

1 **Title**

2 **What women think about consent to research at the time of an**  
3 **obstetric emergency: A qualitative study of the views of a cohort of**  
4 **World Maternal Antifibrinolytic (WOMAN) Trial participants**

5

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27

28 **Shortened running title** (57 characters): Women's views of consent to research  
29 during an obstetric emergency

30 **Tweetable:** *Study reports on women's views of consent to research in an obstetric*  
31 *emergency*

## 32 **Abstract**

33 **Objective:** The WOMAN Trial was the first in the UK to use the option of waiver of informed  
34 consent at the time of an obstetric emergency. This qualitative study aimed to investigate  
35 participants' views of the acceptability of the recruitment methods used.

36 **Design:** Qualitative study using in-depth interviews with women who did and did not give  
37 consent at the time of their recruitment to the WOMAN Trial.

38 **Setting:** Highest UK recruitment site for the WOMAN Trial (129/569). Interviews were  
39 conducted in participants' homes.

40 **Population:** 40 of the 129 women who were recruited to the WOMAN Trial at one UK site  
41 were invited to take part, 15 women were interviewed.

42 **Methods:** Qualitative, interview study

43 **Main outcome measures** Facilitators and barriers to successful recruitment during obstetric  
44 emergencies. Guidance for future researchers.

45 **Results:** Findings revealed that what is important is not so much the consent process used  
46 or a signature on a form, but the way in which consent is obtained. Clinicians who  
47 successfully negotiate consent to research during childbirth emergencies engage in a  
48 "humane choreography" of words and actions. This emphasises the importance of prompt  
49 decision making and treatment, whilst respecting the woman's personal situation and  
50 experience.

## 51 **Conclusions**

52 Our findings do not support a single pathway to consent in the context of an obstetric  
53 emergency. Women understand that consent to research in an emergency is complex.  
54 Clinicians' skills in considering the clinical, ethical and emotional aspects within the context  
55 of the clinical emergency can hamper or promote women's satisfaction.

56

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58 'This research received no specific grant from any funding agency in the public, commercial  
59 or not-for-profit sectors'.

60

61 **Keywords** Consent, research, obstetric emergency, women's views

## 62 **Introduction**

63 Debate about consent to research during the vulnerable time of childbirth and childbirth  
64 emergencies is longstanding.<sup>1-5</sup> Guidelines for the conduct of maternity research where time  
65 is critical recognise how informing all women about potential emergencies in advance may  
66 create unnecessary anxiety.<sup>4</sup> However giving information and gaining consent at the time  
67 can delay potentially lifesaving treatments.<sup>5</sup> The ideal of valid, informed consent becomes  
68 unworkable in some obstetric emergencies and the developments of flexible research  
69 protocols that acknowledge this are welcomed. Understanding the views and experiences of  
70 those directly involved is paramount. Deferred consent precedents have been set and  
71 evaluated in the context of emergency medicine<sup>6-8</sup> and paediatric trials.<sup>9-10</sup> However, in  
72 obstetrics, deferred consent had only been explored hypothetically.<sup>11</sup> The use of a verbal  
73 consent within emergency peripartum trials is associated with professional anxiety.<sup>12</sup> The  
74 completion of the WOMAN Trial presented a unique opportunity to investigate the views of  
75 women who had lived through this experience.

76

77 The WOMAN Trial showed that tranexamic acid, compared to placebo, reduced the risk of  
78 death from PPH by 20%.<sup>13</sup> The trial faced an important challenge in terms of consent, as the  
79 treatment being studied needed to be given at the time women were experiencing a PPH.  
80 The trial design included a range of consent approaches, depending on the woman's  
81 condition (see figure 1). Consent was obtained from women if their physical and mental  
82 capacity allowed (as judged by the treating clinician). If a woman was unable to give  
83 consent, proxy consent was obtained from a relative or representative. If a proxy was  
84 unavailable or unable to consent, consent was deferred and the woman was informed about  
85 the trial as soon as possible, written consent was requested later for data collection. Trial  
86 procedures were compliant with international guidelines and legislative frameworks relating  
87 to consent to emergency research.<sup>13-18</sup> The UK Clinical Trials Regulations Amendment 2<sup>19</sup>

88 and the updated Declaration of Helsinki <sup>20</sup>. In the UK, 569 women were randomised at  
89 seven maternity facilities. 506 of the 569 women were randomised without prior written  
90 consent and 501 women gave retrospective written consent to continue.

91

92 This study aimed to investigate the views of a cohort of the participants in the WOMAN Trial  
93 to identify preferred method(s) of consent, assess the acceptability of waiver of prior consent  
94 and inform future guidance.

95

## 96 **Methods**

97 The study is reported following the consolidated criteria for reporting qualitative research  
98 (COREQ) guidelines.<sup>21</sup> An interpretative qualitative methodology using in depth interviews  
99 was used to investigate women's views.

100

101 Participants were recruited from the UK site where the highest number of WOMAN Trial  
102 participants were recruited (n=129/569). Purposive sampling ensured maximum variation of  
103 interviewees based on the method of consent used. <sup>22</sup> (Figure 2). Forty potential participants  
104 were identified from the randomisation log. Sixteen gave consent while their PPH was  
105 ongoing. Two had prior consent waived and subsequently declined to give written consent.  
106 There were 111 women who had consent waived and gave consent subsequently. Every  
107 fifth woman was invited, this ensured representation across the Trial's duration (n=22).  
108 Written consent by relatives at the time of the emergency was not obtained for any of the  
109 participants. Trial recruitment occurred at the site between October 2011 and July 2013. This  
110 study was conducted once recruitment to the WOMAN Trial in the UK was completed and  
111 international recruitment remained ongoing. Interviews commenced following ethical  
112 approval in March 2015, with the intention that the findings would be available soon after the  
113 results of the WOMAN Trial were available.

114

115 Women were sent an Invitation and Information Sheet, then contacted by telephone. There  
116 were opportunities to ask questions prior to written consent. Interviews were audio-recorded  
117 and conducted using an interview schedule (see Appendix S1). All participants preferred to  
118 be interviewed at home. Family members and children were present during some . Data  
119 saturation was reached after fifteen interviews and evidenced during the final interviews and  
120 confirmed during initial coding. Participants consented to information collection from their  
121 records (see Table 1).

122

123 Interviews were transcribed verbatim to create transcripts for thematic network analysis.<sup>23</sup>  
124 This method has parallels with the basic components of grounded theory, which organises  
125 data into concepts, categories and propositions. GH and CK undertook the analysis. In stage  
126 one; following data familiarisation, a coding framework was devised, first independently, and  
127 then agreed by consensus. MAXQDA11 was used to dissect the text into coded segments.  
128 Four *a priori* codes were assigned and 19 were grounded in the data (Appendix S2). GH and  
129 CK then abstracted and refined themes from coded segments, arranging them into nine  
130 basic themes and three organising themes, from which the global theme was deduced. The  
131 initial thematic network was verified and refined by constant comparative reflection and  
132 discussion. In stage two, GH and CK described and explored the thematic networks further,  
133 before summarising them. In stage three, GH and CK brought the network summaries  
134 together with existing theories, original research questions and the interests underpinning  
135 them. Figure 3 was produced in this final stage.

136

137 GH and MD are practicing midwives. CK is a sociologist and maternity researcher. ZA is an  
138 obstetrician and researcher. GH, MD and ZA were collaborators in the WOMAN Trial. HS  
139 was lead investigator in the WOMAN Trial. The ethical dilemmas raised by the  
140 unprecedented use of the waiver of prior consent provided the impetus for this study.

141 Although there was nothing to suggest that women were concerned about the consent  
142 processes used in the Trial in terms of complaints and declining continuation, the research  
143 team were reluctant to assume this equated to unanimous acceptance. GH, CK and MD  
144 conducted the interviews. As GH and MD were responsible for recruitment to the WOMAN  
145 trial, trial logs were checked to ensure GH and MD did not approach or interview women  
146 they had met in Trial activities.

147

## 148 **Results**

149 Fifteen women participated; eight gave consent to participate in the WOMAN trial while their  
150 PPH was on-going; for seven consent was waived (including one of two women who  
151 declined written consent retrospectively). The study algorithm and sample characteristics are  
152 illustrated in Figure 2. Table 1 reports demographic and clinical characteristics. Figure 3  
153 outlines the thematic structure of the findings. Interviews lasted 20 minutes to 1½ hours. All  
154 transcripts conveyed the global theme "*humane choreography of clinical, emotional and*  
155 *ethical considerations when negotiating consent to research*", underpinned by the three  
156 organising themes (i) Too much to process; (ii) Quality of relationships; and (iii) Making it  
157 right. Figure 3 illustrates the interconnectivity between themes.

158

159

### 160 ***Theme 1 Women's experiences: Too much to process***

161 Thirteen of the fifteen women experienced labour, two had an elective caesarean section;  
162 fourteen gave birth to a live baby. Women explained how their ability to process information  
163 and make decisions was compromised by having just given birth and experiencing a  
164 potentially life-threatening event. A series of undistinguishable interactions with professionals  
165 were described. All women who signed a consent form around the time of Trial entry recalled  
166 being spoken to by professionals who were concerned about bleeding. However, none could

167 remember clearly which conversations related to clinical care and which were about  
168 research: *"I think he [the Doctor] explained that it was a trial to do with stemming blood loss,*  
169 *but that was all a bit hazy. I was sobbing. I actually remember saying am I going to die? I*  
170 *didn't really know at the time what I was saying yes to"* (C13).

171

172 As expected, the consent waiver was used most commonly when a woman's consciousness  
173 was affected. This meant some women remembered very little. Six participants signed  
174 consent for continued participation in the hours or days after recruitment. Few recalled these  
175 discussions or signing the form. Some recalled more when prompted.

176

177 *"Can you remember talking to anybody about taking part in any research?"*

178 *"No."*

179 *"Not at all?"*

180 *"I can't remember that at all."*

181 The interviewer then showed the 'Alert Card' given to all WOMAN Trial participants

182 *"So this is the research that you took part in?"*

183 *"Oh. Right, OK. I have got one of these."*

184 Long pause. *"So I have been involved in it then haven't I?"* (W13).

185

186 Although we expected the consent waiver to be used when a woman's consciousness was  
187 impaired, we did not anticipate how similar the interviews with women recruited using the  
188 three methods would be. Six women lost consciousness, many more described an altered  
189 state of consciousness where they were unable to think or remember clearly.

190

191 Views on providing information and obtaining informed written consent to research at the  
192 time of an emergency varied from hypothetically desirable to an inappropriate  
193 inconvenience. All women understood the need for prompt action and how delays could

194 compromise any possible benefit the research may offer. One who gave prior consent said  
195 *“They could have given me a piece of paper to say I was signing my mortgage away. The*  
196 *signing thing, it’s just it seems quite pointless really”* (C08). A woman, for whom the consent  
197 waiver was used, said *“You couldn’t discuss something like that at that point. It had to be*  
198 *done by someone else”* (W02). Another from the waiver group stressed the immediacy of the  
199 intervention: *“I think you should go ahead if you think it is going to help”* (W16). All but one  
200 participant recruited using the consent waiver of felt the process was acceptable. Her  
201 consciousness appears to have been affected very briefly and she felt there were missed  
202 opportunities for discussion.

203 Amongst women who provided written consent, some were initially shocked to learn others  
204 had been entered into the Trial without; *“I don’t think I would have been happy.”* (C04).  
205 Others disagreed; *“I think when you are in a critical situation, conscious or not, I’d have been*  
206 *happy for them to waiver consent”* (C09). The woman who declined to sign a consent form  
207 retrospectively was not negative *“It needs to be done there and then. Just to go straight to it,*  
208 *in case any more damage happens”* (D02). Her reason for not signing was related to early  
209 hospital discharge.

210 Women’s ability to process information was affected at the time of trial entry and in the days  
211 and weeks afterwards. Women were asked if they looked at Trial information later: *“Not*  
212 *really, you get given all these things, the pack, little red book and you have got this baby in*  
213 *your arms. When I get five minutes to myself I will read the leaflets”* (W16). Overall, women  
214 appeared to have little capacity for research activities in their life-changed, post-birth, post-  
215 PPH, world, for most, the invitation to participate in this study was the first time they had  
216 found time to give the WOMAN Trial a thought.

217

218 Tables S1, S2 and S3 provide more quotes to support the three organising themes.

219

220 **Theme 2 Women’s views: Quality of relationships**

221 With one exception, interviewees demonstrated immense trust in professional expertise. The  
222 degree of trust reflected participant's perceptions of the quality of the relationships that  
223 developed within clinical scenarios. Many recalled interactions where trust and respect was  
224 built or lost. *"I remember these two (doctors) being really excited about the trial. I remember*  
225 *a senior doctor telling them off. I mostly felt at that time that (wife) was a bit of a guinea pig .*  
226 *(Partner of C08).*

227

228 Participants understood the challenges associated with conducting research during  
229 emergencies, and were happy for the obstetrician to carry this burden. Participants appeared  
230 to understand that a placebo was used, interestingly many firmly believed their clinical  
231 situation had been improved by the Trial medication . *"In my eyes it worked. Whether it was*  
232 *water, medication, orange juice, whatever," (W01).*

233

234 The woman who was not satisfied felt by her doctor failed to acknowledge her previous  
235 experiences of motherhood; *"The placenta got stuck. I said to her (Doctor) it's stuck and she*  
236 *said no it's not. I said it is. This is number 3 not number 1. (W22).* Women's views on  
237 whether their birth partner should be involved in decision-making varied, some recognised  
238 how this might be compromised by their own birth experience *"I think they would be in a*  
239 *state at the time" (C05).* Partner's involvement was viewed as a courtesy rather than a  
240 necessity.

241

### 242 **Theme 3 Women's needs: Making it right**

243 While most participants were *"fine"* with the recruitment process, many suggested  
244 improvements. During the WOMAN Trial a brief information leaflet was provided in clinics.  
245 Increasing opportunities for giving information was important; obtaining a signature on a form  
246 was not. Women articulated the difficulties clinicians face in providing balanced information

247 during pregnancy and labour *"I suppose do you wanna scare people by telling them all the*  
248 *things that could go wrong? C08.* Most women felt an individualised approach was best, the  
249 complexity of doing this well was acknowledged *"I don't know whether there is a right way.*  
250 *You've just got to do what you can in the situation at that time" W02.*

251 Providing explanations and answering questions at an appropriate time were crucial.  
252 Professional awareness of the impact childbirth, particularly a traumatic experience, can have  
253 upon cognitive ability was critical. *"They could've come the day after when I was more alert,*  
254 *more aware and I didn't have 20 people coming in and out" W02.* C04 initially appeared  
255 against the idea of retrospective consent, however on reflection, she describes how the  
256 explanation was all important. *"Because it was explained properly, you go, well I accept that*  
257 *and thanks for taking the time to go into it and you know sort of do the right thing."*

258 Many women expressed a positive view of research and verbalised altruism towards other  
259 women and society *"I think it's a very good idea because how else are we meant to learn for*  
260 *other people for the future, W01.*

261 Not missing opportunities for research was also important:

262 *"It doesn't mean that should you come across a lady in my situation at the time the*  
263 *emergency is going on that you can't ask her."*

264 (C04)

265

266 The global theme *humane choreography of consent to research ("how it's done")*  
267 encapsulates what really mattered. How consent was negotiated was judged by perceptions  
268 of respect and the quality of human interactions during care. Women expected every  
269 reasonable effort to be made to communicate with them; they appreciated why this was not  
270 always easy or achievable. From what first appeared as indistinguishable fragmented  
271 memories of giving birth, receiving treatment for PPH and being approached regarding

272 research, emerged the proposition that doing consent well involves a skilful balance and co-  
273 ordination of important aspects amidst a plethora of human emotions. This evoked the  
274 metaphor of a complex dance, dynamic and humanely choreographed when done well;  
275 chaotic and disrespectful when not.

276

## 277 **Discussion**

### 278 **Main findings**

279 Participants favoured no particular WOMAN Trial consent procedure; instead they valued a  
280 humane choreography of informed consent appropriate to their personal situation. This does  
281 not run contrary to the principles in the Declaration of Helsinki or more recent policy  
282 statements that highlight the importance of high-quality respectful, humanised care.<sup>20,24</sup>  
283 Women completely understood the complexity of issues at play and the associated  
284 challenges associated with consent. Participants were less concerned with procedures and  
285 paperwork and more concerned with the quality of human interactions. This was indicative of  
286 feeling professionals had done the right thing at a time when a decision could not be made  
287 fully by the woman herself. The WOMAN Trial research protocol acknowledged how the  
288 differing clinical scenarios of PPH and the clinical status of a woman would determine the  
289 consent procedure used. It was an unanticipated finding of this study just how similar  
290 participants' experiences would be; irrespective of the severity of their PPH or consent  
291 procedure used.

292

293

### 294 **Strengths and limitations**

295 This is the first study of the views of women who have experienced being included in a RCT  
296 of treatment for an obstetric emergency trial where a waiver of consent was used. A key  
297 strength of this study is that it included women who gave their written consent prior to entry  
298 into the Trial and women where prior consent was waived. Opportunities to purposively

299 sample women who declined were limited. Only women who took part in the WOMAN trial  
300 from one UK site were included in this study, including women from other sites may have  
301 resulted in more varied responses. As many of the women interviewed for this study did not  
302 remember the WOMAN Trial, there was a need for to explain what had actually happened.  
303 Views expressed at interview may therefore have been influenced by the short time  
304 participants had to consider their feelings and thoughts. The interviews took place one year  
305 or more after participants were included in the WOMAN trial. Although existing research  
306 suggests that in the long term (1 year or more) women usually describe aspects of their  
307 labours and birth consistently,<sup>26</sup> the effect of this time lapse on participants in this particular  
308 study is unknown.

309

### 310 **Interpretation**

311 Conducting emergency obstetric care trials to improve outcomes for women and negotiating  
312 consent to research in this emergency situation is a necessary component of medical care.  
313 Clinical trials are governed by European Legislation, which set the framework for valid  
314 informed consent as the cornerstone of experimental research involving human beings.<sup>18</sup>  
315 The European Directives made no provision for consent in critical emergency situations. In  
316 2008, UK legislation was introduced to enable researchers to seek consent after a person  
317 had been given an investigational drug or device when the following conditions are met:

318 “(i) treatment is required urgently; (ii) urgent action is required for the purposes of the trial;  
319 (iii) it is not reasonably practicable to obtain consent prospectively; and (iv) an ethics  
320 committee has given approval to the procedure under which the action is taken.”<sup>7</sup> However,  
321 some clinicians remain very uncomfortable deferring written consent.<sup>12</sup>

322 All women in this study could not recall detail of their involvement in the WOMAN Trial. Most  
323 were largely unaware they had been part of a research study, until approached to participate  
324 in this study. This is similar to the experiences of parents whose children were entered into  
325 emergency research<sup>27</sup> and existing studies of women’s experiences of PPH.<sup>28</sup> This loss of

326 memory may, in part, reflect the response of the brain to perceived trauma.<sup>29</sup> This recurrent  
327 finding does however raise an important question about the meaningfulness of informed  
328 consent in any spheres of clinical practice where psychological trauma may occur. Akkad et  
329 al.<sup>30</sup> proposed that truly informed consent may be impossible to achieve within the context of  
330 clinical emergencies. Some of the women included in this study agree, viewing discussing  
331 consent at such a time as “pointless.” Snowden et al, asked women to consider  
332 hypothetically what they would do in this situation.<sup>11</sup> Interviewees rejected decision-making  
333 prior to delivery, and by their partners/representative at the time of the emergency. Preferred  
334 options were antenatal decisions, followed by doctors making decisions at the time of the  
335 emergency. The views of women considering the hypothetical situation were, to an extent,  
336 supported in this study.

337 The principles of informed consent were of utmost importance, at the same time, women  
338 accepted the complexity of when, how, and by whom this is achievable. Vernon, Alfirevic  
339 and Weeks<sup>1</sup> previously described a pathway for consent that acknowledged the importance  
340 of considering women’s individual situations. These findings go further in explaining why a  
341 ‘one size fits all’ consent process is inadequate. What is important is not so much the  
342 process, but the way in which it is undertaken. Hinton et al’s study <sup>31</sup> of near-miss maternal  
343 morbidities supports the importance of the “little things” (personal touches, flexibility, taking  
344 time to explain) in helping women make sense of complex situations and improving  
345 perceptions of care.

346

347 The conduct of the WOMAN Trial did not result in complaints; the absence of complaint is  
348 however a poor measure of acceptability. These findings offer detailed insight that can be  
349 used by researchers planning similar studies. Multiple pathways to consent, when used  
350 appropriately within a range of clinical scenarios, rather than waiver of consent waiver *per*  
351 *se*, appear to be acceptable. The women in this study clearly articulated why complacency  
352 is unacceptable and that efforts to improve consent processes should focus on the quality of

353 human interactions, increasing opportunities to communicate courtesy and impart  
354 information.

355

## 356 **Conclusion**

357

358 The consent procedure in the WOMAN Trial utilised a variety of approaches dependent on  
359 the clinical scenario. Overall all the consent procedures were acceptable, with no difference  
360 in the views of women who gave consent and those where consent was deferred.. The  
361 current study has shown that professional concerns appear largely unfounded, Interviews  
362 illustrated that women remember very little of the emergency or the research. Women  
363 understood that obtaining consent to research in an emergency is complex and they  
364 appreciated an approach which took their own personal situation into consideration. Care  
365 must be taken not to interpret this as consent is unimportant. linicians need to recognise the  
366 importance of a humane choreography of clinical, ethical and emotional considerations and  
367 should focus on developing skills in respectfully obtaining consent in partnership with women  
368 and their families. Professionals could develop skills by practising research recruitment  
369 alongside scenario based emergency drills. It is essential that those responsible in designing  
370 future research trials acknowledge the views of these women.

371

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375

## 376 **Disclosure of Interests**

377 "All authors have completed the ICMJE uniform disclosure form at  
378 [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organisation for the

379 submitted work; no financial relationships with any organisations that might have an interest  
380 in the submitted work in the previous three years; no other relationships or activities that  
381 could appear to have influenced the submitted work.”

### 382 **Contribution to Authorship**

383 GH and CK designed the study with input from ZA and HS. GH, CK and MD conducted the  
384 interviews with women. As GH and MD were responsible for recruiting for women for the  
385 WOMAN trial and obtaining consent, care was taken to ensure GH and MD did not approach  
386 or conduct interviews with women they had met in Trial activities. GH and CK undertook the  
387 data analysis. GH, CK, ZA and HS all contributed to writing the paper

### 388 **Ethical Approval**

389 Ethical approval was granted by the National Research Ethics Service North West- Haydock  
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395

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