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Women's experiences of consent to induction of labour: A qualitative study

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ABSTRACT

Objective: Induction of labour (IOL) does not require formal written consent, and little is known about how consent operates in this context. This prospective study explores pregnant women's experiences of the IOL consent process.
Methods: Qualitative study using semi-structured, interviews with thirteen women admitted to hospital for IOL. Data were analysed using thematic analysis.
Results: Three themes emerged: 1) ***Voluntary nature of consent:*** Some women experienced genuine choice; others perceived pressure to prioritise their baby. 2) ***Understanding the why and how, risks and benefits*****:** Information provision and explanation was often minimal, particularly regarding risks and alternatives to induction. The possibility of IOL failing was not discussed 3***) Non-personalised information process:*** Few women received information specific and relevant to their circumstance.
Practice implications: There is an urgent need for healthcare professionals to be supported in actively facilitating consent consultations which enable women undergoing IOL to make a fully autonomous, informed choice.
Conclusions: Women did not always experience choice about whether to be induced. This sense of disempowerment was sometimes exacerbated by inadequate information provision. The study reveals a practice imperative to address consent in IOL and we suggest there is an urgent need for HCPs to be offered high quality training specific to IOL.

Introduction

Informed consent is central to high quality obstetric practice. Recently there has been a shift from a paternalistic approach to increasing focus on shared decision-making and patient autonomy. This shift is reflected by legal developments notably the landmark case of *Montgomery v Lanarkshire Health Board* [1] which involved a diabetic woman who was not informed of the shoulder dystocia risk and was not offered a caesarean section. This case established that risks should be disclosed if, '*a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.*' [Para 87]. Risk significance is determined by the patient's perceptions, not the healthcare professional's (HCP) opinion. The importance of embracing patients' values was reiterated by the statement, '*she may place great value on giving birth in the natural way and be prepared to take the risks to herself and her baby which this entails. The medical profession must respect her choice unless she lacks legal capacity to decide*' [Para 115]. Voluntariness also has extended precedent in common law and requires consent to be given freely and without coercion [2]. These key principles reiterated in guidance issued by the General Medical Council (GMC) [3] and the National Institute for Healthcare Excellence (NICE) [4] were endorsed in *Montgomery* and subsequent cases [5,6].

NICE guidance [4] outlines the information that HCPs should explain to women offered induction of labour (IOL) including indications, risks (including possible failure) and alternatives. Failure to discuss any of these points questions the extent to which consent is fully informed [7,8]. Existing literature highlights problems with IOL consent globally with numerous women being unaware that IOL was a choice [9,10].

In the United Kingdom there is no specific guidance regarding consent for IOL and no legal requirement for written consent. This, together with uncertainty in the evidence base, including, for example, when to offer induction and the maternal and perinatal consequences of IOL at a specific gestation [7,9], allows for individual interpretation in consent standards. Although recent NICE guidance [4] attempts to address some of these evidential uncertainties its emphasis is on the necessity of

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considering a woman's individual needs and preferences and ensuring that she has an opportunity to discuss alternatives such as expectant management or planned Caesarean section. Since the Montgomery case the way in which the requirement to discuss alternatives should be approached has also been addressed further in law as reflected in the judgment in Duce [11]:

> 'Once it has been decided what are the reasonable alternative treatments, by applying the professional practice test, the doctor is then under a duty of care to inform the patient of those reasonable alternative treatments and of the material risks of such alternative treatments'

Most recently this approach was endorsed by the Supreme Court case, McCullough vs Forth Valley [12] which established that where a doctor identifies reasonable alternative treatments a patient should be informed of all of them and made it explicit that a doctor cannot simply tell the patient about the treatment option which the doctor prefers.

Rates of IOL are increasing globally [13] and in the UK 1 in 5 women are induced annually [14]. Retrospective studies [10,15] indicate that women's involvement in decision-making is not fully supported but there are few prospective UK studies [16,17] and these do not focus on women's experiences of the IOL consent process. Partly this reflects the difficulty in accessing women in what is often a short window of time between either the decision to induce or the admission for IOL and its implementation, yet it is women's contemporaneous views which are likely to offer useful insights into improving the consent process.

This prenatal interview study of women admitted for IOL aimed to qualitatively explore women's experiences of being asked to consent to IOL.

Methods and materials

This study used an interpretive qualitative methodology [18] involving in-depth interviews to explore how pregnant women experience the consent process in IOL. The study design and analytic interpretation were governed by a medico-legal lens. By this we mean that legal theory informs our considerations of the legal, moral, philosophical, and societal influences on matters of medicine and law. This study was approved by the United Kingdom Health Research Authority (REC Reference: 17/YH/0212, IRAS Project ID: 226,310). It is reported with reference to the Consolidated Criteria for Reporting Qualitative Research [19].

Recruitment

Women were recruited via the Labour ward and antenatal care unit of an inner-city hospital offering ante-natal care to approximately 6500 women yearly. The local IOL rate was approximately 24 %. Eligible pregnant women met all the following inclusion criteria:

- Able to understand written and spoken English
- Admitted for imminent IOL
- Aged 18+
- In their first or subsequent pregnancies

Exclusion criteria:

- Lacking mental capacity
- IOL already begun

Prior to their admission for IOL, in accordance with local policy all participants had a consent consultation with their HCP at which they were provided with written and verbal information to allow them to make an informed choice.

All eligible women were identified by a member of the clinical team on admission. The HCP informed all eligible women of the study and if interested in participating the woman was then introduced to the researcher.

Participants were provided with a Participant Information Sheet and invited to ask questions before deciding to participate. Women were reassured that neither participation in nor withdrawal from the study would affect their care and that their interview responses would remain strictly confidential. Sixteen women were consecutively approached to participate by CK on the Labour or ante-natal ward until data saturation was achieved.

Data collection

Thirteen face-to-face semi-structured interviews were conducted during a 3 week period in February/March 2020 to explore the views and experiences of pregnant women; three women immediately declined participation. Interviews were loosely based on an interview guide developed from previous work [20] and refined in discussions with women and healthcare professionals about IOL (Table 1). Interviews aimed to explore women's experience of the consent process in a responsive manner so if, for example, a woman felt she had not actually 'consented' but rather had 'acquiesced,' her reasons for and feelings about this were explored. Socio-demographic details were collected directly from participants.

The researchers were all trained in good clinical practice regarding research studies. MW is a practicing obstetrician (not involved in recruiting participants), CK & SK are medical students, AL & JN are experienced women's health care researchers. None of the researchers were involved in the clinical care of any of the participants.

Data analysis

Interviews were audio-recorded, transcribed verbatim and anonymised to protect participants' identities. All transcripts were compared against the original audio recordings to ensure validity and quality of the transcribed data. Data saturation in relation to the main views raised was reached and evidenced by the diminishingly small number of new issues raised during the final interviews and confirmed during initial coding [21].

Traditional, manual thematic text analysis was selected for this distinctive data set and performed using Braun and Clarke's six-step framework [22]. Initial codes were identified by CK and following discussions and cross-checking with the research team they were combined and refined to produce a set of themes. To ensure consistency, 20 % of transcripts were coded independently by co-researchers (AL, JN, SK). Transcripts were re-read several times and differences discussed until agreement was reached.

Table 1
Interview topic guide.

Pregnant women
What do you think is the main purpose of asking for your consent (Prompts: What do you understand by consent? How does it relate to your view of you making decisions about your care? How was the issue of consent raised with you? How were you prepared when you were asked for your consent? (were you given any preliminary information?) How was the purpose of the consent process explained to you? What do you feel your role was in the process?
What were you told when you were asked for your consent (Prompts: What information was given to you in relation to the decision you were being asked to give your consent for? Were you given any information sheets, websites, or other sources of information. What do you think are the important things to address when discussing consent with a patient? Were risks discussed with you? How were they explained to you? Were benefits discussed with you? How were they explained to you?
How did you feel during the consent process (Prompts: What difficulties, if any, did you experience when you were asked for your consent? Did the doctor/midwife check your understanding when seeking consent? Did you ask any questions? If so did you feel satisfied by the answers you received?
What do you think is the purpose of the consent form?

Results

Thirteen women were interviewed. On average interviews lasted 30 min. Eleven women were primiparous, and two women had previously experienced IOL. Reasons for induction were a combination of being: a) overdue and/or b) an older mother and/or c) gestational diabetes and/or d) large for dates. One woman had rheumatoid arthritis. Table 2 reports participants' demographics.

While demographics are useful for overall context and attributing demographic information to each individual quote enriches interpretation of the data, this was not possible to fully respect and protect participants' confidentiality. Selected quotes are referred to by P followed by numbers (1–13) to reflect the range of participant's views e.g., P7 for participant 7.

Three inter-related themes were identified:

- Voluntary nature of consent
- Understanding the why and how, risks and benefits
- Non-personalised information process

Voluntary nature of consent

Although some women felt they had a choice, most women indicated that they did not experience IOL as a choice but as a ***necessary*** procedure which they should not decline. These women experienced consent as passive acquiescence or pressured agreement rather than as a discussion with their HCP in which they played an active role:

> "It never felt like a choice…the key thing is even knowing that induction is a thing for consent or not because it was absolutely not presented like that … until we pressed the issue, induction never felt like an item that was consent to be given or not; it just felt like it was happening" -P9

Many women trusted their HCPs which sometimes made it more difficult for them to oppose the professional advice, despite wanting to do so.

Although some participants recalled the HCP stating that they **could** refuse IOL, nearly all women experienced the medical advice so strongly as to preclude their refusal often because IOL was explained in terms of being optimal for safety reasons.

> "I wasn't given much choice…it didn't feel like something that I can choose freely because if I wanted to put my baby's safety first then I should consent"-P8
> "You have to agree because otherwise it's going to harm your baby…. You don't have any other choice…There was no options"-P11

Table 2
Participant demographics.

Age in years:	
Mean age (range)	37.5 (32–43)
Ethnicity:	
Caucasian	8
Black	3
Asian	2
Marital status:	
Single/Never married	2
Married/Living with partner	11
Education:	
Degree/Higher degree	12
No formal qualification	1
Employment:	
Employed full time	10
Unemployed	2
Self-employed	1

Most participants were unaware of alternative options to IOL and very few had discussed the option of not being induced. When asked if there were important aspects of IOL which they believed should be discussed and which were not, one woman responded:

> "Whether there are any alternatives, because that definitely wasn't discussed with me"-P7

Some women reported being offered a choice between agreeing to IOL when it was first offered or waiting and agreeing to it later rather than a decision of whether they wanted to be induced or not.

> "I had my options explained…I had to decide either to wait longer or book it…I could have said no and just wait. I don't know for how much longer, probably a week or so"-P12

All women bar one expressed a degree of discomfort with declining IOL. One participant reported having an in-depth discussion with their HCP about how fetal monitoring could be increased if she declined IOL; she was the only woman who considered declining IOL as a realistic alternative.

Understanding the why and how, risks and benefits

Many participants reported that they were not fully informed before agreeing to have an IOL, with some only receiving information, such as procedural details, on the day of induction. One woman indicated that she had not received any information:

> "…not before I consented. After the consent they (HCPs) give you a little brochure about the procedure itself"-P1

The rationale for offering IOL was usually communicated to women and the benefits of IOL were discussed with most women but not all.

> "Benefits have been explained…I do understand why…they want to induce me and not wait"-P3

Participants saw value in understanding the risks as well as the benefits of IOL, though most had not considered raising this with HCPs. Some women did not recall being informed of any risks at all. When asked if risks had been discussed one woman replied:

> "no…I don't know anything. It's my first baby. I haven't a clue. I'm just following my doctor on what he says."-P2

Some women highlighted the importance of understanding risks which were relevant to them, and several women said that HCPs should 'discuss' how the risks applied to them and not rely only on statistics. Some women reported minimal discussion of the associated risks of IOL and described the information received as being vague and general:

> "[Risk discussion was] very brief… I wasn't given anything like 'this is the risk of having an induction.' It was more that 'the risks are very minimal'"-P3

Only one participant recalled discussion of risks related to the birth experience, such as the increased likelihood of an assisted delivery or the potential of unsuccessful induction and subsequent need for a caesarean section. Overall, women believed that IOL would result in a safer birth but had minimal appreciation of potential failure.

Non personalised information processes

Women expected HCPs to provide them with all information relevant to their specific situation upfront in a clear and detailed manner but in many cases, this was not forthcoming forcing women to do their own research.

> "I feel like I had to put more effort into gaining access to the information than I should have"-P1

"I think I understood the answers because I had read about stuff…If I had gone in with no knowledge… I'm not sure that would have been fully satisfactory in terms of answers"-P7

Women were concerned that online statistics were not applicable to their individual situation. Some women were confused and unsettled by their information seeking and worried that the information sources they accessed could mislead them. Many women asked questions because HCPs were not forthcoming in providing information. This was difficult for some women as they were unsure what to ask.

"You have to ask for information. It doesn't feel like people come and just give you all the information…you have to have your questions ready."-P1

"It relied on me as a patient knowing what questions to ask"-P7

For most women, receiving more detailed information from the point of the IOL offer would have improved their understanding.

"[Having all information] would have been more helpful from the start…I didn't know what induction really meant…there are so many other things at the same time happening, the whole experience as a first-time mum, it [her IOL understanding] wasn't building up…"-P4

Discussion of the procedural process is an essential part of IOL consent, yet many women highlighted the absence of such discussion. Many women saw value in understanding the step-by-step process in advance so they could discuss tailoring it to their preferences. Some were surprised by the explanation of the procedure on the day of their induction.

"Not the step-by-step process was explained to me… I have a more generic idea of induction… but not exactly what this hospital would do…what they're doing here today isn't what I expected"-P3

Opinions varied about how much information is the 'right' amount. Some women felt anxious and over-burdened with information. Others felt that being fully informed required provision of relevant statistics and research. Overall, women wanted HCPs to understand their individual perspective on how much information is right for them. Similarly, some women highlighted the importance of understanding risks pertinent to them and felt HCPs should discuss these only using statistics to aid their explanation. Overall, most women wanted more nuanced discussion of how information applied to their individual situation.

Discussion and conclusion

Discussion

In this study we prospectively explored how consent to IOL by interviewing women in the process of IOL. Revealing a complex and often compromised discourse in consent to IOL our key findings are: (1) women's ability to exercise a truly voluntary choice was often undermined, (2) understanding of the why and how, risks and benefits was limited particularly in relation to alternatives to IOL, (3) few women received information specific and relevant to their circumstance.

Placing patients at the centre of decisions regarding their own care is a central tenet of lawful, patient-centred healthcare [10]. However, there is a recognised skills deficit in HCPs ability to engage in consent discussions [23] and our findings reveal that many women felt they had not been offered a genuine choice and had not been full partners in making the decision to undergo IOL. In a medicolegal sense our findings highlight the gap between legal and professional requirements and women's actual experience.

Whilst women 'agreed' to IOL, women's reports indicate that the legitimacy of this 'agreement' was questionable as IOL was presented in the language of mandate, as a 'necessary' procedure rather than as an option to be discussed, making it difficult for all but the most assertive of women to voice their view. Implicit in such presentation is the assumption that women 'should' comply with what their HCP proposes. However unintended such assumptions may be, other studies [8,9] indicate that pregnant women may feel pressurised into accepting an intervention so it seems reasonable to suggest that this may extend to IOL. Our findings also cohere with previous work [9,10] involving HCP's who experience unease about how consent is secured and question whether women's autonomy is always respected.

We were concerned that many women reported not understanding why they were being offered induction or what was involved. Such reports afforded the researcher the opportunity to invite a woman to grant permission for the researcher to raise her concern with a woman's clinical team although, interestingly, none chose to do so. This lack of understanding coexisted with many women reporting that IOL had been presented to them as the *only* safe option for their baby and, implicitly, not something a woman should negotiate. Birth outcomes for the baby are a key measure of women's satisfaction with their birth experience [24] and women are often reticent to challenge a doctor's recommendation [25] also when IOL is presented in the language of welfare of the unborn baby, it is unsurprising that women were compliant with the attendant loss of choice. However well-intentioned such baby-centred advice may be, assuming that all women want decisions made based entirely on what is presumed to be optimal for their unborn child neglects to support a woman's sense of agency and risks failing to give an appropriate voice to a woman's own values and preferences. The role of an HCP is an 'advisory' one and, as emphasised in *Montgomery*, there is, in general, no justification for withholding information to prevent patients from taking an informed decision. As Lords Reed and Kerr stated, '*it is the doctor's responsibility to explain to her patient why she considers that one of the available treatment options is medically preferable to the others, having taken care to ensure that her patient is aware of the considerations for and against each of them.*' In a powerful underlining of these requirements Lady Hale stated, *'Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being'*.

Nonetheless, our findings also indicate that some women constrained their own choice-making. They reported being unlikely to have made the decision to decline IOL even if they had felt empowered to do so as their primary concern was for the health of their baby rather than their own birth preferences, a concern echoed by the 'good mother' narrative so often deployed in discussions with women [25,26]. Yet the situation women face is not straightforward – evidence for the optimal timing of when to offer IOL is equivocal [15] and awaits further exploration of the risk profiles pertaining to different women. Nevertheless, our findings may point towards a 'benign tension' between a well-intentioned but directive HCP and a woman who wants to do the 'right' thing but is unsupported by open discussion of the uncertainties surrounding IOL. What does this mean for ante-natal practice? Previous work suggesting that women struggle to challenge their HCPs recommendations [10,27,28] particularly when the spoken rationale emphasises their baby's safety, cautions HCPs to ensure that this 'fetal-focused decision-making' is truly autonomous and not illusory [29]. Our findings not only strongly echo this caution but also support the case for treating women in a way which respects their autonomy by openly acknowledging the limitations of both existing knowledge concerning IOL and how it might apply to an individual woman. However, systematic review evidence of shared decision-making in healthcare settings indicates that even personalised information tailored to a woman's needs is insufficient to enable shared decision-making and that women need to be explicitly 'enabled' to be active participants in the decision-making process [30]. This underlines the importance of HCPs engaging in consultation dialogues which jointly explore risk and uncertainty in the context of a woman's values and preferences in a non-judgemental and unbiased way. Co-constructing appropriate discussions around uncertainty in all its guises is a high-level professional skill and our findings may suggest it merits greater attention [31].

Equally concerning was our finding that whereas most women understood the benefits of IOL, many had not been appraised of the

attendant risks or, in some cases, their very existence. Apart from well-known risks such as the increased risk of assisted delivery [4], failure of IOL is not uncommon, affecting up to one in four women [32] often necessitating an emergency caesarean section along with associated psychological impacts on a woman who had not been made aware of this possibility [33–35]. However, there is clear evidence that IOL and CS reduce the risk of stillbirth and transparency about the risks of IOL, including possible failure, needs to be considered alongside the risks of continuing the pregnancy. Women's perceptions of their birth experience strongly affect their post-partum mental health so irrespective of the legal and professional imperatives for doctors to disclose relevant risks, it is fundamental to good practice for HCPs to be transparent about risks to minimise undue harm. How can we explain these apparent breaches of consent practice?

We suggest the answer might partly lie in the challenge for HCPs of fostering consent discussions with women which support them in having a truly active role in a decision-making process which is transparent about the uncertainties of IOL. To address this, we suggest there is a need to develop high fidelity simulations which support training HCPs in ways of promoting and implementing decision-making discussions in which women are genuinely informed and free to choose according to their own values and preferences. Integral to such training is helping HCPs to develop ways of supporting and enabling women to take the role they (and their partners) wish within the decision-making process and in overcoming any reluctance by HCPs to share the process of decision-making with women, for fear of the consequences of adverse outcomes of a women's decisions, for which they remain liable [35]. Within such training we suggest that there is a need for HCPs to acknowledge that HCPs attitudes to IOL vary widely and to openly discuss with women both the different professional views on IOL and the difficulties of forecasting the ways in which IOL might eventuate for an individual woman together with the complexities involved in discussing risk statistics [35].

Practice implications

There are opportunities for HCPs to use this research to begin to address shortcomings in the consent process at many stages. Our findings point to the need to strongly reiterate to women throughout the decision-making process that IOL is a woman's choice and to do so in ways that 'enable' women to choose freely. This may indicate a need for more formalised discussions. Addressing women's concerns about the communication of risks and benefits in terms of both the completeness of the information they are provided with and its application to their circumstances seems warranted. We suggest this requires support to be offered to women not only in understanding the nuts and bolts of the factual information but also in helping them to appreciate that the provided information does not come with a clinical guarantee. This underscores the need for consent discussions to give women space to help women consider what the information 'means' to them in the context of their broader personal values and preferences. This might be accomplished by providing pause points throughout the process which focus explicitly on supporting women in thinking about how they feel about making a decision to undergo IOL at a specific juncture. The uncertainties revealed in the present study may be informative to HCPs in helping them.

Strengths and limitations

The prospective study design and the researcher's engagement in the clinical environment enabled a novel in-depth exploration into women's situated accounts of the consent process untainted by a woman's subsequent experience or memory. The sample size allowed data saturation to be achieved and women were interviewed prenatally, minimising recall bias and the possibility of the birth experience altering women's perceptions. All of the women in this study had been admitted for IOL and so had had time to consider their decision. To the extent that time constraints may interfere with a consent process when the decision for IOL is made at the last minute the experiences of women in this study might be presumed to be more favourable than those of women offered IOL after admission which makes our findings more concerning.

We used various means to ensure the quality of the research including pre-testing of the interview schedule, and during coding inter-rater reliability checks, careful attention to "deviant-responses" and the use of comparison [36]. Although interviews were only conducted at one site, this does not deny generalisability of the results as "naturalistic generalisations" [37] can be formed through the qualitative research method. Reflecting on the details in this rich data and its context, the reader can gain personal insight as they recognise similarities with their own experiences and in doing so provide verification of the findings.

Conclusion

In this small sample of well-educated women, the IOL consent process did not provide autonomous choice-making, and we have no reason to believe that they are unrepresentative. This suggests that deficiencies in information provision and adequate discussion of risks and alternatives to induction are common. If so, then this is unacceptable and potentially unlawful. If HCPs are to effect lawful professional practice in the post-Montgomery legal era there is an urgent need for them to receive more training and support in how to implement effective consent to IOL.

Contributions

Study design: JN, AL; data collection: CK, MW; data analysis: CK, JN, AL, SK; and manuscript preparation: CJ, JN, AL. All authors confirm they have seen and approved the final version.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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