women were included or excluded according to the criteria detailed in Tables 3 and 4 below.

Tables 3 and 4: OBS2 study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Aged 18 years+	Women who documented that they did not want to participate in the study during the antenatal period
Gestation period $\geq 24+0$ weeks	Women who declined infusion of red blood cells or blood components
Women should have any one of the following either before delivery or within 12 hours after delivery:	Women with known inherited bleeding disorder
Haemorrhage of about 1500 mL <b>and ongoing bleeding</b> without another complication	Women with placenta accreta diagnosed in the antenatal period
<b>OR</b>	Women who had already received uterine brace sutures, uterine tamponade balloons, radiology intervention or hysterectomy before entering the study
Haemorrhage of about 1000 mL <b>and ongoing bleeding</b> with any of:	Clinical suspicion of amniotic fluid embolism
i) caesarean section, ii) uterine atony, iii) placental abruption, iv) placenta praevia, v) cardiovascular instability, vi) clinical observation of microvascular oozing	Secondary postpartum haemorrhage (starts >12 hours after delivery)

## OBS2 consent pathway

At the time of a PPH women may not have full capacity to give informed consent to participate in research trials because of factors such as pain, medication and physiological factors associated with blood loss such as nausea, dizziness and disorientation. As such a graded approach to consent was adopted by the OBS2 trial. The staged consent protocol is highlighted in more detail in the published trial protocol (39). In brief, all eligible women in the recruiting centres received an introductory leaflet (see Appendix 7) in the antenatal period describing the study and consent process and were asked to sign a form indicating either that they did not wish to take part in the study or to acknowledge that they had received and understood the information. The form was part of the woman's hand held maternity records. If the woman had received the antenatal leaflet but had not indicated either of the above options, professionals were still able to invite them to take part in the trial. Consent was then either taken antenatally, for women who were deemed 'at-risk' or had planned caesareans, during labour or when the PPH occurred. If deemed to have

capacity to provide consent the woman was given an intrapartum patient information sheet and provided written or verbal consent. If deemed not to have capacity the protocol of assigning a legal representative was followed.

### **Recruitment and sampling**

Of the 60 women recruited in Cardiff and Vale NHS health board 42 (70%) completed an expression of interest form for future PPH studies including talking about their experience of being part of OBS2. All 42 women were contacted in accordance with convenience sampling. This non-probability sampling method has no additional parameters other than participants are willing and able to participate. This sampling method was used in favour of purposive sampling because the population pool of 42 women was deemed sufficiently varied, apart from demographics which was inherently biased towards White British ethnicity. Limitations of the sampling method are detailed in the discussion. The 42 women were contacted via email by the research midwife explaining that a researcher (CP) would be contacting them by telephone in the near future to invite them to participate in the study unless they requested otherwise, this was considered an opt-out strategy.

### **Data collection**

Semi-structured face-to-face interviews were conducted by CP a trainee Clinical Psychologist with 6 year's postgraduate clinical experience, at a location convenient to the women. To understand and interpret the women's experience of being invited to take part in research during a PPH it was important to recognise the importance of the experience from the woman's perspective and understand the context in which the consent was given. Therefore, the interview schedule was divided into two parts: labour, birth and PPH experience and experiences of the OBS2 trial and consent process. The interview schedule, information sheet and consent form (see Appendices 8-10) were designed with input from the trial management group, and based on the guidance in the protocol which was developed in collaboration with a maternity lay advisor. The interview schedule was piloted with a participant and a prompt to refer to the antenatal information sheet was added. No other changes were made to the interview schedule and the pilot interview was therefore included in the data. Interviews were audio-recorded using an encrypted digital recorder and transferred, stored and analysed on a secure network drive.

Two guiding principles of sampling methods in qualitative research are appropriateness and adequacy (40). Bowen (41) argues for the importance of sample adequacy over sample size.

Sample adequacy relates to the demonstration that data saturation has been reached, defining this as obtaining depth and breadth of information which ‘sufficiently’ answers the research question (42). The concept of ‘sample adequacy’ was used by the author to guide the data collection process rather than the concept of thematic/data saturation which is limited as data can never be truly saturated, as there is always new data to be discovered (43). Data collection ended after 14 interviews were conducted at which point the first author considered the data to have achieved sample adequacy; specifically, no new concepts emerged during the interview and the research question could be sufficiently answered.

## **Data Analysis**

### ***Rationale for using framework analysis***

Qualitative methods are often aligned with specific epistemological and philosophical approaches which shape the data collection and analysis process. However, framework analysis is not and as such can be applied to inductive or deductive thematic analysis (44, 45). Critics have suggested that focusing entirely on affiliating qualitative methods with epistemological and ontological theories can overshadow the need to ensure methodological robustness (46). Some researchers have suggested that pragmatism should be applied to choosing the appropriate method for addressing specific research questions, rather than focusing on the underlying philosophy (47). Framework analysis was deemed suitable for several reasons. Firstly, framework analysis is centred on the method of thematic analysis which has no alliance to a specific epistemological theory and as such it was deemed a good fit for the aims of research which were underpinned by balancing deductive and inductive principles of analysis. Secondly, the study utilised semi-structured interviews that produced substantial verbatim text with “fractured discourse” (48). The framework tool is helpful in managing large quantities of textual data in a systematic and transparent manner.

### ***Applying principles of framework analysis and conducting a thematic analysis***

Interview transcripts were anonymised then coded using the qualitative coding software NVivo Pro version 11 for Microsoft. Framework analysis (49) was used to identify, analyse and report patterns within and across the interviews. The approach enables a systematic and transparent analysis of the material while facilitating the use of pre-existing empirical evidence to inform the study method. Framework analysis consists of a series of five stages: familiarisation, development of a thematic framework, indexing, charting, and mapping data to enable interpretation. During the familiarisation stage CP listened to recordings, read memos from a reflective diary and

discussed with supervisors. The interview schedule and emergent themes identified during the familiarisation stage informed the initial working thematic framework to filter and index the data. CP indexed all the data, identifying sections of the data that corresponded to a theme on the framework. The framework was tentative throughout indexing to allow for new and unpredicted themes generated by participants. Double-coding took place on (15%) transcripts to ensure indexing consensus and applicability of the framework to the data and research questions. After the final transcript was indexed the thematic framework was finalised and the data were systematically charted and summarised into framework matrices. This aided the first author to enter in to the mapping and interpretation stage and conduct a thematic analysis; identification of recurrent themes within and across participants, typologies and linkages and possible explanations (48,49). The participants were assigned pseudonyms rather than participant number, so that the quotes had a 'voice'. Appendices 11-14 show examples of the analysis process.

### ***Use of Supervision***

OBS2 was based in a general health setting, as part of a trials unit. Supervision with the second and third authors, the academic supervisor and clinical supervisor, was invaluable whilst negotiating these new systems. The fact that the academic supervisor was a Clinical Psychologist and an experienced trials unit researcher enabled open discussions about the complexities of transitioning to and from the different roles, specifically psychologist to researcher. Discussions took place regarding the first author's role and position in the project; reflecting on the transferability of psychologist's meta-competencies to medical and trial settings and how being a psychologist rather than a medical professional/researcher enabled taking a 'naïve/not-knowing' position.

### **Reflexivity Statement**

I, the first author, conducted the qualitative sub-study as part of my Doctorate of Clinical Psychology (DClinPsych) thesis. I am a 30-year-old White British middle class female, in a long-term relationship with no children. As part of the DClinPsych, I split my time between two locations: South Wales and a town in the South West of England. I have 7 years' experience of working clinically in the NHS with individuals across the lifespan. I have limited experience working psychologically in a medical setting, apart from a child health placement during the DClinPsych. However, my mother was a senior paediatric nurse and as such I grew up with a strong awareness and interest in the health profession and the health care system. I have never been treated for a medical emergency, nor have I taken part in a clinical trial. I would describe my

therapeutic approach as integrative, informed mainly by attachment and systemic ideas. I consider myself a passionate clinician and as such feel comfortable in engaging individuals in reflective conversations about their experiences. It is important to note that my position of Trainee Clinical Psychologist may have elicited preconceptions and beliefs from participants and as a result influenced the answers they gave. I have experience of conducting qualitative and quantitative research. Specifically, I have conducted research using thematic analysis, however I am a novice in using the Framework analysis approach. As such, I took time to connect with experienced qualitative researchers in the trials unit who were proficient in applying the framework approach in a health setting. During the research, I kept a reflexive journal. I took time to note down my experiences during the process of data collection and analysis and monitored and considered how beliefs and assumptions that emerged may have influenced the way I engaged with the research and how participants responded to me.

## **Results**

### **Response rate**

Of the 42 women invited to take part, 22 women did not respond to the interview invitation during the period of recruitment: July-November 2016. Possible reasons for women not wishing to take part in the study are: the timescale between the birth and the invite to interview; competing demands; physical or psychological difficulties because of the PPH and not wishing to talk about these; believing they had nothing of value to say and lack of recollection, understanding or interest in the study. Of the 20 women who were contacted, none declined participation in the research study however practical difficulties prevented interviews taking place with six women. 14 (33%) women were interviewed, two of whom were interviewed with their birth partners. One woman had entered the trial via the legal representative consent pathway due to the severity of her PPH and subsequent medical symptoms. However, the legal representative was not interviewed. Interviews lasted between 25 and 70 minutes.

### **Characteristics of participants**

Table 5 below shows some of the individual characteristics of the women. Numerical details such as age and blood loss have been grouped in to ranges to aid anonymity. Some demographic information is reported as overall participant characteristics rather than individual characteristics due to the risk of breaching anonymity. Of the 14 women, 12 were of White British ethnicity, one was White Other and one was White Non-British. 11 women were interviewed between 6-9

months after the birth, two were interviewed 10-13 months and one was interviewed 14-18 months.

Table 5: Individual Characteristics

<b>Pseudonym</b>	<b>Age Range</b>	<b>Delivery Method</b>	<b>Blood Loss ml</b>	<b>Primipara vs. Multiparous</b>
Lauren	40-45	Vaginal	2000-2999	Multiparous
Sarah	25-29	Emergency caesarean	1000-1499	Primipara
Libby	30-34	Emergency caesarean	1500-1999	Multiparous
Amanda	30-34	Vaginal	1500-1999	Primipara
Emma	35-39	Vaginal	3000-3999	Multiparous
Jessica	30-34	Forceps	1500-1999	Primipara
Anna	25-29	Vaginal	1000-1499	Multiparous
Caroline	25-29	Forceps	1000-1499	Multiparous
Mary	40-45	Planned caesarean	1500-1999	Primipara
Chloe	25-29	Forceps	4000-4500	Primipara
Abigail	30-34	Forceps	1500-1999	Primipara
Rebecca	30-34	Forceps	2000-2999	Primipara
Alexandra	35-39	Planned caesarean	1500-1999	Multiparous
Jane	40-45	Planned caesarean	4000-4500	Multiparous

Seven women were first time mothers and the remaining multiparous. All women gave birth to live babies that survived. One woman gave birth to twins, the remaining gave birth to singletons. The range of delivery methods were: planned caesarean (n=3); spontaneous vaginal birth (n=4); emergency caesarean (n=2); and assisted delivery using forceps (n=5). All the women interviewed were medically reported to have had a ‘moderate’ primary PPH and blood loss ranged between 1500-4500ml. In accordance with the PPH classification of a moderate PPH: nine women had a ‘major’ PPH and five had a ‘severe’ PPH. Two women required blood transfusions. One woman had a retained placenta. Three women were allocated to the interventional arm of the study, the remaining the placebo arm.

SES and education levels were not collected as part of the original OBS2 data set, however it was possible to estimate SES based on participant postcodes. Postcodes were input into an online tool which calculates The Welsh Index of Multiple Deprivation (WIMD, 50): a measure of multiple deprivation that is both an area-based measure and a measure of relative deprivation. WIMD is

currently made up of eight separate domains of deprivation. Each domain is compiled from a range of different indicators including income; employment; health; education; access to services; community safety; physical environment and housing. It is interesting to note that out of 14 participants, 10 were living in an area that was ranked as among the ‘50% least deprived place in Wales’. Out of the remaining four women, two were living in areas ranked as ‘10% most deprived’ and two were living in areas ranked as ‘30-50% most deprived’. This highlights that a disproportionate number of women (approximately 71%) who took part in the interviews were from the ‘least deprived’ areas in Wales.

## Themes

Following analysis and interpretation, four themes emerged each with sub-themes (see Table 6).

Table 6: Themes and sub-themes

Themes	Sub-themes
<b>Theme 1: “...induced when not needed to, an epidural that wore off and forceps and episiotomy and lots of stitches” - The birth before the bleed</b>	Subtheme 1.1: The impact of previous complications Subtheme 1.2: “I couldn’t see an end...” Subtheme 1.3: Straightforward vs. complications
<b>Theme 2: “I’ve got like a blur of you know, um well not blood everywhere but um, towels and all sorts you know” - Losing blood</b>	Subtheme 2.1: "...all of a sudden loads of people started rushing into the room” - Awareness of the bleed Subtheme 2.2: “I tried to be focused as I could be...” - Response to the bleed Subtheme 2.3: “Left holding the baby”
<b>Theme 3: “Are you of sound mind?” Women’s perceived ability to make an informed decision</b>	Subtheme 3.1: Recollection of antenatal information Subtheme 3.2: Registering information Subtheme 3.3: Timing of the consent dialogue Subtheme 3.4: Motivation to take part
<b>Theme 4: “...everybody has a different way of dealing with things kind of on an emotional level, so it’s probably very personal.” Preferences for future research consent pathways</b>	Subtheme 4.1: Understanding research language Subtheme 4.2: Antenatal information - signposting vs. discussion Subtheme 4.3: Sensitivity of intrapartum consent

**Theme 1: "...induced when not needed to, an epidural that wore off and forceps and episiotomy and lots of stitches." - The birth before the bleed**

**Subtheme 1.1: The impact of previous complications**

All multiparous women experienced complications before, during or post one of their previous births. None of the women had previously experienced a post-partum haemorrhage. Prior complications significantly impacted on women's current birth experience, including a need to know that their baby was healthy:

" "Is he okay? just tell me (baby's) okay", because...the first emergency caesarean I had, that was all a scary story..."

Emma

**Subtheme 1.2: "I couldn't see an end to it..."**

Women who experienced labour and delivery complications described waves of physical and emotional discomfort, as though on a rollercoaster:

"...so I'd go into labour, I'd get as far as the hospital, and you know I'd get all that way and they'd be like yes you're in labour but you're in the early stages. So, I'd go home and then everything would stop and it would be three days later."

Chloe

Women reported management plans being in a constant state of flux:

"I think initially it was oh I think we need to go do something. Then it was oh we'll wait and see if he does...And then they said no we're going to rush you straight in..."

Sarah

Some women felt completely helpless and panicked due to labour not progressing:

"baby felt utterly stuck and...I did feel like I got to that point where actually panic set in and I thought this is just never going to happen, this is never going to be, I couldn't see an end to it really..."

Jessica

When medical professionals decided to intervene, women described feeling emotionally relieved and a new sense of hope:



“...I did feel an absolute massive wave of relief that it [*protracted labour*] was over...almost like euphoric really...”

Jessica

“...I went from the worse pain I’ve ever known in my life to absolutely no pain”

Abigail

### **Subtheme 1.3: Straightforward vs. complications**

Three women had no labour or delivery complications prior to the blood loss, all of whom had planned caesareans. The remaining women experienced complications that required one or more interventions: induced labour, the use of forceps, an episiotomy or an emergency caesarean. Some women experienced complications due to professional error:

“...induced when not needed to, an epidural that wore off and forceps and episiotomy and lots of stitches.”

Caroline

Others, because of the baby becoming stuck:

“...in the wrong position so she was going back up and not coming so they was trying to turn her, nothing was happening...”

Rebecca

Women who were unable to give birth as planned, felt extremely “upset” when they were unable to give birth “properly” as described by Emma. Some felt as though “everything was going wrong” [Abigail].

## **Theme 2: “I’ve got like a blur of you know, um well not blood everywhere but um, towels and all sorts you know” - Losing blood**

### **Subtheme 2.1: “...all of a sudden loads of people started rushing into the room” - Awareness of the bleed**

Most women reported becoming aware of difficulties following the onset of sudden physical symptoms or a change in pace by professionals, while others described being completely oblivious to any complications. Some women spoke about sensing something was wrong immediately after the birth:

"I got very breathless I couldn't breathe and I kept saying I can't breathe, then I knew something was wrong."

Chloe

These symptoms impacted on women's ability to greet and hold their babies for the first time and carry out their motherly role:

"you're a new mum again and you're freaking out you can't feed your baby...you're not getting that initial holding in".

Alexandra

and their awareness of knowing where their baby was:

"I wasn't aware of where he was or what happened to him and actually that was quite hard"

Chloe

Several women reported awareness that circumstances had changed because of the sudden arrival of more medical staff and panicked conversation:

"I heard somebody say um "Oh have you got that emergency blood just in case?"

Abigail

Although many women recognised that something was wrong they were unaware it was a result of blood loss. The remaining women reported being "oblivious" to the blood loss or the extent of the complications due predominantly to high pain levels and exhaustion which had impacted on their ability to understand the situation:

"I mean I was a bit kind of, I...delirious is a bit of an exaggeration but you do feel quite fuddled when you're in that much pain..."

Jessica

"...like I said I was so exhausted and because it had gone on, like been in labour for the four days before"

Anna

As a result, many women only registered the complications after it happened whilst in recovery.

### **Subtheme 2.2: “I tried to be focused as I could be...” - Reaction to the bleed**

Women’s response to having a bleed linked closely with their level of awareness. Experiencing a feeling of being disconnected from the situation, some women did not respond as perhaps they would usually:

“I knew it wasn’t all quite going to plan but I was too out of it to worry too much”

Sarah

Some women were focused on their family than on their own health. For example, several women did not feel panicked by the situation since the birth had taken place before the bleed and therefore knew their baby was safe:

“Yeah, I could tell there was something, but I wasn’t overly, well I say overly bothered, because I knew ((baby’s name)) was out fine...”

Amanda

However, a small number of women were concerned for their babies due to health complications, reducing consideration of their own medical situation:

“I think if ((baby’s name)) was alright, I think we would have probably realised more what had happened to me...”

Anna

Several women demonstrated pragmatic responses to the bleeding; trusting in the competencies of professionals to stop the blood loss or conversely trying to remain calm as the professionals became more panicked:

“I didn’t feel terrible, I just thought “Well, it’ll get sorted one way or the other, even if I have to go back in [to theatre].”

Mary

### **Subtheme 2.3: “Left holding the baby”**

Most women reported that their birth partners had witnessed the bleeding as it happened. They reported noticing that their partner was distracted at the time but attributing it to being a first-time father or feeling “queasy” when in fact it was because they could see “...a big jar filling with blood” [Rebecca] and witnessed attempts “...to try and stop the bleeding on the floor” [Abigail]. Several women believed the experience had been very distressing for their partners, perhaps more

traumatic than for themselves. They attributed this to several factors including their partner's exposed view of the situation as stated above; their partner not being told what was happening:

"but he did say to me that he was just kind of left with the baby not knowing what was happening"

Lauren

and fearing they were not "going to make it" [Emma]. Jane reported her partner was worried his wife would die and he would be left to bring up their children alone. Mary's partner emphasised that Mary didn't "realise how bad it was!".

### **Theme 3: "Are you of sound mind?" Women's perceived ability to make an informed decision**

#### **Subtheme 3.1: Recollection of antenatal OBS2 information**

For six of the women, their first memory of the OBS2 trial was the antenatal information sheet (AIS) in the maternity packs. This gave them a better understanding of the study protocol and participation requirements. Several of the women reported their first memories of the OBS2 trial was when they were asked to provide consent:

"...he said, "oh just thinking ahead over the next hour or so" "um if this were to happen, how do you feel about um being part of a research project?" ...and I said "yes" straightaway..."

Mary

Many women's first OBS2 memory was at the point of consent. All but two women remembered consenting, only a few remembered clear coherent details of the conversation:

"...but I do remember they did explain it to me thoroughly...and I said yeah that's absolutely fine and they say, they said "are you of sound mind?" and I was like as sound as I could ever be."

Caroline

Three women signed consent forms prior to having planned caesareans due to pregnancy complications and one of these women remembered professionals confirming her consent at the time she became eligible to enter the trial. The collective narrative of women's awareness and

understanding of the trial during the bleed highlights the impact of blood loss on women's ability to register and process consent documents administered during treatment. Some women appeared able to make an informed decision at the time of the emergency because of having read and understood the antenatal information sheet:

“...they sort of, they handed the form back to me and I had the opportunity to look at it and I went “I’ve already read this...so I just went yeah give me the form I’ll sign now.”

Sarah

One woman required a personal legal representative due to the severity of the blood loss and subsequent medical symptoms. This woman had read and signed the AIS and had made an informed decision to take part prior to the birth, a decision she had also shared with her partner:

“((male partner’s name)) did it for me because I was under general anaesthetic when you actually need to do the consent. But I’d filled out all the forms to say I was happy with it all before....”

Chloe

### **Subtheme 3.2: Registering information**

Women reflected on professional's communication about the blood loss. Many reported despite staff making conscious efforts to keep them informed of the situation, they were unable to register the information:

“...I think they were probably explaining, they were talking to me, weren't they? but I think I wasn't really registering because I was thinking about ((baby)).”

Anna

“...but I kept feeling like I wasn't told anything...but ((partner)) tells me that they did keep telling me what was going on, obviously, I just didn't take it in.”

Chloe

A minority of women remembered clear details of the conversations with medical professionals about the blood loss and treatment plan:

“so they said they needed to check how much, and then if there was any issue then we'd talk about [what] needs to happen”

Caroline

### **Subtheme 3.3: Timing of the consent dialogue**

Most women who gave intrapartum consent felt the timing of consent to the OBS2 trial was appropriate given the complexities of the medical situation. Women who had been aware of the AIS and reported feeling informed when they gave intrapartum consent found the process more acceptable. Some women who did not remember seeing the AIS reported that they “didn’t mind” being asked to consent to the trial despite being in a hectic environment and not having much time to decide:

“...I don’t mind doing it but I think it is just not...it’s quite hard to decide whether you want to or not isn’t it?”

Jessica

Other women felt at the time they were approached they were in no state to register the information due to being mid contractions, in pain or in theatre after an arduous labour:

“...down theatre and being jumped on type of thing...I weren’t quite you know in the state of mind I suppose to know what they were on about...to be honest.”

Libby

“...I just shouted at her to quickly get to the end so I can sign it, I didn’t even have to sign it I just put a line on a piece of paper, I couldn’t even hold a pen, I was such a mess at the point that she could have said anything to me and I would have just said yes.”

Jessica

The researcher interpreted that these women felt frustrated at being asked to consider enrolment at this specific time in their birth. It is particularly interesting given women’s feelings about the timing of consent, that no woman explicitly stated they felt the intrapartum consent process was ‘unacceptable’. The closest to this was Abigail who reported she “could have done without it”. It is interesting that professionals appeared to focus on the procedural elements of informed consent e.g. asking patients to read information and then sign a form, and highlights how this is prioritised over process, such as a shared discussion:

“...they asked me to sign the form then I think...you know the signature was all over the place...”

Libby

### **Subtheme 3.4: Motivation to take part**

A minority of women reported being motivated by the potential for the trial medication to help stop the blood loss and “save my life” [Jane]. These beliefs highlight the influence of therapeutic misconceptions on decisions to partake in research; as although women may have been given the drug, this is not the fundamental aim of a trial. Recognition that women may be assigned to the placebo was not reported. Several women perceived the trial as low risk in terms of the possible impact on themselves and were prepared to take part for the benefit of others:

“...that’s no problem, won’t affect me negatively and it will help obviously... you know, research for the future, isn’t it?”

Sarah

“...I trust my doctor you know and I trust the hospital because you know they don’t give me anything...could hurt my body”

Jane

Women spoke about recognising the ‘value’ and ‘importance’ of research to develop better obstetric treatment for women in emergency situations:

“...I want to be a part of it and anything I can do to help then great...let me help somebody else...”

Caroline

“...you realise how much you rely on medical assistance that you get, so if you think well actually you can be part of something that makes things better I don’t think that’s a bad thing.”

Jessica

Lauren reported “you just say yes don’t you”, suggesting a lack of autonomy to decide and the influence of medical paternalism.

## **Theme 4: “...everybody has a different way of dealing with things kind of on an emotional level, so it’s probably very personal.” Preferences for future emergency obstetric consent pathways**

### **Subtheme 4.1: Understanding research language**

Several women emphasised the need to use lay terms and research or medical terminology side by side in information sheets as often the latter is the language used during the emergency. One

partner suggested that information about the randomisation process should be emphasised such as the fact you may not be allocated to the experimental arm of the trial:

“...because you’ve signed up for something and...it’s clear that you could get nothing...”

Mary’s partner

One woman highlighted the need to reassure women that their clinical care would not be undermined by being part of the trial:

“...what I understood from reading you would have that whilst waiting for the other drugs to be administered, so you wouldn’t not get the treatment by the impact of the study.”

Sarah

#### **Subtheme 4.2: Antenatal information - signpost vs. discussion**

Several women would have valued more emphasis on the study during the antenatal period, but recognised that this could be time consuming. Following a visual prompt of the AIS during the interview, most women remembered that they had seen or read the OBS2 study information “oh that’s right I did get one initially” [Mary]. However, on reflection some women highlighted despite having read the AIS they did not register its relevance or connection during the bleed:

“...I certainly did not take it for what it was but then did I read it in great detail? I can’t remember”

Caroline

A minority of women continued to have no recollection of having read the OBS2 information sheet pre-birth “I don’t know many people who did actually have that in their packs...” [Libby]. Although the women had differing views about the usefulness and trial antenatal information, no woman felt it was an unacceptable process. However, many women highlighted it should be broached sensitively through discussion with professionals rather than just placed in packs:

“...if it’s something the midwife goes through with you as part of your preparation...you’re having a one on one with somebody, it’s not a time where taking on information like that is going to be upsetting or that you’re reading it on your own and you might be confused by it.”

Jessica



Many women recognised that there is “no one fits all’ process and the information may provoke anxiety in some women but not others. Therefore, it is down to personal choice.

### **Subtheme 4.3: Sensitivity of timing of the intrapartum consent**

Several women spoke about how a consent process for a trial such as OBS2 could never be acceptable to all, and that some may be receptive and others may be disapproving but there was no other way than to ask them. Many suggested that consent-gaining should be considered during early labour when they are likely to be “a bit clearer with things”. However, one woman who consented in theatre, highlighted that an earlier invitation into the trial would have caused her to panic:

“I guess that it’s a good time to do it, because personally if it had been mentioned before that, I would have panicked, whereas you know, you’ve already gone to theatre, it’s already clear that this isn’t an ideal and normal, natural birth.”

Abigail

She also described had she been asked to consent any later (e.g. at the time of blood loss) it would have felt “reactionary” by professionals whereas she felt the timing for her was “proactive”. Other women suggested consenting pre-labour however they recognised ultimately it is personal preference and for some women this may frighten them more:

“...probably in other cases if somebody is doing that just before your birth, you’d be thinking why are they telling me? Does this happen all the time? and it’s going to panic you even more.”

Amanda

Some felt that it was important for women to have obstetric trial information prior to birth to aid decision-making ability during the emergency:

“It does help. If I hadn’t read that leaflet, if I hadn’t known anything about it and just on that day they’d have said ‘oh right we’re doing this study...’ I might have, just because I wasn’t able to deal with it at the time, just gone ‘No I’m not interested!’ You know?”

Sarah

Sarah highlighted women may respond with an outright no if they were asked to take part in research during a medical emergency that they had no prior knowledge or understanding of.

## **Discussion**

The findings of the study are discussed in relation to the research aims, existing literature and theory and implications for clinical practice, clinical research and further research.

To date there has been no research published on women's experience of consenting to a research trial during a PPH; as such these findings provide a basis for future literature. Women's experiences of and views about enrolment into the OBS2 trial and preferences for future obstetric research pathways are highlighted, as such research aims were achieved.

### **Thematic findings and link to existing literature**

Within this study, the researcher interpreted four themes from women's birth, PPH, and subsequent OBS2 enrolment narratives; the birth before the bleed; losing blood; women's perceived ability to make an informed decision and preferences for future research consent pathways.

#### ***Theme 1: The birth before the bleed***

Most women experienced complications prior to the blood loss and this impacted on their delivery experience. Some women became upset at being unable to deliver in accordance with their birth plan and described feelings of failure, linking to previous literature on the impact of changes to birth plans (51). In addition, some women felt their concerns about physical symptoms during the birth were minimised or overlooked. In recent research, women reported feeling as though their 'embodied knowledge' about the progress of their birth, including feeling as though something was wrong, was disregarded in favour of the clinician's clinical evaluation (52). Research has shown that dismissal of women's concerns during birth has been linked to the development of trauma symptomology (53). The narratives of women who reported previous birth complications highlighted language suggesting experiences of both physical and psychological trauma. Existing literature highlights that women often remember birth experiences with strong emotional attachments (20, 54), particularly if they experience life-threatening complications. As discussed earlier birth trauma is considered "in the eye of the beholder" (23) and as such is a result of the complex interplay of medical, individual, interpersonal and systemic factors.

#### ***Theme 2: Losing blood***

Women are often unaware of obstetric conditions such as PPH due to the comparative rareness of the condition to other obstetric complications (20) and as such women who do experience it are

unprepared. Levels of awareness about the PPH were varied, with some reporting awareness due to physical symptoms and the change in pace by professionals whilst others were “oblivious” due to high levels of pain, medication and physical/emotional exhaustion from labour. Women described several responses to the onset of the PPH, including being pragmatic, feeling disconnected and focused on their family which links to findings from previous PPH research (20-22). Women described their birth partner’s role in the birth and subsequent bleed, and unanimously felt that it was more traumatic for their partner due to their view of the situation, being left with the baby, lack of communication from professionals and fear of their partner dying. These experiences echo previous research (21,22), highlighting the forgotten role of birth partners in PPH experiences and the risk of developing trauma symptoms.

### ***Themes 3 & 4: Women’s ability to give informed consent and preferences for future consent pathways***

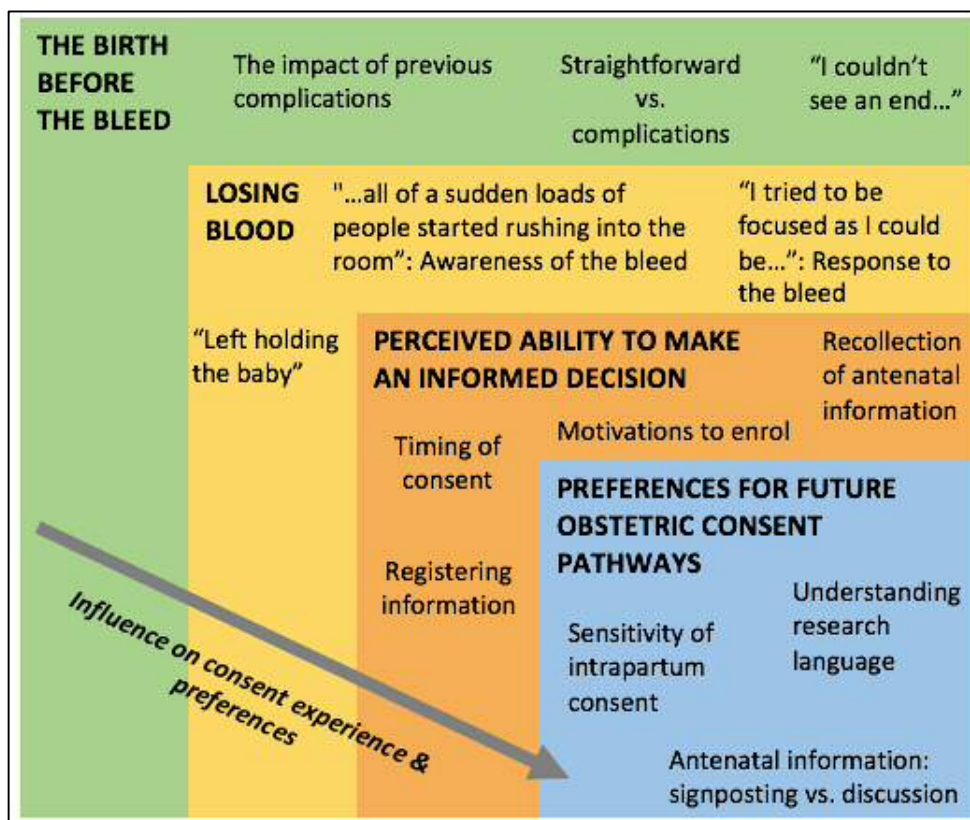
Even without complications it is known that childbirth is a unique context with considerable ethical issues (26). This is due to factors such as the reduced opportunity for dialogue between professional and expectant-mother because of an inherently stop-start event; responsibility for the safety of two lives and physical and emotional vulnerability due to pain and medication. As such there are conflicting beliefs about a woman’s ability to give informed consent during labour, for clinical treatment pathways. A survey of obstetric anaesthetists found that 70% believed that women in active labour would be unlikely to make an informed decision (55). However, others suggest that if a woman had capacity to make an informed decision before labour she would retain this ability in labour (56).

Many women in OBS2 reported making quick, and not necessarily informed decisions about enrolment in the trial, which links closely to Lawton’s findings which highlighted a lack of consideration of risks (38). Women also described how pain, tiredness and overwhelming emotions impacted on their ability to take on information and focus on and interact with professionals, partner and their baby. This reiterates previous literature in the area (20-22), particularly findings from previous perinatal trials (56). Researchers in this study found that many women felt ‘unable to listen’ and that rapid consent decisions were prompted by irritation. Although no woman explicitly stated that they found the intrapartum consent process unacceptable, it is implied by the language used in some of the women’s narrative. Many women who had no recollection of the AIS felt extremely frustrated when the consent dialogue took place. Others who had no recollection of the AIS, appeared to find the consent pathway acceptable given

the nature of the obstetric emergency. These findings highlight the influence of antenatal trial knowledge on women’s ability and comfort in making research enrolment decisions. Reflections on their experiences of the OBS2 consent process informed women’s preferences for future obstetric consent processes. All women felt giving antenatal trial information was an acceptable stage in the consent process but emphasised the need for sensitive management regarding the timing, method and content of information. This reflects recommendations from obstetric professional bodies (34, 35).

The findings from the study highlight women’s experiences of enrolling in the OBS2 trial are influenced by a complex interplay of sub-systems, each holding individual, interpersonal and systemic factors, shown in Figure 3. Women’s experiences of consenting to OBS2, views on the acceptability of such consent and preferences for future research pathways are embedded in their experiences of birth, blood loss and the consent interaction.

Figure 3: Connection between the themes



These experiences/sub-systems influenced women’s overall views of the acceptability of obstetric emergency research. This proposal is based on systems thinking: the belief that it is impossible to

truly understand a phenomenon by reducing it to basic components and that systemic perspective is necessary for comprehending the phenomenon in question (58,59).

## **Implications for obstetric emergency practice and research**

### ***Interactions and dialogue during a PPH***

During obstetric emergencies, there is an urgent need for treatment (1,7) which often negates the provision of information and positive staff-patient interactions. It is vital that obstetric clinicians work collaboratively to provide effective treatment for the woman, her infant and the family, this includes negotiating the difficult task of effective communication during a medical emergency. Effective communication can provide feelings of care and containment for the woman and partner and reduce the risk of developing symptoms of psychological trauma. As highlighted by the findings in this study, clinicians need to be mindful of women's experience of previous birth traumas and the impact of these on response to current obstetric complications. Clinicians should be attuned to women's early reports of concerns and conduct clinical assessments accordingly.

### ***Understanding medical and research terminology***

Women in the study had mixed levels of health and research literacy. Some had strong knowledge and understanding of medical and research terminology, others had limited awareness which may have influenced their comprehension of the OBS2 trial. As such some women misinterpreted clinical research to be underpinned by therapeutic intent (26), replicating findings from research conducted in obstetric (38,57) and non-obstetric emergencies (60-61). Simple strategies such as a research noticeboard and leaflets explaining research paradigms and terminology in the antenatal clinics may support the development of a culture of research in obstetrics and in turn improve women's awareness of research terminology and active clinical obstetric research trials.

### ***Capacity to consent to obstetric emergency research***

It is well documented that physical and emotional factors associated with childbirth such as pain, medication, stress, fear and a focus on the baby (26) can impact significantly on decision-making ability. This can be exacerbated when women then go on to experience a significant blood loss (21-22). It is therefore debatable whether women can give truly 'informed' or 'true' consent during this experience. As such, the addition of antenatal trial information and a staged consent model is preferable and inviting women to consent to intrapartum research needs careful navigation. Professionals need to be mindful of individualised experiences of labour and delivery, severity and response to blood loss; previous birth or other traumatic complications and the likely

influence that these factors will have on a woman's decision to consent to research trials during an obstetric emergency. As stated by one of the women in the study "there is no one fits all" approach: some women will find being invited to take part in intrapartum research acceptable and others will not, it is a case of professional judgment and assessment of capacity and consideration of the medical circumstances.

### ***Antenatal information-sharing process***

Women involved in OBS2 had preferences about antenatal and intrapartum consent pathways. Women, who had experienced antenatal discussions with professionals about trial recruitment, valued this information-sharing opportunity. Snowden et al. (21) found that women and their partners preferred the concept of an antenatal as opposed to intrapartum consent pathway, stating they had a right to know about such trials during their pregnancy. The OBS2 study highlighted two types of women: those who were information 'seekers' e.g. reading through the whole antenatal pack and those who were information 'avoiders' e.g. ignoring the information in the antenatal pack. The discrepancy between women's preferences highlights the need for a two-tiered approach that adheres to the needs of all stakeholders and the ethics of trials: general information sharing through brief antenatal information sheets in packs and publicity in the antenatal clinics followed by the opportunity to discuss relevant research trials with an obstetric professional during individual clinical consultations. Using this information-sharing approach, women can choose to engage or decline discussions with professionals about research trials.

Clinically, midwives are likely to find it difficult to offer to discuss each obstetric research trial with every pregnant woman due to large caseloads. In addition, some obstetric clinicians and researchers have reported that antenatal pathways would be time-consuming and may cause undue anxiety in women who are in fact unlikely to go on to have a PPH (38). Clinicians might lack confidence in discussing research paradigms and trials that they are not regularly part of and therefore may require additional training and support. Alternatively, roles could be divided so that professionals are employed as either a clinical researcher or clinician. This could reduce the burden and responsibility on clinicians and the risk of therapeutic misconception. A variance of this approach is currently in use in the Organ Donation and Transplantation (ODT) service which employs specialist nurses to approach families and discuss consent processes for organ donation and liaise with the clinical team of the deceased patient (62). Although this is not a research environment, ODT does present ethical, legal and practical dilemmas for authorisation of consent.

## **Future research**

There is a lack of studies exploring the preference and views of women who choose not to partake in emergency obstetric research, including targeted PPH studies, due to the difficulties in identifying and accessing this population. Yet it is vital that exploring stakeholders' reasons for declining entry in to emergency obstetric research is a focus of future research to inform the design and conduct of future obstetric trials with the hope of increasing acceptability and therefore participation. Qualitative research is particularly valuable in procuring this information as it enables researchers to explore complex attitudes and preferences on a given topic and the values that underpin these. Future research may also benefit from assessing preferences and acceptability of consenting to emergency obstetric trials over different time points such as within days of giving birth and then a follow-up interview three months later. This could enable researchers to see whether views are static or dynamic over time, specifically during the PPH recovery period and adaption to motherhood.

## **Methodological Strengths and Limitations**

The researcher used guidance on attaining validity in qualitative psychology (63-64) to demonstrate attention to quality and rigour. A strength of the study was that sample included women who had experienced a PPH following a vaginal, assisted or caesarean delivery method, which has often been an exclusion criteria in previous qualitative PPH studies. The views of women who had experienced a 'moderate' PPH ranging from 1500-4500ml were also included, highlighting a variety of medical severity and physical and psychological impact. To date, this is the first study to explore women's experience of having a PPH and enrolling in research during this time.

A limitation of the sample is that only women who had consented to OBS2 and had expressed an interest in future PPH studies were able to be contacted. Thus, the voices of those who chose not to consent and those who did consent but did not wish to take part in follow up research are missing. From those eligible, only a third were captured and no legal representative took part. Data collection stopped following sample adequacy, as described in the method. The researcher used a convenience sampling technique and as such it is acknowledged that the sample is unlikely to be representative of the population being studied, as typically they include small numbers of underrepresented sociodemographic subgroup (65). This is evident in this study, which was dominated by participants who were of White British ethnic background and who lived in the least deprived areas in Wales. Demographics such as socioeconomic status and education level were

not collected by the original trial, however the researcher has been able to estimate these using participant postcodes and the Welsh index for multiple deprivation. Several of the women interviewed appeared to have an interest in medical research and a strong birth narrative due to multiple complications which highlights a further potential sampling bias. Interviews took place between 6-18 months' post birth and therefore the potential for recall bias is acknowledged, although research suggests women have good recollection of childbirth experiences (66).

The researcher attended specialist teaching on qualitative methodology, had in-depth discussions with trial unit researchers experienced in applying framework analysis in a clinical health domain and accessed relevant literature. A significant benefit of using framework analysis is that it provides a clear audit trail, particularly during the stages of data management and analysis. The third author, a researcher with expertise in clinical health psychology and framework analysis double coded 15% of the transcripts, this was to check the coherence and credibility of the developing thematic framework. During the indexing, charting and interpretation stages, the researcher utilised supervision to check the credibility of the structure and coherence of codes and subsequent themes and sub-themes. The first author kept a reflexive diary, notes and memos during the research process which was used to acknowledge the researcher's own motivations, beliefs, values and preconceptions that may influence the direction of the project. In addition, the researcher bracketed interviews to limit subjectivity. The aim was not to abandon assumptions altogether, but to prevent them from imposing on the data (64,67) to help "see and describe the phenomenon" (68). The advantage of bracketing is that researchers spend time "trying to understand the effects of one's experiences rather than engaging in futile attempts to eliminate them" (64, 69).

## **Conclusions**

Women's views of the acceptability of consenting to research during a PPH are contingent on experiences of the birth, the PPH and the consent interaction. The findings highlight the importance of understanding the complex interplay of individual, interpersonal and systemic factors that underpin women's obstetric emergency experiences and how this informs views on obstetric emergency research. The findings of this study can be used to inform future research protocols and clinical practice.



## **Competing interests**

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### **Paper 3: Critical reflection**

Paper 3 evaluates the strengths and limitations of both paper 1 and paper 2. It also highlights implications for clinical practice and future research.

**Word Count: 8,000**

In paper three I critically reflect on elements of my research as reported in paper one and two as well as the research process as a whole. I discuss the implications of the research for clinical practice and the relevance to and role of clinical psychology in these fields. I also consider and reflect on the personal and professional competencies developed during this process.

#### **Personal Context**

Prior to starting the Doctorate of Clinical Psychology (DClinPsych), I identified as a clinician first and foremost. I had limited research experience which entailed conducting service development projects, audits and literature reviews. A key competency I wanted to develop during training was to enhance my research skills and engage in research that was meaningful. As such I was keen to be part of a research project emanating from a clinical trials unit and all the complexities and challenges that are embedded in this system.

Regarding the topic of consent, I have worked clinically within child, forensic and inpatient settings where an individual's autonomy to make every day decisions has been restricted for legal reasons such as detention under the mental health act, ministry of justice orders and criminal convictions. Working as a clinician within these settings, which were most commonly dominated by the medical model, I developed a position of wanting to promote shared health care decision making wherever possible within the bounds that the context allowed.

My clinical experience prior to training had all been in mental health settings and I felt it was important to gain competencies working as a clinician and researcher in a medical health setting. Following a placement in child health and development I developed an interest in working with medical disciplines to deliver shared care. I became interested in the disparity between the approaches taken by psychologists and medical staff to the discussions and involvement of key stakeholders in care decisions. It reminded me of the consent dilemmas I witnessed within mental health settings.

I sought to conduct research that originated from a clinical research dilemma such as consent, driven by policy and practice rather than theory. Following a discussion with the second author of paper one and two, a researcher within the clinical trials unit, an opportunity arose to become part of the OBS2 trial. I was drawn to the topic because of the clinical health setting, the organisational context of the research and because of the opportunity to interview individuals in depth using a qualitative approach about their consent-gaining experience, to inform future research and clinical processes.

## **The Systematic review**

### Developing the question

I was clear that I wanted to explore patients lived experience of consenting to research during a life-threatening medical emergency. On conducting a scoping review, it looked as though there was substantial literature, particularly in the last 10 years. However, after looking at it more closely it was evident that the up-to-date research used a mix between life-threatening and non-life threatening emergency department samples. In addition, I had planned to conduct a qualitative synthesis but after the scoping search it was clear that researchers had used mixed-method trials to capture quantitatively and qualitatively meaningful data. Popularity of qualitative synthesis has increased utilisation of mixed method reviews (1). As such I chose to include mixed-method studies, but focused on the qualitative element of these studies. During the paper review stage, it was clear that there would only be a small sample that fitted the review criteria.

### Literature search and criterion

Within the time parameters of the thesis, I aimed to conduct an ‘exhaustive’ review using a systematic and explicit strategy: predefined subject headings and key words (2, 3). I use the term exhaustive rather than comprehensive in line with Booth’s conceptualisation that exhaustive “conveys the finite nature of resources (e.g. searcher time, money, and access to databases; time to sift)” (2). I feel that this term corresponds with the process of conducting a thesis, as part of the DCLinPsych e.g. alongside clinical placements and academic obligations. Although there is no consensus about whether comprehensive or theoretical sampling should take place in a qualitative evidence synthesis (4); I decided against theoretical sampling for several reasons. Due to the nature of the review question and intended purpose: to explore stakeholder’s views to inform policy and guidance, I decided that it was important to conduct a search that sampled all the available studies in the topic area. Theoretical sampling in qualitative evidence synthesis has been

criticised for aiding “subjective decision-making” (5) and risking omission of studies that may be important to the phenomenon of interest.

I did consider the options of using a specific search tool such as ‘PICOS’ (population, intervention, comparison, outcomes and study design) or ‘SPIDER’ (sample, phenomenon of interest, design, evaluation, research type) to develop a targeted search strategy (6). However, for several reasons I decided to use only two components of the search tool. Due to the poor indexing of qualitative studies or methods and limited use of keywords (6) I decided not to use search terms representing ‘study design’ as I did not want to risk missing relevant studies. In addition, I chose not to use search terms representing the concept of ‘views, perceptions, experiences’ due to the extent of available options. Although intended as a search framework, I found PICOS very useful for clarifying the study inclusion and exclusion criteria and used it as a checklist whilst reviewing the studies. I developed the search terms and overall strategy in collaboration with a specialist medical librarian with experience in conducting medical systematic reviews. As a systematic review novice, I found their guidance invaluable as it enabled efficient navigation of the databases and enhanced my understanding of developing and adjusting search terms according to desired specificity and sensitivity. Research has shown that the inclusion of a librarian correlates with higher quality reported search strategies in general internal medicine systematic reviews (7). As such I believe the guidance of an experienced librarian increased the validity and reliability and therefore the overall rigour of the systematic search and a skill-set for the future.

#### Application of critical appraisal tools in qualitative evidence synthesis

Although widely regarded as an essential component of quantitative systematic review of trials (8), the application and value of critical appraisal in qualitative evidence review and synthesis continues to be a topic of debate (9). Those arguing against the usefulness of critical appraisal in qualitative evidence syntheses highlight that qualitative studies rated as having good methodological rigour do not necessarily translate in to in-depth synthesis findings (10, 11). Within the last two decades, there has been a trend towards critically appraising primary studies within qualitative evidence syntheses to highlight validity and reliability and inform subsequent secondary analysis. As such, there has been a transition from debating the value of critical appraisal in qualitative reviews to debating what criteria to use (9, 12). In accordance with recommendations from The Cochrane Collaboration Qualitative Implementation and Management Group (CQIMG, (13) I used critical appraisal tools to assess the quality of the studies.



### ***Rationale for chosen tools***

After researching critical appraisal tools for qualitative and mixed-method studies, I decided on using the Critical Appraisal Skills Programme (CASP qualitative, (14)) and Mixed Method Assessment Tool (MMAT, (15)). Although there remains no consensus on the quality criteria of mixed-method studies (16), I chose to use the MMAT as the author was transparent about the tools theoretical development: influenced by the work of Ian Hacking a social constructionist and the outcome of a review of several systematic mixed studies reviews (17). It was also the only tool that explicitly incorporated a section on the integration of mixed method components and addressed questions such as 1) is the mixed method design appropriate? 2) are the qualitative and quantitative parts integrated? and 3) are the limitations about this design discussed? Consideration was given to using the Crowe Critical Appraisal Tool (CCAT, (18)) instead of two separate tools, however in comparison to the MMAT and the CASP, the CCAT was more time demanding and I felt it was important to have specific qualitative and mixed method review tools rather than a generic tool (19).

### ***Subjectivity of quality assessment***

With no previous experience using an established critical appraisal tools, I was struck by the apparent subjectivity of the assessment questions in both the CASP and MMAT despite author guidelines. Prior to this work I had made an implicit assumption that critical appraisal tools would be standardised and definitive yet I was left questioning my assessment of the studies. The process highlighted to me the importance of having a second reviewer and discussing and justifying quality decisions and I also developed an understanding of the rationale for a team of reviewers within large scale systematic reviews.

### ***Bias and limitation in the studies***

Whilst conducting the critical appraisal process, I became aware of the difficulties of assessing the quality of a study based on only its reporting in a published article. Poor reporting of qualitative studies is prevalent (9) and this compromises the quality assessment. It prompted me to consider the influence and bias of the diversity of journal reporting guidelines and word count on assessment of quality within and across studies (9). I was particularly frustrated by the lack of reflexive statements in the articles: negating written consideration of the influence and position of the researchers within the research process. This reiterates Franzel et al., findings that reflexivity is often not reported in published papers (20). It was apparent that many of the studies had not used qualitative research reporting guidelines (21), developed to encourage the reporting of details

such as reflexivity. I decided to only include studies which were published in a peer-review journal and in the English Language, despite coming across studies of interest that were part of conference papers which highlights a potential limitation due to publication bias.

### *Sensitivity analyses*

The decision to include or exclude studies from qualitative evidence syntheses following assessment of quality continues to be deliberated (9). Exclusion of studies can seem arbitrary without justification. Tong et al., (22) reiterate the importance of stipulating reasons for exclusion or weighing and statement of thresholds. I decided not to exclude studies based on quality assessment but instead highlight the contribution of the papers to the thematic findings. I took this decision after reading a number of articles that explored the risk and benefits of excluding or weighting poor quality studies (2, 9). However, I could have gone one step further and conducted a sensitivity analysis. Sensitivity analysis weights studies rather than excludes and as such no information is removed from the synthesis but rather a critical context is provided for the reader.

### Rationale for thematic synthesis

I was overwhelmed by the diversity of qualitative synthesis approaches, a common complaint for researchers conducting qualitative reviews (23). However, after reviewing several approaches including meta-synthesis (24); narrative synthesis; and framework synthesis (25), I decided that thematic synthesis, as described by Thomas and Harden (26) was the best fit for the research objectives. Thomas and Harden developed the approach for use in health promotion and public health, to explore stakeholder's views on the appropriateness and acceptability of specific health interventions to inform practice and policy. I believed this corresponded with the objectives of the systematic review question which were two-fold. The first was to identify individuals lived experience and views of consenting to research in a life-threatening emergency setting and the second was to use this information to consider improvements to the way in which research consent pathways are implemented in emergency clinical practice. A further rationale for using thematic synthesis was that it is considered "epistemology-neutral" (27), as such it can be applied to aggregative, configurative and mixed approaches to synthesis (28). I believe that this review is not aligned to a specific ontological or epistemological position.

## Implications for practice

### ***Reflections on professional position: clinical equipoise vs. expert position***

Within a randomised controlled trial (RCT) design, clinicians are required to communicate to the patient a position of clinical equipoise, therefore relinquishing the expert position. It is important for clinicians to recognise the influence their own beliefs and feelings on approach and engagement in trial recruitment. Specifically, beliefs centred on the effectiveness of the treatment interventions in question (therapeutic optimism; (29)) and how they relate and respond to the societal expectation of being an expert and consequently comfort or discomfort with upholding the position of ‘not-knowing’ in an RCT. Not only is it confusing for patients but professionals themselves who are ethically bound by two conflicting medical paradigms (30).

Professionals appear to overestimate patient’s understanding of medical interventions and models of research; as such patients struggle to understand the information given. A patient’s ability to comprehend the research information is dependent on reading level, age and level of health literacy but also external factors such as the content of the information provided and the recruiting professionals communication style. Information sheets should be accessible to patients in populations that are hard to reach or considered vulnerable (e.g. patients who have hearing, sight or speech difficulties, are unable to read or write, speak a different language, have a mental health or cognitive difficulty) to promote inclusivity and prevent findings bias because of poor accessibility. Information sheets and consent forms should be specific to research studies and target populations. Forms should be succinct and provide lay explanations of research and medical terms to promote patient knowledge and understanding and counter low health literacy.

### ***Link to systems theory***

The findings from the synthesis highlighted patients experience of consenting to research during a medical emergency appeared to be influenced by individual and systemic contextual factors: patients medical condition, patient’s belief and value set, patients support network, interaction with professionals, the emergency context and cultural expectations (e.g. perceived role of doctors and the role of research in medicine). I view the findings as relating to systems theory, an interdisciplinary study of systems. Systems theory is based on the premise that a system is an entity with hierarchical, interrelated and interdependent networks, with increasing complexity, which are defined by boundaries and is more than the sum of its parts (31). Systems thinking offers an alternative to reductionist thinking which prioritises individual components, linear connections and often negates the relevance of context (31). To understand a system, it is important to consider the

intrapersonal, interpersonal and macrosystemic factors over time (32). Systems theory can be used to develop an understanding of certain behaviours such as informed consent decisions in emergency settings, in the context of the ecological environment e.g. professional-patient interaction and communication, medical emergency context, cultural and society norms and values on medical research (32). This can ensure that consent processes are considered within the context which can enable efficient problem-solving and implementation of relevant interventions.

## **The Empirical paper**

### Joining the trials unit and project

The prospect of joining a well-established clinical trials unit was both exciting and daunting. I was mindful that I was joining a team of experienced researchers and individuals who had or were currently conducting PhD's and were accustomed to the structure, terminology, policies and procedures of a clinical trials unit. Initially I found it difficult to explain the parameters of the thesis within the DClinPsych and how it sits alongside clinical and academic demands. It was assumed at times that I was completing a PhD and that my time was dedicated solely to the research project. I found I had to clarify my role, the time constraints of the DClinPsych and the competencies I needed to demonstrate in the thesis. At times, I became overwhelmed by the responsibility and task of balancing the requirements of the DClinPsych thesis and the requirements and responsibilities for delivering the qualitative component OBS2 trial.

I was aware of my position within the trials unit hierarchy which, compounded with being a novice researcher, made me question what I could offer the OBS2 project and trials unit. The project was based in general health setting, an area I have little experience of clinically. Supervision with my academic research supervisor was invaluable whilst negotiating this new system. The fact that my supervisor was both a Clinical Psychologist and an experienced trials unit researcher enabled open discussions about the complexities of transitioning to and from the different roles or 'hats' as we labelled the phenomenon. We discussed dilemmas such as clarifying my role and position in the project; identifying the practical support network within the project; and developing competencies in participant recruitment, conducting research interviews and qualitative data analysis. My supervisor helped me reflect on my established meta-competencies and the transferable nature of these competencies to medical and trial settings. We discussed how being a psychologist rather than a medical professional enabled me to take a 'naïve/not-knowing' position within the project and offer a psychological perspective on medical processes.

The OBS2 trial was categorised as a Clinical Trial of an Investigational Medicinal Product (CTIMP): a study that looks at the safety or efficacy of a medicine, food item, placebo in humans (33,34). Learning the terminology and guidelines associated with a CTIMP trial was a learning curve, and completing Good Clinical Practice (GCP) training through the National Institute for Health Research was invaluable in generating an understanding of and the reasons for specific OBS2 trial processes. It was vital that I understood the original OBS2 trial protocol to enable successful and purposeful interviews with women who had consented to this trial.

### Informed consent

Informed consent is a legal obligation based on ethical theories of personal autonomy and self-determination (35). However, the interpretation and implementation of informed consent in clinical practice remains complex. Several clinical models of informed consent have been proposed to bridge the gap between ethical theories and clinical practice (36).

#### ***Clinical models of informed consent***

Models can be divided into those that focus on informed consent as an ‘event’ and those that focus on it as a ‘process’. Wear’s (37) event model of consent is focused on professional’s disclosure of risk information and the actual documentation of the patient’s decision to consent. The role of the patient in the event model is to use the information disclosed by the professional to make a judgement about treatment preference based on their values. There is no acknowledgement of transactional communication between the professional and patient nor the relational nature of the encounter the influence this may have on a patient’s decision-making ability. It adheres to the legal obligation of informed consent rather than ethical ideals of respect for personal autonomy.

The process model, devised by Lidz et al. (38), stipulates two principles before the consent process can be conducted. The first is that the roles of both the professional and patient in the consent transaction need to be defined, with an emphasis on the need for information-sharing rather than information disclosure conversations (36). The second is acknowledging that health professionals and patients have different beliefs, values and understanding about medical treatment, risks and perceived responsibility for treatment decision-making. Lidz et al. suggest that these principles should underpin and inform the information-sharing and decision-making process between professional and patient (38). Faden and Beauchamp (35) criticise this model for suggesting that informed consent can be a shared-decision. They emphasise the need for the decision to be made autonomously and voluntarily by the patient.

The final model to be discussed is Katz's 'conversation model of interaction' (39) which is less prescriptive of the content of the conversation and more reflective about the meaning or intention of the dialogue. Self-determination and personal autonomy principles underpin this theory. Katz's defines self-determination as an individual's right to make a choice free from external pressure and personal autonomy as the psychological capacity of the individual to exercise this right to self-determination. Therefore, he considers self-determination as two interlinked components: 'internal' and 'external'. The external component is the patient's actual choice and the internal component of self-determination is the patient's capacity to "reflect, choose and act" (39) with an awareness of individual and systemic influences. Both the internal and external components should be given equal value. Professionals should engage in information-sharing conversations to discuss not only the details (benefits and risks) of the treatment but also the influence of psychological and systemic factors on decision-making to enable the patient to exercise their right to make an informed choice. Katz's model aims to increase professional's conscious awareness of the ethical principles of informed consent processes in clinical practice rather than consent being seen as simply a legal and procedural event (36).

The event model focuses on the legal role of the professional to disclose all relevant information about treatment options and risks rather than the transactional nature of the dialogue. It therefore places more responsibility on the professional and the patient holds a passive role until the point in which the decision is made. The conversation and process models on the other hand, emphasise the need for the professional and patient to engage in an information-sharing dialogue, founded on exploration of values, beliefs and expectations, prior to patient's making decisions regarding treatment.

Although these models have been developed for implementation in clinical practice, the same principles apply in the context of consent for research. The process of consent to partake in research trials, like in standard clinical practice, is often focused on written documentation or proof that the patient consented. However, it is necessary for researchers and professionals to recognise informed consent as a process, a verbal conversation between professional-patient that shares information on ideas and values, and not just an event, a signed form (40).

### ***Professional guidelines on the ethics of consent***

It is unsurprising that health professionals, even those more senior, may struggle to understand what an informed consent process entails in clinical and research practice given that professional guidelines such as the Nursing Midwifery Council (NMC), General Medical Council (GMC) and British Psychological Society (BPS) provide similar but limited accounts of informed consent processes in clinical practice and research. They denote the importance of information-giving rather than information-sharing: be given “the information they want or need in order to decide whether to take part in research” (41, 42) and “...ensure that clients, particularly children and vulnerable adults, are given ample opportunity to understand the nature, purpose, and anticipated consequences of any professional services or research participation, so that they may give informed consent to the extent that their capabilities allow” (43, 44).

### ***Why explore stakeholder’s experience of the consent-gaining process in research?***

Informed consent is a vital component of ethical requirements to undertake research. Yet, consent-gaining processes are often negated or minimised in reporting’s of studies (45) and therefore avoidant of interpretation, suggesting tokenistic interest in this complex and integral concept. Interest has developed over the last decade in understanding individuals’ experiences and views of the informed consent process (e.g. acceptability and professional-patient communication and interaction) in clinical and research practice. By exploring individuals experience of consenting to a research trial, consent becomes a topic of analysis.

The topic of consent has specific context in Wales given the recent change to use a ‘soft opt-out’ for organ donation under The Human Transplantation (Wales) Act 2015. The soft opt-out works on the premise of 'deemed consent': if an individual has not registered a clear organ donation decision (opt-in or opt-out), they will be treated as having no objection to being an organ donor. (46).

### **Framework analysis**

Framework analysis was developed in the 1980’s by Jane Ritchie and Liz Spencer, researchers in the Qualitative Research Unit at the National Centre for Social Research (NCSR) for use in social policy research. However, the approach is now regularly used in health research (47) and psychology (48). Framework analysis is based on a case and theme approach using five inter-connected stages: familiarisation, indexing, charting, mapping and interpretation. The trademark

of framework analysis is the matrix-based format (49), which enables researchers to systematically reduce and summarise data whilst retaining links to the primary textual narrative (49). The inter-connected stages also allow the researcher to move back and forth across the data iteratively until a coherent account emerges (50). The approach enables a transparent audit trail of the entire process but specifically the interpretation stage, which involves thematic analysis, development of typologies and explanatory analysis.

Framework analysis has been referred to as both a method and an analytical tool by the authors through the stages of development (49-51). The latter is the author's most up-to-date description of the approach. As such I consider framework analysis as a tool to systematically code and manage qualitative data that aims to generate themes (47).

### Rationale for using framework analysis

When I joined the OBS2 qualitative study, the ethics had been written and accepted and as such the choice of qualitative method had been decided. Having said this, I had subsequent opportunities in the ethical amendment for the qualitative sub-study to change the methodology however I believed that framework approach fitted with the design, scope and objectives of the research. The study utilised semi-structured interviews that produced verbatim text with “fractured discourse” (49) which framework is helpful in managing. Regarding scope, there was the potential for a large quantity of qualitative data because 42 women had expressed interest in being part of future PPH studies and it was unclear how many would consent to be part of the OBS2 qualitative study. Further to this, the objectives of the OBS2 qualitative study were two-fold: contextual and evaluative (formative) and as such suitable for the application of framework analysis. A contextual research question aims to explore and describe participants' understanding and interpretations of social phenomena in a way that captures their inherent nature. Formative evaluations are designed to provide information that will help to change or improve a programme or policy, such as protocols for research (50). OBS2 aimed to contextualise women's experience of the consent process within an emergency obstetric setting and evaluate the acceptability of this process to inform consent protocol in future PPH trials.

### Developing the interview schedule

The premise of the questions in the protocol, developed in collaboration with a maternity lay adviser was expanded in to an interview schedule. The interview schedule was developed after



conducting scoping searches of relevant and up-to-date literature and discussions with both supervisors.

#### Participant information sheet and consent-gaining process

From the original OBS2 consenting process there was a group of women who had also expressed interest in being part of future PPH studies including talking about their experience of OBS2. They were initially approached via email by the research midwife on my behalf. The email gave details of the qualitative study and provided a further opportunity for women to opt-out of being contacted. After 2 weeks, I contacted the women by phone.

Whilst writing-up the empirical paper and going through a draft with my course supervisor we realised that although I had gone through the participant information sheet in detail with the women on the phone and then again before the start of the interview and they had given written consent, I had breached the OBS2 protocol because I had not sent out the participant information sheet in the post prior to the interview. I was mortified by my mistake and very much felt like a novice researcher. The senior trials manager and other researchers involved in OBS2 were notified and a report was sent to the quality assurance team within the trials unit to assess the severity of the breach. Quality assurance considered the error as a low risk breach and stipulated that a protocol non-compliance form would need to be completed and it should be considered as an opportunity to learn lessons and prevent future breaches.

I have reflected on this over and over, and I remain unclear why I did not follow this part of the protocol but followed everything else. The only reflection I have is that having spoken to the women on the phone, conversed about the details of the study and participation requirements and explained that I would go through information again when we met, I believed I had provided the necessary information for them to agree to meet and then decide whether to go ahead with the interview. I guess in a sense I transitioned into a clinician during this time rather than a researcher, my focus was on meeting the women in person. I truly believe that this breach did not impact on the women's ability to make an informed choice to take part in the qualitative study. There were numerous stages in the process that enabled the women to opt-out and when we met for the interview, we spent time engaging in information sharing and discussion, reviewing the information sheet and their right to stop the interview at any point. This was also reiterated when the recording started.

It was important for me to be open and honest about this in the thesis because it was a huge learning curve and impacted on my development as a clinician-researcher. I feel it is important to recognise, take ownership, reflect and learn from mistakes to develop personally and professionally.

#### Clinician vs. researcher role: conducting interviews

Some professionals have criticised qualitative research for being “saturated with ethical issues” (52) due to the degree of researcher-participant interaction (53). This, coupled with empirical evidence that barriers to acting ethically occur when professionals wear “too many hats” (53), made me continually reflect on and discuss in supervision ethical constructs such as confidentiality, consent, dual-role, and the influence of politics and power (54). A central topic of conversation in supervision was the similarities and difference in my role as a qualitative researcher conducting research interviews and as a trainee clinical psychologist conducting therapeutic interviews in clinical practice. I was mindful of the sensitive nature of asking women to talk about their experiences of a having a PPH and the possible affect that this may evoke. As a clinician, I regularly interact and support individuals who are emotionally distressed and as such this was something I felt competent in anticipating and managing sensitively whilst still maintaining the role and boundaries of a researcher. As it turned out no woman became acutely distressed whilst discussing their PPH experience and therefore I did not experience having to signpost them to support rather than offer guidance as a clinician would do. I am mindful that had I have experienced this I may have felt differently in the moment.

I believe the fact that I was external to the clinical care, something I was clear to state at the start of the interview, aided more honest reflection from the women on experiences of obstetric care and interaction with professionals. Additionally, my position as a non-medical professional, external to general medical health services enabled me to take a position of naivety during the interviews. I asked for clarification on medical terminology used by the women, in doing so exploring and gaining a sense of each women’s understanding of medical terms. At times, some of the women appeared to look to me for answers if they couldn’t remember the exact name of a medication they were given or a procedure that took place. In the moment, I was aware that even though I did not know the answers, I was drawn to wanting to give suggestions and problem-solve. As such this was something I remained mindful of so as not to enter the role of rescuer and disrupt the woman’s narrative.

During the interviews, there was a narrative that women's emotional wellbeing was negated following the PPH in favour of a focus on physical wellbeing. I found myself becoming frustrated that women had experienced a lack of emotional support, particularly when some women commented on how they had found taking part in the interview and talking about their experiences helpful in processing their feelings and memories of the events. I was aware of this rising affect during the interviews and spent time processing these feelings in my reflective diary after it occurred and within supervision. I came to realise that my background in mental health meant that I was used to being part of systems that prioritise emotional wellbeing and where staff are trained and feel comfortable initiating discussions about the impact of life events on psychosocial wellbeing. After every interview, I wrote an entry in my reflective diary to reflect on process (e.g. attunement and interaction with the women, any children or partners; bias/assumptions that occurred; emotional impact of hearing about their experience) and procedural (written consent process, negotiating the recording device; flow of questions) parts of the interview.

### Data analysis

I was both drawn and daunted by framework analysis. I was drawn to it because I felt it offered a flexible structure and a transparent process that guided the management of the data to aid the interpretation process. However, after reading research articles that had applied framework analysis in practice I became daunted. Researchers had identified difficulties in developing the thematic framework in stage one and knowing when to move through the stages. In addition, many studies were conducted by multiple researchers who found the approach time consuming. At this point I was very aware of the fact that I was a novice qualitative researcher, having conducted a small number of thematic analysis projects. It was important at this point that I sought supervision from my trials unit supervisor, an experienced qualitative researcher who has applied framework analysis in practice. Supervision enabled me to reflect on my novice position but also develop competencies through data analysis practice sessions using NVivo PRO. I had never used NVivo before but I was keen to utilise this platform because of its built-in framework matrix functions. It was all a learning curve for me, and I took every opportunity to meet and talk to other qualitative researchers in the trials unit that had applied framework analysis in practice.

I found the data analysis very labour intensive. At times, it felt like it was an endless process. Framework analysis has several 'data management' stages and this took a substantial amount of time. However, the iterative nature of the thematic framework enabled me to work methodically back and forth within and across interviews without worrying that it was a fixed, definite

framework. When it came to the mapping and interpretation stage I felt completely immersed in the data and had developed ideas about patterns within and across women's narratives of the consent process. I realised the benefit of having spent a considerable amount of time in organising the data (stages 1-3) was that I had been interpreting the data long before the final stage through use of memos, notes and coding.

### OBS2 extra qualitative components

The OBS2 qualitative study protocol documented three sub-sections: interviews with women who had consented to the OBS2 trial; asynchronous focus group with health care professionals involved in gaining consent during the OBS2 trial and a face-to-face focus group with community midwives.

#### ***Community midwives focus group***

The rationale for interviewing the community midwives was to explore how they experienced discussing the antenatal OBS2 trial information with women on their caseload. Time was taken to develop the midwives focus group interview schedule with a senior midwife and researcher based within the trials unit (see Appendix 8). We wanted to focus on finding out the barriers to discussing the antenatal information with the women and midwives comfort and view on incorporating discussions about research trials in clinical consultations. I contacted a senior midwife who was a team leader for one of the community teams and despite OBS2 having finished the year before she was very positive about supporting me to hold a focus group. The focus group was arranged on three occasions between December 2016-March 2017 however it was cancelled each time. On the first occasion, it was cancelled due to my sickness and on the other two occasions due to the midwives needing to prioritise clinical caseload management because of high sickness in the teams. I was disappointed that I was unable to conduct this focus group as I felt it would have provided rich feedback on professionals view of the need and usefulness of antenatal trial information which could have been analysed alongside the women's feedback.

#### ***Consent-gaining health professionals focus group***

Asynchronous methods use a discussion forum to enable researchers and participants to see one another's questions and answers and respond over a set timeframe. Initially OBS2 was going to be a multi-centre trial however only Cardiff contributed to the trial. As such I felt the asynchronous methods no longer suited the design of the trial. In addition, I was aware that the parent trial had been conducted over a year ago and therefore healthcare professionals may not have clear

recollection of consent-gaining interactions. Immersion in the project enabled a different perspective to those who were managerially involved and as such I requested that I make a substantial amendment to the protocol to change the focus group from asynchronous to face-to-face. My rationale was that I believed the opportunity for professionals to interact and converse with one another face-to-face about the topic may promote rich discussion and prompt memories. Following ethics approval, I met with a consultant obstetrician who was part of the OBS2 parent trial and we discussed how best to contact doctors who had been involved in the consent-gaining process. Many doctors had moved to different hospitals as part of rotation in their medical training. I attempted to meet again with the obstetrician to develop interview questions but unfortunately, we could not find a mutual time to meet within the given time frame. The reality that the parent trial had been completed over a year ago, and health professionals were now involved in new clinical trials, impeded any progress or motivation in conducting the qualitative study within the time frame.

#### Rationale for journal

In consultation with the trials unit, I decided to write-up the empirical study for publication in the BMC pregnancy and childbirth journal. I was clear from the start that I wanted the study findings to be accessible to clinicians working in the specialty of obstetrics to help inform future clinical and research practice. I could have chosen a medical ethics journal, however I felt that this would have reduced the accessibility to every day clinicians.

#### Dissemination plan

As part of the qualitative dissemination plan, I offered to send a summary of the findings to the women who participated in the interviews. Those women who were interested in receiving this information will be sent the summary in Summer 2017. The OBS2 team are putting together an application for a larger randomised trial to develop their work (OBS3) and so I will be presenting the results of the research to them. Specifically, the findings of the qualitative study were used to inform the interview schedule for the OBS3 protocol. The trials unit has a newsletter and members of the unit often use a blog to disseminate the headlines of work that has recently been published. I will need to think with the wider OBS2 team about how to disseminate the information to the practitioners in the clinical service.

## Implications for clinical and research practice

### ***Informed consent: a process and an event***

Both the review and empirical study highlighted consent as both a dynamic, relational process between professional and patient and a legal event of signing documentation. Informed consent as process, as advocated by Lidz et al. and Katz (38, 39) has parallels to shared-decision making in clinical practice. Yet consent as solely an event, is heavily employed by health professionals in clinical and research settings (55). It is understandable that during a medical emergency, especially an obstetric emergency where care is divided between the woman and her baby, that professionals may focus on consent as an event: the legalities of disclosing information and asking for a decision. However, it is important for medical professionals to recognise that there is a need to engage in information sharing, discussion, support and validation so that patients might feel better able to decide on research enrolment during this distressing time. In addition, professionals are not obligated to understand the ethical theory underpinning informed consent (56). However it may help professionals to understand the ethics and values base such as self-determination, in order to implement consent processes in a more patient-centred and meaningful way in clinical and research practice (36): treating patients as unique individuals (57) and considering the patients values, views and circumstances (58).

## Relevance to and the role of Clinical psychologists

Clinical psychologists have extensive academic, research and clinical experience and are well positioned to hold senior leadership roles in healthcare. Clinical psychologists have meta-competencies (59) that add value to patient-centred care pathways, developing effective team-working and leading strategic development across research and clinical settings such as medicine and mental health (60). Clinical psychologists can promote the importance of collaboration in the professional-patient relationship and the impact of this on health outcomes (61).

### ***Role in research***

Clinical psychologists are scientist-practitioners (59) and are therefore competent in conducting research, providing therapeutic interventions and integrating the two domains. Skills in building rapport with individuals and delivering important information effectively can be useful when transitioning between clinician-researcher roles. Clinical psychologists, along with lay people, can offer different perspectives and suggestions to pure researchers, when developing research questions, ethics, protocols, stakeholder information sheets and consent pathways. Clinical

psychologists are skilled in collaboratively working with stakeholders in a multitude of complex settings and can therefore offer guidance for conducting research in hard-to-reach or vulnerable populations within medical (e.g. emergency trauma, palliative care, paediatrics) and mental health (learning disabilities, older adults, looked after children) services.

### ***Medical settings***

Clinical psychologists are increasingly employed in medical settings due to the recognition that patients should receive holistic and biopsychosocial care (62, 63). Clinical psychologists can offer a valuable psychosocial perspective, such as providing a systemic and relational context, that can complement the medical model. In addition, Clinical psychologists can be both embedded within a multi-disciplinary medical team or provide input into and across specialities. Ethical and practical challenges remain in the professional-patient process of ensuring informed consent for treatment in medical research trials and practice. Clinical psychologists can open dialogue with other medical professionals about the complexities of informed consent in both standard clinical practice and research trials and highlight the importance of the professional-patient relationship and communication in the informed consent process. Clinical psychologists can offer other health professionals training on the ethical theories of informed consent and a focus on consent as a relational process of information sharing and discussion rather than just a legal, procedural event based on disclosures of risks and signing a written document. They can also offer consultation and supervision for complex cases or consent dilemmas and promote psychological thinking drawing on formulation and theoretical skills and knowledge. Further to this, Clinical psychologists can be involved in strategic development, contributing or leading services and by consulting on clinical, research policies, procedures and more broadly government legislation.

### ***Obstetrics and perinatal settings***

There is increasing recognition of the value of employing clinical psychologists in obstetric and perinatal settings (64). Perinatal services are increasingly recognising the importance of psychological thinking and Clinical psychology leadership has been advocated in perinatal clinical guidelines such as National Institute (NICE) ‘Antenatal and Postnatal Mental Health guidance’ (65) and commissioning reports ‘guidance for commissioners of perinatal mental health services’ (66).

Clinical psychologists can provide preventative evidence-based interventions to women and their families. They can also provide indirect psychological interventions such as consultation, training

and supervision to other health professionals working across the antenatal, intrapartum and postpartum community and hospital pathway. They can work across the connected services to provide continuity of care, champion integration of services and empower active engagement of stakeholders: a key priority for health commissioners (61). A key role of Clinical psychology could be bridging the gap between perinatal medical and mental health services. The profession can play a valuable role in increasing awareness about the risk of emotional distress or psychological trauma for both women and their partners, during and following birth complications such as PPH.

### Impact of the research on my practice

I believe that this research has provided me with opportunities to develop both personally and professionally. Professionally I have developed specific research skills such as conducting systematic searches of databases, synthesising primary data, completing ethics applications, designing interview schedules, conducting interviews and conducting qualitative `data analysis. In addition, I experienced working as part of a clinical trials unit, interacting with experienced researchers, multiple clinical disciplines and stakeholders and adapting my language and communication style accordingly. I now have first-hand experience of conducting research focused on informing service delivery in the NHS, a goal I set at the start of training.

The research also emphasised to me the importance of communication and rapport and information-sharing with stakeholders in clinical practice. It also gave me knowledge of the legal, philosophical and ethical underpinnings of the concept of informed consent of which I didn't have a clear understanding of before. I plan to ensure that in therapeutic practice I engage more heartedly in consent conversations with stakeholders using principles and approaches from the process and conversation models of informed consent rather than perhaps.

### What I would have done differently

With hindsight, if I had been able to be part of the development of the OBS2 qualitative study I would have suggested several changes to the protocol. The applied protocol stipulated that women in the study be sent out the written participant information sheet via post. I would have amended the protocol to state that the interviewer would ask the woman during the phone call how they would like to be sent the written participant information sheet (via post or email) in advance, thus bringing the woman in to the decision-making from the start. Enabling the women to choose how



they would like the written participant information sent to them prior to the interview promotes open dialogue and patient choice.

In addition, I would have included the opportunity to discuss the thematic findings of the study with the women involved to enable respondent validity. I would have suggested that the main themes of the women's interviews be used to provide context and case summaries for discussion within the community midwives focus group and the health professionals focus group. I would hope this would provide a platform to share and discuss women's experiences with professionals to promote reflection on the consent-process from the professional's perspective. Ideally, interviews with the women would have taken place closer to their birth experience.

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## **Appendix 1: Submission guidelines for the International Journal of Emergency Medicine**

### **Reviews Criteria**

Reviews are a feature of the journal that may include, but are not limited to, the following types of articles:

- systematic and substantial syntheses of specific research areas,
- evaluations of progress in specified areas,
- critical assessments with respect to issues

within the scope of *International Journal of Emergency Medicine*.

### **Preparing your manuscript**

#### **Title page**

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review".
  - or for non-clinical or non-research studies: a description of what the article reports.
- list the full names, institutional addresses and email addresses for all authors:
  - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below.
- indicate the corresponding author.

#### **Abstract**

The abstract should not exceed 350 words and should be structured with a background, main body of the abstract and short conclusion. Please minimize the use of abbreviations and do not cite references in the abstract.

#### **Keywords**

Three to ten keywords representing the main content of the article.

#### **Background**

The Background section should explain the background to the article, its aims, a summary of a search of the existing literature and the issue under discussion.

#### **Main text**

This should contain the body of the article, and may also be broken into subsections with short, informative headings.

### **Conclusions**

This should state clearly the main conclusions and include an explanation of their relevance or importance to the field.

### **Declarations**

### **List of abbreviations**

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

### **Ethics approval and consent to participate**

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived).
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate.

Studies involving animals must include a statement on ethics approval.

See our [editorial policies](#) for more information.

If your manuscript does not report on or involve the use of any animal or human data or tissue, this section is not applicable to your submission. Please state "Not applicable" in this section.

### **Consent for publication**

If your manuscript contains any individual person's data in any form, consent to publish must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent to publish. You can use your institutional consent form or our [consent form](#) if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).

If your manuscript does not contain any individual persons data, please state "Not applicable" in this section.

### **Availability of data and materials**

For all journals, SpringerOpen strongly encourages all datasets on which the conclusions of the manuscript rely to be either deposited in publicly available repositories (where available and appropriate) or presented in the main paper or additional supporting files, in machine-readable format (such as spreadsheets rather than PDFs) whenever possible. Please see the list of recommended repositories in our [editorial policies](#).

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For all journals, authors must include an “Availability of data and materials” section in their article detailing where the data supporting their findings can be found. If you do not wish to share your data, please state that data will not be shared, and state the reason.

For instructions on how to cite your data and format this section see preparation/style and formatting.

### **Competing interests**

All financial and non-financial competing interests must be declared in this section. See our [editorial policies](#) for a full explanation of competing interests. If you are unsure whether you or any of your co-authors have a competing interest please contact the editorial office.

### **Funding**

All sources of funding for the research reported should be declared. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared.

### **Authors' contributions**

The individual contributions of authors to the manuscript should be specified in this section. Guidance and criteria for authorship can be found in our [editorial policies](#).

### **Acknowledgements**

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials.

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Group authorship: if you would like the names of the individual members of a collaboration Group to be searchable through their individual PubMed records, please ensure that the title of the collaboration Group is included on the title page and in the submission system and also include collaborating author names as the last paragraph of the “Acknowledgements” section. Please add authors in the format First Name, Middle initial(s) (optional), Last Name. You can add institution or country information for each author if you wish, but this should be consistent across all authors.

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You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

### **Endnotes**

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

### **How to format your references**

Examples of the Vancouver reference style are shown below. Please ensure that the reference style is followed precisely; if the references are not in the correct style, they may need to be retyped and carefully proofread.

**Web links and URLs:** All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. <http://tumor.informatics.jax.org/mtbwi/index.do>. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Authors may wish to make use of reference management software to ensure that reference lists are correctly formatted. An example of such software is Papers, which is part of Springer Science+Business Media.

### **Example reference style:**

#### *Article within a journal*

Smith JJ. The world of science. *Am J Sci.* 1999;36:234-5.

#### *Article within a journal (no page numbers)*

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. *BMC Medicine.* 2013;11:63.

#### *Article within a journal by DOI*

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. *Dig J Mol Med.* 2000; doi:10.1007/s801090000086.

#### *Article within a journal supplement*

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. *Blood* 1979;59 Suppl 1:26-32.

*Book chapter, or an article within a book*

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. *International review of cytology*. London: Academic; 1980. p. 251-306.

*OnlineFirst chapter in a series (without a volume designation but with a DOI)*

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. *Top Curr Chem*. 2007. doi:10.1007/128\_2006\_108.

*Complete book, authored*

Blenkinsopp A, Paxton P. *Symptoms in the pharmacy: a guide to the management of common illness*. 3rd ed. Oxford: Blackwell Science; 1998.

*Online document*

Doe J. Title of subordinate document. In: *The dictionary of substances and their effects*. Royal Society of Chemistry. 1999. [http://www.rsc.org/dose/title of subordinate document](http://www.rsc.org/dose/title%20of%20subordinate%20document). Accessed 15 Jan 1999.

*Online database*

Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. <http://www.healthwise.org>. Accessed 21 Sept 1998.

*Supplementary material/private homepage*

Doe J. Title of supplementary material. 2000. <http://www.privatehomepage.com>. Accessed 22 Feb 2000.

*University site*

Doe, J: Title of preprint. <http://www.uni-heidelberg.de/mydata.html> (1999). Accessed 25 Dec 1999.

*FTP site*

Doe, J: Trivial HTTP, RFC2169. <ftp://ftp.isi.edu/in-notes/rfc2169.txt> (1999). Accessed 12 Nov 1999.

*Organization site*

ISSN International Centre: The ISSN register. <http://www.issn.org> (2006). Accessed 20 Feb 2007.

*Dataset with persistent identifier*

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (*Sorghum bicolor*). *GigaScience Database*. 2011. <http://dx.doi.org/10.5524/100012>.

## Appendix 2: Literature search strategies

### EMBASE

1. (consent\* adj3 research\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
2. (accept\* adj3 research\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
3. (agree\* adj3 research\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
4. exp Emergency Medicine/
5. (emergenc\* adj1 medic\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
6. exp Emergency Service, Hospital/
7. (accident and emergency).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
8. a&e.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
9. emergency department\*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
10. (emergenc\* adj1 surg\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
11. (emergenc\* adj1 operat\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
12. (research\* adj3 participat\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
13. (emergenc\* adj2 situation\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
14. (informed consent\* adj3 research\*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
15. 1 or 2 or 3 or 12 or 14
16. 4 or 5 or 6 or 7 or 8 or 9 or 10 O 11.mp. or 13 [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]

17. exp intensive care/ or critical care medicine.mp.
18. exp emergency treatment/
19. exp emergency care/
20. exp emergency ward/
21. 16 or 17 or 18 or 19 or 20
22. 15 and 21
23. limit 22 to (english language and embase and yr="1947 - current" and article)

### **MEDLINE**

1. (consent\* adj3 research\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2. (accept\* adj3 research\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3. (agree\* adj3 research\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4. exp Emergency Medicine/
5. (emergenc\* adj1 medic\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6. exp Emergency Service, Hospital/
7. (accident and emergency).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8. a&e.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9. emergency department\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

10. (emergenc\* adj1 surg\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11. (emergenc\* adj1 operat\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12. (research\* adj3 participat\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
13. (emergenc\* adj2 situation\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
14. (informed consent\* adj3 research\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15. 1 or 2 or 3 or 12 or 14
16. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 13
17. exp Emergency Treatment/
18. emergenc\* ward\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
19. emergenc\* care\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
20. exp Critical Care/
21. exp Critical Illness/
22. critic\* care medicin\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
23. 16 or 17 or 18 or 19 or 20 or 21 or 22
24. 15 and 23
25. limit 24 to (english language and journal article and 1946-present)

## **PSYCHINFO**

1. (consent\* adj3 research\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2. (accept\* adj3 research\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3. (agree\* adj3 research\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
4. 1 or 2 or 3
5. exp Emergency Medicine/
6. (emergenc\* adj1 medic\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
7. exp Emergency Service, Hospital/
8. (accident and emergency).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
9. a&e.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
10. emergency department\*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
11. (emergenc\* adj1 surg\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
12. (emergenc\* adj1 operat\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
13. (research\* adj3 participat\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
14. (emergenc\* adj2 situation\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
15. (informed consent\* adj3 research\*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
16. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 14
17. 4 or 13 or 15
18. exp Intensive Care/
19. critical\* care\*.mp.
20. emergency\* treatment\*.mp.
21. emergency\* care\*.mp.

22. emergency\* ward\*.mp.
23. 16 or 18 or 19 or 20 or 21 or 22
24. 17 and 23
25. limit 24 to peer reviewed journal
26. limit 25 to (peer reviewed journal and english language)
27. limit 26 to yr="1860 -present"

### CINAHL

S23	S20 AND S21	<b>Limiters</b> - Published Date: 19840101-20161231; English Language; Peer Reviewed; Publication Type: Journal Article; Language: English <b>Search modes</b> - Boolean/Phrase
S22	S20 AND S21	<b>Search modes</b> - Boolean/Phrase
S21	S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S16 OR S17 OR S18 OR S19	<b>Search modes</b> - Boolean/Phrase
S20	S1 OR S2 OR S3 OR S4 OR S5 OR S15	<b>Search modes</b> - Boolean/Phrase
S19	(MH "Critical Care") OR "intensive care" OR (MH "Intensive Care Units")	<b>Search modes</b> - Boolean/Phrase
S18	(MH "Emergency Care") OR "emergency care"	<b>Search modes</b> - Boolean/Phrase
S17	"emergency ward"	<b>Search modes</b> - Boolean/Phrase
S16	(MH "Emergency Treatment") OR "emergency treatment"	<b>Search modes</b> - Boolean/Phrase
S15	AB research* W3 participat*	<b>Search modes</b> - Boolean/Phrase



S14	AB emergenc* W2 situation*	<b>Search modes</b> - Boolean/Phrase
S13	AB emergenc* W1 oper*	<b>Search modes</b> - Boolean/Phrase
S12	AB emergenc* W1 surg*	<b>Search modes</b> - Boolean/Phrase
S11	"emergency department"	<b>Search modes</b> - Boolean/Phrase
S10	"a&e"	<b>Search modes</b> - Boolean/Phrase
S9	"accident and emergency"	<b>Search modes</b> - Boolean/Phrase
S8	AB emergenc* W1 medic*	<b>Search modes</b> - Boolean/Phrase
S7	(MH "Emergency Service") OR "emergency service, hospital"	<b>Search modes</b> - Boolean/Phrase
S6	(MH "Emergency Medicine")	<b>Search modes</b> - Boolean/Phrase
S5	AB informed consent* W3 research*	<b>Search modes</b> - Boolean/Phrase
S4	AB agree* W3 research*	<b>Search modes</b> - Boolean/Phrase
S3	AB accept* W3 research*	<b>Search modes</b> - Boolean/Phrase
S2	AB consent* W3 research*	<b>Search modes</b> - Boolean/Phrase
S1	(MH "Consent (Research)")	<b>Search modes</b> - Boolean/Phrase

### Appendix 3: PICOS criteria tool

PICOS TOOL	<u>INCLUDED</u>	<u>EXCLUDED</u>
<b>PATIENT POPULATION</b>	<ul style="list-style-type: none"> <li>• ADULT PATIENTS (AGED 18 YEARS+)</li> <li>• INCLUDING WOMEN WHO ARE PREGNANT/OR DURING CHILDBIRTH IF MEDICAL EMERGENCY</li> <li style="text-align: center;"><b><u>AND</u></b></li> <li>• REQUIRED EMERGENCY / LIFE THREATENING MEDICAL TREATMENT</li> </ul>	<ul style="list-style-type: none"> <li>• PAEDIATRICS</li> <li>• PATIENTS WITH MINOR INJURIES IN AN EMERGENCY DEPARTMENT/SETTING</li> <li>• PSYCHIATRIC-RELATED MEDICAL EMERGENCIES</li> <li>• PATIENT POPULATION IS ED CONVIENANCE SAMPLE</li> <li>• UNCLEAR OF EXACT NATURE OF REASON FOR ADMISSION TO EMERGENCY DEPARTMENT</li> </ul>
<b>INTERVENTIONS</b>	<ul style="list-style-type: none"> <li>• INVITED TO ENROL IN EMERGENCY RESEARCH USING INFORMED CONSENT PROTOCOL</li> </ul>	<ul style="list-style-type: none"> <li>• CONSENT PROTOCOL FOR USUAL PRACTICE CLINICAL PROCEDURES</li> <li>• CONSENT PROTOCOL FOR NON-EMERGENCY RESEARCH</li> <li>• CONSENT USING ‘EXCEPTION FROM CONSENT’ OR ‘PROXY’ PROTOCOLS</li> </ul>
<b>COMPARATORS</b>	N/A	N/A
<b>OUTCOMES</b>	<ul style="list-style-type: none"> <li>• PATIENT EXPERIENCE /ATTITUDE/ PERCEPTION/VIEWS/OPINIONS</li> </ul>	<ul style="list-style-type: none"> <li>• COMMUNITY CONSULTATION EXPERIENCE/ ATTITUDE/PERCEPTION/ VIEWS/ OPINIONS ONLY</li> <li>• SURROGATE DECISION MAKER EXPERIENCE/ ATTITUDE / PERCEPTION /VIEWS/OPINIONS ONLY</li> <li>• PARENT EXPERIENCE/ATTITUDE/PERCEPTION /VIEWS/OPINIONS</li> </ul>
<b>STUDY DESIGN</b>	<ul style="list-style-type: none"> <li>• QUALITATIVE STUDY</li> <li>• MIXED METHOD; QUALITATIVE METHOD</li> </ul>	<ul style="list-style-type: none"> <li>• QUANTITATIVE OUTCOMES ONLY</li> </ul>
<b>OVERALL DECISION</b>	YES	NO

#### Appendix 4: Critical appraisal of the studies

CASP	1. Clear Aims?	2. Is a Qualitative Methodology appropriate?	3. Research Design appropriate to aims?	4. Recruitment strategy appropriate?	5. Data collection appropriate?	6. Researcher/Participant relationship considered?	7. Ethics considered?	8. Data analysis rigorous?	9. Clear statement of findings?	10. Value of research
<p><b>Gammelgaard et al. (2004)</b></p> <p><b>Danish study</b></p> <p><b>7/10 (70%)</b></p>	Aims explained and relevance justified	Qualitative method appropriate for aims	Statement that grounded theory was used but no reasoning behind this method.	Recruitment strategy and sampling explained. Strategic sampling stated but not linked to grounded theory method.	Data collection process outlined. Q's in interview schedule not stated directly although examples given in findings. No mention of saturation	Interviewer reported as not part of trial - different discipline. 2 pilot interviews were critically evaluated by experts in qualitative interviewing.	Ethics mentioned in relation to RCT but not qualitative part of study. No report of gaining consent for the interview process or confidentiality explained.	No examples given of grounded theory analysis process. Unclear who analysed the data, no mention of limitations or considering potential bias. Sufficient data is presented to support findings	Extensive findings presented, linked to data, detailed discussion. No critical review of credibility of findings.	Findings linked to acute trial literature. Future research ideas given
	Yes-1	Yes-1	Can't tell-0	Yes-1	Yes-1	Yes-1	No-0	Can't tell-0	Yes-1	Yes-1

CASP		1. Clear Aims?	2. Is a Qualitative Methodology appropriate?	3. Research Design appropriate to aims?	4. Recruitment strategy appropriate?	5. Data collection appropriate?	6. Researcher/Participant relationship considered?	7. Ethics considered?	8. Data analysis rigorous?	9. Clear statement of findings?	10. Value of research
Mangset et al. (2008)	Norwegian study	Aims reported and relevance identified	Qualitative method appropriate as exploring patient's experience and views and seeing if they remain the same from acute to recover stage	Data analysis approach stated as 'described by <u>Malterud</u> and based on Giorgi's phenomenological method'	Recruitment strategy and sampling explained and justified.	Data collection process outlined. No interview schedule given. No reference to saturation.	No mention of researcher & participant relationship. No discussion regarding bias in question or data collection stage.	States study was approved by 'Regional Committee for Ethics in Medical Research'. States patients were given info sheet but no mention of gaining consent or confidentiality	Process of analysis described but not in-depth. 4 independent analysts, group discussion on interpretations. Sufficient data used to support findings. Some suggestions for possible bias to the results	Clear findings stated and linked to original question. Linked to previous supporting/conflicting literature findings. Authors discuss credibility of findings.	Links to previous literature, discussed ethics and faults in standardisation of consent processes in acute care. Ideas for acute clinical research consent protocols.
7/10 (70%)		Yes-1	Yes-1	Yes-1	Yes-1	Can't tell-0	No-0	Can't tell-0	Yes-1	Yes-1	Yes-1

CASP		1. Clear Aims?	2. Is a Qualitative Methodology appropriate?	3. Research Design appropriate to aims?	4. Recruitment strategy appropriate?	5. Data collection appropriate?	6. Researcher/Participant relationship considered?	7. Ethics considered?	8. Data analysis rigorous?	9. Clear statement of findings?	10. Value of research
Lawton et al. (2016)	UK study	Aims stated and rationale given	Qualitative methodology discussed and rationale given.	Statement and rationale given for use of 'constant comparison' as the method of choice	Recruitment strategy and purposive sampling explained and justified.	Detailed data collection process given including questions, saturation and amendments to Q's after each interview	Some consideration given to relationship between researchers & pp's during Q development & data collection, including bias and strategies to reduce these	Ethical approval stated. Detail of recruitment info packs and issues of consent and confidentiality discussed.	Detailed analysis process described. Detailed findings reported and multiple examples linking the findings to the data were given. 2 researchers analysed the data independently	Clear findings reported & linked to original Q. Findings discussed and compared in relation to previous study findings.	Valuable findings to add to the existing literature. Future research and clinical practice ideas given.
9/10 (90%)		Yes-1	Yes-1	Yes-1	Yes-1	Yes-1	Can't tell-0	Yes-1	Yes-1	Yes-1	Yes-1

MMAT <sup>2</sup>	<b>1. Qualitative (QUAL) method</b> <ul style="list-style-type: none"> <li>○ Are the sources of QUAL data relevant to the question?</li> <li>○ Is the process for analysing the QUAL data relevant to the question?</li> <li>○ Is appropriate consideration given to how findings relate to the context?</li> <li>○ Is appropriate consideration given to how findings relate to researcher's influence?</li> </ul>	<b>2. Quantitative (QUAN) descriptive method</b> <ul style="list-style-type: none"> <li>○ Is the sampling strategy relevant to the QUAN aspect of the question?</li> <li>○ Is the sample representative of the population under study?</li> <li>○ Are measurements appropriate (clear origin, validity known, standard instrument)?</li> <li>○ Is there an acceptable response rate (60%+)?</li> </ul>	<b>3. Mixed Methods (QUAL &amp; relevant QUAN criteria must also be applied)</b> <ul style="list-style-type: none"> <li>○ Is the MM design relevant to address the question?</li> <li>○ Is the integration of QUAL &amp; QUAN relevant to address the question?</li> <li>○ Is appropriate consideration given to the limitations associated with this integration (e.g. divergence of QUAL &amp; QUAN data or results) in a triangulation design?</li> </ul>
<b>Dickert, Fehr et al.,(2015)</b>  <b>STEMI trial</b>  <b>USA</b>  <b>TOTAL</b> <b>50%</b>	<ul style="list-style-type: none"> <li>○ Selection and eligibility of participants (pp's) clear and relevant to study question.</li> <li>○ Interviews conducted face to face in hospital and one via telephone. All audio recorded and conducted by 1 person. Interview schedule reported and relevant to question. Reported use of 'Template Analysis' with reference. Deductive and inductive coding in accordance with aims. Coding reviewed by more than one person.</li> <li>○ Some discussion regarding influence of context on QUAL findings e.g. discussion post-consent and as such only assessing recall rather than understanding at the time.</li> <li>○ Lack of critical reflection on influence of researcher during stages of the research process. No mention of influence of interactive face to face interview method. No explicit reference to profession of interviewer.</li> </ul>	<ul style="list-style-type: none"> <li>○ Cross-sectional design. Lack of details of specific sample strategy. Inclusion &amp; exclusion criteria explained.</li> <li>○ Sample relevant to study question. Unclear of representative of population under study due to no information regarding total pp's enrolled in parent trial.</li> <li>○ Variables defined and measurements (Likert scale question) relevant to study aim. Questions devised by authors and used in previous study (2013 RAMPART).</li> <li>○ No response rate reported.</li> </ul>	<ul style="list-style-type: none"> <li>○ Embedded</li> <li>○ Rationale given for MM: assess patient's perspectives of consent decisions in emergency cardiac trials.</li> <li>○ MM relevant to study question. QUAL &amp; QUAN integrated during data collection-analysis and interpretation but not explicitly stated by authors. No details of who conducted QUAL &amp; QUAN analysis.</li> <li>○ Some discussion of possible limitations of MM design e.g. unable to determine prevalence of attitudes toward involvement in research decisions. The study assessed recall not consent in-vivo, which could be achieved using a different design e.g. direct observation of consent process during emergency trials.</li> </ul>
	3/4	2/4	3/3

<sup>2</sup> the overall quality of a MM combination cannot exceed the quality of its weakest component. Thus, the overall quality score is the lowest score of the study components. The score is 25% (1) when QUAL=1 or QUAN=1 or MM=0; it is 50% (2) when QUAL=2 or QUAN=2 or MM=1; it is 75% (3) when QUAL=3 or QUAN=3 or MM=2; and it is 100% (4) when QUAL=4 or QUAN=4 or MM=3.

## **Appendix 5: Submission guidelines for BMC Pregnancy and Childbirth**

### **Research article**

#### ***Criteria***

Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research will not be considered.

BMC Pregnancy and Childbirth strongly encourages that all datasets on which the conclusions of the paper rely should be available to readers. We encourage authors to ensure that their datasets are either deposited in publicly available repositories (where available and appropriate) or presented in the main manuscript or additional supporting files whenever possible. Please see Springer Nature's information on recommended repositories. Where a widely established research community expectation for data archiving in public repositories exists, submission to a community-endorsed, public repository is mandatory.

### **Preparing your manuscript**

The information below details the section headings that you should include in your manuscript and what information should be within each section. Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

### **Title page**

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
  - o "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
  - o or for non-clinical or non-research studies a description of what the article reports
- list the full names, institutional addresses and email addresses for all authors or if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

### **Abstract**

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- Background: the context and purpose of the study
- Methods: how the study was performed and statistical tests used
- Results: the main findings

- **Conclusions:** brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration

### **Keywords**

Three to ten keywords representing the main content of the article.

### **Background**

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

### **Methods**

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

### **Results**

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

### **Discussion**

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

### **Conclusions**

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

### **List of abbreviations**

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

### **Declarations**

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and material
- Competing interests



- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

### **Ethics approval and consent to participate**

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate.

Studies involving animals must include a statement on ethics approval. See our editorial policies for more information. If your manuscript does not report on or involve the use of any animal or human data or tissue, please state “Not applicable” in this section.

### **Consent for publication**

If your manuscript contains any individual person's data in any form (including individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.

You can use your institutional consent form or our consent form if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication). See our editorial policies for more information on consent for publication. If your manuscript does not contain data from any individual person, please state “Not applicable” in this section.

### **Availability of data and materials**

All manuscripts must include an ‘Availability of data and materials’ statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access. Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]
- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- All data generated or analysed during this study are included in this published article

[and its supplementary information files].

- The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.

- Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

- The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].

- Not applicable. If your manuscript does not contain any data, please state 'Not applicable' in this section.

More examples of template data availability statements, which include examples of openly available and restricted access datasets, are available here.

BioMed Central also requires that authors cite any publicly available data on which the conclusions of the paper rely in the manuscript. Data citations should include a persistent identifier (such as a DOI) and should ideally be included in the reference list. Citations of datasets, when they appear in the reference list, should include the minimum information recommended by DataCite and follow journal style. Dataset identifiers including DOIs should be expressed as full URLs. For example:

Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare.

2014. <http://dx.doi.org/10.6084/m9.figshare.853801>

### **Competing interests**

All financial and non-financial competing interests must be declared in this section. See our editorial policies for a full explanation of competing interests. If you are unsure whether you or any of your co-authors have a competing interest please contact the editorial office.

Please use the authors initials to refer to each author's competing interests in this section.

If you do not have any competing interests, please state "The authors declare that they have no competing interests" in this section.

### **Funding**

All sources of funding for the research reported should be declared. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared.

### **Authors' contributions**

The individual contributions of authors to the manuscript should be specified in this section.

Guidance and criteria for authorship can be found in our editorial policies. Please use initials to refer to each author's contribution in this section, for example: "FC analyzed and interpreted the patient data regarding the hematological disease and the transplant. RH performed the histological examination of the kidney, and was a major contributor in writing the manuscript. All authors read and approved the final manuscript."

### **Acknowledgements**

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section. See our editorial policies for a full explanation of acknowledgements and authorship criteria. If you do not have anyone to acknowledge, please write "Not applicable" in this section. Group authorship (for manuscripts involving a collaboration group): if you would like the names of the individual members of a collaboration Group to be searchable through their individual PubMed records, please ensure that the title of the collaboration Group is included on the title page and in the submission system and also include collaborating author names as the last paragraph of the "Acknowledgements" section. Please add authors in the format First Name, Middle initial(s) (optional), Last Name. You can add institution or country information for each author if you wish, but this should be consistent across all authors. Please note that individual names may not be present in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

### **Authors' information**

This section is optional.

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

#### **Endnotes**

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

### **References**

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. The reference numbers must be finalized and the reference list fully formatted before submission.

Examples of the BioMed Central reference style are shown below. Please ensure that the reference style is followed precisely. See our editorial policies for author guidance on good citation practice.

**Web links and URLs:** All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. <http://tumor.informatics.jax.org/mtbwi/index.do>. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link (e.g. for blogs) they should be included in the reference.

Example reference style:

*Article within a journal*

Smith JJ. The world of science. *Am J Sci.* 1999;36:234-5.

*Article within a journal (no page numbers)*

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. *BMC Med.* 2013;11:63.

*Article within a journal by DOI*

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. *Dig J Mol Med.* 2000; doi:10.1007/s801090000086.  
114

*Article within a journal supplement*

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. *Blood* 1979;59 Suppl 1:26-32.

*Book chapter, or an article within a book*

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. *International review of cytology.* London: Academic; 1980. p. 251-306.

*Online First chapter in a series (without a volume designation but with a DOI)*

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. *Top Curr Chem.* 2007. doi:10.1007/128\_2006\_108.

*Complete book, authored*

Blenkinsopp A, Paxton P. *Symptoms in the pharmacy: a guide to the management of common illness.* 3rd ed. Oxford: Blackwell Science; 1998.

*Online document*

Doe J. Title of subordinate document. In: *The dictionary of substances and their effects.* Royal Society of Chemistry. 1999. <http://www.rsc.org/dose/title of subordinate document>. Accessed 15 Jan 1999.

*Online database*

Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998.  
<http://www.healthwise.org>. Accessed 21 Sept 1998.

*Supplementary material/private homepage*

Doe J. Title of supplementary material. 2000. <http://www.privatehomepage.com>. Accessed 22 Feb 2000.

*University site*

Doe, J: Title of preprint. <http://www.uni-heidelberg.de/mydata.html> (1999). Accessed 25 Dec 1999.

*FTP site*

Doe, J: Trivial HTTP, RFC2169. <ftp://ftp.isi.edu/in-notes/rfc2169.txt> (1999). Accessed 12 Nov 1999.

*Organization site*

ISSN International Centre: The ISSN register. <http://www.issn.org> (2006). Accessed 20 Feb 2007.

*Dataset with persistent identifier*

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (*Sorghum bicolor*). GigaScience Database. 2011.  
<http://dx.doi.org/10.5524/100012>.

*Figures, tables additional files*

See General formatting guidelines for information on how to format figures, tables and additional files.

## Appendix 6: Qualitative study ethics letter

Scotland A Research Ethics Committee

Research Ethics Service  
2<sup>nd</sup> Floor Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Telephone: 0131 465  
5680  
www.hra.nhs.uk



**Scotland A REC**  
2<sup>nd</sup> Floor Waverley Gate  
2 - 4 Waterloo Place  
Edinburgh  
EH1 3EG  
Tel: 0131-465-5679

23 December 2015

Aude Espinasse  
Research Associate/Trial Manager  
South East Wales Trials Unit  
Institute of Primary Care and Public Health  
Cardiff University  
7th Floor, Neuadd Meirionnydd  
Heath Park  
Cardiff  
CF14 4YS

Dear Aude,

<b>Study title:</b>	<b>Fibrinogen concentrate versus placebo for treatment of postpartum haemorrhage: a prospective double blind randomised control trial</b>
<b>REC reference:</b>	<b>13/SS/0008</b>
<b>Protocol number:</b>	<b>SPON 1155-12</b>
<b>EudraCT number:</b>	<b>2012-005511-11</b>
<b>Amendment number:</b>	<b>13/SS/0008/AM20</b>
<b>Amendment date:</b>	<b>01 December 2015</b>
<b>IRAS project ID:</b>	<b>108633</b>

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Chairman Dr Ian Zealley  
Vice-Chairman Dr Colin Selby

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (CTIMP) [Notice of Substantial Amendment Form]		01 December 2015
Other [Sponsor Amendment Assess-Signed]		25 November 2015
Participant information sheet (PIS) [PIS-Women]	V1.0	20 October 2015
Participant information sheet (PIS) [PIS-Legal Representative]	V1.0	16 October 2015
Participant information sheet (PIS) [PIS-Online Focus Group]	V1.0	03 November 2015
Participant information sheet (PIS) [PIS-Community Midwife]	V1.0	16 October 2015
Participant information sheet (PIS) [Consent Form-Participant Interview]	V1.0	03 November 2015
Participant information sheet (PIS) [Consent Form-Face to Face Focus Group]	V1.0	03 November 2015
Participant information sheet (PIS) [Consent Form-Online Focus Group]	V1.0	03 November 2015
Participant information sheet (PIS) [Consent Form-Legal Representative]	V1.0	03 November 2015
Research protocol or project proposal [Protocol-TC]	V7.0	26 November 2015
Research protocol or project proposal [Protocol-Clean]	V7.0	26 November 2015

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

#### R&D approval

*All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.*

#### Statement of compliance

***The Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.***

***The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.***

***The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.***

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>13/SS/0008: Please quote this number on all correspondence</b>
---

Yours sincerely



**Dr Colin Selby  
Chair**

E-mail: [manx.neill@nhslothian.scot.nhs.uk](mailto:manx.neill@nhslothian.scot.nhs.uk)

Tel: 0131-465-5680



## Appendix 7: OBS2 Antenatal Information Sheet



### Antenatal Information for women A study of treatment for bleeding during childbirth



#### What is the study about?

Staff at this hospital are working on a treatment for women who have a severe bleed during childbirth.

Although severe bleeding during childbirth only happens in around 1 in every 200 births we want to let all women know about this important study.

The new treatment is called Fibrinogen and it helps blood to clot. We want to find out if giving Fibrinogen will reduce the amount of bleeding and the need for a blood transfusion.

We will only give Fibrinogen to women who have a blood test at the time of bleeding that shows their blood is not clotting as well as normal.

If you were to bleed during childbirth, we would like to ask you to join the study. When a woman is bleeding she often feels very unwell. This is why we are asking all women to think about the study before their baby's birth.

#### If you were to bleed, what would being in the study involve?

1. You would still have **ALL** the usual treatments for bleeding such as fluids and drugs through a drip. If you needed a blood transfusion and plasma, the standard way of improving blood clotting, you would still be given them.
2. You would have an extra blood test to check how well your blood was clotting.
3. If your blood was thin, you would be given Fibrinogen or a placebo (dummy drug) while we wait for the routine blood clotting treatment to arrive. We do this as this is the very best way to test new treatments.
4. If you are still bleeding when the routine treatment arrives you would be given it.
5. We would follow your progress until you went home.
6. We would ring you when your baby was 6 weeks old to see how you both are.

#### Please tick one box

I have read and understood the information. If I bleed during childbirth, I may want to join the study.	<input type="checkbox"/>
If I bleed during childbirth I do not want to join the study.	<input type="checkbox"/>

Signed ..... Date .....



**More information about the OBS2 study is on the back of this form.**

Version 1.6, dated 23.05.2013



**What is severe bleeding during childbirth?** A small amount of bleeding immediately following birth is normal and should not worry you. About 1 in 20 women bleed more than 2 pints of blood and this is called a postpartum haemorrhage or PPH. Around 1:200 women have a severe bleed and it is only these women who will be invited into this study. There are many treatments for PPH, and if you have increased bleeding at the time of your baby's birth you will be given all the treatments needed whether you take part in this study or not.

**Why is the study needed?** One reason why some women bleed during childbirth is because their Fibrinogen level is low. This means their blood takes longer to clot. Fibrinogen is known to help with blood clotting in other medical conditions, such as after major surgery. It is not currently known whether giving fibrinogen will help with bleeding during childbirth. A low Fibrinogen level and bleeding happens during 1 in 200 births.

**What is Fibrinogen?** Fibrinogen is a substance in the human body which helps to make strong blood clots. We know that if a woman has a low level of fibrinogen at the time of childbirth bleeding, she is more likely to have a bigger bleed and need a blood transfusion.

**What will happen to me if I take part in this study?** You will only be invited to take part in the study if you have increased bleeding during childbirth. If you choose to take part, as well as having all the normal treatments, we will regularly check how well your blood is clotting. Measuring clotting in the laboratory takes up to an hour. In the study we will be checking blood clotting with a test called a FIBTEM. A FIBTEM test is done on delivery suite and gives a result in 10-15 minutes. This study is also looking at whether using a FIBTEM test is helpful during childbirth bleeding. Most women, when bleeding, have normal blood clotting. If this is the case, you won't need extra treatment to help your blood clot. If your blood is thin, we will urgently order plasma, which is the routine treatment used to thicken the blood, from our blood bank. Before the plasma arrives we will give you either Fibrinogen or a placebo (a dummy treatment) directly into a vein.

If you join in the study a member of the study team will talk to you when you are feeling better, usually the following day, to explain the study in detail. After six weeks, a midwife will contact you by telephone to see how you are and how you are feeling.

**It is important to remember that your routine care during pregnancy and birth, and the treatment of bleeding, will not change in any other way by being part of this study.**

**Will my medical results be kept safe? And what will happen to the results?** The study information will be kept confidential. The results will be published in medical journals but will not include any individual or personal information about you.

**Thinking about the study?** If you are bleeding at the time of childbirth you may not be well enough to decide whether or not you want to be in the study. This is why we would like you to think about the study now. You do not need to make a decision about taking part in this study now but you can tell us that you wouldn't want to take part.

**What happens if I say I am interested in joining the study?**

If you have increased bleeding during childbirth and are well enough, a doctor or midwife will discuss the study with you to ask if you want to take part.

If you are not well enough to think about the study yourself, we will ask the person with you whether they think you would want to be in the study. If there is no one with you who can decide on your behalf we will ask a person looking after you who is not involved in the study.

As soon as you are well enough (usually the next day) we will talk to you about what happened and ask you whether you agree to stay in the study. If you decide that you don't we will remove all your information from the study and not look at any of your medical records.

**If you have any questions about the study please talk to your midwife or obstetrician. If you still have questions then they will arrange for you to talk to one of the study team.**

**More detailed study information is available on request from your midwife or by contacting the study team.**

This leaflet was prepared by the: OBS2 study team

## Appendix 8: Interview Schedule

### Interview Question Schedule:

Thank you for taking the time to speak to me today, as I explained on the phone what we talk about today will be kept confidential. I would like to record our conversation however only direct members of the team and myself will have access to them. They will not be labelled with any information that identifies you; they will be labelled as participant 1, 2, 3 etc. This is to ensure that your identity is protected.

I'd like to check that after going through the above you are still happy to talk to me and you are happy for the conversation to be recorded?

I would like to hear about your experiences and your opinions on certain topics, so there are no right or wrong answers. Anything you say will be really helpful. One thing I would like to mention is that sometimes talking about upsetting or stressful past events brings up strong emotions. If you start to feel overwhelmed or uncomfortable, please let me know at any time and we can talk a break or stop the conversation altogether.

The final thing I would like to check out with you before we start is how do you refer to what happened – do you use the term post partum haemorrhage or is there another term that you relate more to? |

### Part 1: The women's experience of pregnancy, birth and having a PPH

#### **1. Could you tell me about your birth experience?**

*PROMPTS for PPH narrative if needed:*

*What were your expectations and feelings leading up to going in to hospital?*

*What was your experience of labour and the birth?*

*Were you aware of any complications?*

*Did anyone explain what was happening? What did they say?*

*Can you remember how you felt at the time?*

*Consider safety / control*

*Who did you have around you at this time? (family/friends)*

*Did any professionals stand out during this time?*

*Positive and negative views*

*Consider their role in PPH management*

*Women's perceived competency of that prof*

*Transparency in terms of info given*

*Emotional responsiveness / reassurance*

*If PPH happened after the birth ask "could you tell me about your experience of having a PPH, how soon after the birth did this take place? What was your awareness of where your baby was?*

#### **Did you have an opportunity to talk to anybody about this experience?**

*PROMPTS:*

*Who did you talk to? Was it a professional you had met during the birth?*

*How long after the PPH was this?  
Did you request this or was it offered?  
What did you talk about?*

**(Partner /Legal rep experience - if not there ask the women about their perception of how their partner felt during this time)**

**Could you tell me about your experience during the birth of your child?**

*PROMPTS:*

*How did you feel during this process?*

*Were you aware of the complications?*

*If not when did you become aware that there had been complications?*

*What information were you given by professionals?*

*Were you able to stay with your partner the whole time? How did you feel about this?*

*Did you have a chance to talk to anybody about your experiences?*

**Part 2: The consent process** *(explain consent is research word for agreeing to take part)*

We are interested in finding out your experience of being invited into the PPH clinical research trial called OBS2 *(recap if needed)* so we can think about the best way to invite women to take part in the future.

**Women**

**a) Stage 1 booking**

**When can you remember the first time that a professional spoke to you about OBS2?**

**What were your thoughts about the OBS2? Did you realise that this was a research clinical trial and not standard practice?**

**What made you not opt out?**

**Did hearing about the study for complications in birth in the initial stages of pregnancy cause any anxiety? *(Elicit: is it appropriate / necessary to tell 36,000 women per year about the trial as per guidelines or does this provoke unnecessary anxiety?)***

**b) Stage 2 PPH / bleeding**

**At the time of the bleeding, did someone talk to you about consent to take part in OBS2?**

**If so, who do you remember talking to about consent?**

*PROMPTS:*

*Was this someone you had met before? How did this feel?*

*When did you talk to this person?*

*Where (location) were you when you talked to this professional?*

*What did you talk about?*

*How did you feel about talking about consent at this time?*

*Did you feel you had time to process / understand what they had said to you?*

*If not, do you remember someone else talking about consent on your behalf?*

**c) Stage 3 confirmation of consent post PPH**

**Did anyone approach you after the PPH to talk to you about the consent you gave at the time of the bleed?**

**If so, how soon after you experienced the PPH did professionals talk to you to again?**

*PROMPTS:*

*What did you talk about? [consider whether they spoke about their experience as well as consent process]*

*Was this helpful?*

**d) Overall consent process & future directions**

**Did you find the consent process acceptable?**

**How can we make the process easier / better?**

**What changes would you suggest making about how we gain consent for clinical research studies like OBS2?**

*Possible ideas to discuss:*

*Succinct info sheet to read by self or with partner or staff?*

*Verbal descriptions and summaries?*

*Antenatal consent?*

**Partner (if there)**

**What was your experience of the OBS2's consent process?**

*PROMPTS:*

*Were you involved in this discussion? Did you act on behalf of your partner?*

*What information were you given?*

*How did you feel about this process?*

*How did you feel about the timing of this process?*

**Part 3: Closing**

Is there anything else you would like to add that perhaps you think I have missed or you feel is significant?

Is there anything further you would like to know about the research clinical trial?

.....

Thank you for taking the time to talk to me today.

*Give details about counselling, contact details for hospital professionals who they are able to speak to or other agencies.*

## Appendix 9: Participant Information Sheet



### **Fibrinogen concentrate to treat postpartum haemorrhage – OBS2 Study**

#### **PARTICIPANT INFORMATION SHEET:**

#### **OBS2 qualitative interview study: Exploring consent in emergency situations**

We are contacting you as you have agreed when taking part in the OBS2 study to be contacted for further research on post-partum haemorrhage. The OBS2 study involves asking women whether they would like to take part (consent) in a study during an emergency. We would like to find out about your experiences of consenting to OBS2.

Here is some information about the study. Feel free to talk to family and friends about it or discuss it with the research team.

#### **1. What is this study about?**

- You have already agreed to take part in the OBS2 study which aims to find out if giving Fibrinogen will reduce the amount of bleeding and the need for a blood transfusion in severe bleeding during childbirth.
- In this linked study, we would like to explore women's experiences of consenting to the OBS2 study and ways in which the consent process can be improved.

#### **2. Why have I been invited?**

- We are contacting you as you have agreed when taking part in the OBS2 study to be contacted for further research.

#### **3. Do I have to take part?**

- **No.** It is up to you whether or not you want to take part in the study. Deciding to take part will not affect the standard of care you receive now or in the future. If you do want to take part, you will need to provide written consent to take part, by signing and dating the consent form.

#### **4. What will happen to me if I take part?**

- If you say yes (consent) to join this interview study, a researcher will contact you to arrange a convenient time and place to meet and talk about your experiences and views. We would like to audio-record the interview so that we have a full record of what you said.

#### **5. What are the possible benefits or disadvantages of taking part?**

- There are unlikely to be any direct benefits for you but this interview study may provide us with important information on what women think about ways of recruiting people into a research study in an emergency situation. Your views are very important to us. We hope that you will enjoy sharing your views with the researcher.
- It is possible that some people may find it upsetting to talk about their experience. You can choose to stop the interview at any time. If you feel distressed after the interview you can discuss your birth experience with a senior member of hospital staff (contact details below). If you would like we can provide you with contact details of local support including your Health Visitor and GP.

**6. Will my taking part be kept confidential?**

- **Yes**, all information provided will be treated confidentially by the research team. This information will be stored securely by the South East Wales Trials Unit (SEWTU), who is running the study, according to the 1998 Data Protection Act. Your name will not be included in any reports or presentations.

**7. What if I do not want to carry on being part of the study?**

- You can decide to stop taking part at any time during the study, without giving a reason. If you decide to stop taking part, your medical care or legal rights will not be affected in any way.

**8. What will happen to the results of the research study?**

- At the end of the study the results will be published in appropriate journals and presented at conferences. You will not be identified.
- If you would like, we can send a summary of the results after they have been published in the relevant journal(s) for you to read. You will not be identified in any summary or report.

**11. Who has funded and approved the study?**

- This study has been funded by CSL Behring. It has been looked at by an independent Research Ethics Committee. Their job is to protect your safety, rights, wellbeing and dignity.

**12. What if there is a problem?**

- If you are not happy about anything that is happening to you in the study, please let the researcher know or contact the OBS2 Trial Manager (contact details below).

Thank You for Considering Taking Part In This Study

**Please do not hesitate to contact the OBS2 Trial Manager for further information:**

Ms Aude Espinasse  
South East Wales Trials Unit (SEWTU)  
School of Medicine  
Cardiff University  
7th Floor  
Neuadd Meirionnydd  
Heath Park  
Cardiff  
CF14 4YS

email: [espinasseam@cardiff.ac.uk](mailto:espinasseam@cardiff.ac.uk)  
phone: 02920 687512  
fax: 02920 687612



## Appendix 10: Participant consent form



### CONSENT FORM

**Title of Project:** OBS2 qualitative interview study: Exploring consent in emergency situations

Please write your initials in each box

1. I confirm that I have read and understood the participant information sheet (version 1.0) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time.
3. I am willing to discuss my experience and beliefs about consenting to the OBS2 study. I understand that the interview will be audio recorded and the data transcribed. Any information I provide will be kept confidential. All published quotes will be anonymised and comments will not be attributed to any locality.
4. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

Witnessed by:

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

### Appendix 11: A section of the thematic framework

Nodes							
6. Recollection and views on antenatal consent process			0	0	30/03/2017 21:15	CP	
6.1. First memory of OBS2 trial			10	12	07/04/2017 17:24	CP	
6.2. Awareness of OBS2 antenatal consent opt out form			0	0	29/03/2017 19:29	CP	
6.2.1. Aware (before prompting)			5	7	07/04/2017 17:22	CP	
6.2.2. No recollection (even after prompting)			2	4	07/04/2017 17:22	CP	
6.2.3. Recollection (only after prompting)			6	9	22/04/2017 18:46	CP	
6.3. Acceptability of antenatal consent			14	17	01/04/2017 14:47	CP	
6.4. Midwife consistency and rapport during pregnancy			2	2	01/04/2017 15:22	CP	
6.5. Other			2	3	06/04/2017 11:22	CP	
7. Experience of consenting to OBS2 trial			0	0	30/03/2017 21:24	CP	
7.1. Timing of actual consent			14	26	29/03/2017 19:41	CP	
7.2. Ability to give informed consent for OBS2			12	28	29/03/2017 19:24	CP	
7.3. Partners role during OBS2 consent process			12	18	29/03/2017 19:37	CP	
7.4. Interaction and familiarity with Doctor seeking consent			9	11	29/03/2017 19:33	CP	
7.5. Reasons for enrollment in OBS2			12	16	29/03/2017 19:26	CP	
7.6. Consent checked during recovery from PPH in hospital			13	19	01/04/2017 15:07	CP	
7.7. Acceptability of consent			13	24	01/04/2017 13:53	CP	
7.8. Confusion about consent			3	5	09/04/2017 17:27	CP	
7.9. Other			3	3	06/04/2017 11:21	CP	

## Appendix 12: Two examples of indexing

I:	Yeah.	<ul style="list-style-type: none"> <li>7.4. Interaction and familiarity with Doctor seeking consent</li> <li>5.4. woman's physical health</li> <li>3.3. Response to bleeding</li> <li>7.1. Timing of actual consent</li> <li>3.7. Opportunity to talk to someone about PPH experience               <ul style="list-style-type: none"> <li>3.5. Sense of urgency - transition to medical emergency</li> </ul> </li> <li>7.3. Partners role during OBS2 consent process</li> <li>5.5. on birth partner's emotional health</li> <li>1.5. Birth expectations               <ul style="list-style-type: none"> <li>2.4 Concerns for baby's health</li> </ul> </li> <li>6.2.1. Aware (before prompting)               <ul style="list-style-type: none"> <li>2.3. Birth partner involvement</li> </ul> </li> <li>3.6. Separation from family               <ul style="list-style-type: none"> <li>4.2.1. Professional-woman</li> </ul> </li> <li>3.2. Awareness of bleeding &amp; understanding of bleeding</li> <li>7.6. Consent checked during recovery from PPH in hospital</li> <li>4.3. View of professionals competencies               <ul style="list-style-type: none"> <li>1.4. Birth plan and preparations</li> </ul> </li> <li>8.3. changes to information given</li> <li>7.2. Ability to give informed consent for OBS2</li> <li>6.3. Acceptability of antenatal consent</li> <li>7.5. Reasons for enrollment in OBS2</li> <li>PID02</li> </ul>
PID02:	Erm, yeah so we went in on the ... it was a Saturday afternoon we went in to be induced. So we were there, I stayed the Saturday night, I sent my partner home by about 11 o'clock I said well nothing's really happening is it so you go home, get some sleep and come back in the morning. Five o'clock in the morning I woke up bleeding in the induction ward, erm, the midwives were great they sort of ... because they have all the monitoring equipment and they looked for his heartbeat and she couldn't find it initially. And said right, she said don't panic I'm just going to take you upstairs and then she sprinted with my bed [laughs] while I was calling my partner to say you've got to come in now, this is five o'clock in the morning.	
I:	Okay.	
PID02:	So he. err ... obviously it's quite a way to the ((name of	

- 7.1. Timing of actual consent
- 2.2. Method and details of actual delivery
- 2.6. Emotional rollercoaster
- 3.7.1. Timing and relevance
- 8.2. suggestions and reflections on timing of actual consent
- 4.2.3. MDT working
- 8.3. changes to information given
- 5.2. Conversations with partner about birth
- 5.5. on birth partner's emotional health
- 2.5. Feelings about seeing and meeting baby for first time
- 3.6. Separation from family
- 7.2. Ability to give informed consent for OBS2
- 3.4. Perceived or actual severity of bleeding and treatment of bleeding
- 7.6. Consent checked during recovery from PPH in hospital
- 8.1 changes to antenatal consent process
- 5.8. Ability to look after baby
- 5.6. baby's health
- 6.1. First memory of OBS2 trial
- 4.2.2. Professional birth partner
- 7.7. Acceptability of consent
- 2.1. Labour process
- 6.3. Acceptability of antenatal consent
- 7.3. Partners role during OBS2 consent process
- 6.2.1. Aware (before prompting)
- 4.2.1. Professional-woman
- 3.7.2. Missing pieces of narrative
- 3.7. Opportunity to talk to someone about PPH experience
- 5.4. woman's physical health
- 5.9. Other
- 4.3. View of professionals' competencies
- 5.3. woman's emotional health
- PID10
- Coding Density
- 3.2. Awareness of bleeding & understand

General. Do you know, erm, if they tried to gain consent from you prior to the general? I mean obviously that's quite a difficult question.

PID10: No. No they didn't try. I'm pretty sure they didn't try to gain consent. But there was something ... no it was just all of the ... because I had to sign lots of consent things before I went into theatre.

I: I was going to say because there's lots just for ...

PID10: Yeah.

I: ... standard practice.

PID10: So you get a bit overwhelmed with all of the ... but I don't think, I don't think I was asked before I went under the general anaesthetic. I'm not sure anybody knew quite how much I was bleeding before I went under the general anaesthetic.

I: Okay.

PID10: Or that it wasn't going to stop soon.

I: Yeah. I suppose because the sort of breathlessness as well, you know, that's a lot of things going on isn't there? Erm

### Appendix 13: Examples of charting

OBS2 women data analysis V1.14..nvp - NVivo Pro						
FRAMEWORK MATRIX TOOLS						
FRAMEWORK MATRIX						
7. Experience of consenting du						
	A : 7.1. Timing of actual consent	B : 7.2. Ability to give informed consent f or OBS2	C : 7.3. Partners role during OBS2 conse nt process	D : 7.4. Interaction and familiarity with Do ctor seeking consent	E : 7.5. Reasons for enrollment in OBS2	F : 7.6. Consent chec ky from PPH
1 : PID01 Name = PL... Age range... Blood loss... Method of...	<p><u>Whilst in theatre</u></p> <p>"Erm, and whilst I was down there they asked me if I wanted to be part of the study erm, and the Anaesthetist kept saying to me you may need a blood transfusion although it's the last resort erm and that was it, they just removed it and I was fine, luckily I didn't need a blood transfusion."</p> <p><u>Just say yes</u></p> <p>It was when I was erm in the theatre...and when they were going to, when they were going to remove it [placenta] and the Anaesthetist the more senior one who seemed to be in charge said</p>	<p><u>Doctor asks - you just say yes</u></p> <p>"...the Anaesthetist the more senior one who seemed to be in charge said to me would you like to be part of this study erm, and I just, I suppose you just say yes don't you (laughs)"</p> <p><u>Not informed as no time to think or ask questions or take on board information</u></p> <p>"...I don't suppose it was really informed because there weren't, you know perhaps if it was a different situation I could have thought about it and there might have been questions that I wanted to ask...but no, I just said</p>	<p><u>Partner stayed with baby as woman had to go to theatre for manual removal of placenta. Therefore partner not involved in consent process.</u></p> <p><u>Would it have helped if he had been?</u></p> <p>"Er possibly erm but if he'd have said no, oh I don't know if I would have said yes I don't know."</p>	<p>Had met consenting doctor on the delivery suite. "Can't remember exact words" of the discussion.</p> <p>"Erm, I think he, he must have erm asked me if I wanted to take part in a study to help erm investigate or you know research into postpartum haemorrhage or haemorrhage during bleeding erm labour, erm yeah I don't remember very much.</p> <p>If she hadn't been familiar with doctor she would probably have still said yes</p>	<p><u>Stop the bleeding</u></p> <p>"Erm, I suppose you're more likely to agree to taking part because they give you that, that drug don't they to try to stop the, so you want to try everything...to help them to stop the bleeding don't you?"</p>	<p>No not that she r would have found discuss when in l mind</p>
2 : PID02 Name = PL... Age range...	<p><u>Intrapartum - pre emergency C-section - had already seen and decided using antenatal form but hadn't left it signed in folder</u></p> <p>"Erm, and then, I can't remember who it was, but somebody said, you know have you had a chance to see this and I know it's the wrong time but,</p>	<p><u>Had opportunity to look at the study info - but had already made decision during pregnancy but just hadn't signed it and left in notes</u></p> <p>"...But it was, erm ... no I mean it was ... they sort of, they handed the form back to me and I had the opportunity to look at it and I went I've already read this, I know</p>	<p>Not present as hadn't made it back to the hospital "by that point"</p> <p>She mentioned this interview to him but he did not remember her telling him about entering into OBS2 study - probably because not important to him "I'm not, I'm not quite sure how</p>	<p>Doesn't remember the professional who asked for consent during complications</p> <p>"Erm, and then, I can't remember who it was, but somebody said, you know have you had a chance to see this and I know it's the wrong time but, you know, would you consent."</p>	<p><u>No risks to self and will help future research</u></p> <p>"...Because I'd already sort of read it through and decided yeah I can consent to that, that's no problem, won't affect me negatively and it will help obviously, you know, research for the future isn't it?"</p>	<p><u>Remembers detail consent check pos happy with this pr</u></p> <p>"Yes, erm, I forge she did, a couple Erm, and I'm tryi remember now b whole thing is a l she came round t what I'd consente</p>

	A : 2.1. Labour process	F : 2.1.1. Emotional rollercoaster	B : 2.2. Method and details of actual delivery	C : 2.3. Birth partner involvement	D : 2.4 Concerns for baby's health	5. Feelings about seeing and meeting baby for first	G : 2.7. Other
<p>5 : PID05</p> <p>Name = PID05 Age range = 35-45 Blood loss = 3001-3500ml Method of Delivery = VB</p>	<p>Felt some waters broke at home but not 100% sure as "had a caesarean the first time round, so I wasn't really sure what to expect." Contractions didn't start following waters breaking. Assessed and contractions hadn't started. Given Stretch and Sweep procedure to "start things off". Went back home, nothing happened and then in the morning, she went for the growth scan. Twinges started. Sent up to induction ward. Regular contractions but not frequent enough. "I was given prostin, and then, and then from then within literally fifteen, twenty minutes, they were like two minutes apart."</p>	<p>Proud of self for having natural birth</p> <p>"and um it was hard, but I was really, well I can't say I was enjoying it, but I was really, throughout the whole process, I was feeling really well. I suppose I was proud, I was glad that I was going for a natural birth, because I really wanted to experience it.</p> <p>Adrenaline, exhaustion, joy - mixture of emotions</p>	<p>Gas and air took pain away.</p> <p>"...remember sort of waking up from remembering what's happening, "I need to push" and then it was very quick from then"</p>		<p>Concerned about baby, no thought for herself.</p> <p>"...they gave him to me, um but then he was quite quickly taken away, because they needed to stitch me up. So I just remember seeing him, but he wasn't crying and I remember being really worried, I was like "Is he okay?", so I wasn't worried about me. I was like "Is he okay, just tell me he's okay", because I had really, the first emergency caesarean I had there, that was all a scary story, um so I was really wanted to make sure he was alright. Um so they reassured me that he was fine."</p>	<p>Held baby but then taken away due to needing stitches</p> <p>"...gave him to me, um but then he was quite quickly taken away, because they needed to stitch me up.</p> <p>"...because I thought it was all over you know, the whole um, err well pushing and exhaustion, I thought I was just going to be able to. Have the baby with me and that would be it, that would be the end of it, but then it took another, it was a good hour and a half."</p>	
<p>6 : PID06</p> <p>Name = PID06 Age range = 25-35 Blood loss = 1501-2000ml Method of Delivery = AFB</p>	<p>Long experience, had stretch and sweep because overdue. Contractions for about four or five days never progressed. Telephone contact with hospital during this time. Told to come in. No sleep for 3-4 days. "Drained and emotion before got going". Induced due to length of time and low red blood count. Unable to have epidural so induced without pain relief = "the pain was just unbelievable, I didn't think you could be in that much pain and not actually die but it was pretty awful but it was just one of those things so."</p>	<p>Initially confident as second child - panic set in when baby got stuck and in lots of pain. Not end in sight. Changed when consultant stepped in and took control</p> <p>"Erm I think the relief then, I did feel an absolute massive wave of relief that it was over and almost like, almost like it euphoric really, I felt quite stupid when it, I got a bit giggly, well I had a bit of a cry, it's all them emotions isn't it..."</p>	<p>Induced, baby in wrong position (head down but wrong way but not back) "so I couldn't push her out anyway so I ended up having an assisted delivery." In same delivery room as previous birth "oddly reassuring". Panic when pain set in. "baby felt utterly stuck and...I did feel like I got to that point where actually panic set in and I thought this is just never going to happen, this is never going to be, I couldn't see an end to it really..."</p> <p>Consultant stepped in, taken to theatre and given a spinal block and that numbs the pain off this kind of wave of relief stepped in.</p>	<p>Husband with her during labour and birth</p> <p>"I can't imagine not having your partner there or at least somebody whoever it may be whether it's your mum or anyone really, I can't imagine doing that without having somebody there"</p> <p>Partner's expected to leave at 9pm on consultant-led recovery ward.</p>	N/D	<p>One staff member asked if she wanted to be told the sex of her child or look for herself - "I was like just tell me, just tell me (laugh) erm and do you want to hold her straight away I was like oh yeah, so yeah, I got to do all of that "</p> <p>Husband went with midwife to weigh baby and clean her up</p>	<p>Never been in hospital before having first child - didn't know how to work the call button</p> <p>"you're a bit green to it the first time if you've not up on the wh you know ping for help."</p>

**Appendix 14: Workings of a section of thematic analysis - 'the birth before bleed'**

<b>Detected Elements across sub theme 2.1 LABOUR</b>	<b>LABOUR Similar elements grouped together</b>	<b>LABOUR Key Dimensions</b>	<b>Detected Elements across sub theme 2.2 DELIVERY</b>	<b>DELIVERY Similar elements grouped together</b>	<b>DELIVERY Key Dimensions</b>	<b>COMBINED Key Dimensions</b>
Overdue by 2 weeks so induced	Waters broke early	<b>Complications</b>	Normal vaginal birth	Baby stuck x 5	<b>Complication causes</b>	<b>COMBINED Key Dimensions</b>  <b>Straightforward vs. complications</b>  <b>Complication causes</b>  <b>No end in sight</b> <b>Emotional rollercoaster</b> <b>Physical rollercoaster</b>
Bleeding prior to waters breaking	Bleeding pre labour		Retained placenta after birth - passed naturally	Unable to feel to push		
Baby's heart rate dropped	Overdue		Started bleeding on induction ward	Baby in wrong position		
Epidural given at start			Staff broke her waters but nothing happened	Bleeding prior to being induced		
Baby was slow and stuck	Induced Labour	<b>Needing medical support</b>	Rushed to theatre for emergency c-section			
Waters broke at home but contractions did not progress	Stretch and sweep		Baby stuck so taken to surgery to try forceps			
Taken to birthing pool	Drugs to speed up contractions		Knew what was happening as had experienced in 1st birth	Planned c-section x 2 with no delivery complications	<b>Straightforward vs. complications</b>	
Given sweep to start labour			Forceps did not work, required emerg c-sec	Normal vaginal birth		
Given drug to speed up contractions	Baby stuck during labour	<b>Concerns about baby</b>	upset at having to go through it all again	Forceps did not work as planned		
Risk of infection due to waters breaking but no labour	Concerns re baby		Baby stuck so taken to surgery for emerg c-sec	Episiotomy to help deliver baby		
Waters broke at home but contractions did not follow			Sick in theatre due to drugs - felt embarrassed	Emergency c-section as last result		
Given stretch and sweep to start labour	Protracted labour	<b>Physical rollercoaster</b>	During c-sec, used forceps to pull baby back up birth canal	Retained placenta after birth		
Given drug to speed up contractions	Stop-start contractions		Upset at not continuing with planned vaginal birth			
Overdue so induced using stretch and sweep	Waters broke but labour did not start		Gas and air took pain away during stop-start labour	Upset at having to go through complications again	<b>Emotional rollercoaster</b>	
Contractions over 4-5 days but did not progress	Labour did not progress		Proud at having natural birth as had c-sec for 1st birth	Panic at baby being stuck		