

Title

Consent in pregnancy: a qualitative study of the views and experiences of women and their healthcare professionals

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Abstract

Objective: Consent in antenatal settings is contentious, poorly understood and recognised as problematic for pregnant women. This study aimed to investigate participants' views and experiences of the consent process.

Design: Qualitative research performed in a large urban teaching hospital in London. Sixteen pregnant women and fifteen healthcare professionals (obstetricians and midwives) participated. Consent consultations were observed and in-depth interviews carried out with healthcare professionals and pregnant women using semi-structured interview guides. Data were collectively analysed to identify themes in the experiences of the consent process.

Results: Four themes were identified: 1) Choice and shared decision-making. Pregnant women do not always experience consent in a choice-making way and often do not understand information provided to them. 2) Contextualising information disclosure. What is important to women is not only the information but the relational context in which consent is obtained. 3) Quality of HCP-woman relationship. Trust in their healthcare professional sometimes makes women seek less information and conversely. Individualised information is desired by women but professionals found it difficult to ensure that women receive this in practice. 4) Law and professional practice. Doctors are more aware of legal developments in consent related to the *Montgomery* case than their midwifery colleagues, but they are not always certain of the implications.

Conclusion: Results suggest that an effective antenatal consent process which empowers pregnant women requires their understanding of provided information to be elicited. There is a delicate balance to be struck between the trust of a patient in their professional and information-based consent, rather than a simple focus on improving information provision. Whilst recognising women's desire for bespoke consent professionals acknowledged the difficulty of ensuring this in practice. If consent is to remain the legal yardstick of autonomous choice-making, women's understanding and that shared with their healthcare professional needs to be more explicitly addressed.

Keywords: Consent, choice, autonomy, antenatal care, Montgomery, women's experiences/views, professionals' views, invasive procedures, caesarean section.

Introduction

Renewed attention has been given to the contentious issue of patient consent following recent legal developments. Lawful consent requires patients to understand information which allows them to genuinely make choices about their care. Yet despite increasing recognition of the importance of patient autonomy as recently as 2015, Jou et al found that women perceiving pressure from clinicians for caesarean section were significantly more likely to consent to the intervention ¹.

In 2015 the UK Supreme Court ruling on *Montgomery v Lanarkshire Health Board 2015* ² provoked much debate on the implications to consent practice of legal endorsement to a patient-centred approach to medical decision-making. Ms Montgomery is a diabetic whose baby developed cerebral palsy due to shoulder dystocia during delivery. She claimed successfully that she had not been offered the option of having a caesarean section despite having voiced her anxiety at having a trial of labour. The obstetric case of *Montgomery v Lanarkshire Health Board 2015* ² and subsequent cases³⁻⁴ reflects the UK courts increasing insistence that patient autonomy is fully respected via a process of real individualised dialogue between HCPs and patients. Whether such cases have fundamentally changed the basis of information-sharing or simply given legal endorsement to existing professional guidance is debatable⁵ and the practical implementation of a fully dialogical approach remains a grey area. Nonetheless as a matter of law,

'Doctors have a duty to ensure patients are aware of any material risks involved in any recommended treatment and of reasonable alternative' para 87 ²

The test of materiality is whether, in the circumstances of the particular case, the doctor is or should be aware that a reasonable person in the patient's position would be likely to attach significance to a risk. Whether a risk is regarded as material depends on the patient's perspective rather than the HCP's. This emphasis on consultations as individually tailored dialogues aligns with professional guidance ⁶ and with guidance provided by The National Institute for Health and Care Excellence (NICE)⁷. NICE guidance on women who request caesarean section notes that women's views and concerns should be central to the decision-making process. However, little is known about HCP or pregnant women's experiences of the consent process.

This study aimed to explore perceptions of the consent process in women receiving antenatal care and in their HCP.

Methods

This study is reported with reference to the consolidated criteria for reporting qualitative research (COREQ)⁸. An interpretive qualitative methodology using in-depth interviews was used to understand how the consent process is experienced.

Study participants

Participants were recruited from an urban teaching hospital providing antenatal healthcare to approximately 6500 women annually.

Eligible pregnant women met all the following inclusion criteria:

Aged >18 years; First or subsequent pregnancies;

Able to understand spoken and written English;

Managed in consultant or midwife-led antenatal clinic.

Eligible HCPS were practicing obstetric doctors or midwives responsible for managing consultations involving consent for healthcare interventions such as caesarean section, cervical cerclage, external cephalic version and prenatal procedures. All consultations involved the woman giving consent during the consultation.

Combined purposive and convenience sampling aimed to ensure maximum variation of pregnant participants based on the key care decisions being made and to achieve a mix of HCP. Posters explaining the study were displayed in antenatal unit. Eligible women were identified by the HCP overseeing their care. HCP were informed of the study via internal staff communications. Participants were provided with an Information Sheet and invited to ask questions prior to written consent.

Data collection

Sixteen consultations involving consent were observed by the researcher. The aim was to gain an overall sense of woman-HCP understanding and interaction. The researcher made written notes during the consultation noting information such as non-verbal communication, distress and engagement. Face-to-face interviews were used to explore the views and experiences of pregnant women and HCP. The interviews were loosely based on an interview guide (Table 1). Witnessing the consultations allowed the researcher to modify the schedule for each individual as appropriate. For example if, a woman's body language was inconsistent with how she answered a question asked by the HCP this was explored in more detail by the researcher. Family members were present in some

consultations and interviews. Socio-demographic details were collected directly from participants and medical information from their medical records.

Data analyses

All interviews were audio-recorded, transcribed verbatim and anonymised. To ensure validity and quality of the transcribed data the transcripts were double-checked against the original recordings. Data saturation was reached and evidenced during the final interviews and confirmed during initial coding.

Thematic analysis was used to analyse the interview transcripts using an analytical framework approach⁹. Following data familiarisation initial codes were generated in a systematic manner for the entire data set. Codes were collated into potential themes, where similar but separate codes were combined and refined. Themes were reviewed, refined and organised into a final set of organising themes. Transcripts were coded by JN using qualitative data analysis software QSR NVivo 1010 (QSR International, Cambridge, MA). To ensure consistency a random selection of 20% of the transcripts were coded independently by another member of the research team (AL) and differences were discussed until agreement was reached.

The researchers were all HCPS trained in good clinical practice with regard to research studies. AD and JI are practicing obstetricians, AL & JN are experienced women's health care researchers.

Results

Sixteen pregnant women and fifteen HCPS (12 female, 3 male) participated; one midwife declined consent retrospectively. Observed consultations lasted 25–75 minutes. Interviews lasted 20–60 minutes. Table 2 reports demographic and clinical characteristics of pregnant participants.

Selected quotes are referred to by standalone letters (Upper case HCP plus lower case letter for healthcare professionals and upper case P plus lower case letter for pregnant women) to indicate the range of participants represented.

All transcripts demonstrated that consent consultations involve a complex interplay of professional, psychosocial and socio-cultural elements. These were characterised by four themes:

1. Choice and shared decision-making

Choice was frequently mentioned by participants. Some pregnant women felt that although notionally they had a choice their experience entailed them agreeing to what their HCP suggested. This 'contractual compliance' view of consent was reinforced by some HCP. A minority of women felt their consent was sought within an experience of genuine choice and this perception was aided if the woman had previously been seen by the same HCP.

It wasn't a choice, it was me being asked to agree with what they want to do (Pe)

I don't feel it (consent) was really explained – it was more this is what you need to sign (Pf)

All HCP voiced commitment to shared decision-making but they varied in relation to whether their discussions emphasised providing information or whether they encouraged a process of sharing decision-making. When the focus was on information-giving some women experienced consent as a process in which they were made aware of the risks as a way of passing the buck to them

it's for a woman to agree to the proposed procedure . . . to agree with what we want to do (HCPb)

to make a kind of a contract with the patient that that's what we're doing or planning to do (HCPe)

It (consent) should make me feel more in charge but it doesn't . . . I feel very aware that it's intended to make me responsible if things go wrong (Pi)

Some women felt that consent was a way of them gaining a greater sense of being in control. For many women that sense of control was more important than the need for extensive information. In what might be seen as a reversal of the consent process, this need to plan and control became the dominant feature of their ante-natal care to the extent that their sole aim was to secure clinician agreement to what **they** had already decided particularly in relation to securing a caesarean section. Allied to this was a sense of needing to take charge of their own fate.

the most important thing is having a plan, feeling I've got some sort of control that bothers me more than all the nitty gritty information (Pa)

it sounds a bit strange but when you ask me about consent it felt more like I was getting her to agree to what I'd decided if that makes sense (Pm) (maternal request for Caesarean section)

I guess what I'm saying is that I feel you really had to look after your own fate (Pe)

2. Contextualising information disclosure

Despite wanting to be informed many women felt overwhelmed by the amount and complexity of

information offered and felt the information had been provided too rapidly for them to be able to process it. Few women felt they had received insufficient information.

I know they've got to go through everything but there was so much my head was spinning (Pd)

I felt so overwhelmed . . . a bit zombied like I'd agree to anything (Pk)

In terms of risk communication some HCP considered it necessary to spell out all of the risks whilst others were more selective and adopted a 'sensible pragmatism'. For many there was a real dilemma in striking the balance between comprehensive risk disclosures and avoiding making a woman unduly anxious. Allied to the extent of risk disclosure was a difficulty HCP reported in gauging a woman's attitude to risk.

balancing the amount of information is not always easy because we are now living in a society which is overloaded with information so giving the right amount of information is difficult sometimes you don't have time to assess the patient and know what's the right information to give (HCPo)

it's trying to work out how risk averse they are because we get women who jump at 1 in 200 . . . and . . . women where the risk is 1 in 7 and they're like 'oh it's fine' so it's gauging how they perceive risk which is tricky (HCPb) (prenatal diagnosis)

Women's experiences of receiving and understanding information were very mixed. Many women reported uncertainty about what they had been told in some cases to the extent that they felt their consent was vitiated.

I don't necessarily really understand it all (the information) so I suppose I'm agreeing to something which is a bit unknown . . . it's not really consent (Pe)

Many women felt they didn't have a good understanding of what the information provided meant for their particular situation and experienced the information as 'scripted and formulaic' when what they wanted to know was how the information applied to them specifically.

it's our baby that we're interested in, all of the information in the world out there is only as important to us as it affects us . . . we haven't really got the sort of energy, emotional energy I suppose, to think beyond that (Pj)

it kinda feels they're going over a script and I wanted to know which bits applied to me (Pk)

Most women reported being invited to ask questions but were unable to think quickly enough to raise queries and some were reluctant to ask questions for fear it might prejudice their care choices particularly in relation to their securing a caesarean section. Most HCP relied on inviting women to

ask questions to assess women's understanding but only one clinician formally checked understanding.

I didn't (ask any questions) . . . I was so focused on making sure I got the caesarean that I think I didn't want to run the risk of asking anything that might prejudice that. (Pc)

he mentioned the risk to the bladder . . . I've no idea what that's all about (Pf)

she said 95% of people won't rupture their scar but what I really want to know is what that means for me . . . am I more or less likely to be in that 95% (Pd)

HCP hesitated when asked if they provided tailored information. They universally aspired to be responsive to individuals' concerns but recognised that assessing what was important to an individual was a difficult judgment made harder if the HCP had not previously met the woman and was working under a time pressure.

it's just really difficult when you're trying to get a full picture of her and her life and what matters to her and so on in a single consultation (HCPn)

it's not easy in a fast moving clinic especially if they're not very clear on what they want (HCPH)

I probably don't do it (assess understanding) as well as I should I often go through all the benefits and risks and then say do you have any questions or is there anything you'd like to clarify (HCPd)

3. Quality of clinician–woman relationship:

The relationship between a woman and HCP strongly influenced how women sought and responded to information relating to their care. Women who did not have an established trusting relationship with their HCP tended to want more detailed information. Conversely many women reported that their innate trust in their HCP was more important than the detailed ins and outs of any proposed intervention. In some cases this innate trust translated into a reluctance to ask questions or become overly informed – a preferring 'not to know'.

I want to know the information but the more important factor is G (doctor) and him saying that's what this information means and not just means for everyone else but what it means for me – that's really important because you know you could be the one who's not quite like everyone else They're trying to do what's best and so I'm consenting to a (caesarean) section on that basis but it's on the basis of trusting them rather than on a sort of options appraisal of my own (Pn)

I'm really lucky because I do (trust the doctor) and I think that's really more important than the ins and outs (Pb)

The primacy of the care relationship was echoed by HCP.

(some clinicians are) totally alarmist and of course in the legal framework that's broadly right . . . but in a doctor-patient relationship it's probably the worst thing you can do . . . this is the bit we're losing now as doctors . . . it's becoming so medically legal (HCPg)

Linked to the notion of trust many women reported that explicit recognition by their clinician of the emotional dimensions of the information made it more meaningful to them. Women reported gaining confidence and welcoming the reassurance offered when their HCP endorsed a decision they had made – “that’s a good decision”.

I know all the information is there from a very cool-headed way but that's not really it . . . it was much nicer when they were saying you're going to be fine and I found that much better from a psychology point of view rather than do I understand all the information – sometimes it's just too much focus on giving all the information (Pk) (prenatal diagnosis)

4. Law and professional practice

All, bar one, of the HCP were aware of the *Montgomery* ruling. Whereas most of the midwives had a vague knowledge of it being ‘something to do with consent’, all of the obstetricians were aware of the details of the case. Obstetricians expressed variable views about its implications to practice with particular concerns being voiced in relation to whether consent should now be required for ‘normal’ vaginal delivery.

I vaguely remember that – that's to do with consent I think isn't it or something like that (HCPb – midwife, fetal medicine)

Obstetricians’ views on whether their practice had changed since the *Montgomery* ruling varied but most felt their practice had changed to some degree. Several obstetricians reported: being: more risk averse, open to women’s views and informing women about risks more broadly. They were also less likely to give a personal opinion and more likely to check what information had been provided by junior staff.

If the patient wants to take a risk when I go through alternative options I'm more open to it (HCPj)

I inform patients more broadly about the risks of any sort of intervention far more than I would have previously even things like taking antibiotics (HCPd)

I'm less likely to give my personal view now and probably a bit more likely to agree to what a woman wants (HCPn)

It's made me more risk averse and certainly more aware of the legal ramifications of my clinical practice (HCPo)

A minority of obstetricians felt their practice was unchanged, either because it was already in line with the *Montgomery* guidance or because indiscriminate disclosure of risks was considered incompatible with good care.

I think my practice is reasonably compliant, I don't think that I'm an alarmist and I don't like to make patients feel they're putting their life on the line just to protect myself from something that might, you know, point zero nine per cent go wrong (HCPf)

(has your practice changed) Not myself, but younger doctors yes . . . people are just you know watching their backs (HCPg)

Discussion

Main findings

Despite the ascendancy of patient autonomy our findings support the view that consent involves a woman's acquiescence to what was proposed by a HCP. This evidence of a culture of expected compliance reiterates previous work⁸. It is a culture reinforced by language which refers to consent having been 'obtained' implying it is something done *to* a woman rather than the result of a conversation *between* two parties. Reframing patient 'consent' as a 'choice' process seems a simple way to at least signal an intentional partnership.

The compliance view was in contrast with a more consumerist view suggested by women who reported needing to 'manage' their HCP to achieve their goal, in what could be seen as a reversal of the consent process. This was an unexpected finding considering NICE's guidance⁷ on maternal request caesarean section but may reflect women's awareness that only a quarter of Trusts follow the guidance¹¹. It also highlights a need for wider policy consideration about whether women should have a right to demand an intervention in the context of resource-limited services (see *Burke 2005*)¹².

Informational overwhelm is a clear threat to autonomous decision-making and one which doctors are cautioned against in *Montgomery*² (para 90). Many pregnant women felt overwhelmed by information and desired a more bespoke consent process using information tailored to *their* circumstances.

Of concern was our finding that many women did not understand all the information they had been given making the legitimacy of their consent questionable. HCP in this study invariably invited questions from women whilst stopping short of formally assessing women's understanding. Yet, as

stated in the case of *Wyatt v Curtis (2003)* 'there is arguably something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about' ¹³. Techniques such as teach-back to assess patients' understanding have improved comprehension in the context of surgical consent ¹⁴. We suggest that antenatal consent consultations may be similarly improved by the inclusion of measures that take the onus off the woman to ask pertinent questions.

Women in this study strongly wanted to be provided with individualised information. The significance of a particular risk is a uniquely personal matter, likely to reflect hybrid factors. Hence, judging what a 'material' risk to a woman requires a degree of knowledge about that woman and her wider social values which may not be readily ascertainable within the time constraints of a single consultation. How, therefore, is a HCP supposed to know what information is right for a particular woman? It seems an intractable request and we were unsurprised that HCP responded uncertainly about the extent to which they provided tailored consent a problem compounded when the woman was previously unknown to them.

Against this backdrop we found concern among HCP about the 'correct' way of counselling women in relation to the risks of 'normal' vaginal delivery. We agree with others that this requires urgent clarification ¹⁵⁻¹⁶. It also suggests a more general need to consider whether consent should be a routine requirement of clinical consultations in all healthcare settings whatever care plan results. Whilst such a move has resource implications it aligns with the notion of genuine choice.

Our findings strongly indicated the nuanced role played in consent encounters by the relationship between a pregnant woman and her HCP. Some women only sought cursory information, their trust in their HCP being sufficient to trump any inclination to seek more detailed information. Such trust-based consent contrasted with the experiences of less trusting women who sought detailed information, apparently as a way of managing their uncertainty. These findings will not surprise supporters of a relational approach to autonomy ¹⁷⁻¹⁹ and are reinforced by the *Montgomery* judgment which repeatedly insists that the doctor's 'advisory role' 'involves dialogue'². It has interesting implications for initiatives using web-based decision aids to inform women. Decision aids can support patients' knowledge and help them to focus on what matters to them ²⁰. These are important components of an effective consent process. However, if 'information seeking' is, in part, a proxy for personal trust, we suggest that it will be important for designers of decision aids to pay careful regard to the design of the whole consultation.

Montgomery is viewed as a landmark case in consent practice, it triggered intense professional debate, so it was encouraging that most of the HCPS were aware of it. Additionally, contrary to the findings of O'Brien et al ²¹ all the obstetricians in this study were familiar with the details of the case.

By contrast, however, their midwifery colleagues had limited knowledge. Midwives play a key role in consenting patients for antenatal interventions, and our findings strongly support a need for them to be afforded opportunities to develop their knowledge of consent.

Reflecting the ambiguity surrounding the implications of the *Montgomery* case²²⁻²⁴ obstetricians in this study were divided as to whether the ruling had changed their clinical practice. It seems that rather than a seismic change in practice, what judgments such as *Montgomery* and sequelae cases²⁻⁴ have done is highlighted the uncertainty inherent in the complex business of clinical consultations and embellished it with the additional uncertainty of the scope of the materiality test.

We believe this is the first study of the views and experiences of both pregnant women and HCP in antenatal consent settings. A key strength of this study was the researchers' immersion in the clinical environment. This, together with the combining methodology of detailed observation and interviews, facilitated a robust understanding of participants' experiences. The women in this study had a good command of English so it is unknown whether our findings would have been different in non-English speakers. We aimed to explore a wide variety of decisions in the antenatal setting and although this has revealed many key issues we may have failed to capture some nuances of particular decisions and contexts.

Conclusion

Our findings suggest that an effective antenatal consent process which empowers pregnant women requires their understanding of the provided information to be elicited. There is a delicate balance to be struck between the trust of a patient and their HCP and information-based consent, rather than a simple focus on improving information provision. Whilst recognising women's desire for bespoke consent, HCP acknowledged the difficulty of ensuring this in practice. If consent is to remain the legal yardstick of autonomous choice-making, women's understanding and that shared with their healthcare professional needs to be more explicitly addressed.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

The authors' contributions were as follows. Anne Lanceley (AL) and Jackie Nicholls (JN) conceived the study. AL was the site investigator. JN and AL initiated the study design and Anna David (AD) and Joseph Iskaros (JI) helped with implementation. JN recruited the study participants, conducted the observations and participant interviews. JN conducted the qualitative analysis and AL reviewed the codes. JN drafted the manuscript, which was amended following comments from all other authors. All authors read and approved the submitted manuscript. All listed authors meet the criteria for authorship and no individual meeting these criteria has been omitted.

Ethical approval

Ethical approval was obtained from the Health Research Authority (REC Reference: 17/YH/0212, IRAS Project ID: 226310).

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