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Doctors' perspectives of informed consent for non-emergency surgical procedures: a qualitative interview study

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Abstract

Background The need to involve patients more in decisions about their care, the ethical imperative and concerns about ligation and complaints has highlighted the issue of informed consent and how it is obtained. In order for a patient to make an informed decision about their treatment, they need appropriate discussion of the risks and benefits of the treatment.

Objectives To explore doctors' perspectives of gaining informed consent for routine surgical procedures.

Design Qualitative study using semi-structured interviews selected by purposive sampling. Data were analysed thematically.

Setting and Participants Twenty doctors in two teaching hospitals in the UK.

Results Doctors described that while consent could be taken over a series of consultations, it was common for consent to be taken immediately prior to surgery. Juniors were often taking consent when they were unfamiliar with the procedure. Doctors used a range of communication techniques to inform patients about the procedure and its risks including quantifying risks, personalizing risk, simplification of language and use of drawings. Barriers to effective consent taking were reported to be shortage of time, clinician inexperience and patients' reluctance to be involved.

Discussion and Conclusion Current consent processes do not appear to be ideal for many doctors. In particular, junior doctors are often not confident taking consent for surgical procedures and require more support to undertake this task. This might include written information for junior staff, observation by senior colleagues when undertaking the task and ward-based communication skills teaching on consent taking.

Introduction

Informed consent for a surgical procedure is a process by which patients grant permission for doctors to perform an invasive procedure with knowledge of the possible risks and benefits. The informed consent process requires good communication between patient and doctor and relies on a professional commitment to good practice. The process is usually formally documented by the reading and signing by both patient and clinician of a 'consent form'. Informed consent is considered to be a legal and ethical requirement in many countries if a surgical procedure is to be undertaken; the consent process serves to inform and protect the patient and also the clinician as it demonstrates the patient has been informed.

In the UK, the General Medical Council (GMC), British Medical Association and the Department of Health have provided advice on what information should be shared with patients prior to them consenting to surgery. Information should indicate why surgery is required, the perceived benefits and risks, and all options of available treatment, including the option not to receive active treatment.[1–3] Previously, NHS trusts and health boards have been free to develop their own consent documentation (using the Department of Health model if they wish to do so). In April 2014, the Welsh Government updated their standard consent forms with the intention that the forms would be easier to use and provide greater assurance that clinicians are meeting required standards for informed consent.

The GMC emphasizes that doctors should engage patients in discussions regarding suggested treatment options, allowing them to come to an informed decision based upon the information they have received.[1,4] Hence, during the consent process, patients should be supplied with all the relevant information, be able to understand that information, have enough time to consider it and not be acting under duress.[1,3] However, guidance from regulating bodies does not give specific advice on how benefits and risks of procedures should be presented to patients or how they should be tailored to individual patients.

Guidance states that the person providing treatment must ensure valid, informed consent has been obtained from the patient before the procedure commences.[1,3] The task of seeking consent can be delegated to another person, providing that person is trained and qualified, and has sufficient knowledge of the procedure.[1,3] Junior medical staff often obtain informed consent for surgical procedures.[5] However, newly qualified doctors tasked to take consent may lack understanding of procedures for which they have little or no experience,[6,7] which could lead to poor discussion of the risks.

Information-sharing is core to the informed consent process. To do this effectively, doctors must first assess patients' information needs. Doctors may struggle with underestimating, or overestimating, amounts of information they give, and confuse patients with medical terminology.[8] Organizational problems also appear to complicate the consent process. Guidance recommends that consent be gained at least on the day before surgery; however, the consent process is often completed just hours before the patient is taken to theatre.[2] Many doctors view the consent process as a 'perfunctory chore';[4] standardized consent forms may make the discussion feel repetitive, reducing doctors' regard for patients' concerns.[9]

Most previous studies exploring the consent process for surgical procedures have focussed on patient perspectives[10–15] and conclude that current consent processes are often inadequate as patients often have limited understanding of the process, are frightened or disempowered by the process, or feel that they have either not understood or not been told relevant information about their treatment. One study which has reviewed consent documents has demonstrated doctors' variability in covering complications.[16] There has been little exploration of the consent process from the doctors' perspective; our literature search identified only three previous studies,[17–19] all of which were conducted in developing countries. To our

knowledge, there have been no qualitative interview studies conducted in a developed country that focus on doctors' perspectives of informed consent for surgical procedures.

We therefore set out to explore the process by which doctors achieve informed consent for non-emergency surgical procedures. Specifically, we were interested in doctors' perspectives of the informed consent process: how doctors communicate risk, barriers doctors face in gaining informed consent for surgical procedures, and how the current informed consent process can be improved.

Methods

Participants and procedures

The study was conducted with NHS ethical approval. Qualitative methods were chosen to allow exploration of doctors' perceptions of gaining informed consent for surgical procedures. Recruitment of participants was by purposive sampling. Doctors working in two teaching hospitals in the UK were recruited to represent a range of experiences to increase transferability to other settings and so we selected a sample on the basis of clinical grade and surgical specialty. Clinical grades encompassed junior doctors, specialist registrars (SpR) (doctors who are receiving advanced training in the surgical speciality) and consultants (senior surgeons). Doctors working in general surgery, obstetrics and gynaecology, ophthalmology, trauma and orthopaedics, urology, and vascular surgery were approached by email, followed up by a phone call. A sample frame of possible participants (164 in total) was constructed based on medical grade and surgical specialty, and from that list, we used a stratified random sampling method via a random number generator to identify doctors to invite to participate in the study. Doctors were given an information sheet to ensure they understood their role within the study and the researchers' reasons for conducting the research. Informed written consent was taken immediately prior to data collection.

We conducted a brief literature review on the process of consent which revealed a lack of studies on doctors' perspectives of the consent process. The literature review then informed an initial question schedule focussing on views about how the consent process was undertaken. The interview schedule was piloted on two doctors working in ophthalmology (data from these pilot interviews were incorporated into the final analysis). Development of subsequent questions was iterative; questions were adapted accordingly as new insights emerged during the pilot stage, which allowed formulation of the finalized interview schedule (Table 1).

Data collection

Interviews were conducted with doctors who consented to take part in the study between August 2011 and February 2013. Interviews were conducted at the hospital site in private rooms by SM, AC-S or EP. All the three interviewers were trained in qualitative interviewing prior to data collection. Interview questions were semi-structured in nature ensuring that pertinent topics were covered, while allowing flexibility to pursue doctors' experiences and opinions in more depth.[20] Interviews lasted 34 min on average (ranging between 14 and 65 min). All interviews were audio-recorded, and the interviewer also made brief field notes.

Data were reviewed after 15 interviews had been conducted, at which point data saturation was evident and no new themes were emerging from newly collected data.[21] An additional set of interviews with doctors in obstetrics and gynaecology were conducted to ensure no new themes emerged specific to this speciality. At interview 20, data were reviewed for evidence of saturation, and it was decided that interviewing could conclude.

Data analysis

Interviews were audio-recorded, transcribed verbatim and anonymized. Transcripts were

Table 1 Finalized Interview Schedule

Number	Question	Prompts
1	Describe the process you use when you seek consent	• What do you say first? • What do you cover? • What do you leave out? • What is important? • What is not important? • Any variations in your approach?
2	Are there any barriers that exist to you achieving what you think would be a good consent process?	• Time? • Organization? • Language?
3	What is your view of the current consent process?	• Good and bad experiences?
4	Do you have any concerns about the consent process?	• Worries?
5	Have you received any training or guidance in the consent process?	• Medical school teaching? • Teaching from senior colleagues? • Time spent in theatre?
6	Are there any changes that you would like to make to the consent process?	• Time? • Organization? • Other team members?
7	What do you understand by shared decision making? What strategies do you use to ensure shared decision making with patients?	• Doctor–patient relationship?
8	Do you use any forms of decision support tools when consenting patients?	• Do you use DVDs, information leaflets? • Do you use diagrams? • Do you refer patients to websites?

analysed using thematic analysis – a common method of qualitative data analysis used in health research for exploring questions about salient issues.[22] Thematic analysis involves examination and comparison of participant responses, to create a classification of themes that recur across the data set.[22] Analysis was inductively conducted by SM alongside data collection to ensure that notable topics that emerged during interviews could be incorporated and clarified in future interviews. Frequent meetings between researchers took place to confer about emerging themes and codes. Twenty percent of interview transcripts ($n = 4$) were doubled coded by two of the authors (SM and FW). A final coding framework was developed (Table 2), incorporating themes and subthemes. To assist management of the data set, we used qualitative data analysis software (QSR NVivo 8.0).[23]

Results

Participants

Twenty doctors participated in the study including eight junior doctors, three specialist registrars and nine consultants, across six surgical specialties (Table 3). Of the 20 doctors interviewed, 10 were male and 10 were female; on average, doctors had held their medical degree for 13 years (ranging between 1 and 35 years); and 17 had qualified from UK medical schools.

The results are presented under four thematic themes as follows: *logistics and processes, information-sharing and risk communication, barriers to the consent process* and *improving the consent process* (Table 4). Each theme will be exemplified with data extracted from interview transcripts, alongside a participant identifier, to reflect main points of interest.

Table 2 Finalized coding framework

Code	
Communication and information	• Assessing information needs • Barriers • Lay language • Personalization • Purpose • Risks • Quantification • Terminology • Visualization
Experiences	• Colleagues • Good and bad practice • Perceived barriers • Pressure
Improvements	• How to make changes? • What needs to be done? • Obstacles to change
Patients	• Expectations • Preference • Patient fear • Understanding
Processes	• Consent form • Where? • When? • Who gains consent? • Who else is involved?
Shared decision making	• Decision support • Feasibility • Barriers to SDM
Training	• Confidence • Undergraduate and postgraduate • Training others
Timing	• Concerns • How long to consent? • Impact • Pressures

Table 3 Participant characteristics (grade and surgical specialty)

	Junior Doctor	Specialist Registrar	Consultant	Total
General surgery	1		2	3
Obstetrics and gynaecology	2	2	2	6
Ophthalmology		1	1	2
Trauma and orthopaedics	3		2	5
Urology			1	1
Vascular surgery	2		1	3
Total	8	3	9	20

Table 4 Themes and subthemes describing clinicians' views and experiences of the informed consent process for surgical procedures

Themes	Subthemes
Logistics and processes	• Time and place • Who is consenting? • Involvement of other health-care workers
Information-sharing and risk communication	• Language and communication aids • Discussing death • Quantifying risk • Personalizing risk
Barriers to the consent process	• Patient engagement • Unfamiliarity with procedures • Pressure from senior colleagues • Timing
Improving the consent process	• Gaining experience • Training • Information guides for junior clinicians • Involving other colleagues

Logistics and processes

Time and place

Our participants reported that they felt it would be preferable if the consent process was routinely started in the pre-operative clinic. It was felt this would allow patients more time to consider information, and give patients better opportunities to ask questions.

> Information giving occurs in the clinic. What the procedure will be, what it will entail, risks etcetera, and then before they have the procedure, whether it is the day before or the morning of, that is when the form is signed. (Consultant 1, Ophthalmology)

However, this ideal was regularly not achieved as the doctors in this study admitted that it is not uncommon practice for patients to be consented for elective procedures on the morning of, or even moments before surgery,

leaving them with little time to discuss information with patients.

> It happens quite a lot actually, you turn up to a ward and you find out that this patient is going down to theatre this morning, or within the next 10 minutes. (Junior 1, General Surgery)

Who is taking consent?

Most doctors were aware of the guidance that consenting responsibilities should fall to the surgeon performing the procedure. However, many of the participants gave examples of how senior doctors delegate responsibility of gaining consent to junior doctors because the medical hierarchy permits such occurrences.

> The person doing the operation should do the consent, but it's not always feasible… Say for a fractured neck of femur, if I'm the person who clerks that person in, I'm expected to consent them for the operation. (Junior 6, Trauma and Orthopaedics)

There were consultants who stated they would obtain consent for procedures and did not rely on junior staff for this task, but other senior staff felt that in some circumstances, it was appropriate for properly briefed juniors to undertake the task.

Some doctors were of the opinion that patients are more willing to discuss information with nurses than doctors, but one clinician expressed concern about involving non-medically trained staff in the consent process, as they lack experience of not having seen or performed the surgical procedure.

> In the previous hospital I worked consent was done by nurse practitioners who had supposedly been trained in consent for procedures, but once you had seen their consent forms it was apparent that they had not seen or performed the operation. (Specialist Registrar 2, Obstetrics and Gynaecology)

Information-sharing and risk communication

Language and communication

During interviews, many participants discussed how medical terminology and surgical jargon can confuse and frighten patients. Some doctors demonstrated their ability to simplify and adapt their language to a level that is understandable to the layperson.

> I'd say 'One of the risks associated with having a colonoscopy done is perforation of your bowel which is the segment of tubes in the tummy that we're going to be looking at, and the reason why this can happen is because the cameras and the probes that we use can sometimes poke through the very soft lining of your bowel. (Junior 1, General Surgery)

Visual aids, such as anatomical diagrams, were also thought to be helpful, particularly among junior doctors.

Discussing death

Discussions with patients surrounding the subject of death as a complication of undergoing general anaesthetic were described as tentative and uncomfortable. Many junior doctors admitted to struggling to address the subject adequately or avoiding it completely.

> It's a horrible thing to bring up isn't it? It's something I've got to say that I don't voluntarily engage in it with patients unless they are sort of pointing me down that line. (Junior 2, Vascular Surgery)

Doctors noted that discussions concerning death were only relevant when they considered patients to be in a high-risk category or having significant comorbidities, as this makes the discussion seems less fraught and gives doctors an appropriate lead-in to initiating such conversations.

> I wouldn't spontaneously bring up death, unless there was significant co-morbidities. (Consultant 4, Trauma and Orthopaedics)

Quantifying risk

Doctors reported that they often present procedure-specific risk in numerical formats to aid patients' understanding of potential surgical complications. Methods of risk quantification ranged from using simple ratios to percentages. However, several doctors expressed reservations regarding risk quantification, as they felt

that patients may misinterpret information, resulting in their failure to understand the degree to which they are at risk.

> It can be confusing if you say there's a 10% risk of infection, they might think that means all patients will have an infection to a 10% degree, i.e. a little bit of infection, rather than it being you've either got it or you haven't. (Consultant 3, Urology)

Instead, these doctors felt that it was important to verbalize risk in a form that patients are likely to understand, as this may help patients appreciate risks associated with surgical procedures.

Barriers to the consent process

Patient engagement

A number of doctors in our study reflected on the challenges of engaging patients in the consent process. One reported problem was the belief that patients who are in an emotionally charged state would find it difficult to process and retain information.

> The amount of information that patient has taken on board in the last half an hour is phenomenal, they're massively emotionally charged, what you have told them will go in one and out the other. (Consultant 2, Obstetrics and Gynaecology)

Some doctors also discussed that they sometimes were required to consent patients who were 'less searching than others' – wanting either to sign the consent form without acknowledging information, or deferring the decision to the doctor.

> Some patients will say "I don't actually want to know anything about the procedure, I just want you to get on and do it". (Consultant 7, Vascular Surgery)

When faced with disengaged patients, many doctors in our study reported that they attempted to continue to provide information to ensure they comply with their legal requirements.

> If the patient didn't want to know anything, which has happened to me a few times I would just say to the patient that I do have to go through this with you even though you don't want to for legal reasons I need to. (Junior 8, Obstetrics and Gynaecology)

Unfamiliarity with procedures

Many junior doctors admitted to feeling inexperienced and ultimately lacking in confidence to consent for procedures of which they had little or no exposure. They were acutely aware of their inabilities to answer patients' questions.

> The main problem is that I don't feel prepared to take consent on everything that I'm required to. Even with simple things like how long the procedure will take, I've got no idea and you feel a bit stupid when they ask you something. (Junior 4, Trauma and Orthopaedics)

Both junior and senior doctors noted that junior doctors' unfamiliarity with procedures meant that patients were not receiving all the relevant information, ultimately impairing the informed consent process.

> I think that many juniors are consenting patients if they don't really understand what they are consenting patients for, and I suspect the discussion over risk is incomplete. (Consultant 4, Trauma and Orthopaedics)

A number of junior doctors reported feeling pressured by senior colleagues to consent for procedures. In many circumstances, juniors admitted to worrying about irritating seniors and nursing staff if they expressed a reluctance to take consent.

> I feel that I'm put in a difficult situation where I'm expected by other doctors to engage in a process and take the consent. They must know that if you don't know about the procedure you're not supposed to take the consent. If you don't do it, it seems to incite a reaction and it's difficult to know how to manage that. (Junior 4, Trauma and Orthopaedics)

Time to consent

Doctors of all grades agreed that busy working schedules and long job lists limit the amount of time that they have to consent patients.

Some reflected that this resulted in them giving restricted information or fewer opportunities for the patient to ask questions.

> Obviously the amount of information depends on the amount of time we've got, so if it is a busy clinic, they will get less information. (Consultant 1, Ophthalmology)

Improving the consent process

Training

While consultants admitted that junior doctors were perhaps inexperienced in their abilities to gain valid informed consent, they also reflected that undertaking this role was an important part of their learning about the consent process.

> I don't think newly qualified doctors should be ruled out altogether because it's important for them to start learning the process. (Consultant 5, General Surgery)

Some doctors suggested that the teaching on the process of gaining consent for surgery should be incorporated into undergraduate curriculums, as this would partially ready junior doctors when they take up surgical posts. However, a few doctors explained that simply *teaching* medical students how to gain consent from patients would be ineffective and that *practical experience* of gaining consent for medical students as part of the ward-based training was the most effective way to learn the skills.

> You can teach people as much as you want, until they start doing it, you won't really embed it into them. (Consultant 6, General Surgery)

Interventions

A number of junior doctors suggested that they should be provided with brief booklets that describe the range of procedures they are expected to consent patients for, and detail procedure-specific information, including how procedures are performed and the perceived benefits and risks associated with such procedures.

> I think something needs to be given to us, to make sure you have all the [procedure-specific] information on it. (Junior 2, Vascular Surgery)

Discussion

This qualitative study of 20 doctors, working across six surgical specialties, reveals that last-minute consenting for non-emergency surgery is not uncommon, and responsibilities of gaining informed consent for surgical procedures often fall to junior doctors who have never undertaken the procedure. While GMC policy states that where it is impractical for a senior clinician to take consent, responsibility of consent can be assigned to someone who is suitably trained and qualified, the policy also states that the person taking consent must have sufficient knowledge of the procedure.[1] However, our data indicate that junior doctors do not always feel competent in their consenting abilities and feel pressure to consent for procedures for which they are unfamiliar. This has also been found by medical students and junior doctors while obtaining consent for pelvic examination.[24]

A particular finding of our study is that there is clinician support for consent being seen as a process over time and possibly over several consultations rather than a one-off event. Currently, it is clear that the 'consenting of the patient' often occurs shortly before the patient undergoes the procedure. There are two main problems with this. Firstly, the patient may attend for the procedure because they assume the procedure is going to benefit them but they may not fully understand both the benefits and the harms. Without this full understanding, there is risk at least of 'decisional regret'.[25] Secondly, shortly before the procedure, the patient will have immediate concerns about the procedure on their mind, for example whether they are going to suffer pain, and may not be considering the longer term consequences of the procedure. They will also find it more difficult to retain and consider the information at this more stressful time. This supports the approach of the patient

being given time before the admission to hospital to consider all the information about their procedure. Some patients may choose not to engage with this process and put their 'faith' in the clinician; however, for the majority, it is likely to produce benefits.[25]

The discussion over the small anaesthetic risk associated with death is a major source of discomfort for many junior doctors, often leading to avoidance of the subject and its subsequent omission from the consent form. Juniors should be encouraged to include the risk of death and other serious outcomes even if they know or suspect that the patient does not wish to know this information. Working in time-pressured environments compromises the amount of information patients receive, sparking concerns about how well-informed patients are. Several areas of improvement were identified; juniors requested more theatre time to advance their knowledge of procedures, and there were suggestions to implement consent training into undergraduate curriculums and requests to provide juniors with written information guides. It was also felt that consent processes would be improved if consent discussions were more consistently conducted with patients earlier, for example during pre-operative hospital visits.

There are aspects of our findings that resonate with previous studies exploring doctors' perspectives of informed consent for surgical procedures in other countries.[17–19] Our doctors noted that working in time-pressured environments affects the quality and amount of information they impart to patients, consistent with findings from previous focus-group and questionnaire-based studies.[17–19]

While in previous studies, patients reported that they felt doctors deliberately withheld information and undervalued patient autonomy,[17–19] doctors in our study described patients who demonstrate preferences not to receive any information. As previous studies of doctors' experiences have been conducted in developing countries, it is possible that these differences may be due to cultural expectations about patients' participation in health care. For example within the UK, and many other developed nations, patients' values, preferences and experiences have been given increasing emphasis in clinical interactions in an effort to promote patient-centred care. Guidance indicates that irrespective of patients' wishes, doctors must supply patients with information.[1,25] Our participants, especially juniors, expressed an awareness of this, emphasizing that they would persist in providing information and would implore patients to listen.

Previous research on patients' perspectives of the process of consent for treatment indicates that many patients feel disempowered by the consent process and do not fully understand either the process or the information provided to them.[10–15] Again this resonates with some of the findings from our study as our clinician participants indicated that some of the patients remain unengaged with the decision-making process. Whether it is a lack of understanding or a lack of patient engagement that is the problem, it is clear that barriers exist to involving patients in good-quality consent discussions.

We recognize that our data are collected from two hospitals in one region of the UK, which could limit generalizability to other hospitals. We acknowledge that we may have failed to obtain important data from doctors working in other surgical specialties not interviewed. However, consistency of themes that emerged across the range of surgical specialties selected, and similar experiences of different clinician grades, supports transferability of our findings to other surgical fields.

Several types of interventions to improve informed consent discussions have been developed including written information, structured consent forms and audio-visual aids.[26] Our study identified that doctors did employ a range of communication methods, including quantification and diagrams, but tended to rely mostly on the structured consent form.

This study demonstrates that current consent processes appear not to be ideal for many doctors. Problems arise due to juniors consenting for procedures of which they have little

procedure-specific knowledge, the often-rushed nature of the consent taking, an avoidance of discussion of death and a perceived lack of engagement on behalf of some patients. Given that patients also find the consent process unsatisfactory, some of these problems may be improved if patients were to be better informed about the process of consent as well as informed about the procedure. Improvements also need to be made to the training of doctors. Changes to the Foundation Programme should be implemented to allow juniors more theatre time to gain first-hand experience of surgical procedures, and written information packages detailing procedure-specific information provided to juniors at job induction. Changes in practice should ensure senior doctors observe juniors engaged in consent discussions with patients. Incorporation of experience in gaining consent into the medical undergraduate curriculum could be undertaken during communication skill sessions and ward-based teaching.[27] We recognize logistical issues, specifically lack of time, will be difficult to address. However, reorganizing clinician workflows may also be required to prevent last-minute consenting of patients.

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Conflict of Interests

None.

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