

Informed consent in hospital practice: health professionals' perspectives and legal reflections

HEYWOOD, R., MACASKILL, A. <<http://orcid.org/0000-0001-9972-8699>> and WILLIAMS, K.

Available from Sheffield Hallam University Research Archive (SHURA) at:

<https://shura.shu.ac.uk/2169/>

This document is the Accepted Version [AM]

Citation:

HEYWOOD, R., MACASKILL, A. and WILLIAMS, K. (2010). Informed consent in hospital practice: health professionals' perspectives and legal reflections. *Medical Law Review*, 18 (2), p. 152. [Article]

Copyright and re-use policy

See <http://shura.shu.ac.uk/information.html>

INFORMED CONSENT IN HOSPITAL PRACTICE: HEALTH PROFESSIONALS' PERSPECTIVES & LEGAL REFLECTIONS

DR ROB HEYWOOD*, PROFESSOR ANN MACASKILL**, DR KEVIN WILLIAMS***

I. Introduction

Informed consent to medical treatment is a vexed topic; medically, legally and ethically. Consent is underpinned by the notion of personal autonomy, and the right to self-determination. In a medical context this translates into the right of the patient to decide which treatment to agree to or refuse. The 'informed' element of consent depends upon the provision of information by the doctor together with a degree of understanding of that information from the patient. This poses problems for medical professionals as it is difficult to gauge the exact amount of information they must give to a patient and the level of understanding which must follow in order to render any consent legally and ethically valid. Arguably, this problem has been exacerbated by the uncertain nature of the law in respect of information disclosure. The English courts have not found it easy to articulate the scope of a doctor's legal duty of disclosure nor have they clarified with any certainty how this should be judged.[1] It is difficult to determine whether or not the law's imprecision has impacted upon consent procedures in clinical settings and, if it has, how. It is against this backdrop that the following study is set.

This article presents the findings of an empirical research project exploring informed consent in secondary care from the perspective of health care professionals in the UK.[2] A range of health care professionals actively involved in obtaining informed consent in their practice were interviewed to investigate the dynamics of consent and identify how it is obtained. The paper also examines what is important to health care professionals when dealing with patients. Eight consultants, three registrars, three house officers/senior house officers and six nurses were interviewed. A thematic analysis of all the interview transcripts was conducted and the resultant themes are discussed.

The study found that health care professionals take consent seriously and view it as a shared-decision making process. However, there is a feeling that the process has now become too bureaucratic. The clinicians acknowledge the importance of communication in consent and highlight ways in which patient understanding can be improved. The findings identify a general willingness to disclose information to patients and a reluctance to deliberately withhold anything, yet there remains a degree of uncertainty about precisely what should be disclosed and when it may be appropriate to exercise professional discretion. The article concludes by reflecting on these findings from a critical legal perspective.

II. BACKGROUND AND JUSTIFICATION

Jones provided the setting for this study. His work began to alert lawyers of the need to explore informed consent beyond the courts and suggested that in order to understand its true meaning one must look beyond the mere legal doctrine.[3] Consent procedures in secondary hospital care are more formal than in primary care but questions remain about the dynamics of these procedures, which are poorly understood, and how they relate to legal theory. The lack of empirical research in this area provided the justification for the study.

III. METHODS

A. Participants

In total 20 interviews were undertaken with consultants (N=8)[4], registrars (N=3)[5], senior house officers and house officers (N=3)[6], and nurses of various different grades comprising consultant nurse practitioners, ward sisters and staff nurses (N=6).

B. Procedure

Initial contact was made with the consultant who was the head of the department in which the majority of the research took place. Participant information sheets were disseminated at the weekly management meetings and at this stage a number of clinicians expressed an interest in the study. Before agreeing to take part in the research, the participants were given the opportunity to question the researcher and their informed consent was obtained. The procedure for recruiting participants may give the impression that the medical professionals involved were largely self-selecting. This is true insofar as all the participants were volunteers who, presumably, had some interest in the subject. To an extent, this problem is inescapable in much empirical research since those who have no interest will simply not take part and coercion on the part of the researcher to recruit uninterested parties would be unethical. With this in mind, the potential for bias was recognised and accounted for in the thematic analysis and the limitations of this study are highlighted at various junctures in this paper.

C. Research Design

The aim of this study was to generate in-depth, qualitative data by engaging in dialogue and guided conversation with clinicians actively involved in the consent process. Semi-structured interviews were used. The chief advantage of this model is that it is flexible and open to changes in sequence so that the researcher can follow up the answers given and the stories told.[7] A number of interview schedules were devised with broad themes. These themes were formulated by the research team where it was decided that, in order to allow for legal reflection at the end of the study, the questions should address what happens in practice, the views and opinions of the various parties concerning what they perceive as being important in consent, and the difficulties inherent in the process. The interviews were conducted up to a point of saturation.[8]

D. Methodological Considerations

Qualitative research of this kind has limitations which need to be considered at an early stage of any study. Due to ethical constraints it was only possible to gain access to participants from one hospital in the UK and, as the study was voluntary, the research team had no control over the specialisms of the participants interviewed. Therefore, it is important to stress that the findings in this qualitative study should not be interpreted in a generalised manner. Semi-structured interviews alone are also restrictive in the sense that they only demonstrate what participants *say they do* rather than what *they actually do*. In order to establish what really happens in practice other sources of data are required. As such, observations of practice were used at a later stage of the first named author's PhD in order to triangulate the study.[9] To prevent the findings from becoming too closely aligned with what the participants describe the methodology draws on the philosophical underpinnings of both phenomenology and hermeneutics. Todres and Wheeler explain how this is possible by suggesting the two are 'natural bed-fellows' and that neither boundary is too rigid nor permeable in terms of a research methodology. [10] In this sense phenomenology focuses on rich description grounding the research inquiries and hermeneutics adds reflexivity to the research turning to the meaningful questions and concerns that are relevant. Thus, the first section of the study focuses on description before proceeding to analyse the important issues from a critical legal perspective.

E. Ethics

The study was scrutinised by the local NHS Ethics Committee and gained full ethical and research governance approval.

F. Data Analysis

The interviews were tape recorded, transcribed and uploaded into the software package NVIVO. The findings were then analysed using computer software to identify recurring themes.[11]

IV. FINDINGS: DESCRIPTIONS OF PRACTICE AND MEDICAL OPINION

The themes are presented in the order in which they were identified. The importance attached to each theme is noted in a footnote after the relevant heading. The level of importance of a theme was assessed by the number of times it occurred within the transcripts.

A. Theme 1: The Importance of Consent as a Continuing & Shared-Decision Making Process[12]

Consent seems to be viewed as a *process* in which both the doctor and the patient should be involved.

Nurse Practitioner No 5: ...informed consent I think it is absolutely vital, it is one of the things that as a nurse practitioner I try to think of as sort of one of my babies really. I try to make sure that when I am taking consent from a patient that I think about all the things that I would want to know myself if that was me sat there. I think it is absolutely vital really and not just to protect us really but more so for the patient...that they are making an informed choice about what they are agreeing to be involved in. Because I know that I would want to receive all the relevant information.

The findings suggest that for the participants under investigation, the real importance of consent is bound up in the needs of the patient. It is viewed as a two-way transaction.[13] It seems that consent is seen as vital, not for the protection of medical practitioners, but for the protection of patients. This point demonstrates one of the limitations of this paper. Health care professionals may well view consent as a mutual process, but these findings only portray the views of one party within this transaction. There is existing empirical evidence that suggests patients do not view consent as reciprocal but instead perceive it as a *necessary* step to the obtaining of treatment. [14] Thus, whilst medical professionals may recognise the desirability of a two-way transaction, it may not operate this way in practice if patients fail to understand that the purpose of the consent process is to respect their autonomy, to offer them the opportunity to become involved in their treatment decisions, and to give them the final say about what is done to them.

In order to encourage patient involvement there is a strong feeling that consent should not be a single event but an on-going process consisting of a number of consultations with all levels of medical practitioners involved in the treatment. This is particularly the case for cancer treatments or where the patient suffered from serious bowel complaints.

Surgical Registrar No 3: Before we see patients we will consent them in clinic. They will be given opportunities to ask questions, to go away and think about other questions that they might like to ask, address those questions again later on before the procedure, before the final completion of their consent preferably not in the room two minutes before they have the procedure. It is a symbiotic and active relationship between the patient and the physician.

All the participants in the study expressed a view that delegation in the consent process is acceptable. The results indicate that it does take place in practice, both as a mechanism for saving time and for teaching purposes.

Consultant No 4: I think it is very important to delegate consent if it is appropriate and at the right time. It is a very important part of training it is an essential part of training for Registrars to consent. I think the BMA did great harm in the advice that came out that no junior doctor should be allowed to gain consent. It is absolute rubbish because it makes the modern generation of young doctors feel as though "oh we don't have anything to do with consent." But...you need consent every time you touch a patient, you need consent every time you write a prescription form, consent is at the centre of medicine. Everything that you can think of to mention needs consent and this modern generation need to be aware that if you take on a job you need to take on the consent.

Thus, it seems clear that in some situations those undertaking the medical procedure may not be the same person(s) as those taking consent. Whilst this in itself is not unusual, a strong caveat was placed on delegation by all the participants which was that the person obtaining the consent must themselves be capable of performing the procedure as this will mean that that they have the

necessary understanding of core elements such as risks, benefits and alternatives which need to be explained to the patient.

B. Theme 2: Problems with the Consent Form[15]

At time this study was conducted, each individual Trust had a measure of discretion as to the precise design of their consent form. The consent form discussed in this study was specific to the Trust under investigation but was based broadly on what is now a standard NHS model. Typically, consent in secondary care is obtained in writing though the medical practitioners within the study seem to suggest the process has become too formalised and bureaucratic. They perceive the most important basis for consent as being an ethical imperative grounded in the wishes and needs of the patient, which is about more than obtaining a signature on a form. They suggest there is a danger that lengthy and elaborate forms detract from the consent process itself, a process which should discuss the treatment, its risks and benefits.

Harmonising consent procedures may well be bureaucratically appealing insofar as it provides some consistency and certainty at least for doctors, if not patients. Doctors have mapped out for them, via the medium of the form, what they ought to be discussing with patients. Yet, attempting to impose some level of harmonisation on consent procedures that cover a range of specialisms is very difficult. Flexibility and professional judgment provide the key to effective consent procedures as there is a need to tailor the process to the situation of the particular patient.[16] It appears the participants feel that a generalised consent form has the potential to fetter this.

Consultant No 1: Now I object in many ways to the standard consent form that this hospital has...the consent form is a generic consent form, which is actually misleading...but the Trust, as advised by the lawyers, have said that we have to use this ridiculous form. In a sense the consenting is a number of events...but because of the form I think it is nothing to do with consent. Now that signing of the consent form might be me saying to patient "sign this consent form." The radiographers will be entirely happy if there is a signature on the form even if I haven't gone through the proper process of consenting...

Concerns were raised over problems with bureaucracy and 'red-tape' in the consent process. The feeling was that this is driven by 'the law.' The contention is grounded in the fact that both doctors and patients involved in the consent process may be happy to proceed with treatment based on the fact that there is a signature on a form. A signature is certainly not conclusive evidence that any discussion whatsoever has taken place between the doctor and the patient about the proposed procedure.

C. Theme 3: Disclosure, Openness and Transparency[17]

The results suggest a commitment towards openness and disclosure and a willingness to talk through the risks of procedures with patients.

Surgical Registrar No 3: It is extremely important. The process of informed consent is integral to our practice...you need to tell them about the risk of perforation, the risk of death, the risk of a bleed and other associated problems as well, such as a stroke, myocardial infarction, post endoscopic complications such as pain. The whole range must be explained.

It seems that when risks are not disclosed, this is due to mere inadvertence on the part of the

medical practitioners or the result of the genuine exercise of what is perceived to be professional discretion. Arguably, the latter could be viewed as paternalistic in nature which to some may be problematic. Whether or not medical practitioners are aware of the potential significance and dangers associated with this is uncertain.[18]

There is a general reluctance to withhold information and the legal concept of a therapeutic privilege was largely unrecognised. The medical practitioners found difficulty in providing examples where they would rely on it or where the information would be so damaging to justify *complete* avoidance of disclosure.

Consultant No 3: I don't like the concept of withholding information because I think that that necessarily is not totally helpful. There maybe situations where the patients' intelligence or insight or illness doesn't allow them to fully understand it and you have to talk to the relatives more about it but I don't commonly and regularly withhold information.

There appears to be a presumption in favour of disclosure and uncertainty as to the precise nature and applicability of the therapeutic privilege. Whether this is an accurate reflection of actual day-to-day practice remains open to speculation. It is possible that some of the medical practitioners in the study do withhold some information but do not perceive it as being done by reference to a therapeutic privilege; rather they view it as professional discretion in tailoring information to the needs of individual patients. The exercise of professional discretion is explored further below.

D. Theme 4: Problems with Risk and Information Disclosure[19]

There is confusion and uncertainty surrounding what risks to disclose. The common perception amongst the medical practitioners is that risk disclosure varies depending on the precise nature of the procedure and the severity of the consequences should the risk materialise. Risk calculus in medical disclosure entails a delicate balancing act and so disclosure cannot be judged solely by reference to the likelihood of a risk transpiring. The rate of occurrence has to be counterbalanced against the magnitude of harm when deciding what to tell a patient. By way of example, a certain risk may occur frequently in a particular operation, but the potential harm caused by that risk may be so trivial that disclosure would not be necessary. By the same token, there may only be a slight chance that a certain risk will occur but its consequences may be so severe that the patient must nonetheless be told about it.

Consultant No 2: Yes I mean let us say for example the consent for a hernia operation...the threshold in percentage terms for informed consent is something like...2% OK. But then if you get a significant complication that is a lot rarer but is well recognised then you have to tell them that as well. Moving away from hernias for the moment...I think the best example might be bowel surgery where you have got the risk of patient nerve damage which might be perceived to be less than 1% for example. I can't remember off the top of my head...but there are certain operations that are well known to cause a very severe problem but only very rarely and you need to spell those out.

Despite clear recognition of the need to perform a balancing act, a significant amount of attention is paid to percentages and statistical precision, with emphasis on the figure of between 1 to 2 per cent occurrence rates as the apparent threshold for risk disclosure. It is possible that this figure is

a result of anecdotal collegial stories about legal action.[20] Irrespective of this, there remains at least some acknowledgement that in certain situations patients must be told about risks lower than this figure. This accurately reflects Lord Browne-Wilkinson's often cited example in *Sidaway* in the Court of Appeal that the 'materiality of any particular risk must depend on the relationship between the object to be achieved by the operation and the nature of the risk involved. If there is a half per cent risk of total paralysis that might well be a material risk in the context of an operation designed to get rid of a minor discomfort but not in the context of an operation required to avoid death. The decision as to the materiality of a risk depends on the balancing of benefits and risks.' [21]

In order to meet the legal obligations relating to consent, the nature of the information provided to patients centres mainly on risk disclosure. However, the participants also indicated the desirability of disclosing the benefits of treatment in order that patients can conceptualise the importance of the procedure, helping them to rationalise their predicament and reach an informed decision.

Consultant No 7: ...Yes I think I tend to do it the other way round. I tend to say "you need this operation because you have got a cancer that is about to block the bowel and if we don't remove it then you will be seriously ill...and there is a good chance that this will cure the cancer." The downside is...and we are obliged to tell you these risks...". So I tend to put the positive first and tell them why I think they need it and then I come in with what the risks are.

A number of the participants worried that if only risks are disclosed the patient may not appreciate the true worth of the treatment and may become confused, frightened and anxious. Thus, patients need to be told about the benefits and consequences of failing to go ahead with the procedure in all cases.

Common practice appears to involve firstly explaining what is wrong with the patient, explaining why the treatment is necessary and then discussing the potential drawbacks in the form of risks. It is within the middle component where medical practitioners attempt to frame things in a positive light. The underlying issue is one of balance. It is possible to conclude that whilst there is a greater emphasis on risks, disclosure should not be based *solely* on this and that other types of information are equally important.

There is also a general agreement about the theoretical desirability of disclosing alternative treatments to patients despite an underlying concern that this is not always practical. Depending on the patient's condition, surgery may be the only available option and practitioners may be reluctant to engage them for fear of creating false hope. A further concern centres on the possibility that if the patient is provided with too many options, they may become confused and anxious, which may have an adverse effect on the decision-making process. In situations like this, the medical practitioners openly acknowledge that they would be likely to guide the patient towards their preferred course of action.

Consultant No 7: ...Some of the patients...will go and look up the information for themselves and may come back with it, but most of the patients actually don't know the recurrence rates of the different operations. So we are having to give the information effectively again by leading them into the operation which you think is best for them. If you give them the facts they will pick the same one as you usually.

In certain situations it seems the medical practitioners decide what treatment to offer patients based on their own preferences for evidence-based practice. Where alternatives are available, the

decision to opt for one course of action over another appears to be left to the professional judgment of the doctors. The participants were careful to stress the importance of clinical discretion in consent perhaps recognising that patients, like people, differ and may benefit from a tailored approach to disclosure, an attitude which is embraced by the GMC in its most recent guidance on consent.[22]

Nurse Practitioner No 5: ...I mean this is the thing about consent particularly in relation to, say, endoscopy when you are giving sedation. You have to make a very balanced decision about what you need to tell that patient as an individual because you might get somebody very fit and well, where the risk of giving sedation is actually very minimal whereas you might get somebody who is much more elderly where the risk of giving sedation is obviously much higher. So I do try and give it on an individual basis and think about them as an individual.

This exercise of clinical judgement is a necessary part of the consent process allowing disclosure to be defined by reference to the individual.[23]

E. Theme 5: Underlying Paternalism & Best-Interests[24]

Paternalistic healthcare practice is premised on the idea that treatment decisions should be made for patients by experts. The view of a doctor or nurse as a professional with superior knowledge to that of the novice patient is often relied upon as justification for this approach. In a medical context, the concept of best-interests may be viewed by some as a natural corollary of paternalism as one would hope that any treatment decision made for a patient is in fact made with their best-interests in mind. Nonetheless, this will not always be the case because the undesirable situation may arise in which a medical professional may act paternalistically to make a decision for a patient which cannot ever be viewed as being in their best-interests. Equally, a medical practitioner can act in a patient's best-interests without ever having to make the decision for them.

This attitude was apparent from the medical professionals in this study signifying that whilst best-interests and paternalism are two concepts which can sometimes be closely aligned, there is a difference.

Nurse Practitioner No 5: When I am taking consent what is foremost in my mind is the patient, that I want them to be able to decide that what I am offering them and what I am proposing to do to them is in their best interests.

The opinion from the participants is that paternalism is no longer acceptable. However, some suggest they would always act in the patient's best interests and that this *is* acceptable, perhaps reinforcing their view that paternalism and best-interests are inherently different concepts. Even though a transparent and open relationship is looked upon favourably, there is evidence that in some circumstances some clinicians may be economical with the truth depending on their perception of needs of the individual before them.

Consultant No 4: I think I do it all the time. I don't every time I consent a hernia go down the complete list of risks that every single patient might get. And there are people, as I say, who don't want to know but at some level...I will make a decision. So every time you consent you make a decision...it is my judgement where I draw the line.

This conduct is not perceived by the participants as paternalistic in nature, even though in some circumstances it could be; rather this is seen perhaps as an acceptable exercise of professional

judgement.

F. Theme 6: Communication Breakdown and Patient Understanding[25]

Every participant acknowledged that good communication skills from *both* medical practitioners and patients are the key to effective consent procedures. There is however concern over the fact that the communication process may break down within medical consultations. There appear to be two perceived reasons for this.

First, broadly there are two types of patients; those who actively seek out information and who are willing to become involved in their healthcare, and those who do not want to know as much preferring to proceed in blissful ignorance.

Consultant No 4: Yes I mean a lot of what I personally do is based on a basic psychological appraisal. Patients in information gathering fall into 2 groups. There are around 30% of the patient population who don't want to know anything and they are difficult because all they want to do is sign the consent form. They don't want any risks given they would rather walk away from it and you have to make a decision as to what length you will push them to listen. Most normal people are absolutely fine with it and they will keep on requesting further information. I would then go beyond my normal level in order to make sure that they are informed of every single risk. So you are making a basic and fairly primitive psychological assessment as to whether you should force the information on a patient or whether you would be overloading the patient with too much information.

The willingness of a patient to communicate is perceived to be linked to their individual personality. The perception is that the disparity in power also has a bearing on the patient's willingness to communicate and engage with the doctor about their treatment.

House Officer: ...we come round in big groups of people and stand at the end of the bed and don't let them know what is going on. Or because they come to a clinic and they are scared of what is going on...that they might have to have some horrible operation. Yes definitely...they are sat in a bed with no clothes on and we are all standing at the end of the bed writing down notes.

The medical practitioners are conscious that patients may sometimes feel intimidated and vulnerable in the face of medical expertise. This may lead to a reluctance to ask questions for fear of embarrassment caused by poor understanding, anxiety over difficulties articulating questions appropriately, or a reluctance to engage deriving from the notion that the 'doctor knows best.' The other explanation is that some patients may simply be reluctant to ask for fear of hearing the worst.[26]

The legal emphasis is undoubtedly on disclosure, yet the information imparted may be largely meaningless unless the patient has the capacity to understand what is being said. Thus, understanding was highlighted as being an important factor in informed consent, though it was also thought of as problematic because understanding is subjective. The difficulty for medical practitioners is how patients interpret information. The perception is that, in some circumstances, patients will be unable to comprehend what is being said and will become confused, frightened and anxious. Without understanding their condition and why treatment is needed, the patient cannot conceptualise and weigh the information in the balance rendering any disclosure and

subsequent consent procedure largely empty. Thus, a number of the health care professionals focus on how to enhance understanding. In the face of severe illness and bad news, the patient may have great difficulty retaining and comprehending information regardless of what steps the doctor takes to help. Some patients may pretend to understand when actually they do not. Ensuring *complete* understanding is not only unrealistic but also unnecessary, so the emphasis must therefore switch to ensuring that the patient can balance the benefits against the risks.

Consultant No 8: I will try and put it in terms that a patient can understand. I will say “there is 1:100 chance of death from this procedure” and they will say “that is not a very big risk is it?” I will say “well I wonder...if you were travelling on an aeroplane to America, and on the side of the aeroplane it said ‘we fall out of the sky 1:100 times’ would you get on that aeroplane?” The answer is no, of course they wouldn’t. But if they were in some war torn state in Africa, and they were about to be shot and there was one plane leaving that had the same message on it, would you get on the plane? Of course you would.

The study lends support to the suggestion that clinicians think an effective way to facilitate patient understanding of risk is to use analogies, something patients can relate to.[27] Attention is also paid to how things are said as this influences how information comes across to patients and how it is interpreted. In addition, a number of the clinicians indicate the desirability of using both literature and illustrations to enhance patient understanding. Drawing things for patients allows them to visualise what is wrong and how it is going to be corrected; written information is useful for explaining things to patients in a simple manner allowing them time to formulate questions away from the consultation.

Some patients leave consultations having been advised to read up about their condition, and later return with extensive literature on the subject, which may be irrelevant, excessive or inaccurate, particularly where it has been obtained off the Internet.

Consultant No 8: ...when the internet first got going they would come with reams of paper and ask me to comment on this that and the other. And I said “I am not going to comment on this, you have come for my opinion that is someone else’s opinion and therefore you have to take that and weigh it in the balance.” The problem is that most of the information that you get from the Internet will come from 2 different types of sites... the good sites where they are from University based hospitals in the States giving good information, and the bad sites which are private clinics that are actually touting for business.

Medical practitioners acknowledge that if guided to the correct sites, the Internet can be a useful resource. However, there is a lot of information contained on the web that is both inaccurate and potentially misleading. When patients access this a great deal of time has to be spent allaying unnecessary patient concerns. Further problems are created by information from abroad where medical techniques may differ from those offered in this country. Some overseas techniques may not be evidenced-based practices and the practitioner here is left having to justify why they will not perform a particular new and innovative procedure that may be on offer elsewhere.

G. Theme 7: The Law Encouraging Defensive Medicine[28]

Defensive medicine is more usually discussed in relation to diagnosis and treatment. It may be perceived by some, including the participants, that defensive medicine is not associated with

consent. However, there is *indirect* evidence relating to what might be classified as defensive medicine and thus some tentative conclusions may be drawn from this study.

There is some evidence of 'excessive' risk disclosure where medical practitioners think they *have* to tell patients about risks they otherwise would not have disclosed.

Consultant No 8: No in fact there are times when the patient says "I don't want to know that." And I say, "I am sorry I am going to tell you."

This attitude *may* be attributable to the law and could be detrimental to both the doctor patient relationship and the consent process as a whole.[29] This has to be approached with caution. It appears that despite some feeling that the law forces their hand to disclose, the doctors also feel it is important to exercise clinical judgement and discretion in tailoring information to suit the needs of individual patients. This is almost a contradiction. Perhaps the most plausible interpretation is that they try to maintain clinical discretion but feel the law is eroding this.

A further issue centres on the patient entitlement to waive their right to informed consent. Even in situations where the patient explicitly states they do not want to hear information about risks, and voluntarily place themselves in the hands of the doctor, there is evidence that some of the participants insist, regardless of the patient's request not to be informed. This appears to be commonly associated with the law and the fear of legal action should anything untoward happen.

Nurse Practitioner No 5:...I think that there is argument that we feel obliged to tell patients everything because you are worried that if you don't say it, and then god forbid the 1:1000000 risk happens, that they are going to say to you "well you never said that." So I suppose there is a bit of defensive medicine going on there.

It is very difficult to draw any firm conclusions about the influence of the law and whether or not it encourages defensive medicine. One of the main reasons for this resides in the fact that it is very hard to identify precisely what is meant by defensive medicine.[30] One possible explanation focuses on unnecessary tests and procedures that squander time and money.[31] Equally, one may equate defensive medicine with over cautious practice which demonstrates that it perhaps should not always be viewed as a bad thing. These definitions, however, do not fit neatly with consent practices and information disclosure in clinical settings. For the purposes of this study, defensive medicine is defined as exposing the patient to excessive information about risks and alternatives which may be unnecessary in the circumstances, and refusing to acknowledge the patient is entitled to waive their right to certain information, practices which are justified on the grounds of the need to avoid legal liability.

If, as is suggested above, defensive medicine is taken to mean the changing of clinical practices in order to guard against legal action, this is not necessarily a bad thing, particularly given that one of the goals of tort law is to influence how doctors and other health care professionals act and to encourage higher standards of care.[32] Thoroughness in information disclosure is desirable; it is only when disclosure becomes excessive that it may be detrimental to patients by triggering unnecessary alarm. What amounts to 'excessive disclosure' will inevitably vary depending on the individual patient in question but it is certainly possible that some disclosure practices are unwarranted and have an adverse affect. Arguably, any disclosure which facilitates understanding and decision-making should be viewed positively, but there may come a point when too much information may obstruct this by causing confusion, fear and anxiety amongst patients.

Though there is evidence that clinical negligence claims generally are decreasing,[33] research tells us that malpractice lawsuits probably do impact upon the way in which doctors practice medicine, and that some of what they do may not help patients.[34] A possible explanation is that doctors have anxieties about medical malpractice lawsuits that go well beyond the real risks they face.[35] Thus, rather than the legal rules having any direct effect, it is the *perceived* threat of liability which causes concern.

H. Theme 8: Reliance on Professional Guidelines[36]

Whilst some of the medical practitioners are aware of the documentation from the Department of Health and General Medical Council about consent, the majority admit to having little knowledge of these protocols. This is hardly surprising given empirical evidence that doctors are unaware of other guidelines, such as the GMC's code mandating emergency treatment.[37] Even where they are aware of the guidelines, the clinicians admit that often the attention paid to them in practice is minimal for two reasons. First, medical practitioners have only limited time to read and digest such recommendations. Second, they are seen as over-complex and an impractical model of how consent should be obtained, eroding any scope for clinical discretion.

Consultant No 3: You have to pay attention to them but the trouble is sometimes they are not totally practical...the danger is that people are overwhelmed with paper and don't read them anyway. They do it to cover themselves so that if anything goes wrong it is the doctors' fault that they didn't follow the guidelines so to speak. That doesn't help at the end of the day what it comes back to is does the patient understand what is being done to them.

Whilst detailed and elaborate guidelines may serve as a marker for good practice, enhancing consent in clinical settings, they may become little more than an unworkable ideal largely ignored by those who should be relying on them most.

V. LEGAL AND CRITICAL REFLECTION

A. The Consent Form

Jones has suggested that 'for those who consider that consent is merely a medico-legal requirement which must be endured in order to protect the doctor, there is a danger that they will engage in a formulaic process which does little to inform the patient, and, ironically, just as little to protect the doctor.'[38] The medical practitioners in this study do not perceive consent as being just a 'medico-legal requirement.'[39] They demonstrate a commitment towards keeping the patient informed and look positively on the concept of shared-decision making.[40] However, the language used by the participants reflects a view that the detailed nature of the consent form stifles some of the professional discretion that is needed in order to render consent a process in which the patient is truly involved. [41] The medical practitioners perceive the over-complex nature of the standard NHS form as being driven by the law and believe this has turned consent into a regimented and bureaucratic procedure. This creates the risk, identified by Jones, that medical practitioners are left '"consenting the patient", a term which suggests that consent is something that is *done to* the patient, usually for the purposes of avoiding legal liability, not a process that the patient participates, much less controls.'[42]

B. Problems with Risk Disclosure

Berry has suggested:

'Difficulties in assessment, perception and management of risk all have implications for risk communication. If we do not have accurate information about the "real" level of risks in most situations, if people perceive risk differently and vary in what they believe to be an appropriate balance between risk and reward...then determining what information to present to them, and in what form, is far from straightforward.'

As negligence is now the dominant basis for legal actions based on inadequate disclosure, and as this tort is predicated on harm, the requirement to provide necessary information preceding any operation has inevitably focused on the risks inherent in treatment.[44] As a result, medical practitioners' perceptions of consent have been tainted and, despite the fact that consent should not be solely about risks, the development of the law has undoubtedly encouraged prominence to be attached to this aspect of it. This is problematic not least because the concept of informed consent arguably has less to do with the liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects.'

In the past, the English courts have not welcomed the American legal doctrine of informed consent.[46] Thus, the problem for the law has been reaching a consensus on how to judge the adequacy of clinicians' disclosure, a matter on which arguably it has yet to reach any firm conclusions.[47] The findings here reflect the view that doctors are also unsure about what to disclose in practice, although whether or not this confusion is caused by the law remains uncertain. For clinicians to be influenced by the law's uncertainty it would have to be proved that they know something about it and the indications are that the medical practitioners in the study only had a vague understanding of what the law says.[48] Thus, it is possible that their confusion about what to disclose comes from elsewhere, perhaps stemming from uncorroborated collegial anecdotes about disclosure.

The results of this study seem to indicate two things. First, the medical practitioners say risks are disclosed by reference to the probability of them materialising, and, second, that attention is given to the patient as an individual and the seriousness of the procedure's associated risks. As well as considering what *ought* to be disclosed to the patient, there must also be scope for taking into account what *should not* be disclosed in relation to their particular circumstances. How does this reflect on the various legal standards of care?

Even though the English courts have never explicitly endorsed the prudent patient standard of disclosure as formulated in *Canterbury*, it is safe to say that disclosure is no longer dictated *solely* by the *Bolam* standard.[49]

It seems that medical practitioners are now under an obligation to disclose all risks that the court would deem significant based on *its* objective assessment of what the reasonable patient would want to know.[50] In reaching its conclusions, it is crucial for the court to remember that what constitutes a significant risk cannot be defined solely by reference to the percentage chance of it transpiring, the *nature* of the risk must also be considered and this factor is arguably more important than its incidence. If percentages are relied on too heavily to dictate disclosure trends this has the potential to overlook the fact that the significance of risk will vary from patient to patient, based not only on the seriousness of their condition and the overall state of their general health, but also the wider social factors that affect the lifestyle of the patient.[51] Risks must be considered in context for, as Kennedy suggests, the recourse to probabilities creates the unfortunate impression that the law can produce a standard of care which substitutes mathematics

and probability theory for the uncertain terms which provide the framework within which the law of negligence operates. He further highlights the problem that there may well be disagreement amongst medical practitioners as to the precise number to be assigned to the chance of a particular risk materialising.[52] The courts have recognised these dangers but have often become embroiled in referring to percentages by way of example.[53] Understandably, the medical profession have clung to this as a method of providing a benchmark against which disclosure can be measured, but a major difficulty for patients is how to interpret these statistics.[54]

In order to combat interpretational problems, Gutteling and Wiegman propose that the principal 'ground rule' of risk communication is that the information should be customised to the receiver's needs.[55] Whilst the medical practitioners in this study do acknowledge that some consideration is given to the needs of the individual, with so much emphasis placed on percentages, the subjective element of understanding risk disclosure has the potential to become lost. Indeed, Gutteling and Wiegman suggest that effective risk communication ought to address the questions that are relevant to the receiver, be comprehensible, and not add further confusion.[56]

A further difficulty for the law is whose point of view counts when the significance of a risk is judged. Based on Lord Woolf MR's judgment in *Pearce*, it seems to be a question for the courts.[57] This study supports Maclean's recent assertion that 'the question of a risk is a subjective issue coloured by the individual's character, experiences and goals' and that a real danger is created where the law applies an objective test to what is essentially a subjective matter.[58] He further argues that if the test were subjective it would be more sensitive to patient autonomy.[59] However, this potential approach has been criticised[60] prompting Maclean to call for some empirical research to 'give a voice to the reasonable patient.'[61] Thus, building on Kennedy's assertion that 'the law must be perforce uncertain, and not seek to incorporate tests which...could be invoked against the interests of patients'[62], this study demonstrates the importance of a test for disclosure based on what the hypothetical patient would consider significant in the *actual* patient's situation.[63]

C. Excessive Risk Disclosure: Perceptions of the Law

Some years ago Kennedy stated:

'In the context of disclosure of information, the very notion of a professional standard is something of a nonsense. There is simply no such standard, if only because the profession has not got together to establish which risks should be disclosed to which patients in which circumstances.'[64]

This statement may have some truth to it. However, the fact that historically the profession did not get together to establish a standard for disclosure does not in itself mean that one did not exist. For example, there is a recognised standard for competent surgery but the medical profession has never got together to fix such a standard. Whilst it appears that medical practitioners are confused over exactly what to disclose, the findings suggest that the clinicians in this study operate within a framework of disclosure that is dictated by a benchmark figure of one per cent. Thus, in the hospital where this research took place, there appeared to be at least a *degree* of harmonisation over disclosure.

The courts have never stipulated that all risks around the one per cent mark have to be

disclosed and whilst in some circumstances this may represent good practice[65], in others it may not.[66] Disclosure is very much a subjective issue and consideration has to be given to the level of information the particular patient wants. Miller has suggested that patients differ in the amount and type of information they wish to receive. He categorised patients into two broad groups: the so-called 'blunters', who use defensive mechanisms of avoidance and denial to deal with threats; and 'monitors', who seek out information about the threat. These two groups need different approaches to information giving.[67] This is confirmed by a number of the clinicians who said that not all patients want to be informed about all risks, and that regimented disclosure of all risks around the one per cent mark in every situation removes an important element of clinical discretion.[68]

The law supports professional discretion in terms of either the *Bolam* test or the therapeutic privilege.[69] The findings seem to suggest that whilst medical practitioners want to maintain a degree of professional discretion in respect of disclosure, they are unaware that the law allows them to do so.

If the underlying purpose of the law is to respect and protect patient autonomy, it must recognise the patient's right of waiver. [70] There is a distinct lack of legal authority on this matter which led Kennedy and Grubb to suggest that the law will recognise the waiver probably sometimes but not always.[71] It seems clear that in the appropriate circumstances the law should allow a competent patient to waive their right to pre-operative information and to proceed in ignorance. Once it is established that the doctor's initial intention was to disclose, then provided the patient expresses a clear wish to invoke the waiver and does so both competently and voluntarily, it seems highly unlikely that the courts will impose liability on medical practitioners for non-disclosure. Thus, in a legal sense, the key question becomes: what are the restrictions, if any, on the waiver?

Kennedy and Grubb suggest that the patient may waive the right to information as to risks, but not to information about the nature and purpose of the proposed procedure as it would be against public policy to allow them to do so.[72] There is clear merit in this claim, although pure autonomists may take issue with such an assertion. There is also a pragmatic and evidential difficulty in establishing whether or not a valid waiver exists. Any patient that has instigated legal action will presumably deny it and, in the absence of any documentary evidence, the courts may be slow to accept that the patient effectively informed the doctor that they did not want to be informed. The reality of the matter is that it may turn on an assessment of whose evidence is the most credible on the day, a question which will always remain uncertain. In order to safeguard against this, documentary evidence of the waiver is essential and this one potential benefit of the consent form, which should include a provision which allows the patient to acknowledge they have relinquished their right to pre-operative information.

If the law is slow to recognise the valid use of clinical judgment in disclosure, or the patient's right of waiver, it risks endorsing a culture of 'excessive risk disclosure', or, on an alternative interpretation, defensive medical practice. Nonetheless, it seems clear that in the correct circumstances the law will allow the use of discretion in disclosure and recognise the right of waiver. The problem is that this may be misunderstood by the medical professionals. This attitude seems attributable to a *perceived* fear of the law by clinicians. As Baker suggests 'the gap between the myth and reality does not mean we should cut back on liability. Instead, it means that we need to convince doctors to take the same evidence-based approach to understanding malpractice law suits that we would like them to take to medical practice.'[73]

D. Disclosure Beyond Risks

Looking beyond the mere disclosure of risks to discussing the benefits of treatment ought to be viewed as good practice.[74] A counter argument is that if doctors frame things in a positive way, patients will remember more about the benefits and this has the potential to overshadow the seriousness of the risks.[75] It may be that patients will often look to the positives. A balance needs to be struck in order to afford the patient the opportunity to place into context the need for the proposed treatment so they can make a more reasoned decision.

In respect of disclosing alternative procedures, there is a lack of English authority on this issue.[76] Kennedy and Grubb say that in *Sidaway* none of their Lordships referred to any duty to advise patients of alternatives.[77] With respect, this is inaccurate. Lord Scarman stated that his interpretation of the duty to disclose should encompass alternatives to the recommended treatment.[78] In order that the duty to disclose fulfils its intended purpose, there must be some consideration afforded to the requirement to disclose alternatives. It appears from our findings that there is some disagreement over this, though some clinicians intimate it is appropriate to discuss treatment options with patients. Yet, in the same breath, examples were provided where decisions seem to be implicitly made for patients, justified on the grounds of evidence-based practice or the personal preference of clinicians. From a legal perspective this is dubious practice which may be open to future challenge. Despite the fact that in the past little attention has been paid to this component of the duty, there is evidence that this is changing. *Pearce*, for example, was concerned with the choice between no intervention, induction and caesarean section.[79] The risks associated with the latter two options were disclosed, but the risks inherent in the consultant's preferred choice, the natural delivery, were not. Even though the claim eventually failed, it was recognised that the omission to disclose the relevant risks of one particular treatment option denied the patient the opportunity to make an informed choice thereby providing the basis for legal action. More recently, in *Birch v University College Hospitals NHS Trust*,[80] the defendant hospital was held liable for failing to discuss with the patient the different imaging methods of the MRI scan and the angiogram and the comparative risks and benefits associated with each. It was found as fact that had the different treatment options been discussed with the patient she would have opted for the MRI scan and thus avoided the injury which was caused by immediate recourse to the angiogram.[81]

Thus, increasingly, it seems that if clinicians fail to discuss and offer different treatment options to patients, and injury transpires, they run the risk of being held liable for withholding information about possible alternatives. This is particularly the case where, for example, the procedure opted for by the consultant carries with it a greater degree of risk, both in the chances of it materialising and its severity, as opposed to an alternative procedure carrying considerably less risk. Denying patients a choice by reference to 'evidence-based practice' may be viewed by some as little more than medical paternalism in the sense that clinicians are not painting a complete picture for patients and are actually preventing them from having the final say on their treatment in command of the full facts. Choosing procedures on the grounds of personal preference, convenience and allocation of resources may, in the future, be frowned upon by the courts and is likely to play second fiddle to considerations of patient autonomy. [82]

E. Enhancing Understanding & Communication

In contemporary medical care we may see more attention paid to the 'understanding' component of consent, and the focus of the patients' legal arguments may switch towards the opportunities they were given to understand the information provided, particularly if risk disclosure becomes a

regimented process in which the patient is bombarded with information. However, to date, little attention has been paid by the courts to the duty to facilitate understanding. *Smith v Tunbridge Wells HA*[83] is one of only a few cases to consider the question of understanding.[84] Morland J. suggested:

'When recommending a particular type of surgery or treatment, the doctor, when warning of the risks, *must take reasonable care to ensure that his explanation of the risks is intelligible to his particular patient*. The doctor should use language, simple but not misleading, which the doctor perceives from what knowledge and acquaintanceship that he may have of the patient (which might be slight), will be *understood by the patient* so that the patient can make an informed decision as to whether or not to consent to the recommended surgery or treatment.'

[85] [author emphasis added].

Grubb warns that this should not be interpreted so as to impose too heavy a burden on the doctor; the doctor's duty remains one of reasonableness in English law.[86] The correct reading of Morland J.'s judgment must therefore be that there is a requirement only for the doctor to take *reasonable steps* to make the information intelligible and understandable.[87] The trouble is that the courts have yet to articulate what those reasonable steps might be.[88] An interesting comparison may be drawn here between the standard of disclosure in negligence and the informed consent provisions contained in the clinical trial regulations. In the latter, the participant is entitled to an interview during which he or she is given the *opportunity* to understand the objectives, risks and inconveniences of the trial.[89] This, of course, provides a frame of reference for identifying which steps must be taken to enhance understanding, and would no doubt be a useful starting point in any examination of reasonableness on the part of the doctor. This study also provides some examples of good practice that can be used to facilitate understanding. The courts could develop these into guidelines to assist them in determining whether a doctor has done enough to enhance this aspect of consent. Good communication leads to higher levels of understanding. Patients prefer it when doctors are good communicators and this undoubtedly improves what they understand. The use of information sheets, diagrams and visual aids also enhances comprehension, as does the use of analogies to allow patients to contextualise the severity and the need for treatment.

These, coupled with the dissemination of written information, provide valuable methods of improving patient knowledge.[90]

Educating the patient to a level where they achieve complete understanding is an unrealistic goal and would place an unworkable duty on clinicians. However, this is not to say that the law cannot assess the reasonable steps that should be taken to assist the patient to understand the implications of the proposed treatment. This would encourage clinicians to create a culture in which patients better comprehend treatment and so express a more sufficiently informed consent.

F. Consent as a Continuing Process

One of the main problems with consent is that the law does not view it as a continuing process to the extent that it perhaps should. Therefore there is a difference between the way in which the law approaches its analysis of consent and the way in which the medical practitioners here say it is

actually carried out in practice. The focus of the legal inquiry in the cases has centred on the reasonableness or otherwise of the exchange between the medical practitioner obtaining the signature (usually but not always the consultant) and the patient. The law has never really engaged in a wider examination of whether or not the patient was kept informed at numerous stages of the treatment process by different levels of healthcare professionals. The law's assessment of consent concentrates on the isolated incident of when it was obtained and if disclosure was reasonable at that point. This overlooks whether or not patients were given the maximum opportunity to make a considered choice leading Williams to suggest that in negligence 'self-determination is seen in functional terms - as a part of the doctor's duty of care - rather than in terms of the patient's right to make a considered choice, the legal inquiry tends to focus on what, if anything, the doctor said...and whether any disclosure was adequate.'[91]

If consent is obtained merely on the morning of the operation, it may be perceived by patients and doctors as something that is just a bureaucratic necessity and the rationale underpinning the process itself may be ignored. In contrast, the opportunity to exercise self-determination is advanced if consent is viewed in a progressive manner which begins the moment the patient is referred to hospital. Even if signing the form is not performed until a later date, the regular communication of information should form part of an on-going process. It seems the clinicians in this study realise that what they do prior to the formalities associated with consent forms an integral part of consent, the purpose of which is to keep the patient as 'informed' as possible. From a legal point of view, if it can be proved that the patient was provided with information about risks, benefits and alternatives on many different occasions and was afforded opportunities to ask questions with different clinicians, this may go some way towards inclining a court to reach the conclusion that the patient was indeed kept 'reasonably' informed.

Legally speaking, delegating consent appears to make little difference as the focus remains on what is actually said, rather than who says it.[92] On the other hand, if medical staff are unaware of what the procedure entails then clearly they should not take the patient's consent. It has been demonstrated in this study that specialist nurses play an active role in the consent process and a number of consultants highlight the important role that delegation has in educating and training junior doctors about the importance of consent. [93] Thus, as long as there remains adequate supervision, involving a variety of medical practitioners may be beneficial.

G. Professional Guidelines: Setting a New Standard

Jones comments that 'as professional attitudes to the question of information disclosure change...patients will become entitled to more information under the *Bolam* standard.'[94] The standards of the profession are changing demonstrating a commitment towards keeping the patient better informed than was once the case.[95]

Nevertheless, whether or not professional guidelines can be used to define a new legal standard of care in respect of information disclosure is uncertain.[96] First, the standard set by these guidelines is in advance of what the law requires and, second, the courts are under no obligation to follow these standards. Undoubtedly they will provide some guidance and the courts may often be inclined to rely on them. However, whether the protocols are transferable in the sense that they can be determinative of what constitutes a legally valid consent is questionable. For them to have

any practical effect, clinicians have to be aware of them. It appears from the findings that even though many are aware of their existence, they are unaware of their substantive content. Whilst legally speaking ignorance is no excuse, for the guidelines to have any practical worth the standards set must be put into practice.[97] The participants in this study believe that some of them are unduly idealistic and fail to account for the realities of the consent process. If compliance with the guidelines is unachievable in practice, and cannot realistically be met by clinicians, there is an inescapable difficulty in allowing them to mould the legal standard of care. However, even if professional guidelines have little *direct* effect on practice they may have an *indirect* influence in the form of a slow trickle down effect. In this sense even though doctors may not be immediately aware of the guidelines, over time their content will permeate the mind of doctors through case reporting and the medical press which will inevitably have some bearing on future practice.

VI. CONCLUSIONS

It was suggested at an early stage in this article that as the study was based in only one hospital within the UK care must be taken in generalising the findings. However, the research encompassed a range of specialisms at a prestigious hospital whose practices probably accord with national standards and to that extent may be a fair reflection of views on consent in secondary care. Moreover what the study lacks in representativeness, it makes up for in terms of depth. It provides insights into the way in which a group of medical practitioners perceive the concept of informed consent and highlights what they say about the difficulties they face in practice. The study demonstrates that a misperception of the law may be a cause of confusion in relation to disclosure trends and ambivalence as to what extent clinical discretion is acceptable in practice. The law itself remains imprecise and does little to allay these fears. Arguably, it places too much emphasis on risk disclosure and documentation, which are only two facets of a much bigger picture. The participants in the study emphasise that consent should be viewed holistically and centre on patients as individuals, something which looks beyond the mere legal horizon. These opinions are of particular interest, especially when compared to the findings of an earlier paper written by the present authors, the focus of which was on patient perceptions of the consent process.[98] The indication was that the patients under investigation perhaps viewed consent differently than the medical practitioners here insofar as they believed it was a necessary requirement of treatment which is performed to protect the doctor rather than themselves.[99] Additionally, even though patients welcome the provision of information, it may well be that in the majority of cases this information is not used in the actual making of any treatment *decision*. In both studies clinicians and patients do share parallel views about the desirability and importance of information, communication and understanding. Yet, despite these similarities, there was very little recognition from patients that the consent process itself is designed to safeguard their right of autonomous choice. With this in mind, a further problem with consent may be the different expectations of both parties within the process, a matter which perhaps ought to be the subject of further empirical investigation in the future.

* LLB (Hons), PhD. Lecturer in Law, University of East Anglia. R.Heywood@Uea.Ac.Uk.

** MA, PhD, AFBPS. Professor of Health Psychology, Sheffield Hallam University.

*** LLB

(Hons), LLM, PhD. Reader in Law, Sheffield Hallam University.

This article comes from the first author's PhD, a wide-scale empirical study investigating informed consent in practice. This study was approved by South Yorkshire NHS Ethics Committee. There are no conflicts of interest.

The authors would like to thank the Review's anonymous referees for their useful and constructive comments on an earlier draft of this paper.

[1] See *Sidaway v Board of Governors of the Bethlem Royal Hospital and others* [1985] AC 871; *Pearce v United Bristol Healthcare Trust* (1998) 48 BMLR 118.

[2] The first author would like to thank all the health professionals who kindly participated in the study.

[3] M Jones, 'Informed Consent and Other Fairy Stories' (1999) 7 Med L Rev 103, 123.

[4] The participants were from a range of different specialisms including general and colorectal surgery, neuro surgery, gynaecology/obstetrics and orthopaedics.

[5] The participants were based in general and colorectal surgery and endoscopy. The medical input into the study advised that consultants and registrars perform similar duties. Accordingly, for the purposes of thematic analysis, the consultants' and registrars' interviews were combined.

[6] Only a limited number of senior house officers and house officers were available to take part in the study due to the frequency of their surgical rotations. Accordingly, the number of specific themes in relation to these grades was reduced. As these participants were involved in surgical rotations, they had experience in a range of specialisms. At the time they were interviewed they were based in the department of general and colorectal surgery.

[7] For discussion see S Kvale, *Interviews: An Introduction to Qualitative Research Interviewing* (Sage, London 1996).

[8] This is the point where it becomes evident that the participants are covering the same issues and no new themes emerge from the analysis.

[9] See R Heywood, 'The Law and Practice of Consent to Medical Intervention' (PhD Thesis, Sheffield Hallam University 2006).

[10] L Todres and S Wheeler, 'The Complementarity of Phenomenology, Hermeneutics and Existentialism as a Philosophical Perspective for Nursing Research' (2001) 38 *International Journal of Nursing Studies* 1, 6.

[11] Due to the qualitative nature of this work there are no references in the discussion to the numbers of participants or to percentages but the number of times a theme occurred is reported as an indication of importance.

[12] There were a total of 128 occurrences across the interviews: 68 occurrences in the consultants/registrars' interviews, 14 in the SHO/house officers' interviews and 46 in the nurses' interviews.

[13] In support of this model of healthcare and decision making see, D Feldman-Stewart and others, 'Practical Issues in Shared Decision Making' (2000) 3 *Health Expectations* 46.

[14] For discussion see R Heywood and others, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection' (2008) 24 JPN 104 at 106, 115.

[15] There were a total of 82 occurrences across the interviews: 48 occurrences in the consultants/registrar's interviews, 9 in the SHO/house officers' interviews and 25 in the nurses' interviews.

[16] This issue is identified and discussed below in the context of theme 4.

[17] There were a total of 63 occurrences across the interviews: 33 occurrences in the consultants/registrar's interviews, 15 in the SHO/house officers' interviews and 15 in the nurses' interviews.

[18] This issue is explored in greater detail in theme 5 below.

[19] There were a total of 179 occurrences across the interviews: 120 occurrences in the consultants/registrar's interviews, 11 in the SHO/house officers' interviews and 48 in the nurses' interviews.

[20] See below n 48.

[21] *Sidaway v Board of Governors of the Bethlem Royal Hospital and others* [1984] 1 QB 493 at 521-522.

[22] See GMC 'Consent: Patients and Doctors Making Decisions Together' (2008). Tailoring information to particular types of patients is explored below n 67.

[23] For discussion on the desirability of disclosing information by reference to the individual see AJ Brooks and others, 'Information Required to Provide Informed Consent for Endoscopy: An Observational Study of Patients' Expectations' (2005) 37 *Endoscopy* 1136; TE Quill, 'Autonomy in a Relational Context: Balancing Individual, Family, Cultural, and Medical Interests' (2002) 20 *Families, Systems and Health* 229.

[24] There were a total of 31 occurrences across the interviews: 23 occurrences in the consultants/registrar's interviews, 1 in the SHO/house officers' interviews and 7 in the nurses' interviews.

[25] There were a total of 229 occurrences across the interviews: 112 occurrences in the consultants/registrar's interviews, 43 in the SHO/house officers' interviews and 74 in the nurses' interviews.

[26] For consultant perspectives on what should be disclosed to cancer patients see EJ Gordan and CK Daughery, 'Hitting You over the Head: Oncologists' Disclosure of Prognosis to Advanced Cancer Patients' (2003) 12 *Bioethics* 142. For patient perspectives on the amount of information desired about terminal illnesses see SJ Marwit and SL Datsun 'Disclosure Preferences about Terminal Illness: An Examination of Decision-Related Factors' (2002) 26 *Death Studies* 1; SJ Yardley and others, 'Receiving a Diagnosis of Lung Cancer: Patients' Interpretations, Perceptions and Perspectives' (2001) 15 *Palliative Medicine* 379.

[27] See below n 90 for further discussion.

[28] There were a total of 98 occurrences across the interviews: 52 occurrences in the consultants/registrar's interviews, 21 in the SHO/house officers' interviews and 25 in the nurses' interviews.

[29] For empirical evidence in support of this see BM Stanley and others 'Informed Consent:

How Much Information is Enough?' (1998) 68 *ANZ Journal of Surgery* 788.

[30] See for discussion T Baker, 'The Goods on Defensive Medicine' in T Baker, *The Medical Malpractice Myth* (University of Chicago Press, Chicago 2005) 118.

[31] G McGovern and A Simpson, 'We're Reaping What We Sue' (2002) *Wall Street Journal* 17.

[32] Baker, above n 30. For UK literature see also JB Fanning, 'Uneasy Lies the Neck that Wears a Stethoscope: Some Observations on Defensive Medicine' (2008) 24 *JPN* 93; A Symonds, 'Reactions to Perceived Risk: Defensiveness in Clinical Practice' (2003) 9 *Clinical Risk* 182; G McFarlane, 'Clinical Negligence – Risk Management and Reporting' (2001) 2 *JPIL* 164.

[33] The most recent figures from the NHSLA suggest that in 2007/08 there were 5,470 claims (including potential claims) under its clinical negligence schemes (*NHSLA Fact Sheet No 3*, November 2008). Between 2002-03 there were 7,798 estimated claims. Between 2003-04 they decreased to 6,251 (*NHSLA Fact Sheet No 3*, August 2004). During 2004-05 there were 5,609 estimated claims (*NHSLA Fact Sheet No 3*, July 2005). For further discussion see The Report of the House of Commons Constitutional Affairs Committee on the Compensation Culture (Third Report of Session 2005-06 Vol .1). Jones has indicated that allegations of inadequate disclosure are rarely the principal basis for the negligence action. See Jones, above n 3 at 122 and also G Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*' (1991) 70 *Canadian Bar Review* 423.

[34] D Kessler and M McClellan, 'The Effects of Malpractice Pressure and Liability Reforms on Physicians' Perceptions of Medical Care' (1997) 60 *Law and Contemporary Problems* 81; D Kessler and M McClellan, 'Do Doctors Practice Defensive Medicine?' (1996) 111 *Quarterly Journal of Economics* 353; S Zuckerman, 'Medical Malpractice: Claims, Legal Costs, and the Practice of Defensive Medicine' (1984) 3 *Health Affairs* 128. Despite this, there is evidence that the overall impact of defensive medicine on health care-costs is small. See Baker, above n 30 at 134.

[35] Baker, above n 30 at 135.

[36] There were a total of 22 occurrences across the interviews: 16 occurrences in the consultants/registrar's interviews, 2 in the SHO/house officers' interviews and 4 in the nurses' interviews.

[37] See K Williams, 'Doctors as Good Samaritans: Some Empirical Evidence Concerning Emergency Treatment in Britain' (2003) 2 *JLS* 258, 268. Only 54% of doctors recognised their professional obligation (GMC) to treat patients in emergencies.

[38] See Jones, above n 3 at 126.

[39] In *Chatterton v Gerson* [1981] 1 All ER 257 it was stated that in English law, once that patient is informed in broad terms about the nature of the procedure and signs the consent form, a legal claim in battery is no longer an option.

[40] For discussion see Feldman-Stewart, above n 13; H Teff, 'Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance' (1985) 101 *LQR* 432.

[41] For an interesting discussion in support of this see RV Clements, 'Informed Choice: Should We Bin the Consent Form?' (2005) *Clinical Risk* 69.

[42] Jones, above n 3 at 125.

[43] D Berry, *Risk, Communication and Health Psychology* (Open University Press, Berkshire 2004) 23.

[44] *Chatterton*, above n 39.

[45] For a general discussion see TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (6th edn OUP, New York 2008).

[46] In America, the phrase informed consent derives from the case of *Salgo v Leland Stanford, Jr, University Board of Trustees* 154 Cal. App. 2d 560, 317 P. 2d 170 (1957). However, the later famous case of *Canterbury v Spence* (1972) 464 F.2d 772 developed what is sometimes referred to as the legal doctrine of informed consent within the remit of the negligence action. This places an obligation on doctors to disclose all the material risks that the reasonable patient would want to know in the circumstances. To speak of an American legal doctrine of informed consent is perhaps misleading as it gives the false impression that it is of general application across all states. Some US states still rely on the reasonable doctor standard of disclosure and one state still treats risk disclosure as a matter for liability in battery. See the Pennsylvanian cases of *Gray v Grunnagle*, 423 Pa. 144, 223 A.2d 663 (1966); *Cooper v Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971). The English courts have never fully accepted the *Canterbury* doctrine. See *Sidaway*, above n 1.

[47] Historically in England there was considerable debate over whether disclosure should be judged in accordance with the accepted standards of the medical profession (*Bolam*), or from the point of view of the reasonable patient (*Canterbury*). See *Sidaway*, above n 1. Now, apart from some fine-tuning, it seems fairly clear following *Pearce* and *Chester* that the standard is what the reasonable doctor believes the reasonable patient would need to know. See *Pearce*, above n 1; *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134. For discussion see AR Maclean, 'The Doctrine of Informed Consent: Does it Exist and Has it Crossed the Atlantic?' (2004) LS 386; M Brazier, 'Patient Autonomy and Consent to Treatment' (1987) 7 LS 169.

[48] The participants were never asked directly about their understanding of the law and so this did not develop into a theme within its own right. However, they were asked where the emphasis on 1 to 2 per cent risk disclosure came from and there was a strong indication that this was categorically what the law required.

[49] For a recent and interesting discussion see J Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2009) 17 Med L Rev 76.

[50] Academics have argued about whether or not this is an indirect acceptance of the American doctrine of informed consent. Brazier and Miola state that the reasonable doctor test received a 'real body blow' as a result of the decision in *Pearce*, above n 1. See M Brazier and J Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 Med L Rev 85, 110. However, one problem with this approach is in what sense the court can actually make an objective assessment of what the reasonable patient would want to know. The courts may think this is what they are

doing when actually they are not. All the courts can do is consider what ought reasonably to have been disclosed in the circumstances. This surely demands at least some thought about the patient's position in addition to an assessment of the medical evidence pertaining to the nature and frequency of the risk in question. This has led Maclean to suggest that the test is reduced to no more than an examination of what the reasonable doctor believes the reasonable patient ought to find significant to a decision. See for discussion A Maclean, 'Beyond *Bolam* and *Bolitho*' (2002) 5 Med L Int 205, 214.

[51] For discussion of risk calculus, see above theme 4.

[52] I Kennedy, 'The Patient on The Clapham Omnibus Postscript: The House of Lords' Decision' in I Kennedy, *Treat Me Right : Essays in Law and Medical Ethics* (Clarendon Press, Oxford 1988) 200.

[53] This clearly happened in *Pearce* where a great deal of emphasis seemed to be placed on percentages in identifying the significance (or otherwise) of a 0.1/0.2 per cent risk. See *Pearce*, above n 1.

[54] The Secretary of State for Trade and Industry once suggested that 'fifty per cent of the public doesn't actually know what 50% means.' See Patricia Hewitt quoted in the *Independent*, 30th November 2002.

[55] JM Gutteling and O Wiegman, *Exploring Risk Communication* (Kluwer, Dordrecht 1996) 121.

[56] *Ibid.*

[57] *Pearce*, above n 1 at 124.

[58] A Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence' (2005) 7 Med L Int 1, 12.

[59] Maclean, above n 58 at 11.

[60] Lord Scarman in *Sidaway* stated that the law does not operate in utopia and a subjective approach would create a danger of self-serving testimony given with the benefit of hindsight. See *Sidaway*, above n 1 at 888. See also Maclean above. However, Brazier points out that this approach may not be any more absurd than attempting to second-guess what the hypothetical reasonable patient may want to know. Brazier, above n 47 at 189.

[61] Maclean, above n 58.

[62] Kennedy, above n 52 at 200.

[63] Arguably the Australian case of *Rogers v Whitaker* (1992) 109 ALR 625 advocates a standard of disclosure which contains a *specific* subjective element. For discussion see D Chalmers and R Schwartz, '*Rogers v Whitaker* and Informed Consent in Australia: A Fair

Dinkum Duty of Disclosure' (1993) 1 Med L Rev 139, 150. See also K Tickner 'Rogers v Whitaker – Giving Patients a Meaningful Choice' (1995) 15 OJLS 109. The Court of Appeal has, of late, shown a degree of sympathy towards the subjective position of the patient without explicitly saying so. See *Wyatt v Curtis* [2003] EWCA Civ 1779; [2003] WL 22827037.

[64] Kennedy, above n 52 at 189.

[65] The obligation to disclose all risks within the region of 1-2% is not mentioned in any of the guidance given from the GMC or the DoH. See GMC 'Consent: Patients and Doctors Making Decisions Together' (2008); Department of Health Circular 'Good Practice in Consent Implementation Guide: Consent to Examination or Treatment' (2001). However, a recent article suggested the standard level of disclosure in modern medicine encompasses all risks within the region of 1-2% and above. See W Hussain and others, 'Consent and Invasive or Interventional Cardiology' (2001) 7 *Clinical Risk* 127, 129. In the recent House of Lords' decision of *Chester v Afshar* (above n 47) the surgeon was held liable for failing to disclose a risk which stood at around 1-2%. The question as to whether this failure constituted a breach was not open to debate. The court stated categorically that the surgeon was clearly negligent in failing to disclose this.

[66] For a general discussion of excessive disclosure and medical practice see R Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Medical Practice' (2005) 7 *Med L Int* 93.

[67] See SM Miller, 'Coping with Impending Stress: Psychophysiological and Cognitive Correlates of Choice' (1979) 16 *Psychophysiology* 572. One of the consultants in this study referred to the patients who do not want to know as 'blockers.'

[68] See N Beresford and others, 'Risks of Elective Cardiac Surgery: What Do Patients Want to Know?' (2001) 86 *Heart* 626. For further empirical evidence see CW Lidz and others, 'Therapeutic Misconceptions and the Appreciation of Risks in Clinical Trials' (2004) 58 *Social Science & Medicine* 1689-1697; see also AG Fraser, 'Do Patients Want to be Informed?' (1984) 4 *British Heart Journal* 468.

[69] If the *Bolam* test is applied the law supports professional discretion in the sense that it defers its objective powers of assessment to a peer-review of what is professionally accepted practice. If however the reasonable patient standard of disclosure is used, the therapeutic privilege operates as a component of this standard of care to allow doctors to withhold information if they feel it will be detrimental to the mental or physical health of the patient. Thus, if the doctor withholds information on these grounds there is simply no breach. For an Australian case in which the therapeutic privilege was applied see *Battersby v Tottmann* (1985) 37 SASR 524 (SA Sup Ct). For further discussion see R Mulheron, 'The Defence of Therapeutic Privilege in Australia' (2003) 11 *JLM* 201.

[70] For discussion on how the waiver can be tied into the therapeutic privilege in order that the law can account for the passive patient see Heywood, above n 66.

[71] See I Kennedy and A Grubb, *Medical Law* (3rd edn Butterworths, London 2000) 752.

[72] *Ibid.*

[73] Baker, above n 30 at 135.

[74] Balancing risks and benefits is a complex exercise. For example, the risks associated with a medical procedure are typically of a totally different nature, form and frequency compared with the benefits. For most patients there is only a single benefit sought from a procedure; the risks are multiple. A further complication is that different people will attach different values to the different dimensions. Thus, risk and benefit are fundamentally evaluative terms. See A Edwards and others, 'Concepts in Risk-Benefit Assessment: A Simple Merit Analysis of Medicine?' (1996) 15 *Drug Safety* 1.

[75] RJ Hekkenberg and others, 'Informed Consent in Head and Neck Surgery: How Much do Patients Actually Remember?' (1997) 26 *Journal of Otolaryngology* 155; DK Smith and others, 'Informed Consent to Undergo Serum Screening for Down's Syndrome: The Gap Between Policy and Practice' (1994) 309 *BMJ* 776.

[76] The jurisdictions which have made most inroads into this are Canada and the United States of America. For a Canadian example see, *Haughian v Paine* (1987) 37 DLR (4th) 624 (Sask CA); and *Truman v Thomas* (1980) 611 P 2d 902 (Cal Sup Ct) for an American example.

[77] Kennedy and Grubb, above n 71 at 711.

[78] See *Sidaway*, above n 1 at 876.

[79] See *Pearce*, above n 1.

[80] [2008] EWHC 2237.

[81] For discussion see R Heywood, 'Medical Disclosure of Alternative Treatments' [2009] 68 *CLJ* 30.

[82] Most notably, in *Chester v Afshar* (above n 47) there was evidence of the courts warming to the idea that autonomy is significant as an ideal in itself, and not just as a component in a negligence action. See S Devaney, 'Autonomy Rules OK' (2005) 13 *Med L Rev* 102. For a general discussion of the changing nature of the law and its attitude towards patient rights see H Brooke, 'Patients, Doctors and the Law (1963-2003): A Few Reflections' (2004) 72 *Medico-Legal Journal*; D Irvine, 'The Patient, The Doctor, Their Lawyers and the Judge' (1999) 7 *Med L Rev* 255.

[83] [1994] 5 *Med LR* 334.

[84] See also *Lybert v Warrington Health Authority* (1995) 25 *BMLR* 91; *Smith v Salford Health Authority* [1994] 5 *Med LR* 321. The need for patient comprehension was also stressed in *Pearce*, above n 1 at 124.

[85] *Smith*, above n 83 at 339.

[86] See A Grubb, 'Medical Negligence: Information and *Bolam*' (1995) 3 Med L Rev 198, 201. Grubb notes that in Canada, the more onerous duty seems to be the law. See *Ciarlariello v Keller* (1993) 100 D.L.R. (4th) 609 (Can. Sup. Ct.).

[87] See, for example, K Williams, 'Comprehending Disclosure: Must Patients Understand the Risks They Run?' (2000) 4 Med L Int 97 at 101.

[88] For an interesting discussion of the problems with patient understanding and the law see AR Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (Cambridge University Press, Cambridge 2009); NC Manson and O O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press, Cambridge 2007).

[89] See Medicines for Human Use (Clinical Trials) Regulations 2004, Schedule 1 Part 3.

[90] There is empirical evidence relating to the benefits of decision-aids and written information in the consent process. See R Barrett, 'Quality of Informed Consent: Measuring Understanding Among Participants in Oncology Clinical Trials' (2005) 32 *Oncology Nursing Forum* 751; A Barratt and others, 'Use of Decision Aids to Support Informed Choices about Screening' (2004) 329 *BMJ* 507; D Feldman-Stewart, 'A Decision Aid for Men with Early Stage Prostate Cancer: Theoretical Basis and a Test by Surrogate Patients' (2001) 4 *Health Expectations* 221; M Schapira and J VanRuiswyk, 'The Effect of an Illustrated Pamphlet Decision-Aid on the Use of Prostate Cancer Screening Tests' (2000) 49 *The Journal of Family Practice* 418. For evidence on the effectiveness of written information see EM Taylor and others, 'Patients' Receipt and Understanding of Written Information about a Resuscitation Policy' (1998) 12 *Bioethics* 64.

[91] Williams, above n 87 at 99.

[92] A case search of both Westlaw and LexisNexis returned no results in which delegation was a legal issue in negligent disclosure cases.

[93] B Sooin and others, 'Informed Consent: A Case for More Education of the Surgical Team' (1993) 75 *Annals of the Royal College of Surgeons of England* 62.

[94] Jones, above n 3 at 125.

[95] See *Hatcher v Black*. *The Times*, July 2nd, 1954.

[96] Samanta *et al.* identified that the appellate courts have never been asked to make a definitive statement on the role of guidelines as standards for liability in clinical negligence. However, they appear to have been used to assess the appropriate of doctors' conduct in the withholding or withdrawal of life sustaining treatment. See *Airedale NHS Trust v Bland* [1993] 1 All ER 821 and *Burke v GMC* [2005] EWCA 103. Equally, there is a paucity of evidence concerning the use of guidelines in defining the standard care in the courts of first instance. See *Re C (a minor) (medical treatment)* [1998] Lloyd's Rep. Med. 1 in which the courts approved the guidance from the Royal College of Paediatrics and Child Health. See also *Early v Newham Health Authority* (1994) 5 Med. L.R. 214 (guidelines adopted provided evidence of a reasonable standard

of anaesthesia); *DF v St George's Healthcare NHS Trust* [2005] EWHC 1327 (guidelines from the Royal College of Gynaecologists and Obstetricians gave a clear indication that an instrumental delivery was not acceptable practice). See also *Thomson v James and others* (1996) 31 BMLR 1; *Penney, Palmer and Cannon v East Kent Health Authority* [2000] Lloyd's Rep. Med. 41. For further discussion see A Samanta and others, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard' (2006) 14 Med L Rev 321.

[97] In *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 it was stated by McNair J. at 587 that it was no defence for those who 'obstinately and pig-headedly carry on with some old technique.'

[98] Heywood and others, above n 14.

[99] *Ibid.*